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42 CFR Parts 412, 413, 424, et. al
Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 424, 476, and 489

[CMS–1588–P]

RIN 0938–AR12

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers

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, 2012. We also are proposing to update 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 updated rate-of-increase limits would be effective for cost reporting periods beginning on or after October 1, 2012.

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 implementing certain statutory changes made by the Affordable Care Act. These proposed changes would be applicable to discharges occurring on or after October 1, 2012.

In addition, we are proposing changes relating to determining a hospital's full-time equivalent (FTE) resident cap for the purpose of graduate medical education (GME) and indirect medical education (IME) payments. We are proposing new requirements or revised requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities (IPFs)) that are participating in Medicare. We also are proposing new administrative, data completeness, and extraordinary circumstance waivers or extension requests requirements, as well as a reconsideration process, for quality reporting by ambulatory surgical centers (ASCs) that are participating in Medicare.

We are proposing requirements for the Hospital Value-Based Purchasing (VBP) Program and the Hospital Readmissions Reduction Program.

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 25, 2012.

ADDRESSES: When commenting, please refer to file code CMS–1588–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–1588–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–1588–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–1588–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, Graduate Medical Education, 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.

Mollie Knight, (410) 786–7948, Market Basket for LTCHs Issues.

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

James Poyer, (410) 786–2261, Inpatient Quality Reporting and Hospital Value-Based Purchasing—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.

James Poyer, (410) 786–2261, and Barbara Choo, (410) 786–4449, Inpatient Psychiatric Facility Quality Reporting Issues and PPS-Exempt Cancer Hospital Quality Reporting Issues.

Anita Bhatia, (410) 786–7236, Ambulatory Surgical Center Quality Reporting 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 the 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 are no longer published as part of the annual IPPS and 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 2013 IPPS Final Rule Home Page'' or ''Acute Inpatient—Files for Download''. The LTCH PPS tables for this FY 2013 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–1588–F. 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
ASCQR Ambulatory Surgical Center Quality Reporting
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
CDC Center for Disease Control and Prevention
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 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
LTCHQR Long-Term Care Hospital Quality Reporting
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
MMEA Medicare and Medicaid Extenders Act of 2010, Public Law 111–309
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
NHSN National Healthcare Safety Network
NQF National Quality Forum
NTIS National Technical Information Service
NTTAA National Technology Transfer and Advancement Act of 1991 (Pub. L. 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]
PCH PPS-exempt cancer hospital
PCHQR PPS-exempt cancer hospital quality reporting
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
TPS Total Performance Score
UHDDS Uniform hospital discharge data set

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I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This proposed rule would make payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it would make payment and policy changes for the Medicare hospitals under the long-term care hospital prospective payment system (LTCH PPS). It also makes policy changes to programs associated with Medicare IPPS hospitals and LTCHs.

Under various statutory authorities, we are proposing to make changes to the Medicare IPPS, to the LTCH PPS, and to other related payment methodologies and programs for FY 2013. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a

reasonable cost basis, the Secretary use a prospective payment system (PPS).

• Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; and cancer hospitals. Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.

• 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), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of long-term care hospitals (LTCHs) described in section 1886(d)(1)(B)(iv) of the Act.

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

• Section 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.

• Section 1886(d)(4)(D) of the Act, which 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.

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

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

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

• Section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act and amended by section 10309 of the Affordable Care Act, which establishes the ''Hospital 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.

2. Summary of the Major Provisions

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

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 prospective adjustment under section 1886(d)(3)(A)(vi) of the Act.

Section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an additional one-time adjustment to the standardized amounts to offset the estimated increase or decrease in aggregate payments for FYs 2008 and 2009 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.

After accounting for adjustments made in FYs 2008 and 2009, we have 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. Without making this adjustment, our actuaries estimated that annual aggregate payments would be increased by approximately $4 billion. Furthermore, an additional one-time adjustment of −5.8 percent would be required to fully recapture overpayments (estimated at approximately $6.9 billion) due to documentation and coding that occurred in FY 2008 and FY 2009, as required by section 7(b)(1)(B) of Public Law 110–90.

CMS has thus far implemented a −2.0 percent (of a required −3.9 percent) prospective adjustment, and completed the full one-time −5.8 percent recoupment adjustment (−2.9 percent in both FYs 2011 and 2012). In FY 2013, we are proposing to complete the remaining −1.9 percent prospective adjustment, while also making a +2.9 percent adjustment to remove the effect of the FY 2012 one-time recoupment adjustment. We have also determined that a cumulative adjustment of −5.4 percent is required to eliminate the full effect of documentation and coding changes on future payments to SCHs and MDHs. After accounting for adjustments made to the hospital-specific rate in FY 2011 and FY 2012, an additional prospective adjustment of −0.5 percent is necessary to complete the full −5.4 adjustment. We are proposing a full −0.5 percent adjustment to the hospital-specific rate, in keeping with our policy of applying equivalent adjustments, when applicable, to other subsection (d) hospital payment systems.

We also are proposing an additional adjustment to account for documentation and coding effects that occurred in FY 2010. After review of comments and recommendations from MedPAC, CMS analyzed FY 2010 claims

using the same methodology as previously applied to FYs 2008 and 2009 claims. CMS estimates that there was a 0.8 percentage point effect due to documentation and coding that did not reflect an actual increase in patient severity. Our actuaries estimate that this 0.8 percentage point increase resulted in additional aggregate payments of approximately $1.19 billion. Therefore, we are proposing an adjustment of −0.8 to the standardized amount and a −0.8 percent adjustment to the hospital-specific rate. This would result in a total documentation and coding adjustment of +0.2 percent (−1.9 plus +2.9 plus −0.8) to the standardized amount and a −1.3 percent (−0.5 plus −0.8) adjustment to the hospital-specific rate.

b. Hospital-Acquired Conditions (HACs)

Section 1886(d)(4)(D) 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.

In this proposed rule, we are proposing two new conditions, Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures and Pneumothorax with Venous Catheterization, for the HAC payment provisions for FY 2013 under section 1886(d)(4)(D) of the Act. We also are proposing to add diagnosis codes 999.32 (Bloodstream infection due to central venous catheter) and 999.33 (Local infection due to central venous catheter) to the existing Vascular Catheter-Associated Infection HAC category for FY 2013.

c. Reduction of Hospital Payments for Excess Readmissions

We are proposing a number of policies to implement section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act, which establishes the Hospital Readmissions Reduction Program. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payments to account for excess readmissions of selected applicable conditions, which are acute myocardial infarction, heart failure, and pneumonia. We are proposing the applicable hospitals that included in the Hospital Readmissions Reduction Program, the methodology to calculate the adjustment factor, the portion of the hospital's payment that is reduced by the adjustment factor, and the process under which the hospitals have the opportunity to review and submit corrections for their readmissions information prior to the information being posted on the *Hospital Compare* Web site.

d. Long-Term Care Hospital-Specific Market Basket

We are proposing to update LTCH payment rates with a separate market basket comprised of data from only LTCHs, which we refer to as a ''LTCH-specific market basket.'' We are proposing to implement a stand-alone LTCH market basket based on FY 2009 Medicare cost report data. The method used to calculate the cost weights and the price proxies used are generally similar to those used in the FY 2008-based RPL market basket that was finalized for the FY 2012 IPPS/LTCH PPS final rule. The primary difference is that we are using data from LTCH providers only.

e. Expiration of Certain Payment Rules for LTCH Services and the Moratorium on the Establishment of Certain Hospitals and Satellite Facilities and the Increase in the Number of Beds in LTCHs and LTCH Satellite Facilities

Moratoria on the implementation of certain LTCH payment policies and on the development of new LTCHs and LTCH satellite facilities and on bed increases in existing LTCHs and LTCH satellite facilities established under sections 114(c) and (d) of the MMSEA (Pub. L. 110–173) as amended by section 4302 of the ARRA (Pub. L. 111–5) and further amended by sections 3106 and 10312 of the Affordable Care Act are set to expire during CY 2012, under current law.

The moratoria established by these provisions delayed the full implementation of the following policies for 5 years beginning at various times in CY 2007:

- The full application of the ''25-percent payment adjustment threshold'' to certain LTCHs, including hospitals-within-hospitals (HwHs) and LTCH satellite facilities for cost reporting periods beginning on or after July 1, 2007, and before July 1, 2012, or cost reporting periods beginning on or after October 1, 2007, and before October 1, 2012, as applicable under the regulations at §§ 412.534 and 412.536.
- The inclusion of an ''IPPS comparable per diem amount'' option for payment determinations under the short stay outlier (SSO) adjustment at § 412.529 of the regulations for LTCH discharges occurring on or after December 29, 2007, but prior to December 29, 2012.
- The application of any one-time budget neutrality adjustment to the LTCH PPS standard Federal rate provided for in § 412.523(d)(3) of the regulations from December 29, 2007, through December 28, 2012.
- In general, the development of new LTCHs and LTCH satellite facilities, or increases in the number of beds in existing LTCHs and LTCH satellite facilities from December 29, 2007, through December 28, 2012, unless one of the specified exceptions to the particular moratorium was met.

In this proposed rule, we are proposing to extend the existing delay of the full implementation of the 25-percent payment adjustment threshold for an additional year; that is, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013, as applicable. Although we are proposing to extend the moratoria relating to the application of the ''25-percent threshold'' payment adjustment for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013, the moratoria will expire for several regulatory provisions for cost reporting periods beginning before July 1, 2012, prior to the effective date of the proposed extension, affecting freestanding LTCHs, grandfathered hospitals-within-hospitals (HwHs), and grandfathered satellites. This gap in the continued application of the moratorium is a result of the July 1, 2007 effective date of section 114(c)(1) of the MMSEA as amended by section 4302(a)(1) of the ARRA which was based on the former July 1 through June 30 regulatory cycle for the LTCH PPS.

We are proposing an additional 1-year extension in the delay of the full application of the 25-percent payment adjustment threshold policy because we believe, based on a recent research initiative, that we could soon be in a position to propose revisions to our payment policies that could render the 25-percent payment adjustment threshold policy unnecessary. In light of this potential result, we believe it is prudent to avoid requiring LTCHs (or CMS systems) to implement the full reinstatement of the policy for what could be a relatively short period of time.

We are not proposing to make any changes to the SSO policy as it currently exists in the regulations at § 412.529.

Accordingly, consistent with the existing regulations at § 412.529(c)(3), for SSO discharges occurring on or after December 29, 2012, the ''IPPS comparable per diem amount'' option at § 412.529(c)(3)(i)(D) would apply to payment determinations for cases with a covered length of stay that was equal to or less than one standard deviation from the geometric average length of stay for the same MS–DRG under the IPPS (that is, the ''IPPS comparable threshold'').

The moratoria on the development of new LTCHs or LTCH satellite facilities and on an increase in the number of beds in existing LTCHs or LTCH satellite facilities are set to expire on December 29, 2012, under current law.

We are proposing to make a one-time prospective adjustment under § 412.523(d)(3) of the regulations (which would not apply to payments for discharges occurring on or before December 28, 2012, consistent with the statute) and to transition the application of this adjustment over a 3-year period. Regulations at § 412.523(d)(3) provide for the possibility of making a one-time prospective adjustment to the LTCH PPS rates so that the effect of any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years.

f. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(vii) of the Act, hospitals are required to report data on measures selected by the Secretary for the Hospital IQR Program in order to receive the full annual percentage increase. In past rules, we have established measures for reporting and the process for submittal and validation of the data.

In this proposed rule, we are proposing programmatic changes to the Hospital IQR Program for the FY 2015 payment determination and subsequent years. These proposed changes would streamline and simplify the process for hospitals and reduce burden. We are proposing to reduce the number of measures in the Hospital IQR Program from 72 to 59 for the FY 2015 payment determination. We are proposing to remove 1 chart-abstracted measure and 16 claims based measures from the program for the FY 2015 payment determination and subsequent years. We are proposing to remove these measures for a number of reasons, including that these measures are losing NQF endorsement, are included in an existing composite measure, are duplicative of other measures in the Hospital IQR Program, or could otherwise be reported on *Hospital Compare* in the future under the authority of section 3008 of the Affordable Care Act. In addition, we are proposing to adopt three claims-based measures, one chart-abstracted measure and a survey-based measure regarding care transitions, which we will collect using the existing HCAHPS survey, to the measure set for the FY 2015 payment determination and subsequent years. We also are proposing to adopt a structural measure for the FY 2016 payment determination and subsequent years.

In an effort to streamline the rulemaking process, we are proposing to retain measures for all subsequent payment determinations, unless specifically stated otherwise, through rulemaking. We also are proposing to adopt certain changes to the Hospital IQR Program measures that arise out of the NQF endorsement maintenance process without going through further rulemaking to adopt such changes. To ensure that hospitals that participate in the Hospital IQR Program are submitting data for a full year, we are proposing that hospitals that would like to participate in the Hospital IQR Program for the first time must submit a completed Notice of Participation by December 31 of the calendar year preceding the first quarter of the calendar year in which chart-abstracted data submission is required for any given fiscal year. In addition, if a hospital wishes to withdraw from the program, it would have until May 15 prior to the start of the payment year affected to do so. In order reduce the burden associated with validation, we are proposing to reduce the base annual validation sample from 800 to 400, with an additional sample of up to 200 targeted hospitals. All hospitals failing validation would be included in the 200 hospital supplement, with a random sample drawn from hospitals meeting one or more additional targeting criteria. We also are proposing to require passing scores on both the chart-abstracted clinical process of care and hospital-acquired infection measure set groupings to pass validation, rather than only requiring one passing score for all validated measures.

g. Hospital Value-Based Purchasing Program

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. 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.

We previously published the requirements and related measures to implement the Hospital Inpatient VBP Program in a final rule issued in the **Federal Register** on April 29, 2011 (76 FR 26490, May 6, 2011, and 76 FR 26495 through 26511) and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51653 through 51660). In this proposed rule, we are proposing to add requirements for the FY 2015 Hospital Inpatient VBP Program. Specifically, we are proposing to add one additional clinical process of care measure, AMI–10: Statin Prescribed at Discharge, and two additional outcomes measures—an AHRQ Patient Safety Indicators composite measure and CLABSI: Central Line-Associated Blood Stream Infection. We also are proposing to add a measure of Medicare Spending per Beneficiary in the Efficiency domain.

3. Summary of Costs and Benefits

- Proposed FY 2013 Documentation and Coding Adjustment: Section 7(b)(1)(A) of Pub. L. 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 prospective adjustment under section 1886(d)(3)(A)(vi) of the Act. Section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an additional one-time adjustment to the standardized amounts to offset the estimated increase or decrease in aggregate payments for FYs 2008 and 2009 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.

After accounting for adjustments made in FYs 2008 and 2009, we have 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.

Without making this adjustment, our actuaries estimated that annual aggregate payments would be increased by approximately $4 billion. Furthermore, an additional one-time adjustment of −5.8 percent would be required to fully recapture overpayments (estimated at approximately $6.9 billion) due to documentation and coding that occurred in FY 2008 and FY 2009, as required by section 7(b)(1)(B) of Public Law 110–90.

CMS has thus far implemented a −2.0 percent (of a required −3.9 percent) prospective adjustment, and completed the full one-time −5.8 percent recoupment adjustment (−2.9 percent in both FYs 2011 and 2012). In FY 2013, we are proposing to complete the remaining −1.9 percent prospective adjustment, while also making a +2.9 percent adjustment to remove the effect of the FY 2012 one-time recoupment adjustment. We have also determined that a cumulative adjustment of −5.4 percent is required to eliminate the full effect of documentation and coding changes on future payments to SCHs and MDHs. After accounting for adjustments made to the hospital-specific rate in FY 2011 and FY 2012, an additional prospective adjustment of −0.5 percent is necessary to complete the full −5.4 percent adjustment. We are proposing a full −0.5 percent adjustment to the hospital-specific rate, in keeping with our policy of applying equivalent adjustments, when applicable, to other subsection (d) hospital payment systems.

In addition, we are proposing an additional adjustment to account for documentation and coding effects that occurred in FY 2010. After review of comments and recommendations from MedPAC, CMS analyzed FY 2010 claims using the same methodology as previously applied to FYs 2008 and 2009 claims. CMS estimates that there was a 0.8 percentage point effect due to documentation and coding that did not reflect an actual increase in patient severity. Our actuaries estimate that this 0.8 percentage point increase resulted in additional aggregate payments of approximately $1.19 billion. Therefore we are proposing an adjustment of −0.8 to the standardized amount, and a −0.8 percent adjustment to the hospital-specific rate.

The total IPPS documentation and coding adjustment of +0.2 percent (−1.9 plus +2.9 plus −0.8) would increase total payments by approximately $200 million. The total adjustment to the hospital-specific rate would be −1.3 percent (−0.5 plus −0.8), and would decrease total payment by $312 million. The combined impact of the proposed FY 2013 documentation and coding adjustments would reduce total payments by approximately $112 million.

- Hospital-Acquired Conditions (HACs). For FY 2013, we are proposing to continue to implement section 1886 (d)(4)(D) of the Act that addresses certain hospital-acquired conditions (HACs), including infections. We are proposing to add two additional conditions for FY 2013, Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures and Iatrogenic Pneumothorax with Venous Catheterization. The projected savings estimate for these two conditions is less than $1 million, with the total estimated savings from HACs for FY 2013 projected at $24 million dollars.
- Reduction to Hospital Payments for Excess Readmissions. We are proposing a number of policies to implement section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act, which establishes the Hospital Readmissions Reduction Program. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payments to account for excess readmissions of selected applicable conditions, which are acute myocardial infarction, heart failure, and pneumonia. This provision is not budget neutral. A hospital's readmission payment adjustment is the higher of a ratio of a hospital's aggregate dollars for excess readmissions to their aggregate dollars for all discharges, or 0.99 (that is, or a 1-percent reduction) for FY 2013. In this proposed rule, we estimate that the Hospital Readmissions Reduction Program will result in a 0.3 percent decrease, or approximately $300 million, in payments to hospitals.
- Long-Term Care Hospital-Specific Market Basket. The proposed FY 2009-based LTCH-specific market basket update (as measured by percentage increase) for FY 2013 is currently forecasted to be the same as the market basket update based on the FY 2008-based RPL market basket at 3.0 percent (currently used under the LTCH PPS). Therefore, we are projecting that there would be no fiscal impact on the LTCH PPS payment rates in FY 2013 as a result of this proposal. In addition, we are proposing to update the labor-related share under the LTCH PPS for FY 2013 based on the proposed relative importance of each labor-related cost category in the proposed FY 2009-based LTCH-specific market basket. Although this proposal would result in a decrease in the LTCH PPS labor-related share for FY 2013, we are projecting that there would be no effect on aggregate LTCH PPS payments due to the regulatory requirement that any changes to the LTCH area wage adjustment (including the labor-related share) are adopted in a budget neutral manner.
- Update to the LTCH PPS Standard Federal Rate, including the Expiration of Certain Payment Rules for LTCH Services and the Moratorium on the Establishment of Certain Hospitals and Satellite Facilities and the Increase in the Number of Beds in LTCHs and LTCH Satellite Facilities. Based on the best available data for the 427 LTCHs in our database, we estimate that the changes we are presenting in the preamble and Addendum of this proposed rule, including the proposed update to the standard Federal rate for FY 2013, the proposed changes to the area wage adjustment for FY 2013, and changes to short-stay outliers and high cost outlier would result in an increase in estimated payments from FY 2012 of approximately $100 million (or about 1.9 percent). Although we are generally projecting an increase in payments for all LTCHs in FY 2013 as compared to FY 2012, we expect rural LTCHs to experience a larger than average increase in payments (3.6 percent) primarily due to the proposed changes to the area wage level adjustment. Rural hospitals generally have a wage index of less than 1; therefore, the 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 2013 as compared to FY 2012. In addition, the effect of the proposed extension of the moratorium on the application of the ''25 percent threshold'' payment adjustment policy, as provided by section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(a) and 10312(a) of the Affordable Care Act, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2012, is estimated to result in a payment impact of approximately $170 million to LTCHs. Overall, we estimate that the increase in aggregate LTCH PPS payments in FY 2013 will be $270 million.
- Hospital Inpatient Quality Reporting Program. In this proposed rule, we discuss our requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for FY 2015. We estimate that approximately 95 hospitals may not receive the full annual percentage increase in any fiscal year. 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 2015.

We are proposing supplements to the chart validation process for the Hospital IQR Program. Starting with the FY 2015 payment determination, we are proposing a modest increase to the current Hospital IQR Program validation sample of 18 cases per quarter to 27 cases per quarter in order to capture data on CLABSI, CAUTI, and SSI measures. However, in order not to increase the Hospital IQR validation program's overall burden to hospitals, we are proposing to reduce the total sample size of hospitals included in the annual validation sample from 800 eligible hospitals to 600 eligible hospitals.

We provide payment to 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. The requirement of an additional 9 charts per hospital submitted for validation, combined with the decreased sample size, will result in approximately 1,800 additional charts per quarter being submitted to CMS by all selected hospitals. Thus, we estimate that we would expend approximately $66,600 per quarter to collect the additional charts we need to validate all measures.

- Hospital Value-Based Purchasing Program. The Hospital Value-Based Purchasing Program for FY 2013 is statutorily mandated to be budget neutral. We believe that the program's benefits will be seen in improved patient outcomes, safety, and experience of care. We cannot estimate these benefits in actual dollar and patient terms because the program does not commence until FY 2013 payments.

B. Summary

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

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

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

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

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. (We note that the statutory provision for payments to MDHs expires at the end of FY 2012, that is, after September 30, 2012.) 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.

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

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

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123(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.

C. 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 2013

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, 2011, and 2012 were implemented in the June 2, 2010 Federal Register notice (75 FR 31118), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50042) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51476).

In this proposed rule, we are proposing to implement, or continuing in FY 2013 to implement, the following provisions (or portions of the following provisions) of the Affordable Care Act that are applicable to the IPPS, the LTCH PPS, and PPS-exempt cancer hospitals:

- Section 3001 of Public Law 111–148, which provides for establishment of a hospital inpatient value-based purchasing program under which value-based incentive payments will be made in a fiscal year to hospitals that meet performance standards established for a performance period with respect to discharges occurring during FY 2014.
- Section 3004 of Public Law 111–148, which provides for the submission of quality data for LTCHs beginning in FY 2014 in order to receive the full annual update to the payment rates beginning with FY 2015 and the establishment of quality data measures by FY 2013 for the FY 2015 payment determination.
- Section 3005 of Public Law 111–148, which provides for the establishment of a quality reporting program for PPS-exempt cancer hospitals beginning with the FY 2014 program year, and for subsequent program years.
- Section 3025 of Public Law 111–148, which establishes a hospital readmissions reduction program and requires the Secretary to reduce payments to applicable hospitals with excess readmissions effective for discharges beginning on or after October 1, 2012.
- Section 3125 and 10314 of Public Law 111–148, which modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals, effective only for discharges occurring during FYs 2011 and 2012. Beginning with FY 2013, the preexisting low-volume hospital qualifying criteria and payment adjustment, as implemented in FY 2005, will resume.
- Section 3401 of Public Law 111–148, which provides for the incorporation of productivity adjustments into the market basket updates for IPPS hospitals and LTCHs.
- Section 10324 of Public Law 111–148, which provides 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 2013.

• Section 3137 of Public Law 111–148, which requires the Secretary to submit to Congress a report that includes a plan to comprehensively reform the Medicare wage index under the IPPS. In developing the plan, the Secretary was directed to take into consideration the goals for reforming the wage index that were set forth by MedPAC in its June 2007 Report to Congress and to consult with relevant affected parties.

• Section 5503 of Public Law 111–148, as amended by Public Law 111–152 and section 203 of Public Law 111–309, which provides for the reduction in FTE resident caps for direct GME under Medicare for certain hospitals, and the ''redistribution'' of the estimated number of FTE resident slots to other qualified hospitals. In addition, section 5503 requires the application of these provisions to IME in the same manner as the FTE resident caps for direct GME.

• Section 5506 of Public Law 111–148, which added a provision to the Act that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria up to the number of the closed hospital's FTE resident caps. The Secretary is directed to ensure that the aggregate number of FTE resident cap slots distributed is equal to the amount of slots in the closed hospital's direct GME and IME FTE resident caps, respectively.

D. 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 2013. 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 2013.

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 this proposed rule, we include the following:

• Proposed changes to MS–DRG classifications based on our yearly review.

• Proposed application of the documentation and coding adjustment for FY 2013 resulting from implementation of the MS–DRG system.

• A discussion of the Research Triangle Institute, International (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 adjustment in MS–DRG payments for FY 2013.

• A discussion of the FY 2013 status of new technologies approved for add-on payments for FY 2012 and a presentation of our evaluation and analysis of the FY 2013 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Public Law 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 2013 wage index update using wage data from cost reporting periods beginning in FY 2009.

• Analysis and implementation of the proposed FY 2013 occupational mix adjustment to the wage index for acute care hospitals.

• 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 2013 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 2013 hospital wage index.

• Determination of the labor-related share for the proposed FY 2013 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 discussed proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412, 413, and 476, including the following:

• The proposed rules for payment adjustments under the Hospital Readmissions Reduction Program based on hospital readmission measures and the process for hospital review and correction of those rates.

• Proposed clarification regarding the duration of the classification status of SCHs.

• The proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.

• Proposed payment adjustment for low-volume hospitals for FY 2013.

• The statutorily required IME adjustment factor for FY 2013, a clarification of the requirements of timely filing of claims for Medicare Advantage enrollees for IME, direct GME, and nursing and allied health education payment purposes, and a proposal to apply the timely filing requirements to the submission of no-pay bills for purposes of calculating the DSH payment adjustment.

• Proposal for counting labor and delivery beds in the formula for determining the payment adjustment for disproportionate share hospitals and IME payments.

• Discussion of the expiration of the MDH program in FY 2012.

• Proposed changes to the inpatient hospital update for FY 2013, including incorporation of a productivity adjustment.

• Proposed changes relating to GME and IME payments, including proposed changes in new growth period for new residency programs from 3 years to 5 years for new teaching hospitals; clarification related to the 5-year period following implementation of reductions and increases to hospitals' FTE resident caps; and proposals and clarifications related to the preservation of resident cap positions from closed hospitals.

• Proposed conforming changes to regulations relating to reporting requirements for pension costs for Medicare cost-finding purposes.

• Discussion of the Rural Community Hospital Demonstration Program and a proposal for making a budget neutrality adjustment for the demonstration program.

• Proposed delay in the effective date of regulations relating to hospital routine services furnished under arrangements.

4. Proposed FY 2013 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 2013 and

the proposed MS–DRG documentation and coding adjustment for FY 2013.

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.

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 2013. Specifically, we are proposing the following major changes: a 1-year extension of the moratorium on the full implementation of the ''25-percent threshold'' payment adjustment at 42 CFR 412.534 and 412.536; a ''one-time prospective adjustment'' to the standard Federal rate phased in over a 3-year period (which would not be applicable to payments for discharges occurring on or before December 28, 2012, consistent with the statute); an LTCH-specific market basket; and annual updates to the LTCH PPS standard Federal rate and to other payment factors.

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

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

- Proposed requirements for the Hospital Inpatient Quality Reporting (IQR) Program as a condition for receiving the full applicable percentage increase.
- The proposed establishment of a quality reporting program for PPS-exempt cancer hospitals.
- Proposed requirements for the Hospital Value-Based Purchasing Program.
- Proposed revisions to the quality reporting measures under the LTCH quality reporting program.
- Proposed quality data reporting requirements for ambulatory surgical centers (ASCs).
- The establishment of the Inpatient Psychiatric Facilities Quality Reporting Program

8. 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 2013 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 2013 for certain hospitals excluded from the IPPS.

9. 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 2013 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.

10. 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, LTCHs, ASCs, and IPFs.

11. 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 2013 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).
- 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.

12. 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 2012 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 addressed these recommendations in Appendix B of this proposed rule. For further information relating specifically to the MedPAC March 2012 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

For general information about the MS–DRG system, including yearly reviews and changes to the MS–DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43764 through 43766), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50053 through 50055), and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51485 through 51487).

C. Adoption of the MS–DRGs in FY 2008

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

D. Proposed FY 2013 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

In the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189), we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS–DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. (Currently, there are 751 MS–DRGs, which include 4 additional MS–DRGs that we adopted 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 Law110–90 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, and we finalized the FY 2008 adjustment through rulemaking, effective on October 1, 2007 (72 FR 66886).

For FY 2009, section 7(a) of Public Law 110–90 required a documentation and coding adjustment of −0.9 percent, and we finalized that adjustment through rulemaking (73 FR 48447). The documentation and coding adjustments established in the FY 2008 IPPS final rule with comment period, which reflected the amendments made 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 only 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 performed a retrospective evaluation of the FY 2008 data for claims paid through December 2008 using the methodology first described in the FY 2009 IPPS/LTCH PPS final rule (73 FR 43768 and 43775) and later discussed in the FY 2010 final rule (74 FR 43768 through 43772). We performed the same analysis for FY 2009 claims data using the same methodology as we did for FY 2008 claims (75 FR 50057 through 50068). The results of the analysis for the FY 2011 proposed and final rules, and subsequent evaluations in FY 2012, supported that the 5.4 percent estimate accurately reflected the FY 2009 increases in documentation and coding under the MS–DRG system. We were persuaded by both MedPAC's analysis (as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50064 through 50065) and our own review of the methodologies recommended by various commenters that the methodology we employed to determine the required documentation and coding adjustments were sound.

5. Prospective Adjustments for FY 2008 and FY 2009 Authorized by Section 7(b)(1)(A) of Public Law 110–90 and Section 1886(d)(3)(vi) of the Act

In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43767 through 43777), we

opted to delay the implementation of any documentation and coding adjustment until a full analysis case-mix changes based on FY 2009 claim data could be completed. We refer readers to the FY 2010 IPPS/LTCH PPS final rule 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 percent. 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 that do not reflect real changes in case-mix 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 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. 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 because we finalized a −2.9 percent recoupment adjustment for that year. 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). 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.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51489 and 51497), we indicated that because further delay of this prospective adjustment will result in a continued accrual of unrecoverable overpayments, it was imperative that we implement a prospective adjustment for FY 2012, while recognizing CMS' continued desire to mitigate the effects of any significant downward adjustments to hospitals. Therefore, we implemented a −2.0 percent prospective adjustment (a reduction of a proposed −3.15 percent adjustment) to the standardized amount to partially eliminate the full effect of the documentation and coding changes that do not reflect real changes in case-mix 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 in section II.D.6. of this preamble), and after considering other payment adjustments to FY 2012 rates proposed elsewhere in the FY 2012 proposed rule, we indicated that we believe a −2.0 percent adjustment would allow for a significant reduction in potential unrecoverable overpayments, yet would maintain a comparable adjustment level between FY 2011 and FY 2012, reflecting the applicable percentage increase with a documentation and coding adjustment. We stated that we recognize that an additional adjustment of −1.9 percent (3.9 percent minus 2.0 percent) would be required in future rulemaking to complete the necessary −3.9 adjustment to meet CMS' statutory requirement under section 7(b)(1)(A) of Public Law 110–90.

For FY 2013, we are proposing to complete the prospective portion of the adjustment required under section 7(b)(1)(B) of Public Law 110–90. We are proposing a −1.9 percent adjustment to the standardized amount for FY 2013. This adjustment would remove the remaining effect of the documentation and coding changes that do not reflect real changes in case-mix that occurred in FY 2008 and FY 2009. We believe it is imperative to implement the full remaining adjustment, as any further delay would result in an overstated standardized amount in FY 2013 and any future years until a full adjustment is made. We believe that the offsetting nature of the FY 2012 recoupment adjustment (described in section II.D.6. of this preamble) will mitigate any negative financial impacts of this prospective adjustment.

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

As discussed in section II.D.3. 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. Our actuaries estimated that this 5.8 percentage point increase resulted in an increase in aggregate payments of approximately $6.9 billion. Therefore, as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50062 through 50067), we determined that an aggregate adjustment of −5.8 percent in FYs 2011 and 2012 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, consistent with the policies that we have adopted in many similar cases, in the FY 2011 IPPS/LTCH PPS final rule, we made 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 allowed 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).

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.

Therefore, for FY 2012, in accordance with 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 completed 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 (76 FR 51489 and 51498). Because these adjustments, in effect, balanced out, there was no year-to-year change in the standardized amount due to this recoupment adjustment for FY 2012.

The −2.9 percent adjustment in each of the 2 previous fiscal years completed the required recoupment for overpayments due to documentation and coding effects on discharges occurring in FYs 2008 and 2009. In this FY 2013 proposed rule, we are proposing to make a final +2.9 percent adjustment to the standardized amount. This adjustment would remove the effect of the onetime −2.9 percent adjustment implemented in FY 2012. 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.

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. (We note that the MDH program expires in FY 2012, as discussed in section IV.H. of this proposed rule.) 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 documentation and coding 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/RY 2010 LTCH PPS 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 FY 2010 proposed and final rules for a more complete discussion.

As we have noted previously, because hospitals paid on the basis of their hospital-specific rate, including SCHs (and MDHs until the end of FY 2012), 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 were 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. 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 hospitals paid on the basis of their hospital-specific rate. We note that, for FY 2013, this adjustment would only apply the SCHs because the MDH program expires in FY 2012 (as discussed in section IV.G. of this preamble). 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 adjustment needed to be made, as opposed to a −3.9 percent remaining adjustment for IPPS hospitals.

After finalizing a −2.9 percent prospective adjustment in FY 2011 (75 FR 50067 through 50071), we finalized a prospective adjustment to the hospital-specific rate of −2.0 percent for FY 2012 (76 FR 51499) instead of our proposed adjustment of −2.5 percent. Making this level of adjustment allows CMS to maintain, for FY 2012, consistency in payment rates for different IPPS hospitals paid using the MS–DRG. We indicated in the final rule that because this −2.0 percent adjustment no longer reflects the entire remaining requirement adjustment amount of −2.5 percent, an additional −0.5 percent adjustment to the hospital-specific payment rates would be required in future rulemaking.

For this FY 2013 proposed rule, we are proposing to complete the remaining prospective adjustment to account for the documentation and coding effect that occurred in FY 2008 and FY 2009 by applying a −0.5 percent adjustment to the hospital-specific rate. We continue to believe that SCHs had the same opportunity to benefit from improvements in documentation and coding that did not reflect an increase in patient severity, and we continue to believe that any resulting adjustments should be applied similarly to all subsection (d) hospitals, when possible. In FY 2013, we are proposing a prospective adjustment of −1.9 percent to the standardized amount. Therefore, we believe it is also appropriate to propose a −0.5 percent adjustment to the hospital-specific rate for FY 2013.

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 documentation and coding 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.

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 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

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 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 that do not reflect real changes in case-mix 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. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50072 through 50073), 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.

Because the Puerto Rico-specific rate received a full prospective adjustment of −2.6 percent in FY 2011, we proposed no further adjustment in the proposed rule for FY 2012. For FY 2013, we also are not proposing any adjustment to the Puerto Rico-specific rate.

10. Proposed Prospective Adjustments for FY 2010 Documentation and Coding Effect

Section 7(b)(1)(A) of Public Law 110–90 required CMS to make prospective documentation and coding adjustments under section 1886(d)(3)(A)(iv) of the Act if, based upon a review of FY 2008 and FY 2009 discharges, we determined that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix during FY 2008 or FY 2009 and that were different than the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90. However, section 1886(d)(3)(A)(vi) of the Act authorizes adjustments to the average standardized amounts if the Secretary determines such adjustments to be necessary for any subsequent fiscal years in order to eliminate the effect of coding or classification changes that do not reflect real changes in case-mix. After review of comments and recommendations received in a FY 2012 comment letter from MedPAC (available on the Internet at: *http://www.medpac.gov/documents/06172011_FY12IPPS_MedPAC_COMMENT.pdf*), we analyzed claims data in FY 2010 to determine whether any additional adjustment would be required to ensure that the introduction of MS–DRGs was implemented in a budget neutral manner. While we expect that the impacts of documentation and coding behavior in response to the introduction of MS–DRGs in FY 2008 will eventually decline to insignificant levels, we analyzed FY 2010 data on claims paid through December 2011 using the same claims-based methodology as described in previous rulemaking (73 FR 43768 and 43775). We determined a total prospective documentation and coding effect of 1.008 percent for FY 2010. Our actuaries have estimated that this 0.8 percentage point increase resulted in an increase in aggregate payments of approximately $1.19 billion in FY 2010. Therefore, we also are proposing an additional −0.8 percent adjustment to account for the effects of documentation and coding changes that did not reflect real changes in case-mix in FY 2010.

The combined total prospective adjustment to the standardized amount proposed for FY 2013 under Public Law 110–90 to account for documentation and coding effects in FY 2008 and FY 2009 and under section 1886(d)(3)(A)(vi) of the Act to account for documentation and coding effect in FY 2010 is −2.7 percent (−1.9 percent plus −0.8 percent). The proposed adjustment would eliminate the effect of documentation and coding that did not reflect real changes in case-mix for discharges occurring during FYs 2008, 2009, 2010. While we are making no proposals regarding future fiscal years at this time, we plan to continue to monitor and analyze additional claims data and make adjustments, when necessary, as authorized under 1886(d)(3)(A)(vi) of the Act. We note that the proposed total adjustment to the proposed FY 2013 standardized amount would be +0.2 percent because these prospective adjustments will be offset by the completion of the recoupment adjustment under section 7(b)(1)(B) of Public Law 110–90, as discussed below.

We note that while we have decided to review FY 2010 claims data to determine whether additional prospective adjustments are necessary (as discussed earlier), section 7(b)(1)(B) of Public Law 110–90 does not authorize CMS to calculate any retrospective adjustment for overpayments made in FY 2010, nor to recover any related overpayments beyond FY 2012. The Secretary's authority under section 1886(d)(3)(A)(vi) of the Act is limited to prospective adjustments.

	Remaining prospective adjustment for FYs 2008–2009	Prospective adjustment for FY 2010	Proposed prospective adjustment for FY 2013	Removal of onetime recoupment adjustment in FY 2013	Combined proposed documentation & coding adjustment for FY 2013
Level of Adjustments	−1.9%	−0.8%	−2.7%	+2.9%	+0.2%

Consistent with our proposal for IPPS hospitals paid on the basis of the standardized amount, our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act, and based upon our review of FY 2010 claims data, we also are proposing an additional −0.8 percent adjustment to the hospital-specific rate to account for documentation and coding changes in FY 2010 that did not reflect real changes in case-mix. We believe that a full prospective adjustment for hospitals paid based on the hospital-specific rate is the most appropriate means to take into 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. Therefore, we are proposing a combined adjustment of −1.3 percent (−0.5 percent + −0.8 percent) to the hospital-specific rate, accounting for all documentation and coding effects observed between FY 2008 though FY 2010.

Based upon our analysis of FY 2010 claims data, we found no significant additional effect of documentation and coding in FY 2010 that would warrant any additional adjustment to the Puerto Rico-specific rate.

As in prior years, the FY 2008, FY 2009, and FY 2010 MedPAR files are available to the public to allow independent analysis of the FY 2008 and FY 2009 documentation and coding effects. 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.

E. Refinement of the MS–DRG Relative Weight Calculation

1. Background

Beginning in FY 2007, we implemented relative weights for DRGs based on cost report data instead of charge information. We refer readers to the FY 2007 IPPS final rule (71 FR

47882) for a detailed discussion of our final policy for calculating the cost-based DRG relative weights and to the FY 2008 IPPS final rule with comment period (72 FR 47199) for information on how we blended relative weights based on the CMS DRGs and MS–DRGs.

As we implemented 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 the Research Triangle Institute, International (RTI) to study the effects of charge compression in calculating the relative weights and to consider methods to reduce the variation in the cost-to-charge ratios (CCRs) across services within cost centers. For a detailed summary of RTI's findings, recommendations, and public comments that we received on the report, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (73 FR 48452 through 48453).

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, 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 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 the items that should be reported in these respective cost centers, we adopted the commenters' recommendations that hospitals should use revenue codes established by the AHA's National Uniform Billing Committee to determine the items that 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 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.

As we discussed in the FY 2009 IPPS final rule (73 FR 48458, respectively) and in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68519 through 68527), in addition to the findings regarding implantable devices, RTI also found that the costs and charges of computed tomography (CT) scans, magnetic resonance imaging (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 the 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 costs from charges on claims data. 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. (We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080) for a detailed discussion of the reasons for the creation of standard cost centers for CT scans, MRI, and cardiac catheterization.) The new standard cost centers for CT scans, MRI, 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.

2. Summary of Policy Discussion in FY 2012

In the FY 2009 IPPS 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. However, as noted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43782), due to delays in the issuance of the revised cost report CMS 2552–10, we determined that a new CCR for Implantable Devices Charged to Patients might not be available before FY 2013. Similarly, when we finalized the decision in the FY 2011 IPPS/LTCH PPS final rule to add new cost centers for CT scans, MRI, 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).

Accordingly, during the FY 2012 IPPS rulemaking (76 FR 51502), we 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 was necessary to have a critical mass of cost reports filed with data in this cost center. We checked the availability of data in the ''Implantable Devices Charged to Patients'' cost center on the FY 2009 cost reports, but we did not believe that there was a sufficient amount of data from which to generate a meaningful analysis in this particular situation. Therefore, we did not propose to use data from the ''Implantable Devices Charged to Patients'' cost center to create a distinct CCR for ''Implantable Devises Charged to Patients'' for use in calculating the MS–DRG relative weights for FY 2012. We indicated that we would reassess the availability of data for the ''Implantable Devices Charged to Patients'' cost center for the FY 2013 IPPS/LTCH PPS rulemaking cycle and, if appropriate, we would propose to create a distinct CCR at that time.

3. Discussion for FY 2013

To calculate the MS–DRG relative weights, we use two data sources: the MedPAR file as the claims data source and the HCRIS as the cost data source. We adjust the charges from the claims to costs by applying the 15 national average CCRs developed from the cost reports. In the past several years, we have made progress in changing the cost report to add the ''Implantable Devices Charged to Patients'' cost center. At this time, there is a sizeable number of hospitals in the FY 2010 HCRIS that have reported data for ''Implantable Devices Charged to Patients'' on their cost reports beginning during FY 2010. However, we note that, during the development of this proposed rule, we have been able to access only those cost reports in the FY 2010 HCRIS with fiscal year begin dates on or after October 1, 2009, and before May 1, 2010. This is because cost reports with fiscal year begin dates of May 1, 2010,

through September 30, 2010, were filed on the new cost report Form 2552–10, and cost reports filed on the Form 2552–10 are not currently accessible in the HCRIS. Normally, we pull the HCRIS dataset that is 3 years prior to the IPPS fiscal year (that is, for the FY 2013 relative weights, we would use the FY 2010 HCRIS, which includes data from cost reports that begin on or after October 1, 2009, and before October 1, 2010). However, because data from the Form 2552–10 cost reports are not currently available, to ensure that the relative weights are calculated with a data set that is as comprehensive and accurate as possible, we are proposing to calculate the FY 2013 relative weights with data from FY 2010 cost reports for providers with fiscal year begin dates of on or after October 1, 2009, and before May 1, 2010, and to back fill with data from FY 2009 cost reports for those providers that have fiscal year begin dates on or after May 1, 2010 through September 30, 2010. Further complicating matters is that, due to additional unforeseen technical difficulties, the corresponding information regarding charges for implantable devices on hospital claims is not yet available to us in the MedPAR file. Without the breakout in the MedPAR file of charges associated with implantable devices to correspond to the costs of implantable devices on the cost report, we believe that we have no choice but to propose to continue computing the relative weights with the current CCR that combines the costs and charges for supplies and implantable devices. When we do have the necessary supplies and implantable device data on the claims in the MedPAR file to create distinct CCRs for supplies and implantable devices, perhaps for FY 2014, we also hope that we will have data for an analysis of creating distinct CCRs for MRI, CT scans, and cardiac catheterization. Prior to proposing to create these CCRs, we will first thoroughly analyze and determine the impacts of the data. Distinct CCRs for implantable devices, MRIs, and CT scans would be used in the calculation of the relative weights only if they were first finalized through rulemaking.

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

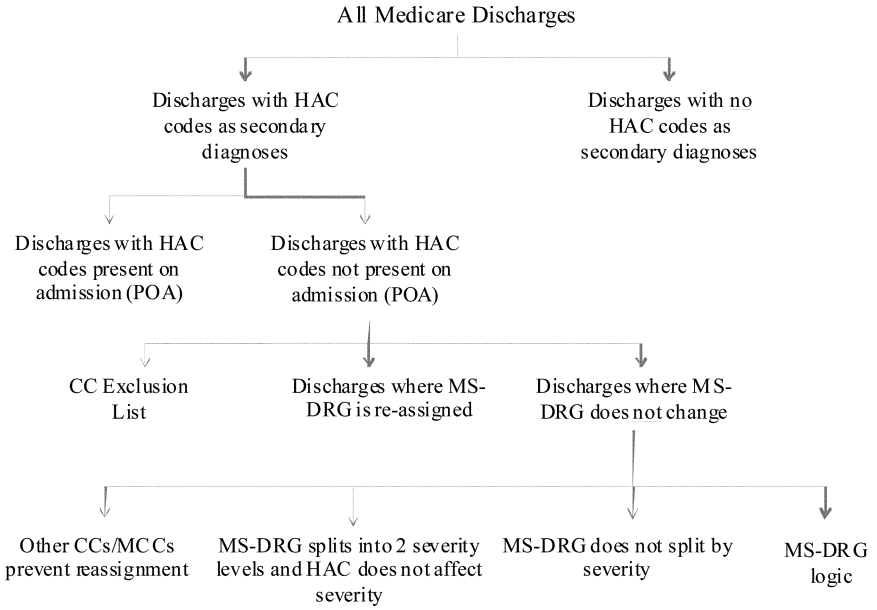
1. Background

Section 1886(d)(4)(D) of the Act addresses certain hospital-acquired conditions (HACs), including infections. This provision is part of an array of Medicare tools that we are using to promote increased quality and efficiency of care. 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 261 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.

Section 1886(d)(4)(D) 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.

Effective for discharges occurring on or after October 1, 2008, pursuant to the authority of section 1886(d)(4)(D) of the Act, Medicare no longer assigns an inpatient hospital discharge to a higher paying MS–DRG if a selected condition is not present on admission (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. In addition, Medicare continues to assign a discharge to a higher paying MS–DRG if a selected condition is POA. When a HAC is not POA, payment can be effected in a manner shown in the diagram below.



2. HAC Selection

Beginning in FY 2007, we have set forth proposals, and solicited and responded to public comments, to implement section 1886(d)(4)(D) of the Act through the IPPS annual rulemaking process. For specific policies addressed in each rulemaking cycle, including a detailed discussion of the collaborative interdepartmental process and public input regarding selected and potential candidate HACs, we refer readers to the following rules: 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); the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23880) and final rule (75 FR 50080); and the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25810 through 25816) and final rule (76 FR 51504 through 51522). A complete list of the 10 current categories of HACs is included on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html*.

In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25813 through 25814) and FY 2012 IPPS/LTCH PPS final rule (76 FR 51507 through 50509), we proposed but did not finalize the candidate condition Contrast-Induced Acute Kidney Injury. Instead, we deferred the decision making on this condition as a selected HAC until future rulemaking and such a time when improved coding for the condition is available.

3. Present on Admission (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 previous rulemaking, we provided both CMS and CDC Web site resources that are available to hospitals for assistance in this reporting effort. For detailed information regarding these sites and materials, including the application and use of POA indicators, we refer the reader to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51506 through 51507).

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:* Under the HAC policy, we treat HACs coded with ''Y'' and ''W'' indicators as POA and allow the condition on its own to cause an increased payment at the CC/MCC level. We treat HACs coded with ''N'' and ''U'' indicators as Not Present on Admission (NPOA) and do not allow the condition on its own to cause an increased payment at the CC/MCC level. We refer readers to the following rules for a detailed discussion: The FY 2009 IPPS proposed rule (73 FR 23559) and final rule (73 FR 48486 through 48487); the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule (74 FR 24106) and final rule (74 FR 43784 through 43785); the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23881 through 23882) and final rule (75 FR 50081 through 50082); and the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25812 through 25813) and final rule (76 FR 51506 through 51507).

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.*

Beginning on or after January 1, 2011, hospitals were 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. 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, which can be located at the following link on the CMS Web site: *http://www.cms.gov/manuals/downloads/Pub100_20.pdf*. 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.

In addition, as discussed elsewhere in section III.G.9. of the preamble of this proposed rule, the 5010 format allows the reporting and effective January 1, 2011, the processing of up to 25 diagnoses and 25 procedure codes. As such, it is necessary to report a valid POA indicator for each diagnosis code, including the principal and all secondary diagnoses up to 25.

4. HACs and POA Reporting in ICD–10–CM and ICD–10–PCS

As we stated in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51506 and 51507), in preparation for the transition to the ICD–10–CM and ICD–10–PCS code sets, further information regarding the use of the POA indicator with the ICD–10–CM/ICD–10–PCS classifications as they pertain to the HAC policy will be discussed in future rulemaking.

At the March 5, 2012 meeting of the ICD–9–CM Coordination and Maintenance Committee, an announcement was made with regard to the availability of the ICD–9–CM HAC list translation to ICD–10–CM and ICD–10–PCS code sets. Participants were informed that the list of the current ICD–9–CM selected HACs has been translated into codes using the ICD–10–CM and ICD–10–PCS classification system. It was recommended that the public review this list of ICD–10–CM/ICD–10–PCS code translations of the current selected HACs available on the CMS Web site at: *http://www.cms.gov/ICD10/17_ICD10_MS_DRG_Conversion_Project.asp*. The translations can be found under the link titled ICD–10–CM/PCS MS–DRG v29 Definitions Manual Table of Contents—Full Titles—HTML Version in Appendix I—Hospital Acquired Conditions (HACs). The translation list also is available on the CMS Web page at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/icd10_hacs.html*. We encourage the public to submit comments on these translations through the HACs Web page using the CMS ICD–10–CM/PCS HAC Translation Feedback Mailbox that has been set up for this purpose under the Related Links section titled ''CMS HAC Feedback.'' The final HAC list translation from ICD–9–CM to ICD–10–CM/ICD–10–PCS will be subject to formal rulemaking.

In the meantime, we continue to encourage readers to review the educational materials and draft code sets currently available for ICD–10–CM/ICD–10–PCS on the CMS Web site at: *http://www.cms.gov/ICD10/*. In addition, the draft ICD–10–CM/ICD–10–PCS coding guidelines can be viewed on the CDC Web site at: *http://www.cdc.gov/nchs/icd/icd10cm.htm*.

5. Proposed Changes to the HAC Policy for FY 2013

a. Proposed Additional Diagnosis Codes to Existing HACs

As changes to diagnosis codes and new diagnosis codes have been proposed and finalized for the list of CCs and MCCs, we have modified the list of selected HACs to reflect these changes. While there are not any new diagnosis codes being proposed for FY 2013, there were new and revised diagnosis codes effective October 1, 2011 (FY 2012) that were not finalized in time for inclusion in the FY 2012 IPPS rulemaking. Therefore, we are now proposing to add two of these codes to an existing HAC category. We are proposing to add diagnosis codes 999.32 (Bloodstream infection due to central venous catheter) and 999.33 (Local infection due to central venous catheter) to the Vascular Catheter-Associated Infection HAC category for FY 2013. These codes were created in response to a request discussed at the March 9–10, 2011 ICD–9–CM Coordination and Maintenance Committee meeting to better identify specific types of infections (systemic vs. local) that occur as a result of central venous catheter placement.

Previously, there was only one existing HAC code (999.31 (Infection due to central venous catheter)) in the Vascular Catheter-Associated Infection HAC category. With the creation of codes 999.32 and 999.33, effective October 1, 2011, the title for code 999.31 was revised to ''Other and unspecified infection due to central venous catheter.'' Therefore, codes 999.32 and 999.33 provide further specificity as to the type of infection due to a central venous catheter. We refer readers to page 45 of the topic packet found at the following link on the CDC ICD–9–CM Web page at *http://www.cdc.gov/nchs/data/icd9/TopicpacketforMarch2011_HA1.pdf* for further information.

Shown in the table below are these proposed two diagnosis codes with their corresponding descriptions and their CC/MCC designations.

ICD–9–CM code	Code descriptor	CC/MCC designation
999.32	Bloodstream infection due to central venous catheter	CC
999.33	Local infection due to central venous catheter	CC

We are inviting public comments on the proposed adoption of these two ICD–9–CM diagnosis codes designated as CC/MCCs that are listed above, to be added to the Vascular Catheter-Associated Infection HAC category as indicated for FY 2013.

b. Proposal To Add New HAC Condition: Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures

We discuss below our rationale for proposing a new condition, Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures, for selection for FY 2013 as a HAC under section 1886(d)(4)(D) of the Act. As described in more detail in section II.F.1. 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 are inviting public comment on the degree to which these conditions fulfill these statutory requirements, as well as clinical, coding, and prevention issues on our proposal to add Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures as a condition subject to the HAC payment provision for discharges occurring on or after October 1, 2012.

CIED therapy reduces morbidity and mortality in selected patients with cardiac rhythm disturbances.[1] More than 500,000 CIEDs are implanted each year in the United States and 70 percent of CIED recipients are age 65 or older.[2] However, this benefit with regard to the treatment of cardiac rhythm disturbances is somewhat reduced by complications following device placement, including infections. Patients can present with early or late infections because of CIED placement.[3] Two-thirds of these infections are caused by Staphylococcus aureus and coagulase-negative Staphylococcus species. Treatment of these infections usually entails surgical explantation of the device, sometimes under general anesthesia and a prolonged course of intravenous antibiotics, along with external electrical support in a monitored intensive care setting. The rate of CIED infection is increasing faster than the rate of CIED implantation,[4] and there are published data on the mortality and cost associated with CIED infection or the relationship of these outcomes to different CIED types.

There is not a unique code that identifies SSI Following CIED Procedures. However, the condition can be identified as a subset of discharges with ICD–9–CM diagnosis code 996.61 (Infection and inflammatory reaction due to cardiac device, implant and graft) or 998.59 (Other postoperative infection). Our clinical advisors believe that diagnosis code 996.61 or 998.59, in combination with the associated procedure codes below, can accurately identify SSI Following CIED Procedures. The procedure codes are:

- 00.50 (Implantation of cardiac resynchronization pacemaker without mention of defibrillation, total system [CRT–P]);
- 00.51 (Implantation of cardiac resynchronization defibrillator, total system [CRT–D]);
- 00.52 (Implantation or replacement of transvenous lead [electrode] into left ventricular coronary venous system);
- 00.53 (Implantation or replacement of cardiac resynchronization pacemaker pulse generator only [CRT–P]);
- 00.54 (Implantation or replacement of cardiac resynchronization defibrillator pulse generator device only [CRT–D]);
- 37.80 (Insertion of permanent pacemaker, initial or replacement, type of device not specified);
- 37.81 (Initial insertion of single-chamber device, not specified as rate responsive);
- 37.82 (Initial insertion of single-chamber device, rate responsive);
- 37.83 (Initial insertion of dual-chamber device);
- 37.85 (Replacement of any type pacemaker device with single-chamber device, not specified as rate responsive);
- 37.86 (Replacement of any type of pacemaker device with single-chamber device, rate responsive);
- 37.87 (Replacement of any type pacemaker device with dual-chamber device);
- 37.94 (Implantation or replacement of automatic cardioverter/defibrillator, total system [AICD]);
- 37.96 (Implantation of automatic cardioverter/defibrillator pulse generator only);
- 37.98 (Replacement of automatic cardioverter/defibrillator pulse generator only);
- 37.74 (Insertion or replacement of epicardial lead [electrode] into epicardium);
- 37.75 (Revision of lead [electrode]);
- 37.76 (Replacement of transvenous atrial and/or ventricular lead(s) [electrode]);
- 37.77 (Removal of lead(s) [electrode] without replacement);
- 37.79 (Revision or relocation of cardiac device pocket); and
- 37.89 (Revision or removal of pacemaker device).

We are proposing to identify Surgical Site Infection Following CIED Procedures with diagnosis code 996.61 or 998.59 in combination with one or more of the above associated procedure codes. We believe the condition meets the three criteria for inclusion on the HAC list, as discussed in greater detail below.

First, the condition is one that is high cost and high volume. We reviewed Medicare claims data in the FY 2011 MedPAR file. For FY 2011, we found that there were 859 inpatient discharges coded with Surgical Site Infection Following CIED Procedures as specified by diagnosis code 996.61 or 998.59 when reported with one or more of the above cited associated procedure codes submitted through Medicare claims. The cases had an average cost of $51,795 for the entire hospital stay. We found that there were 583 inpatient discharges coded with Surgical Site Infection Following CIED Procedures as specified by diagnosis code 996.61 or 998.59 when reported with one or more of the above cited associated procedure codes submitted through Medicare claims reported as POA. These POA cases had an average cost of $41,999. We also found that there were 276 inpatient discharges coded with Surgical Site Infection Following CIED Procedures as specified by diagnosis code 996.61 or 998.59 when reported with one or more of the above cited associated procedure codes submitted through Medicare claims reported as NPOA. These NPOA cases had an average cost of $72,485. We note that these data are consistent with other data presented for current HACs. Therefore, we believe this condition is high cost and high volume.

In addition, we reviewed the literature regarding this condition. Infection associated with CIED procedures resulted in a substantial incremental increase in admission mortality and long-term mortality, and varies with the type of CIED. For the purposes of this proposal, we are considering CIED procedures in the

[1] Epstein, A. E., J. P. DiMarco, *et al.* (2008). ''ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices): developed in collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons.'' *Circulation* 117(21): e350–408.

[2] Zhan, C., W. B. Baine, *et al.* (2007). ''Cardiac device implantation in the United States from 1997 through 2004: a population-based analysis.'' *J Gen Intern Med,* 23 Suppl 1: 13–19.

[3] Baddour, L. M., A. E. Epstein, *et al.* (2010). ''Update on cardiovascular implantable electronic device infections and their management: a scientific statement from the American Heart Association.'' *Circulation,* 121(20048212): 458–477.

Baddour, L. M., A. E. Epstein, *et al.* (2010). ''Update on Cardiovascular Implantable Electronic Device Infections and Their Management: A Scientific Statement From the American Heart Association.'' *Circulation,* 121(3): 458–477.

[4] Greenspon, A. J., J. D. Patel, *et al.* (2011). ''16–Year Trends in the Infection Burden for Pacemakers and Implantable Cardioverter-Defibrillators in the United States 1993 to 2008.'' *Journal of the American College of Cardiology* 58(10): 1001–1006.

aggregate. Several large studies showed CIED infection associated with an approximately 5 percent to 8 percent inhospital mortality as well as a 17.5 percent to 35.1 percent one year mortality.[5] Additionally, there is a significant cost impact for patients who suffer infections after CIED implantation. A recent large analysis of 2007 data on over 200,000 Medicare beneficiaries demonstrated the mean hospital cost of CIED infections to be $28,676 to $53,349, compared with a mean hospital cost ranging from $12,468 to $36,851 for beneficiaries without infection.[6] This additional information supports our conclusion from our analysis of data in the MedPAR file that this condition is high cost.

Second, the condition of Surgical Site Infection Following CIED Procedures, as specified in our proposal, is a CC under the MS–DRG system. We have not identified any additional administrative or operational difficulties associated with proposing this condition as a HAC.

Third, because there are widely recognized guidelines for the prevention of Surgical Site Infection Following CIED Procedures, we believe the condition is reasonably preventable through application of evidenced-based guidelines. A large randomized controlled trial demonstrated that prophylactic preoperative antibiotics reduced CIED infection by 81 percent in patients who received them.[7] Well-accepted guidelines for the prevention and prophylaxis of CIED infection now exist supporting the use of prophylactic antibiotics.

We are inviting public comment on whether Surgical Site Infection Following CIED Procedures 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 condition as a proposed condition subject to the HAC payment provision for FY 2013 (for discharges occurring on or after October 1, 2012). We are particularly interested in receiving comments on the degree to which Surgical Site Infection Following CIED Procedures is reasonably preventable through the application of evidence-based guidelines.

c. Proposal To Add New HAC: Iatrogenic Pneumothorax With Venous Catheterization

We discuss below our rationale for proposing a new condition, Iatrogenic Pneumothorax with Venous Catheterization, for selection as a HAC for FY 2013 under section 1886(d)(4)(D) of the Act. We had previously proposed Iatrogenic Pneumothorax more generally as a HAC in the FY 2009 IPPS rulemaking (73 FR 48485).

In the FY 2009 IPPS final rule (73 FR 48485), we considered Iatrogenic Pneumothorax as a condition but did not finalize it due to commenters' concerns about the preventability of the condition when following the evidence-based guidelines. Most commenters opposed the selection of Iatrogenic Pneumothorax as a HAC and indicated that the evidence-based guidelines often acknowledge that Iatrogenic Pneumothorax is a known relatively common risk for certain procedures. Further, with regard to evidence-based guidelines, many commenters opposed designation of this condition as a HAC due to a lack of consensus within the medical community regarding its preventability.[8] Some commenters offered suggestions to exclude certain procedures or situations, including central line placement, thoracotomy, and the use of a ventilator, if Iatrogenic Pneumothorax were to be selected as a HAC. In that rule, we noted that we would continue to review the development of evidence-based guidelines for the prevention of Iatrogenic Pneumothorax if evidence warrants and consider Iatrogenic Pneumothorax as a HAC in the future. We refer readers to that final rule for a more detailed discussion (73 FR 48485). To address concerns raised by commenters in FY 2009, we reviewed changes in the standard of care and evidence-based guidelines to identify specific situations where Iatrogenic Pneumothorax would be considered reasonably preventable and identified venous catheterization as one such instance.

Pneumothorax is defined as the presence of air or gas in the pleural cavity, which is the space between the covering of the tissue of the lung and parietal pleura, or the part of the pleura that lines the chest wall. The presence of air in this space partially or completely collapses the lung and is life threatening. Air can enter the intrapleural space through a passage through the chest wall. Iatrogenic Pneumothorax is a type of traumatic pneumothorax that results from incursion into the pleural space secondary to diagnostic or therapeutic medical intervention, such as needle placement for central line catheter guidance.

There is no unique code that identifies Iatrogenic Pneumothorax with Venous Catheterization. However, Iatrogenic Pneumothorax with Venous Catheterization can be identified as a subset of discharges with ICD–9–CM diagnosis code 512.1 (Iatrogenic pneumothorax). Our clinical advisors believe that diagnosis code 512.1, in combination with the associated procedure code 38.93 (Venous catheterization NEC), can accurately identify Iatrogenic Pneumothorax with Venous Catheterization. We are proposing to identify Iatrogenic Pneumothorax with Venous Catheterization reported in combination with diagnosis code 512.1 (Iatrogenic pneumothorax) and procedure code 38.93 (Venous catheterization NEC). We recognize that, in quality measurement such as with the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicator (PSI) Number 6 (Iatrogenic Pneumothorax Rate), exclusion criteria are used to increase the accuracy of identifying these cases. We believe that, by limiting our proposal to include Iatrogenic Pneumothorax as a HAC only in the context of venous catheterization, we have improved our ability to accurately identify these cases. While we are not proposing exclusion criteria, we welcome public comment in this regard. In addition, we believe this more narrowly tailored condition meets the three criteria for inclusion on the HAC list, as discussed in greater detail below.

First, the condition is one that is high cost and high volume. We reviewed Medicare claims data in the FY 2011 MedPAR file. We found that there were 4,467 inpatient discharge cases coded for Iatrogenic Pneumothorax with Venous Catheterization as specified by diagnosis code 512.1 reported with procedure code 38.93. The cases had an average cost of $39,128 for the entire hospital stay. We found that there were 612 inpatient discharge cases coded for Iatrogenic Pneumothorax with Venous Catheterization as specified by diagnosis code 512.1 reported with procedure code 38.93 submitted through Medicare claims reported as POA. These POA cases had an average cost of $26,693. We also found that there were 3,855 inpatient discharge cases coded for

[5] Tarakji, K. G., E. J. Chan, *et al.* (2010). ''Cardiac implantable electronic device infections: Presentation, management, and patient outcomes.'' *Heart Rhythm* 7(8): 1043–1047.

[6] Sohail, M. R., C. A. Henrikson, *et al.* (2011). ''Mortality and cost associated with cardiovascular implantable electronic device infections.'' *Arch Intern Med* 171(20): 1821–1828.

[7] de Oliveira, J. C., M. Martinelli, *et al.* (2009). ''Efficacy of Antibiotic Prophylaxis Before the Implantation of Pacemakers and Cardioverter-Defibrillators: Results of a Large, Prospective, Randomized, Double-Blinded, Placebo-Controlled Trial.'' *Circ Arrhythm Electrophysiol,* 2(1): 29–34.

[8] Ahan, *et al.* ''Accidental Iatrogenic Pneumothorax in Hospitalized Patients,'' *Medical Care,* 44(2):182–6, Feb. 2006.

Iatrogenic Pneumothorax with Venous Catheterization as specified by diagnosis code 512.1 reported with procedure code 38.93 submitted through Medicare claims reported as NPOA. These NPOA cases had an average cost of $41,102. We note that these data are consistent with other data presented for current HACs. Therefore, we believe this condition is high cost and high volume.

In addition, we reviewed the literature regarding this condition. The cannulation of veins (that is insertion of a catheter) with central venous catheterization is an important aspect of patient care for the administration of fluids and medications and for monitoring purposes. Eight percent of hospitalized patients receive a central venous catheter, and more than 5 million central venous catheters are inserted in the United States each year. Indwelling catheters have several known complications and side effects associated with their use, such as infections or vessel damage. Additionally, there are risks associated with the placement of central venous catheters including the risk of pneumothorax for central catheters placed in the upper area of the patient's neck or chest when placed in the internal jugular or subclavian veins. Mechanical complications associated with Iatrogenic Pneumothorax are reported to occur in 5 to 19 percent of patients.[9]

Second, the condition of Iatrogenic Pneumothorax with Venous Catheterization as specified in our proposal is a CC under the MS–DRGs.

Third, there are widely recognized guidelines that address the prevention of Iatrogenic Pneumothorax with Venous Catheterization, and we believe that Iatrogenic Pneumothorax in the context of venous catheterization is reasonably preventable through application of these evidenced-based guidelines.

In terms of guidelines, the AHRQ, in a 2001 report ''Making Health Care Safer: A Critical Analysis of Patient Safety Practices'' (AHRQ Publication No. 01–EO58) recommended the use of ultrasound for the placement of all central venous catheters as one of its 11 practices aimed at improving patient care. Current standard placement techniques for these venous catheters rely on the knowledge of anatomic landmarks and other indicators to guide the initial cannulation of the vein. The increase in the number of small, advanced and portable 2D ultrasound devices has inspired the use of these newer ultrasound devices in central venous line placement, as now direct visualization of the target vessel can be achieved, making it easier to avoid these complications. Recommendations for the use of ultrasound as an adjunct to central venous line placement now exist and are based on supportive literature Category A (Randomized controlled trials report statistically significant (P _ .01) differences between clinical interventions for a specified clinical outcome) with a Level 1 weight of scientific evidence (multiple randomized controlled trials with the aggregated findings supported by meta-analysis).[10] Several studies have shown a decrease in the mechanical complication rate with the use of ultrasound during line placement.[11] Guidelines for performing ultrasound guided vascular cannulation have been recently published.[12]

We believe new evidence-based guidelines provide substantial clinical guidance for reasonable prevention when this condition occurs in the context of venous catheterization. We are inviting public comment on whether Iatrogenic Pneumothorax with Venous Catheterization 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 proposed condition, as a condition subject to the HAC payment provision for discharges occurring on or after October 1, 2012. We are particularly interested in public comment on how limiting the condition to situations in which it occurs in conjunction with venous catheterization influences preventability, and whether additional limits should be considered in the context of venous catheterization.

With the exception of the condition of Iatrogenic Pneumothorax with Venous Catheterization, at this time, we do not believe that additional analysis exists that would require us to change our previous determinations regarding the previously considered candidate HACs in the FY 2008 IPPS final rule with comment period (72 FR 47200 through 47218), the FY 2009 IPPS final rule (73 FR 48471 through 48491), the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43782 through 43785), and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51510 through 51511). We refer readers to these rules for a detailed discussion that supports our determination regarding each of the previously considered candidate HACs and continue to encourage public dialogue about refinements to the HAC list.

6. RTI Program Evaluation Summary

On September 30, 2009, a contract was awarded to Research Triangle Institute, International (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. The evaluation includes conditions that are currently treated as HACs and also previously considered candidate conditions. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (50085 through 50101), and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51512 through 51522) for a fuller description of this evaluation and findings to date regarding analysis of FY 2009 and FY 2010 data, respectively. Summary and detailed data were 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/*. RTI's analysis of the FY 2011 MedPAR data file for the HAC–POA program evaluation is being prepared for the FY 2013 IPPS/LTCH PPS final rule. When these summary and detailed data are available, they also will be made publicly available on the two Web sites noted above.

In addition to the evaluation of HAC and POA MedPAR claims data, RTI has also conducted analyses on readmissions due to HACs and the incremental costs of HACs to the health care system, a study of spillover effects and unintended consequences, as well

[9] McGee, D. C. and M. K. Gould (2003). ''Preventing Complications of Central Venous Catheterization.'' *New England Journal of Medicine,* 348(12): 1123–1133.

[10] Echoc, A., U. R., B. T., A. S., O. A., A. T., S. O., C. A., T. F., O. T. (2010). ''Practice Guidelines for Perioperative Transesophageal Echocardiography.'' *Anesthesiology,* 112(5): 1084–1096 1010.1097/ALN.1080b1013e3181c1051e1090.

[11] Hind, D.: ''Ultrasonic device for central venous cannulation: Meta-analysis.'' BJM, 2003, vol. 327, 7411:361–364; and

Troianos, C. A., G. S. Hartman, *et al.* (2012). ''Guidelines for Performing Ultrasound Guided Vascular Cannulation: Recommendations of the American Society of Echocardiography and the Society of Cardiovascular Anesthesiologists.'' *Anesthesia and Analgesia,* 114(1): 46–72.

[12] Troianos, C. A., G. S. Hartman, *et al.* (2012). ''Guidelines for Performing Ultrasound Guided Vascular Cannulation: Recommendations of the American Society of Echocardiography and the Society of Cardiovascular Anesthesiologists.'' *Anesthesia and Analgesia,* 114(1): 46–72.

as an updated analysis of the evidence-based guidelines for selected and previously considered HACs. Reports on these analyses have been made publicly available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html*.

G. Proposed Changes to Specific MS–DRG Classifications

In this FY 2013 IPPS/LTCH PPS 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.

We encourage 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 2013, comments and suggestions should have been submitted by early December 2011. The comments that were submitted in a timely manner are discussed below in this section.

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

a. Ventricular Assist Devices (VADs)

A ventricular assist device (VAD) is a mechanical circulatory device or pump that is used to partially or completely support heart function and blood flow in patients with a damaged or weakened heart. The device takes blood from the ventricles of the heart and helps pump the blood to the rest of the body.

Some VADs are intended for short-term use, often for patients who are recovering from heart attacks or heart surgery, while other VADs are intended for long-term use (months to years and, in some cases, for life). VADs are not the same device as artificial hearts, which are designed to completely take over cardiac function and generally require the removal of the patient's native heart.

VADs are designed to assist the ventricles, either the right (RVAD) or the left (LVAD), and, in some cases, both ventricles at once (BiVAD). The type of VAD used depends on the patient's underlying heart disease and the pulmonary arterial resistance that determines the load on the right ventricle. LVADs are the most commonly used, but when pulmonary arterial resistance is high, right ventricular assistance becomes necessary and an RVAD may be inserted. Long-term VADs are normally used to help maintain a patient's quality of life while he or she awaits a heart transplant. This process is known as a ''bridge to transplant.'' However, sometimes the insertion of an LVAD becomes the final treatment for the patient, which is known as ''destination therapy.'' In this case, the VAD is a permanent implant, and no heart transplantation occurs. In a smaller number of cases, the implantation of a VAD, combined with pharmaceutical therapy, has enabled the native heart to recover sufficiently to allow the VAD to be explanted, a ''bridge to recovery.''

We have issued a national coverage determination (NCD) entitled ''Artificial Hearts and Related Devices'' under Section 20.9 of the Medicare Coverage Manual (Pub. No. 100–3). This NCD, which describes CMS' requirements for coverage of medical services provided to Medicare beneficiaries for the insertion of VADs, can be found at the CMS Web site at: *https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=246&ncdver=5&NCAId=211&ver=20&NcaName=Artificial+Hearts&bc=ACAAAAAAIAAA&*. We refer readers to this Web site for the complete viewing of the NCD for the insertion of VADs.

The assignment of procedure codes used to describe the insertion of VADs has been discussed repeatedly in IPPS rulemaking, for the CMS–DRGs (in effect prior to FY 2008) and more recently for the MS–DRGs (FY 2008 to present). We refer readers to the FY 2003 IPPS final rule (67 FR 49989) for a complete discussion of the assignment of these procedure codes up to that date. In addition, the topic was discussed in FY 2005; we refer readers to the FY 2005 IPPS final rule (69 FR 48927 through 48930) for a complete discussion regarding the assignment of these procedure codes for FY 2005. Specifically, for FY 2005, we moved ICD–9–CM procedure code 37.66 (Insertion of implantable heart assist system) from CMS–DRG 525 (Other Heart Assist System Implant) to CMS–DRG 103 (Heart Transplant). When we adopted the MS–DRG classification system in FY 2008, former CMS–DRG 103 remained in the Pre-MDC section but was renamed and subdivided into MS–DRG 001 (Heart Transplant or Implant of Heart Assist System with MCC) and MS–DRG 002 (Heart Transplant or Implant of Heart Assist System without MCC).

For FY 2013, we have received a request to restructure MS–DRGs 001 and 002 by removing all of the procedure codes that describe the insertion of a device, leaving only procedure codes 33.6 (Combined heart-lung transplantation) and 37.51 (Heart transplantation) in the heart transplant DRGs. The requestor further asked that the remaining device codes be assigned to newly created MS–DRGs. The requestor believed that, within the existing MS–DRG grouping, CMS is underpaying for services to patients who have a VAD implanted and overpaying for services to patients who have heart transplantations. The requestor believed that the recommended restructuring ''would allow defined grouping of cases with the higher level of resource [sic] required reflected in payment.''

We have reviewed data in the September 2011 update of the FY 2011 MedPAR file and found that the average length of stay for heart transplantations and VAD implantation cases are very similar (35.1 days for heart transplantations and 36.63 days for VAD implantations). We also found that the average cost for VAD implantation cases alone is higher than the average cost of heart transplantation cases. The table below includes our findings.

MS–DRG	Number of cases	Average length of stay	Average cost
MS–DRG 001—All Cases	1,235	36.97	$164,846
MS–DRG 001—Cases with Heart Transplant without VAD	384	35.1	123,472
MS–DRG 001—Cases with VAD Insertion Alone	811	36.85	181,915
MS–DRG 002—All Cases	313	19.66	89,818
MS–DRG 002—Cases with Heart Transplant without VAD	172	15.1	58,890
MS–DRG 002—Cases with VAD Insertion Alone	140	25.31	128,069

We believe that this higher average cost could be attributable to the cost of the device itself. There are very few VADs approved by FDA; therefore, we believe this small group of manufacturers is able to set their own charges in the market. We point out that the IPPS is not designed to pay solely for the cost of devices. The MS–DRG classification system (and more importantly, the IPPS) is not based solely on the cost of devices.

Rather, the MS–DRG system is a patient classification system that provides an average means of relating the type of patients a hospital treats (that is, case-mix) to the costs incurred by the hospital. We have previously stated that, ''Central to the success of the Medicare inpatient hospital prospective payment system is that DRGs have remained a clinical description of why the patient required hospitalization. We believe it would be undesirable to transform DRGs into detailed descriptions of the technology and processes used by the hospital to treat the patient. If such a transformation were to happen, the DRGs would become largely a repackaging of fee-for-service without the management and communication benefits. The separation of the clinical and payment weight methodologies allows a stable clinical methodology to be maintained, while the payment weights evolve in response to changing practice patterns. The packaging of all services associated with the care of a particular type of patient into a single payment amount provides the incentive for efficiency inherent in a DRG-based prospective payment system. Substantial disaggregation of the DRGs into smaller units of payment, or a substantial number of cases receiving extra payments, would undermine the incentives and communication value in the DRG system.'' (66 FR 46904)

The results of our review of the claims data for MS–DRGs 001 and 002 are summarized in the following table.

Code	Description of code(s)	Number of cases
MS–DRG 001 (Heart Transplant or Implant of Heart Assist System With MCC)		
All codes		1,235
33.6 or 37.51	Combined heart-lung transplantation or Heart transplantation	384
33.6 or 37.51 with 37.66	Combined heart-lung transplantation or Heart transplantation with Insertion of implantable heart assist system (VAD).	11
37.52	Implantation of total internal biventricular heart replacement system (Artificial heart)	2
37.66	Insertion of implantable heart assist system (VAD)	811
37.60 with 37.64	Implantation or insertion of biventricular external heart assist system + Removal of external heart assist system(s) or device(s).	1
37.63 with 37.64	Repair of heart assist system + Removal of external heart assist system(s) or device(s)	0
37.64 with 37.65	Removal of external heart assist system(s) or device(s) + plant of single ventricular (extracorporeal) external heart assist system.	22
	Multiple VADs without heart transplant	22
MS–DRG 002 (Heart Transplant or Implant of Heart Assist System With MCC)		
All codes		313
33.6 or 37.51	Combined heart-lung transplantation or Heart transplantation	172
33.6 or 37.51 with 37.66	Combined heart-lung transplantation or Heart transplantation with Insertion of implantable heart assist system (VAD).	0
37.52	Implantation of total internal biventricular heart replacement system (Artificial heart)	0
37.66	Insertion of implantable heart assist system (VAD)	140
37.60 with 37.64	Implantation or insertion of biventricular external heart assist system plus Removal of external heart assist system(s) or device(s).	0
37.63 with 37.64	Repair of heart assist system + Removal of external heart assist system(s) or device(s)	0
37.64 with 37.65	Removal of external heart assist system(s) or device(s) + plant of single ventricular (extracorporeal) external heart assist system.	1
	Multiple VADs without heart transplant	4

In general, we believe that the IPPS should accurately recognize differences in utilization for clinically distinct procedures. However, we also reiterate the language in the FY 2009 IPPS final rule that the payments under a prospective payment system are predicated on averages (73 FR 48443). To create a new MS–DRG specific to VAD implantation would require basing that MS–DRG almost exclusively on the presence of procedure code 37.66, representing a single procedure and currently one manufacturer with FDA approval. Currently, other manufacturers are reported to be in clinical trials with their VADs. This approach negates our longstanding method of grouping like procedures and diminishes the concept of averaging. Further, we are concerned that ignoring the structure of the MS–DRG system solely for the purpose of increasing payment for one device would set an unwarranted precedent for defining all of the other MS–DRGs in the system (73 FR 48497 and 48498).

The commenter requested that we create two new MS–DRGs for the VADs and that the requested MS–DRGs be divided based on the presence or absence of an MCC. We point out that the final rule establishing the MS–DRGs sets forth five criteria, all five of which are required to be met in order to warrant creation of a CC or an MCC subgroup within a base MS–DRG. The criteria can be found in the FY 2008 IPPS final rule with comment period (72 FR 47169). The original criteria were based on average charges; we now use average costs (FY 2007 IPPS final rule (71 FR 47882)). To reiterate, these criteria are as follows:

- 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 cost between subgroups.

As procedure code 37.66 predominates in our claims data for VAD implantations, we are including the following table demonstrating the cost difference between MS–DRG 001 and MS–DRG 002.

MS–DRG	Number of cases	Average cost
001—Cases with procedure code 37.66	811	$181,915
002—Cases with procedure code 37.66	140	128,069

As stated in the FY 2008 IPPS final rule with comment period, all five criteria must be met in order to subdivide an MS–DRG into MCC and non-MCC severity levels. In this instance, the number of cases in MS–DRG 002 containing procedure code 37.66 is 140, not the minimum number of 500 cases as established by the MS–DRG severity criteria. Therefore, even if we were to create a new MS–DRG for VAD implantation, unless we further divided the MS–DRG based on the presence of an MCC, we would substantially overpay approximately 15 percent of total VAD cases. However, we could not create multiple MS–DRGs for VAD implantation without ignoring our rules for subdividing MS–DRGs.

For these reasons, for FY 2013, we are not proposing to make any changes to the structure of MS–DRGs 001 and 002. We are inviting public comment on our proposal.

b. Allogeneic Bone Marrow Transplant

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50101), 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 MS–DRGs 014 and 015 because of differences in costs associated with the procedures in these two MS–DRGs. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51525 through 51526), we further subdivided MS–DRG 015 into two severity levels, by deleting MS–DRG 015 and creating MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC); and MS–DRG 017 (Autologous Bone Marrow Transplant without CC/MCC). We created MS–DRGs 014 and 015 as these groups meet all five criteria for subdivision by severity level that we established in the FY 2008 IPPS final rule with comment period (72 FR 47169). As we discussed in the FY 2012 IPPS/LTCH PPS final rule, MS–DRG 014 did not meet the criteria for subdivision by severity level.

During the comment period for the FY 2012 IPPS/LTCH PPS proposed rule, we received a public comment regarding related and unrelated allogeneic bone marrow transplants (which are captured in MS–DRG 014) that had not been the subject of a proposal in that proposed rule. This issue was referred to briefly in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51557), but we did not address the issue because we considered the comment to be out of the scope of provisions of the proposed rule. However, we are addressing this issue in this FY 2013 proposed rule. The commenter recommended that MS–DRG 014 be subdivided into two MS–DRGs based on related and unrelated transplant donor source.

Allogeneic bone marrow transplantation utilizes the bone marrow or stem cells from a donor that is either related (sibling or other close family member) or unrelated (not a close family member of the recipient) in the treatment of certain cancers and bone marrow diseases. Allogeneic transplant recipients must have a tissue type that matches the donor. According to the commenter, a related donor will typically be managed by the transplant facility from human leukocyte antigen (HLA) molecular typing through mobilization and collection, while an unrelated donor requires the use of donor registry for searching and collection process. According to the commenter, the unrelated donor setting adds significant costs to the transplant that would not be incurred in the related transplant setting.

Currently, there are three ICD–9–CM procedure codes that identify the transplant donor source:

• 00.91 (Transplant from live related donor)
• 00.92 (Transplant from live non-related donor)
• 00.93 (Transplant from cadaver)

In our analysis of data in the FY 2011 MedPAR file, we found 467 cases assigned to MS–DRG 014 with average costs of approximately $64,403 and an average length of stay of approximately 24.8 days. There were 125 cases that reported procedure code 00.91 on the claim as the related transplant donor source with average costs of approximately $55,969 and an average length of stay of approximately 24.1 days. In our analysis of the unrelated donor source, we included the cases reported with the transplant from a cadaver donor source (code 00.93) with the transplant from a live nonrelated donor source (code 00.92). There were 213 cases that reported either code 00.92 or 00.93 as the transplant donor source with average costs of approximately $64,837 and an average length of stay of approximately 23 days. There were 129 cases that did not report a transplant donor source with average costs of approximately $71,859 and an average length of stay of approximately 28.5 days. The following table illustrates our findings:

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 014—All cases	467	24.8	$64,403
MS–DRG 014—Live related donor (code 00.91)	125	24.1	55,969
MS–DRG 014—Live nonrelated donor (code 00.92) or cadaver (code 00.93)	213	23	64,837
MS–DRG 014—No donor source	129	28.5	71,859

We note that one quarter of the cases (129 out of 467 cases) that did not report a transplant donor source code had the highest average costs of approximately $71,859, compared to $55,969 for live related donors and $64,837 for live nonrelated or cadaver donors and $64,403 for the overall average cost of cases within MS–DRG 014. The cases without a transplant donor source code also had a longer length of stay (28.5 days) than the live-related donor cases

(24.1 days), the live nonrelated or cadaver cases (23 days), and the overall cases (24.8 days) assigned to MS–DRG 014.

Based on these findings, we believe that it would not be advisable to include cases without a transplant donor source code with the live nonrelated or cadaver donor cases, as we believe it would encourage providers not to report the transplant donor source code. All possible options must be included in any MS–DRG reconfiguration. Therefore, cases with no reported transplant donor source code must be included in the updated logic because this is the group with the highest average costs. Our clinical advisors reviewed this issue and do not support splitting MS–DRG 014 into two MS–DRGs because a quarter of the cases did not provide a transplant donor source. Therefore, we have concluded that the cases reported with a transplant donor source code are appropriately assigned to MS–DRG 014 and that MS–DRG does not warrant further subdivision. Without more complete information on donor source, we are not proposing that MS–DRG 014 be subdivided at this time. We are inviting public comment on our proposal not to subdivide MS–DRG 014 into two MS–DRGs based on related and unrelated donor source.

2. MDC 4 (Diseases and Disorders of the Ear, Nose, Mouth and Throat): Influenza With Pneumonia

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51557), we discussed a public comment that we considered out of the scope of the FY 2012 proposed rule. Therefore, we did not address the issues in the final rule. The commenter requested that we consider reassigning cases with a combined diagnosis of influenza with pneumonia from a set of simple pneumonia MS–DRGs to a set of MS–DRGs that captures a more severe type of pneumonia. The specific request involves cases now assigned to MS–DRGs 193 (Simple Pneumonia and Pleurisy with MCC), 194 (Simple Pneumonia and Pleurisy with CC), and 195 (Simple Pneumonia and Pleurisy without MCC/CC) being moved to MS–DRGs 177 (Respiratory Infections and Inflammations with MCC), 178 (Respiratory Infections and Inflammations with CC), and 179 (Respiratory Infections and Inflammations without MCC/CC).

We examined data in the FY 2011 MedPAR file on cases that reported diagnosis code 487.0 (Influenza with pneumonia) as the principal diagnosis with an additional secondary diagnosis code for one of the following types of pneumonia:

- 482.0 (Pneumonia due to Klebsiella pneumoniae)
- 482.1 (Pneumonia due to Pseudomonas)
- 482.40 (Pneumonia due to Staphylococcus, unspecified)
- 482.41 (Methicillin susceptible pneumonia due to Staphylococcus aureus)
- 482.42 (Methicillin resistant pneumonia due to Staphylococcus aureus)
- 482.49 (Other Staphylococcus pneumonia)
- 482.81 (Pneumonia due to anaerobes)
- 482.82 (Pneumonia due to Escherichia coli [E. coli])
- 482.83 (Pneumonia due to other gram-negative bacteria)
- 482.84 (Pneumonia due to Legionnaires' disease)
- 482.89 (Pneumonia due to other specified bacteria)

Currently, when one of the pneumonia codes listed above is reported as a principal diagnosis, the case is assigned to MS–DRG 177, 178, or 179. However, when the patient has been diagnosed with one of these types of pneumonia and also has influenza, the ICD–9–CM coding book directs the coder to report diagnosis code 487.0 as the principal diagnosis and to assign an additional secondary code to describe the specific type of pneumonia. This reporting results in cases with diagnoses of both influenza and specific types of pneumonia being assigned to MS–DRG 193, 194, or 195 (Simple Pneumonia and Pleurisy with MCC, with CC, or without CC/MCC, respectively), instead of MS–DRG 177, 178, or 179. The commenter requested that we reassign cases reporting code 487.0 as the principal diagnosis with one of the specific pneumonia codes listed above as a secondary diagnosis to MS–DRGs 177, 178, and 179.

We analyzed data from the MedPAR file on cases with patients with pneumonia and found the following:

MS–DRG	Number of cases	Average length of stay	Average cost
MS–DRG 177—All cases	69,128	8.20	$13,002
MS–DRG 178—All cases	59,559	6.40	9,193
MS–DRG 179—All cases	14,108	4.65	6,365
MS–DRG 193—All cases	125,892	6.28	9,589
MS–DRG 193—Cases with principal diagnosis code 487.0 and with a secondary diagnosis code of 482.0, 482.1, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, or 482.89	57	9.3	15,867
MS–DRG 193—Cases with principal diagnosis code 487.0 and without a secondary diagnosis code of 482.0, 482.1, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, or 482.89	1,320	6.93	10,416
MS–DRG 194—All cases	191,030	4.73	6,524
MS–DRG 194—Cases with principal diagnosis code 487.0 and with a secondary diagnosis code of 482.0, 482.1, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, or 482.89	59	6.9	9,752
MS–DRG 194—Principal diagnosis code 487.0 and without a secondary diagnosis code of 482.0, 482.1, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, or 482.89	2,088	5.16	6,871
MS–DRG 195—All cases	80,253	3.53	4,660
MS–DRG 195—Cases with a principal diagnosis code 487.0 and a secondary diagnosis code of 482.0, 482.1, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, or 482.89	12	4.8	5,842
MS–DRG 195—Cases with principal diagnosis code 487.0 and without a secondary diagnosis code of 482.0, 482.1, 482.40, 482.41, 482.42, 482.49, 482.81, 482.82, 482.83, 482.84, or 482.89	1,065	3.78	4,580

The data showed that cases reporting a principal diagnosis code 487.0 with one of the pneumonia codes listed above as a secondary diagnosis have significantly higher average costs ($15,867 in MS–DRG 193, $9,752 in MS–DRG 194, and $5,842 in MS–DRG 195) than those cases reported without one of the pneumonia codes listed above as a secondary diagnosis ($10,416 in MS–DRG 193, $6,871 in MS–DRG 194, and $4,580 in MS–DRG 195), and also the overall average costs for all cases in MS–DRGs 193, 194, and 195 ($9,589, $6,524, and $4,660, respectively). The influenza and pneumonia cases had average costs that more closely align with the average costs of cases currently assigned to MS–DRGs 177, 178, and 179 ($13,002, $9,193, and $6,365, respectively).

As a result of our analysis, the data support the commenter's request that we reassign cases reporting a principal diagnosis code 487.0 and an additional secondary diagnosis code for one of the pneumonia codes listed above, from MS–DRGs 193, 194, and 195 to MS–DRGs 177, 178, and 179. Our clinical advisors also support reassigning these cases to MS–DRGs 177, 178, and 179. Therefore, for FY 2013, we are proposing to reassign cases with a principal diagnosis code 487.0 and an additional secondary diagnosis code of one of the following pneumonia codes listed as a secondary diagnosis codes from MS–DRGs 193, 194, and 195 to MS–DRGs 177, 178, and 179: 482.0; 482.1; 482.40; 482.41; 482.42; 482.49; 482.81; 482.82; 482.83; 482.84; and 482.89.

We are inviting public comment on our proposal for FY 2013.

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

a. Percutaneous Mitral Valve Repair With Implant

We received a request to reassign procedure code 35.97 (Percutaneous mitral valve repair with implant) to the following MS–DRGs:

- MS–DRG 216 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac with MCC);
- MS–DRG 217 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac with CC);
- MS–DRG 218 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac without CC/MCC);
- MS–DRG 219 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac with MCC);
- MS–DRG 220 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac with CC); and
- MS–DRG 221 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac without CC/MCC).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51528 through 51529), we discussed reassigning procedure code 35.97 from MS–DRGs 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively) and MS–DRGs 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). In that final rule, we stated that we did not have sufficient claims data on which to base and evaluate any proposed changes to the current MS–DRG assignment. Procedure code 35.97 was created for use beginning October 1, 2010 (FY 2011) after the concept of percutaneous valve repair was presented at the March 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 was 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 stated that while the procedure code is assigned to MS–DRGs 246 through 251, the most likely MS–DRG assignments would be MS–DRGs 250 and 251, as described above. As we stated in the FY 2012 IPPS/LTCH PPS final rule, because procedure code 35.97 had only been in use since October 1, 2010, there were no claims data in the most recent update of the MedPAR file at that time to evaluate any alternative MS–DRG assignments. Therefore, we did not make any MS–DRG assignment changes for procedure code 35.97 for FY 2012.

For this proposed rule, we have analyzed claims data from the FY 2011 MedPAR file on the procedure that describes mitral valve repair with implant and found the following:

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 216—All Cases	9,624	16.44	$61,015
MS–DRG 217—All Cases	5,655	10.24	41,324
MS–DRG 218—All Cases	995	7.43	34,587
MS–DRG 219—All Cases	15,336	12.53	50,176
MS–DRG 220—All Cases	18,455	7.53	34,150
MS–DRG 221—All Cases	4,719	5.59	29,082
MS–DRG 231—All Cases	1,170	12.17	49,728
MS–DRG 231—Cases with Procedure Code 35.97	4	13.75	35,409
MS–DRG 232—All Cases	1,010	9.16	37,820
MS–DRG 232—Cases with Procedure Code 35.97	9	13.56	46,008
MS–DRG 246—All Cases	29,299	5.20	20,725
MS–DRG 247—All Cases	109,661	2.39	13,014
MS–DRG 248—All Cases	13,562	6.35	19,785
MS–DRG 248—Cases with Procedure Code 35.97	1	32.00	110,262
MS–DRG 249—All Cases	35,100	2.86	11,806

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 250—All Cases	8,313	7.07	19,673
MS–DRG 250—Cases with Procedure Code 35.97	39	9.77	29,753
MS–DRG 251—All Cases	31,316	2.92	12,658
MS–DRG 251—Cases with Procedure Code 35.97	98	2.69	18,651

We note that most of the cases were found in MS–DRGs 250 and 251, as we predicted in the FY 2012 IPPS/LTCH PPS final rule based on FDA's terms of the clinical trial for MitraClip™. As stated earlier, the device is to be implanted in patients without any additional surgeries performed. There were 39 cases in MS–DRG 250 with average costs of $29,753 (which includes cases with an MCC). These average costs are significantly lower than the average costs of $61,015 for cases in MS–DRG 216, and the average costs of $50,176 for cases in MS–DRG 219 (which includes cases with an MCC). There were 98 cases in MS–DRG 251 (without MCC) with average costs of $18,651. These average costs also are lower than the average costs of comparable cases in MS–DRGs 217, 218, 220, and 221, whose average costs range from a high of $41,324 to a low of $29,082. While the average costs of mitral valve repair cases are higher than the average costs of other cases assigned to MS–DRGs 250 and 251, they are significantly less than the average costs of cardiac valve replacement cases assigned to MS–DRGs 216 through 221. Our analysis of the claims data does not support reassigning the procedure that describes percutaneous mitral valve repair with implant from MS–DRGs 250 and 251 to MS–DRGs 216 through 221. Our clinical advisors also support maintaining the current assignment of this procedure in MS–DRGs 250 and 251. Therefore, based on our findings, we are not proposing to reassign procedure code 35.97 from MS–DRGs 250 and 251 to MS–DRGs 216 through 221.

We are inviting public comment on our proposal to maintain the current assignment of procedure code 35.97 in MS–DRGs 250 and 251 and not to reassign the procedure code to MS–DRGs 217 through 221.

b. Endovascular Implantation of Branching or Fenestrated Grafts in Aorta

The fenestrated (with holes) graft device is designed to treat patients with abdominal aortic aneurysms (AAA). Current treatment options for patients with AAAs include open surgical repair, endovascular repair using stent-grafts, or medical management.

Aneurysmal disease that extends proximally to the level of the renal arteries is usually indicative of more extensive aortic disease and comorbidities. As a result, many of these patients are at a higher overall risk when undergoing open surgical repair. In addition, these patients are often not suitable for endovascular treatment with currently available endografts because the length of healthy aorta is insufficient to provide an adequate seal at the proximal end. The indications for use for many of the standard endografts call for an aortic neck length greater than or equal to 15 millimeters.

Published industry reports estimate that 8 percent to 30 percent of patients with AAAs that need repair have aortic necks of less than 15 millimeters in length. One institution has reported that over half of its patients with AAAs were considered ineligible for endovascular aneurysm repair or endovascular aortic repair (EVAR) due to an inadequate length of nondiseased aorta. These patients also were predominantly contraindicated for open repair.

Prior to the development of a fenestrated graft device, the only treatment option available to a large number of these high-risk patients would have been medical management. Open surgical repair is too challenging to frail patients, as it requires supraceliac clamping of the aorta and may result in renal ischemia, mesenteric ischemia, or atheroembolization of the visceral vessels of the aorta. EVAR with a standard endograft is not a viable option either because the shortened neck precludes an adequate proximal end seal, which can lead to type I endoleaks (leaking of blood around the device into the aneurysm resulting in continued pressurization of the aneurysm). Medical management alone leaves these patients at high risk for AAA-related morbidity and mortality. These suboptimal choices led to the creation of fenestrated endografts that can seal above the renal arteries while maintaining access and uninterrupted blood flow to branch vessels of the aorta.

The fenestrated graft is currently under clinical trial in the United States, but has not yet received FDA approval. One of the two companies that are conducting clinical trials expects to receive FDA approval in the second quarter of 2012. Both companies listed on the FDA clinical trial Web site are still recruiting participants.

At the September 15, 2010 meeting of the ICD–9–CM Coordination and Maintenance Committee, the topic of fenestrated graft was presented with a request for a unique procedure code. As a result of that meeting, and additional meetings with manufacturers throughout the year, procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta) was created for use beginning October 1, 2011 (FY 2012). This code is assigned to MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively).

We have received a request from a manufacturer to reassign procedure code 39.78 from MS–DRGs 252, 253, and 254 and to MS–DRGs 237 and 238 (Major Cardiovascular Procedures with MCC and without MCC, respectively). The requestor stated that the assignment to MS–DRGs 252, 253, and 254 violates both of CMS' stated principles regarding assigning new codes to MS–DRGs that reflect both clinical coherence and similar consumption of resources.

From the standpoint of clinical coherence, the requestor noted that, while procedures in MS–DRGs 252, 253, and 254 are vascular procedures, the procedures do not involve the aorta. The requestor further notes that AAA repairs, both open and endovascular, are assigned to MS–DRGs 237 and 238. From the standpoint of similar consumption of resources, the requestor included anticipated device costs of $17,424 to $21,824 for a fenestrated endovascular procedure. The requestor noted that these costs only represent the device and do not include any additional resources required during the hospitalization. The requestor believed that the device costs are more similar to devices used in MS–DRGs 237 and 238.

CMS' practice is to assign new codes to MS–DRGs where similar procedures are also located. In terms of clinical coherence, CMS assigned the new code to the vascular procedure MS–DRGs (252, 253, and 254) where other noncoronary endovascular procedures for blood vessel repair also are assigned. This decision was based on our practice

to group similar procedures together, in this case repairs to blood vessels, especially for new codes when CMS has no data history.

With regard to resource consumption, we point out that procedure code 39.78 was created for use effective with discharges on or after October 1, 2011. Our review of data in the MedPAR file shows no utilization of this code because it is too new. That is, we have no claims data that would either prove or disprove the requestor's supposition that procedure code 39.78 is not adequately paid under MS–DRGs 252, 253, and 254. As discussed elsewhere in this preamble, CMS is not a device classification system. Therefore, because there are very few companies currently marketing their fenestrated graft devices, we are concerned that these companies are able to set their own charges in the market.

In addition, the requestor opined that ''an argument could possibly be made that the increased device costs and longer procedural times for [procedure code] 39.78 suggest assignment into MS–DRG 237 alone would be appropriate,'' although the requestor further stated that, without a significant volume of actual claims data, it might be more reasonable [for CMS] to take a conservative approach and assign these procedures to either MS–DRG 237 or MS–DRG 238. We note that MS–DRGs 237 and 238 are paired MS–DRGs, with both MS–DRGs containing the same procedure codes, but which have been subdivided based on the formula for the presence or absence of comorbid or complicating conditions. It is not an inherent part of the GROUPER logic to assign a code to only one DRG in a set of paired or triplicate MS–DRGs.

We will continue to evaluate the clinical coherence and resource consumption costs that impact this code and the current MS–DRG assignment. We also note that the requestor has expressed its intent to apply for New Technology status, provided that its anticipated FDA approval is granted in time for this year's IPPS update.

Because there is no data history for procedure code 39.78 that would justify a reassignment based on either clinical coherence or resource consumption, we are not proposing to make a change to the MS–DRG assignment of procedure code 39.78 for FY 2013. We believe that procedure code 39.78 has been appropriately placed within the MS–DRG structure. We are inviting public comment on our proposal.

4. MDC 10 (Endocrine, Nutritional, and Metabolic Diseases and Disorders): Disorders of Porphyrin Metabolism

We received a request for the creation of a new MS–DRG to better identify cases where patients with disorders of porphyrin metabolism exist, to recognize the resource requirements in caring for these patients, to ensure appropriate payment for these cases, and to preserve patient access to necessary treatments. Porphyria is defined as a group of rare disorders (''porphyrias'') that interfere with the production of hemoglobin that is needed for red blood cells. While some of these disorders are genetic (inborn) and others can be acquired, they all result in the abnormal accumulation of hemoglobin building blocks, called porphyrins, which can be deposited in the tissues where they particularly interfere with the functioning of the nervous system and the skin.

Treatment for patients suffering from disorders of porphyrin metabolism consists of an intravenous injection of Panhematin® (hemin for injection). This pharmaceutical agent became the first drug approved under the Orphan Drug Act for rare diseases in 1983. It is the only FDA-approved prescription treatment for acute intermittent porphyria.

ICD–9–CM diagnosis code 277.1 (Disorders of porphyrin metabolism) describes these cases, which are currently assigned to MS–DRG 642 (Inborn and Other Disorders of Metabolism). We analyzed data from the FY 2011 MedPAR file for cases assigned to this MS–DRG. As shown in the table below, we found a total of 1,447 cases in MS–DRG 642 with an average length of stay of 4.63 days and average costs of $7,400. We then analyzed the data for cases reporting diagnosis code 277.1 as the principal diagnosis in this same MS–DRG. We found a total of 330 cases, with an average length of stay of 6.12 days and average costs of $11,476.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 642—All cases	1,447	4.63	$7,400
MS–DRG 642—Cases with principal diagnosis code 277.1	330	6.12	11,476

While the average costs for the 330 cases reporting a principal diagnosis code of 277.1 were higher than all cases in MS–DRG 642 ($11,476 versus $7,400), the volume of affected cases is small, representative of approximately 20 percent of all of the cases in MS–DRG 642. Under our existing policy (76 FR 51487 and 51488), in deciding whether to make modifications to the MS–DRGs, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different from the remaining patients in the MS–DRG. We evaluate the utilization of resources related to patient care using average costs and length of stay and rely 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 consider both the absolute and percentage differences in average costs between the cases we selected for review and the reminder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that were extreme in terms of charges or length of stay. Further, we consider the number of patients who have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases. Therefore, we have determined that the findings do not support the creation of a new MS–DRG.

We acknowledge the importance of ensuring that patients diagnosed with a disorder of porphyrin metabolism have adequate access to care and receive the necessary treatment. Despite the fact that our data analysis did not demonstrate support for the creation of a new MS–DRG at this time, we also explored an alternative option. In reviewing the medical MS–DRGs in terms of resources and clinical coherence that are also located within MDC 10, we found three MS–DRGs that we believe are similar to MS–DRG 642. We analyzed data from the MedPAR file on cases in MS–DRGs 643, 644, and 645 (Endocrine Disorders with MCC, with CC, and without CC/MCC, respectively) to determine if the cases reporting a principal diagnosis code of 277.1 would be more appropriately reassigned from MS–DRG 642 to MS–DRGs 643, 644, and 645. Upon examination of the data,

we found that the average costs of these cases were $10,835, $6,816, and $4,762, respectively, as shown in the table below.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 643—Cases with principal diagnosis code 277.1	6,562	7.11	$10,835
MS–DRG 644—Cases with principal diagnosis code 277.1	12,769	4.89	6,816
MS–DRG 645—Cases with principal diagnosis code 277.1	5,979	3.40	4,762

Based on these findings, if we were to reassign cases where disorders of porphyrin metabolism (diagnosis code 277.1) were reported as the principal diagnosis with a secondary diagnosis designated as a CC (MS–DRG 644) or with a secondary diagnosis that was not a CC/MCC (MS–DRG 645), Medicare would pay significantly less for these cases than they are now paid under MS–DRG 642. Therefore, it would not be appropriate to reassign cases reporting a principal diagnosis code of 277.1 from MS–DRG 642 to MS–DRGs 643, 644, and 645. In addition, our clinical advisors did not support this reassignment. The MS–DRG classification system on which the IPPS is based comprises a system of averages. As such, it is understood that, in any particular MS–DRG, it is not unusual for a small number of cases to demonstrate higher than average costs, nor is it unusual for a small number of cases to demonstrate lower than average costs. Upon review of the MedPAR data and the alternative option discussed, our clinical advisors agree that the current MS–DRG assignment for diagnoses of disorders of porphyrin metabolism (diagnosis code 277.1) to MS–DRG 642 is most appropriate at this time.

As stated previously, we acknowledge and recognize the severity of symptoms that patients diagnosed with disorders of porphyrin metabolism may experience. We also are sensitive to concerns about access to care and treatment for these patients. We will continue to monitor this issue and determine how to better account for the variation in resource utilization within the IPPS for these cases.

In summary, we are not proposing to create a new MS–DRG or to reassign cases reporting a principal diagnosis code of 277.1 to MS–DRGs 643, 644, and 645 for FY 2013. We are inviting public comment on our proposal.

5. Proposed Medicare Code Editor (MCE) Changes

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into an MS–DRG.

We are proposing to make a change to the MCE edits which includes the creation of a new length of stay edit for continuous invasive mechanical ventilation for 96 consecutive hours or more.

It was brought to our attention that a number of hospitals reporting ICD–9–CM procedure code 96.72 (Continuous invasive mechanical ventilation for 96 consecutive hours or more) may be inaccurately reporting this code. As the title of the procedure code implies, a patient must have received continuous mechanical ventilation for 96 hours or more in order for this code to be assigned. This equates to a patient being hospitalized for at least a 4-day length of stay and having received continuous invasive mechanical ventilation for a minimum of 4 days. Therefore, a patient with a length of stay less than 4 days who received continuous invasive mechanical ventilation should not have procedure code 96.72 reported on the claim.

The ICD–9–CM classification system contains three procedure codes that identify and describe continuous invasive mechanical ventilation: Procedure code 96.70 (Continuous invasive mechanical ventilation of unspecified duration); procedure code 96.71 (Continuous invasive mechanical ventilation for less than 96 consecutive hours); and procedure code 96.72 (Continuous invasive mechanical ventilation for 96 consecutive hours or more). To assist in the accurate assignment of these codes, guidance in the form of a ''Note'' is provided within the designated procedure section of ICD–9–CM. This ''Note'' describes the calculation of the number of hours during a hospitalization in which a patient receives continuous invasive mechanical ventilation. In addition, coding advice pertaining to appropriate code assignment for mechanical ventilation has been published in various editions of the American Hospital Association's (AHA's) *Coding Clinic for ICD–9–CM.*

We analyzed the FY 2011 MedPAR data to determine how many cases reported procedure code 96.72 with a length of stay less than 4 days. Specifically, we reviewed cases reporting procedure code 96.72 with a length of stay of 1 day, 2 days, or 3 days. We found a total of 595 cases meeting those criteria. The data analysis showed there were 89 cases reporting procedure code 96.72 with a length of stay of 1 day and average costs of $5,948, 134 cases reporting procedure code 96.72 with a length of stay of 2 days and average costs of $7,776, and 372 cases reporting procedure code 96.72 with a length of stay of 3 days and average costs of $11,613.

The data also demonstrate that the 595 cases found were distributed across a wide range of MS–DRGs, with the top two (in terms of volume) being MS–DRG 207 (Respiratory System Diagnosis with Ventilator Support 96+ Hours) and MS–DRG 870 (Septicemia or Severe Sepsis with Mechanical Ventilation 96+ hours). We note that the two MS–DRGs with the highest volume of cases reporting procedure code 96.72 and having a length of stay less than 4 days are the two MS–DRGs that specifically reference ''96+ hours'' in their titles. More importantly, a large percentage of these cases reporting procedure code 96.72 in error are being grouped to the incorrect MS–DRGs, resulting in significant overpayments. For example, of the 89 cases reporting procedure code 96.72 with a length of stay of 1 day, 31 cases were grouped to MS–DRGs 207 and 870. Of the 134 cases reporting procedure code 96.72 with a length of stay of 2 days, 54 cases were grouped to MS–DRGs 207 and 870. Lastly, of the 372 cases reporting procedure code 96.72 with a length of stay of 3 days, 160 cases were grouped to MS–DRGs 207 and 870. Therefore, the data show that a total of 245 cases (41 percent) were grouped to MS–DRGs 207 and 870 in error, resulting in approximately $25,000 in increased payments for each case (or approximately $6 million in increased payments for all 245 cases). Based on the results of these figures for that portion of the total 595 cases found,

there is an even larger dollar amount that is being overpaid to hospitals. These overpayments justify the proposed corrective actions.

However, we also note that the presumed amount of overpayments for claims having a length of stay less than 4 days, as discussed above, is merely an estimate based on the data analysis that has been conducted at this time. We are aware that, for particular circumstances such as those patients who may require observation services, it is possible to have procedure code 96.72 reported on the claim with a length of stay less than 4 days. Although unlikely, a patient might be briefly ventilated in an extended outpatient stay following a toxic ingestion with loss of protective reflexes or following outpatient procedures with a prolonged effect of anesthesia. A subsequent conversion to an inpatient stay would cause the costs to be attributable to the stay, while the days themselves were not reported in the inpatient date span on the claim. Similar effects could occur following an observation stay for a patient on chronic home or skilled nursing facility ventilation. It is for this reason that we are proposing a new edit in which claims found to have procedure code 96.72 with a length of stay less than 4 days would be returned to the provider for validation and resubmission. Instructions in the form of a Change Request (CR) would be issued prior to the implementation date. We are inviting the public to comment on our proposal to create this edit, effective for FY 2013.

6. 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 lower average costs than the class ordered below it.

We are proposing limited changes to the MS–DRG classifications for FY 2013, as discussed in sections II.G.1. and 4. of this preamble. In our review of these proposed changes, we did not identify any needed changes to the surgical hierarchy. Therefore, we are not proposing any changes to the surgical hierarchy for Pre-MDCs and MDCs for FY 2013.

7. Complications or Comorbidity (CC) Exclusions List

a. Background

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 2013

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.[13]

(1) No Revisions Based on Changes to the ICD–9–CM Diagnosis Codes for FY 2013

For FY 2013, we are not proposing to make any revisions to the CC Exclusions List. There were no changes made to the ICD–9–CM coding system, effective October 1, 2012, due to the partial code freeze. (We refer readers to section II.G.9. of the preamble of this proposed rule for a discussion of ICD–9–CM coding system.)

(2) Suggested Changes to the MS–DRG Severity Levels for Diagnosis Codes for FY 2013

(A) Protein-Calorie Malnutrition

We received a request that we consider changing the severity levels for the following protein-calorie malnutrition diagnosis codes:

- 263.0 (Malnutrition of moderate degree)
- 263.1 (Malnutrition of mild degree)
- 263.9 (Unspecified protein-calorie malnutrition)

It was suggested that we change the severity level for diagnosis codes 263.0 and 263.1 from a non-CC to a CC, while changing the severity level for diagnosis code 263.9 from a CC to a non-CC. We received this comment during the comment period for the FY 2012 IPPS/LTCH PPS proposed rule. We referred to this issue briefly in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51557). We indicated that we considered this comment outside of the scope of the proposed rule, as we did not propose any severity level changes to these codes for FY 2012, and did not address it in the final rule. However, we are addressing this issue in this FY 2013 proposed rule.

For this proposed rule, we analyzed the claims data in the FY 2011 MedPAR file for diagnosis codes 263.0, 263.1, and 263.9. 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 with comment period (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 suggests 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 with comment period (72 FR 47158 through 47161).

The following chart shows the analysis for each of the protein-calorie malnutrition diagnosis codes:

[13] 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); the FY 2011 final rule (75 FR 50114); and the FY 2012 final rule (76 FR 51542). 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.

Code	Diagnosis description	CC level	Cnt 1	Cnt 1 impact	Cnt 2	Cnt 2 impact	Cnt 3	Cnt 3 impact
263.0	Malnutrition of moderate degree	Non-CC	6,040	2.14	21,383	2.61	21,635	3.20
263.1	Malnutrition of mild degree	Non-CC	4,139	2.22	11,598	2.50	8,921	3.13
263.9	Unspecified protein-calorie malnutrition	CC	2,737	2.16	165,825	2.54	178,044	3.34

We ran the following data as described in FY 2008 IPPS final rule with comment period (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 2.14 to a high of 2.22. 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 a MCC. The C1 findings suggest that these codes are more like a CC than a non-CC. The C2 findings ranged from 2.50 to 2.61. 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. The C2 findings of 2.50 for diagnosis code 263.1 and 2.54 for diagnosis code 263.9 suggest these codes are more similar to a CC than a non-CC, while the finding of 2.61 for diagnosis code 263.0 is borderline more similar to a MCC than a CC or non-CC when there is at least one other secondary diagnosis code that is a CC but none that is an MCC.

CC conditions typically have a C1 value over 1.75, a C2 value under 2.5, and a C3 value under 3.2. MCC conditions typically have a C1 value over 2.4, a C2 value over 2.8, and a C3 value over 3.3. We concluded that diagnosis code 263.0 is more similar to a CC than an MCC.

Therefore, the C1 and C2 findings support changing diagnosis codes 263.0 and 263.1 from a non-CC to a CC and maintaining code 263.9 as a CC. Our clinical advisors reviewed this issue and are in support of these findings that these conditions are more appropriately classified as CCs. Based on the data and clinical analysis, we are proposing for FY 2013 to change diagnosis codes 263.0 and 263.1 from a non-CC to a CC. We are not proposing any change to the severity level for diagnosis code 263.9. We are inviting public comment on our proposals.

(B) Antineoplastic Chemotherapy Induced Anemia

We received a request from a commenter that the severity level for diagnosis code 285.3 (Antineoplastic chemotherapy induced anemia) be changed from a non-CC to a CC. We received this comment during the comment period for the FY 2012 IPPS/LTCH PPS proposed rule. We referred to this issue briefly in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51557). In that rule, we indicated that we considered this comment outside of the scope of the proposed rule because we did not propose any severity level changes to diagnosis code 285.3 for FY 2012; therefore, we did not address the issue in the final rule. However, we are addressing this issue in this FY 2013 proposed rule. We examined claims data in the FY 2011 MedPAR file for diagnosis code 285.3 according to the approach that we used in FY 2008 as described above. The following table illustrates our findings:

Code	Diagnosis description	CC level	Cnt 1	Cnt 1 impact	Cnt 2	Cnt 2 impact	Cnt 3	Cnt 3 impact
285.3	Antineoplastic chemotherapy induced anemia.	Non-CC	1,937	1.36	11,858	2.21	6,036	3.11

As discussed above, a value close to 1.0 in the C1 field suggests that the diagnosis code produces the same expected value as a non-CC. A value of 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 finding for diagnosis code 285.3 of 1.36 supports the current severity level of a non-CC. The C2 finding of 2.21 for diagnosis code 285.3 suggests that this code is more similar to a CC than a non-CC but not as significant as an MCC when there is at least one other secondary diagnosis code that is a CC. CC conditions typically have a C1 value over 1.75, a C2 value under 2.5, and a C3 value under 3.2.

Therefore, the C1 and C2 findings do not support changing the severity level for diagnosis code 285.3 to a CC. In addition, our clinical advisors reviewed this issue and support the decision not to change the severity level for diagnosis code 285.3 because the anemia is inherent in the treatment of cancer and does not qualify as a CC. As a result of our data analysis as well as the advice of our clinical advisors, we are not proposing any change to the severity level for diagnosis code 285.3 for FY 2013. We are inviting public comment on our proposal.

(C) Cardiomyopathy and Congestive Heart Failure, Unspecified

We received a comment that recommended changes to the severity levels for the cardiomyopathy and congestive heart failure, unspecified codes. The commenter recommended that cardiomyopathy codes, which are currently classified as CCs, be changed to non-CCs and diagnosis code 428.0 (Congestive heart failure, unspecified) be changed from a non-CC to a CC. According to the commenter, these proposed changes would better represent the resources utilized in caring for this population and reduce the administrative burden in clarifying these diagnoses with providers. We received this comment during the comment period for the FY 2012 IPPS/LTCH PPS proposed rule. We referred to this issue briefly in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51557). We indicated that we considered this comment outside of the scope of the proposed rule because we did not propose any severity level changes to these codes for FY 2012; therefore, we did not address it in the final rule. However, we are addressing this issue in this FY 2013 proposed rule.

The commenter did not provide a list of the cardiomyopathy codes. We identified the following codes for analysis of the claims data in the FY 2011 MedPAR file:

• 425.4 (Other primary cardiomyopathies)
• 425.5 (Alcoholic cardiomyopathy)
• 425.7 (Nutritional and metabolic cardiomyopathy)
• 425.8 (Cardiomyopathy in other diseases classified elsewhere)
• 425.9 (Secondary cardiomyopathy, unspecified)
• 428.0 (Congestive heart failure, unspecified)

We did not include diagnosis codes 425.11(Hypertrophic obstructive cardiomyopathy) and 425.18 (Other hypertrophic cardiomyopathy) for our analysis because these two codes were created in FY 2012 and the data are not yet available. We examined claims data according to the approach that we used in FY 2008 as described above. The following table illustrates our findings:

Code	Diagnosis description	CC Level	Cnt 1	Cnt 1 impact	Cnt 2	Cnt 2 impact	Cnt 3	Cnt 3 impact
425.4	Other primary cardiomyopathies	CC	39,489	1.47	243,719	2.18	139,689	3.20
425.5	Alcoholic cardiomyopathy	CC	438	1.68	2,643	2.19	1,670	3.26
425.7	Nutritional and metabolic cardiomyopathy	CC	60	1.18	869	2.17	799	3.14
425.8	Cardiomyopathy in other diseases classified elsewhere.	CC	940	1.19	5,967	2.15	5,171	3.14
425.9	Secondary cardiomyopathy, unspecified	CC	356	1.56	2,078	2.07	1.372	3.22
428.0	Congestive heart failure, unspecified	Non-CC	304,963	1.40	634,241	2.16	748,649	3.06

The table above shows that the C1 findings for the cardiomyopathy codes ranged from a low of 1.18 to a high of 1.68. A value close to 1.0 in the C1 field suggests that the diagnosis code produces the same expected value as a non-CC. A value of 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 the majority of these cardiomyopathy codes are more similar to a non-CC than a CC. The C2 findings ranged from a low of 2.07 to a high of 2.19. These findings suggest that these cardiomyopathy codes are more similar to a CC.

The C1 finding for diagnosis code 428.0 of 1.40 suggests that the condition is more similar to a non-CC than a CC. The C2 finding for diagnosis code 428.0 of 2.16 suggests that the secondary diagnosis is more similar to a CC than a non-CC.

The data are mixed between the C1 and C2 findings for the cardiomyopathy codes and do not consistently support a change in the severity level. Our clinical advisors reviewed these issues and are not in support of proposing any changes to the severity levels for these codes. Our clinical advisors stated that the diagnosis of cardiomyopathy (diagnosis codes 425.4 through 425.9) is generally severe, with significant impact on the patient requiring additional monitoring resources and cognitive effort, and is appropriately classified as a CC.

The data are mixed between the C1 and C2 findings for the congestive heart failure, unspecified, diagnosis code 428.0. Our clinical advisors reviewed these issues and are not in support of proposing any changes to the severity level of code 428.0. They indicated that diagnosis code 428.0 is very nonspecific and does not identify the severity of the heart failure, and concluded that the current classification for code 428.0 as a non-CC is appropriate. As a result of our data analysis and clinical advisors' review of these issues, we are not proposing any changes to the severity level for the cardiomyopathy and congestive heart failure, unspecified codes for FY 2013. We are inviting public comment on our proposal.

(D) Chronic Total Occlusion of Artery of the Extremities

We received a request to change the severity level designation for diagnosis code 440.4 (Chronic total occlusion of artery of the extremities) to a CC. Currently, the diagnosis code is classified as a non-CC. Chronic total occlusion of artery of the extremities forms when plaque accumulates in an artery over an extended period of time, resulting in total cessation of blood flow. We analyzed claims data in the FY 2011 MedPAR file for this diagnosis code according to the approach that we used in FY 2008 as described above. The following table illustrates our findings:

Code	Diagnosis description	CC level	Cnt 1	Cnt 1 impact	Cnt 2	Cnt 2 impact	Cnt 3	Cnt 3 impact
440.4	Chronic total occlusion of artery of the extremities.	Non-CC	8,439	1.38	8,057	2.70	5,366	3.23

The C1 finding of 1.38 for diagnosis code 440.4 supports the current designation of this diagnosis code as a non-CC. However, the C2 findings of 2.70 suggests that this code is similar to a CC or perhaps an MCC, as this value is near to 3.0, which suggests that this condition is similar to an MCC. However, we would expect a higher C1 value such as 2.4 for this condition to qualify as an MCC.

The C1 and C2 findings support changing diagnosis code 440.4 from a non-CC to a CC. Our clinical advisors reviewed this issue and are in support of changing the severity level because this condition behaves as a CC. Therefore, we are proposing to change the severity level for diagnosis code 440.4 from a non-CC to a CC for FY 2013. We are inviting public comment on our proposal.

(E) Acute Kidney Failure With Other Specific Pathological Lesion in Kidney

We received a request to consider changing the severity level for diagnosis code 584.8 (Acute kidney failure with other specified pathological lesion in kidney). This diagnosis code's severity level is currently classified as an MCC. We examined claims data for this code in the FY 2011 MedPAR file according to the approach described above. The following table illustrates those findings.

Code	Diagnosis description	Severity level	Cnt 1	Cnt 1 impact	Cnt 2	Cnt 2 impact	Cnt 3	Cnt 3 impact
584.8	Acute kidney failure with other specified pathological lesion in kidney.	MCC	12	0.98	13	1.89	1,350	3.17

As discussed above, a C1 value close to 1.0 in the C1 field suggests that the diagnosis code produces the same expected value as a diagnosis code that has been classified as a non-CC. A value close to 2.0 in the C1 field suggests that the condition is more similar to a CC severity level than a non-CC severity level, but not as significant in resource usage as an MCC severity level. In this case, the C1 value finding for diagnosis code 584.8 of 0.98 suggests that this diagnosis code is more similar to a non-CC than an MCC. A C2 value close to 3.0 suggests that the condition is more similar to an MCC than a CC or a non-CC. A C2 value close to 2.0 suggests that the condition is more similar to a CC than a non-CC. The C2 value finding for diagnosis code 584.8 of 1.89 supports classifying the severity level of this diagnosis code as a CC. Therefore, the C1 and C2 value findings support changing the severity level of diagnosis code 584.8 from an MCC to a lower severity level, that is, a CC. Our clinical advisors reviewed this issue and stated that this condition behaves as a CC. Therefore, they supported changing the severity level of this diagnosis code to a CC. Based on the clinical analysis and consistent with supporting claims data, we believe that the severity level of diagnosis code 584.8 should be changed from an MCC to a CC. Therefore, we are proposing to change the severity level of diagnosis code 584.8 from an MCC to a CC for FY 2013. We are inviting public comment on our proposal.

(F) Pressure Ulcer, Unstageable

We received a request to consider changing the severity level for diagnosis code 707.25 (Pressure ulcer, unstageable) from its current classification as a non-CC to an MCC. This issue was referred to as an out-of-scope public comment in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51557), but was not addressed in that rule.

For this FY 2013 proposed rule, we analyzed claims data for diagnosis code 707.25 from the FY 2011 MedPAR file according to the process and approach described above. The following table illustrates our findings:

Code	Diagnosis description	CC level	Cnt 1	Cnt 1 impact	Cnt 2	Cnt 2 impact	Cnt 3	Cnt 3 impact
707.25	Pressure ulcer, unstageable	Non-CC	1,839	1.87	7,161	2.46	13,285	3.08

As discussed above, a C1 value close to 2.0 suggests the condition is more similar to a CC than a non-CC severity level but not as significant in resource usage as an MCC. The C1 value finding of 1.87 for diagnosis code 707.25, which is near but not that close to a 2.0, suggests that this code is more similar to a CC than an MCC. A C2 value of close to 3.0 suggests the condition is more similar to an MCC than a CC or non-CC. The C2 value finding for diagnosis code 707.25 is 2.46, which is not close to 3.0 and, therefore, the data do not support classifying this as an MCC. The C1 and C2 findings are more supportive of a classification as a CC than an MCC. There is another problem with this request to change diagnosis code 707.25 from a non-CC to an MCC. Currently, only stages III and IV pressure ulcers are MCCs. This unstageable code captures a pressure ulcer whose stage has not been determined. It would be inappropriate to assume that a pressure ulcer reported with diagnosis code 707.25 might be a stage III or IV pressure ulcer. Our claims data C1 and C2 findings do not support the fact that this code acts as an MCC. As mentioned earlier, the claims data are more supportive of a classification as a CC than an MCC. We asked our clinical advisors to review this issue. Our clinical advisors agree that the data findings and their own clinical evaluation support not changing the severity level of this diagnosis code to a CC or an MCC. Our clinical advisors recommend that unstageable pressure ulcers should continue to be classified as a non-CC because the stage is not clearly designated as a stage III or IV. Unstageable codes do not delineate what the stage of the ulcer might be. As a result of our data analysis as well as the advice of our clinical advisors, we believe that unstageable pressure ulcers should continue to be classified as a non-CC. Therefore, we are proposing that diagnosis code 707.25 remain a non-CC for FY 2013.

We are inviting public comment on our proposal not to change the severity level for diagnosis code 707.25 for FY 2013.

For FY 2013, there are proposed changes to Table 6G (Additions to the CC Exclusion List). As we discuss earlier, we are proposing to change the severity level for diagnosis codes 263.0, 263.1, and 440.4 from a non-CC to a CC. There are no proposed changes to Table 6H (Deletions to the CC Exclusion List). These tables, which contain codes that are effective for discharges occurring on or after October 1, 2012, 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 diagnosis for which there is a CC exclusion is shown in Tables 6G and 6H 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 available through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS*. Beginning with discharges on or after October 1, 2011, the indented diagnoses were not recognized by the GROUPER as valid CCs for the asterisked principal diagnosis.

To assist readers in identifying the proposed changes to the MCC and CC lists that occur as a result of our review of severity levels for several ICD–9–CM diagnosis codes, we are providing the following summaries of those proposed MCC and CC changes for FY 2013. There will be no new, revised, or deleted diagnosis codes for FY 2013. Therefore, there will be no Tables 6A, 6C, and 6E published for FY 2013.

Summary of Proposed Additions to The MS–DRG MCC List—Table 6I.1

There are no proposed additions to the MS–DRG MCC List.

SUMMARY OF PROPOSED DELETIONS FROM THE MS–DRG MCC LIST—TABLE 6I.2

Code	Description
584.8	Acute kidney failure with other specified pathological lesion in kidney.

SUMMARY OF PROPOSED ADDITIONS TO THE MS–DRG CC LIST—TABLE 6J.1

Code	Description
263.0	Malnutrition of moderate degree.
263.1	Malnutrition of mild degree.
440.4	Chronic total occlusion of artery of the extremities.
584.8	Acute kidney failure with other specified pathological lesion in kidney.

Summary of Proposed Deletions From the MS–DRG CC List—Table 6J.2

There are no proposed deletions from the MS–DRG CC list.

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 29.0, is available on a CD for $225.00. Version 30.0 of this manual, which will include the final FY 2013 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.

8. 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.[14]

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.

[14] 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, FY 2011 and FY 2012, 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); the FY 2011 final rule (75 FR 50122); and the FY 2012 final rule (76 FR 51549).

Therefore, for FY 2013, 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 2013, 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 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 2013, 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.1. through 4. of this preamble, we are not proposing to add any diagnosis or procedure codes to MDCs for FY 2013.

9. Proposed 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

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 $29.00 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 2013 at a public meeting held on September 14, 2011 and finalized the coding changes after consideration of comments received at the meetings and in writing by November 18, 2011. For FY 2013, there were no changes to the ICD–9–CM coding system due to the partial code freeze or for new technology. Therefore, there will be no new, revised, or deleted diagnosis and procedure codes that are usually announced in Tables 6A (New Diagnosis Codes), 6B (New Procedure Codes), 6C (Invalid Diagnosis Codes), 6D (Invalid Procedure Codes), 6E (Revised Diagnosis Code Titles), and 6F (Revised Procedure Codes). Therefore, these tables will not be published as part of this FY 2013 proposed rulemaking.

Copies of the minutes of the procedure codes discussions at the Committee's September 14, 2011 meeting and March 5, 2012 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 14, 2011 meeting and March 5, 2012 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*.

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of Public Law 108–173 included a requirement for updating 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, 2012 implementation of an ICD–9–CM code at the September 14, 2011 Committee meeting. Therefore, there were no new ICD–9–CM codes implemented on April 1, 2012.

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 was to 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). However, the Secretary of Health and Human Services has issued a proposed rule that would delay, from October 1, 2013, to October 1, 2014, the compliance date for the International Classification of Diseases, 10th Edition diagnosis and procedure codes (ICD–10). The proposed rule, CMS–0040–P, went on display at the Office of the Federal Register on April 9, 2012, and was published in the Federal Register on April 17, 2012 (77 FR 22950) and is available for viewing at: *http://www/gpo.gov/fdsys/browse/collection.action?collectionCode=FR*.

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 ICM–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 and September 14, 2011 ICD–9–CM Coordination and Maintenance Committee meetings that a partial freeze of both ICD–9–CM and ICD–10 codes will be implemented as follows:

- The last regular annual update to both ICD–9–CM and ICD–10 code sets was 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.
- On October 1, 2013, there were to be only limited code updates to ICD–10 code sets to capture new technology and diagnoses as required by section 503(a) of Pub. L. 108–173. There were to be no updates to ICD–9–CM on October 1, 2013, as the system would no longer be a HIPAA standard and, therefore, no longer be used for reporting. With the proposed ICD–10 implementation delay, there will be only limited code updates to both ICD–9–CM and ICD–10 to capture new technology and new diagnoses on October 1, 2013.
- On October 1, 2014, regular updates to ICD–10 were to begin. As stated earlier, HHS has issued a proposed rule that would delay the compliance date of ICD–10 from October 1, 2013, to October 1, 2014. If this delay is implemented, there would be only limited ICD–10 code updates for new technologies and new diseases on October 1, 2014. There will be no updates to ICD–9–CM on October 1, 2014, as the system will no longer be a HIPAA standard and, therefore, no longer be used for reporting. Full ICD–10 updates would begin on October 1, 2015, 1 year after the implementation of ICD–10.

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 14, 2011 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

CMS is currently processing 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 diagnosis and 25 procedures; however, CMS' system limitations allowed for the processing of only the first 9 diagnosis codes and 6 procedure codes. We discussed this change in processing claims in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127), in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25843), in a correction notice issued in the **Federal Register** on June 14, 2011 (76 FR 24633), and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51553). As discussed in these prior rules, CMS undertook an 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 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. We will continue to process up to 25 diagnosis codes and 25 procedure codes when received on the 5010 format.

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 at the same time as ICD–10 (75 FR 50127 and 50128). As we

stated earlier, the Secretary of Health and Human Services has issued a proposed rule that would delay the compliance date of ICD–10 from October 1, 2013 to October 1, 2014. 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 Version 26.0 (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–DRGs Version 28.0 also included 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 reviewed comments on the ICD–10 MS–DRGs Version 28.0 and made updates as a result of these comments. We called the updated version the ICD–10 MS–DRGs Version 28 R1. We posted a Definitions Manual of ICD–10 MS–DRGs Version 28 R1 on our ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.gov/ICD10/17_ICD10_MS_DRG_Conversion_Project.asp*. To make the review of Version 28 R1 updates easier for the public, we also made available pilot software on a CD–ROM that could be ordered through the National Technical Information Service (NTIS). A link to the NTIS ordering page was provided on the CMS ICD–10 MS–DRG Web page. We stated that we believed that, by providing the ICD–10 MS–DRG Version 28 R1 Pilot Software (distributed on CD–ROM), the public would be able to more easily review and provide feedback on updates to the ICD–10 MS–DRGs. We discussed the updated ICD–10 MS–DRGs Version 28 R1 at the September 14, 2011 ICD–9–CM Coordination and Maintenance Committee meeting. We encouraged the public to continue to review and provide comments on the ICD–10 MS–DRGs so that CMS could continue to update the system.

In FY 2012, we prepared the ICD–10 MS–DRGs Version 29.0, based on the FY 2012 MS–DRGs (Version 29.0) that we finalized in the FY 2012 IPPS/LTCH PPS final rule. We posted a Definitions Manual of ICD–10 MS–DRGs Version 29.0 on our ICD–10 MS–DRGs Web site. We also prepared a document that describes changes made from Version 28.0 to Version 29.0 to facilitate a review. The ICD–10 MS–DRGs Version 29.0 was discussed at the ICD–9–CM Coordination and Maintenance Committee meeting on March 5, 2012. Information was provided on the types of updates made. Once again the public was encouraged to review and comment on the most recent update to the ICD–10 MS–DRGs.

We provided information on a study conducted on the impact on converting MS–DRGs to ICD–10–CM and ICD–10–PCS. Information on this study is summarized in a paper entitled ''Impact of the Transition to ICD–10 on Medicare Inpatient Hospital Payments.'' This paper is posted on the CMS ICD–10 MS–DRG conversion Web site at: *http://www.cms.gov/ICD10/17_ICD10_MS_DRG_Conversion_Project.asp*. The paper describes CMS' approach to the conversion of the MS–DRGs from ICD–9–CM codes to ICD–10 codes. The study was undertaken using the ICD–9–CM MS–DRGs Version 27.0 (FY 2010) and converted to the ICD–10 MS–DRGs Version 27.0. The study estimated the impact on aggregate payment to hospitals and the distribution of payments across hospitals. The paper was distributed and discussed at the September 15, 2010 ICD–9–CM Coordination and Maintenance Committee. The impact of the conversion from ICD–9–CM to ICD–10 on Medicare MS–DRG hospital payments was estimated using 2009 Medicare data. The study found a hospital payment increase of 0.05 percent using the ICD–10 MS–DRGs Version 27.0. For detailed information on this study, we refer readers to the complete report which is posted on the CMS Web site at: *http://www.cms.gov/ICD10/17_ICD10_MS_DRG_Conversion_Project.asp*.

CMS provided an overview of this hospital payment impact study at the March 5, 2012 ICD–9–CM Coordination and Maintenance Committee meeting. This presentation followed presentations on the creation of ICD–10 MS–DRGs Version 29.0. A summary report of this meeting can be found on the CMS Web site at: *http://www.cms.gov/ICD9ProviderDiagnosticCodes/03_meetings.asp*. At this March 2012 meeting, CMS announced that it would produce an update on this impact study based on an updated version of the ICD–10 MS–DRGs. This update will provide additional information to the public as CMS is evaluating refinements made to the ICD–10 MS–DRGs based on public comments.

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 will be implemented at the same time as ICD–10 and 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.

H. Recalibration of MS–DRG Weights

1. Data Sources for Developing the Proposed Weights

In developing the proposed FY 2013 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 2011 MedPAR data used in this proposed rule include discharges occurring on October 1, 2010, through September 30, 2011, based on bills received by CMS through December 31, 2011, 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 2011 MedPAR file used in calculating the proposed relative weights includes data for approximately 10,354,422 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare

Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the December 31, 2011 update of the FY 2011 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service. Claim types ''61,'' ''62,'' ''63,'' and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the proposed relative weights for FY 2013 also excludes claims with claim type values not equal to ''60.'' The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. Normally, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year (that is, for the calculation of the FY 2013 MS–DRG relative weights, we use data from the FY 2010 HCRIS, which are data from cost reports that began on or after October 1, 2009 and before October 1, 2010). However, during the development of this proposed rule, we have found that those cost reports in the FY 2010 HCRIS dataset with fiscal year begin dates that are on or after May 1, 2010, and before October 1, 2010, are not accessible. This inaccessibility is because cost reports with fiscal year begin dates of May 1, 2010, through September 30, 2010, were filed on the new cost report Form 2552–10, and cost reports filed on Form 2552–10 are not currently accessible in the HCRIS. However, because data from cost reports filed on Form 2552–10 are not currently available, to ensure that the FY 2013 MS–DRG relative weights are calculated with a dataset that is as comprehensive and accurate as possible, we are proposing to calculate the FY 2013 MS–DRG relative weights with data from FY 2010 cost reports for providers with fiscal year begin dates of on or after October 1, 2009 and before May 1, 2010, and to backfill with data from FY 2009 cost reports for those providers that have fiscal year begin dates on or after May 1, 2010 through September 30, 2010. We used cost report data for the December 31, 2011 update of the HCRIS for FY 2009 and FY 2010 in calculating the proposed FY 2013 relative cost-based weights.

2. Methodology for Calculation of the Proposed Relative Weights

The methodology we used to calculate the proposed FY 2013 MS–DRG cost-based relative weights based on claims data in the FY 2011 MedPAR file and data from the FY 2009 and FY 2010 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2013 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 96.3 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), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an ''N'' indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. 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 an ''N'' or a ''U'' in the POA field. This resetting ''forced'' the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

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 and FY 2010 cost report data.

The 15 cost centers that we used in the proposed relative weight calculation are shown in the following table. The table shows the lines on the cost report and the corresponding revenue codes that we used to create the 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	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Routine Days	Private Room Charges	011X and 014X		Adults & Pediatrics (General Routine Care)	C_1_C5_25	C_1_C6_25	D4_HOS_C2_25	C_1_C5_30	C_1_C6_30	D3_HOS_C2_30
	Semi-Private Room Charges	012X, 013X and 016X-019X								
	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_C5_31	C_1_C6_31	D3_HOS_C2_31
	Coronary Care Charges	021X		Coronary Care Unit	C_1_C5_27	C_1_C6_27	D4_HOS_C2_27	C_1_C5_32	C_1_C6_32	D3_HOS_C2_32

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Burn Intensive Care Unit	C_1_C5_28	C_1_C6_28	D4_HOS_C2_28	C_1_C5_33	C_1_C6_33	D3_HOS_C2_33
				Surgical Intensive Care Unit	C_1_C5_29	C_1_C6_29	D4_HOS_C2_29	C_1_C5_34	C_1_C6_34	D3_HOS_C2_34
				Other Special Care Unit	C_1_C5_30	C_1_C6_30	D4_HOS_C2_30	C_1_C5_35	C_1_C6_35	D3_HOS_C2_35
Drugs	Pharmacy Charges	025X, 026X and 063X		Intravenous Therapy	C_1_C5_48	C_1_C6_48	D4_HOS_C2_48	C_1_C5_64	C_1_C6_64	D3_HOS_C2_64
						C_1_C7_48			C_1_C7_64	

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Drugs Charged To Patient	C_1_C5_56	C_1_C6_56	D4_HOS_C2_56	C_1_C5_73	C_1_C6_73	D3_HOS_C2_73
						C_1_C7_56			C_1_C7_73	
Supplies and Equipment	Medical/Surgical Supply Charges	0270, 0271, 0272, 0273, 0274, 0277, and 0621, 0622, 0623		Medical Supplies Charged to Patients	C_1_C5_55	C_1_C6_55	D4_HOS_C2_55	C_1_C5_71	C_1_C6_71	D3_HOS_C2_71
						C_1_C7_55			C_1_C7_71	
		0275, 0276, 0278, 0624		Implantable Devices Charged to Patients	C_1_C5_55.30	C_1_C6_55.30	D4_HOS_C2_55.30	C_1_C5_72	C_1_C6_72	D3_HOS_C2_72
						C_1_C7_55.30			C_1_C7_72	
	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_C5_96	C_1_C6_96	D3_HOS_C2_96
						C_1_C7_66			C_1_C7_96	

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	Used Durable Medical Charges	0293		DME-Sold	C_1_C5_67	C_1_C6_67	D4_HOS_C2_67	C_1_C5_77	C_1_C6_97	D3_HOS_C2_97
						C_1_C7_67			C_1_C7_97	
Therapy Services	Physical Therapy Charges	042X		Physical Therapy	C_1_C5_50	C_1_C6_50	D4_HOS_C2_50	C_1_C5_66	C_1_C6_66	D3_HOS_C2_66
						C_1_C7_50			C_1_C7_66	
	Occupational Therapy Charges	043X		Occupational Therapy	C_1_C5_51	C_1_C6_51	D4_HOS_C2_51	C_1_C5_67	C_1_C6_67	D3_HOS_C2_67
						C_1_C7_51			C_1_C7_67	
	Speech Pathology Charges	044X and 047X		Speech Pathology	C_1_C5_52	C_1_C6_52	D4_HOS_C2_52	C_1_C5_68	C_1_C6_68	D3_HOS_C2_68
						C_1_C7_52			C_1_C7_68	

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Inhalation Therapy	Inhalation Therapy Charges	041X and 046X		Respiratory Therapy	C_1_C5_49	C_1_C6_49	D4_HOS_C2_49	C_1_C5_65	C_1_C6_65	D3_HOS_C2_65
						C_1_C7_49			C_1_C7_65	
Operating Room	Operating Room Charges	036X		Operating Room	C_1_C5_37	C_1_C6_37	D4_HOS_C2_37	C_1_C5_50	C_1_C6_50	D3_HOS_C2_50
For all DRGs but Labor & Delivery						C_1_C7_37			C_1_C7_50	
		071X		Recovery Room	C_1_C5_38	C_1_C6_38	D4_HOS_C2_38	C_1_C5_51	C_1_C6_51	D3_HOS_C2_51
						C_1_C7_38			C_1_C7_51	

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Labor & Delivery	Operating Room Charges	072X		Delivery Room and Labor Room	C_1_C5_39	C_1_C6_39	D4_HOS_C2_39	C_1_C5_52	C_1_C6_52	D3_HOS_C2_52
ONLY FOR THE 6 Labor & Delivery DRGs						C_1_C7_39			C_1_C7_52	
370, 371, 372, 373, 374, 375				Obstetrics Clinic	C_1_C5_63	C_1_C6_63	D4_HOS_C2_63	C_1_C5_93	C_1_C6_93	D3_HOS_C2_93
						C_1_C7_63			C_1_C7_93	
Anesthesia	Anesthesia Charges	037X		Anesthesi-ology	C_1_C5_40	C_1_C6_40	D4_HOS_C2_40	C_1_C5_53	C_1_C6_53	D3_HOS_C2_53
						C_1_C7_40			C_1_C7_53	
Cardiology	Cardiology Charges	048X and 073X		Electro-cardiology	C_1_C5_53	C_1_C6_53	D4_HOS_C2_53	C_1_C5_69	C_1_C6_69	D3_HOS_C2_69

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_53			C_1_C7_69	
		0481		Cardiac Catheterization				C_1_C5_59	C_1_C6_59	D3_HOS_C2_59
									C_1_C7_59	
Laboratory	Laboratory Charges	030X, 031X, and 075X		Laboratory	C_1_C5_44	C_1_C6_44	D4_HOS_C2_44	C_1_C5_60	C_1_C6_60	D3_HOS_C2_60
						C_1_C7_44			C_1_C7_60	
				PBP Clinic Laboratory Services	C_1_C5_45	C_1_C6_45	D4_HOS_C2_45	C_1_C5_61	C_1_C6_61	D3_HOS_C2_61
						C_1_C7_45			C_1_C7_61	
		074X, 086X		Electro-encephalography	C_1_C5_54	C_1_C6_54	D4_HOS_C2_54	C_1_C5_70	C_1_C6_70	D3_HOS_C2_70

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_54			C_1_C7_70	
Radiology	Radiology Charges	040X		Radiology - Diagnostic	C_1_C5_41	C_1_C6_41	D4_HOS_C2_41	C_1_C5_54	C_1_C6_54	D3_HOS_C2_54
						C_1_C7_41			C_1_C7_54	
		0333, 0339, 0342		Radiology - Therapeutic	C_1_C5_42	C_1_C6_42	D4_HOS_C2_42	C_1_C5_55	C_1_C6_55	D3_HOS_C2_55
		0343 and 344		Radioisotope	C_1_C5_43	C_1_C6_43	D4_HOS_C2_43	C_1_C5_56	C_1_C6_56	D3_HOS_C2_56
						C_1_C7_43			C_1_C7_56	
		035X		Computed Tomography (CT) Scan				C_1_C5_57	C_1_C6_57	D3_HOS_C2_57
									C_1_C7_57	

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
	MRI Charges	061X		Magnetic Resonance Imaging (MRI)				C_1_C5_58	C_1_C6_58	D3_HOS_C2_58
									C_1_C7_58	
Emergency Room	Emergency Room Charges	045x		Emergency	C_1_C5_61	C_1_C6_61	D4_HOS_C2_61	C_1_C5_91	C_1_C6_91	D3_HOS_C2_91
						C_1_C7_61			C_1_C7_91	
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_C5_62	C_1_C6_62	D3_HOS_C2_62
						C_1_C7_46			C_1_C7_62	
	Blood Storage / Processing	039x		Blood Storing, Processing, & Transfusing	C_1_C5_47	C_1_C6_47	D4_HOS_C2_47	C_1_C5_63	C_1_C6_63	D3_HOS_C2_63

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_47			C_1_C7_63	
Other Services	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_C5_75	C_1_C6_75	D3_HOS_C2_75
						C_1_C7_58			C_1_C7_75	
	Outpatient Service Charges	049X and 050X		Other Ancillary	C_1_C5_59	C_1_C6_59	D4_HOS_C2_59	C_1_C5_76	C_1_C6_76	D3_HOS_C2_76
	Lithotripsy Charge	079X				C_1_C7_59			C_1_C7_76	
	Clinic Visit Charges	051X		Clinic	C_1_C5_60	C_1_C6_60	D4_HOS_C2_60	C_1_C5_90	C_1_C6_90	D3_HOS_C2_90

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
						C_1_C7_60			C_1_C7_90	
	Ambulance Charges	054X		Ambulance	C_1_C5_65	C_1_C6_65	D4_HOS_C2_65	C_1_C5_95	C_1_C6_95	D3_HOS_C2_95
						C_1_C7_65			C_1_C7_95	
				Observation beds	C_1_C5_62	C_1_C6_62	D4_HOS_C2_62	C_1_C5_92	C_1_C6_92	D3_HOS_C2_92
						C_1_C7_62			C_1_C7_92	
					C_1_C5_6201	C_1_C6_6201	D4_HOS_C2_6201	C_1_C5_92.01	C_1_C6_92.01	D3_HOS_C2_92.01
						C_1_C7_6201			C_1_C7_92.01	
	ESRD Revenue Setting Charges	080X and 082X-088X (but not 086X)								
	(excluding Labor & Delivery DRGs)									

Cost Center Group Name (15 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field		Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-96	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-96	Medicare Charges from HCRIS (Worksheet D-4, Column & line number) Form CMS-2552-96	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
				Rural Health Clinic	C_1_C5_6350	C_1_C6_6350	D4_HOS_C2_6350	C_1_C5_88	C_1_C6_88	D3_HOS_C2_88
	Professional Fees Charges	096X, 097X, and 098X				C_1_C7_6350			C_1_C7_88	
				FQHC	C_1_C5_6360	C_1_C6_6360	D4_HOS_C2_6360	C_1_C5_89	C_1_C6_89	D3_HOS_C2_89
						C_1_C7_6360			C_1_C7_89	
				Home Program Dialysis	C_1_C5_64	C_1_C6_64	D4_HOS_C2_64	C_1_C5_94	C_1_C6_94	D3_HOS_C2_94
						C_1_C7_64			C_1_C7_94	
				Other Reimbursable	C_1_C5_68	C_1_C6_68	D4_HOS_C2_68	C_1_C5_98	C_1_C6_98	D3_HOS_C2_98
						C_1_C7_68			C_1_C7_68	

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3. Development of National Average CCRs

We developed the national average CCRs as follows:

Using the FY 2009 and FY 2010 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. We then created CCRs for each provider for each cost center (see prior table for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. We then took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–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 proposed FY 2013 cost-based relative weights were then normalized by an adjustment factor of 1.5877342556 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 2013 are as follows:

Group	CCR
Routine Days	0.514
Intensive Days	0.442
Drugs	0.199
Supplies & Equipment	0.335
Therapy Services	0.370
Laboratory	0.142
Operating Room	0.238
Cardiology	0.145
Radiology	0.136
Emergency Room	0.226
Blood and Blood Products	0.389
Other Services	0.397
Labor & Delivery	0.451
Inhalation Therapy	0.189
Anesthesia	0.109

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 2013 IPPS/LTCH PPS proposed rule, we are proposing to use that same case threshold in recalibrating the MS–DRG weights for FY 2013. Using data from the FY 2011 MedPAR file, there were 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 aged 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 aged 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 received 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 2013, 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 2012 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 2012 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 2012 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 2012 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
791	Prematurity with Major Problems	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
792	Prematurity without Major Problems	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
793	Full-Term Neonate with Major Problems	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
794	Neonate with Other Significant Problems	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
795	Normal Newborn	FY 2012 FR weight (adjusted by percent change in average weight of the cases in other MS–DRGs).

4. Bundled Payments for Care Improvement (BPCI) Initiative

a. Background

Section 3021 of the Affordable Care Act, codified at section 1115A of the Act, authorizes CMS to test innovative payment and service delivery models with the goal of reducing Medicare program expenditures while preserving or enhancing the quality of care furnished to individuals. Because initiatives established under this authority could result in IPPS hospitals receiving a payment different than what they otherwise would receive under the IPPS, we believe it is important to identify how these initiatives are addressed in the context of MS–DRG recalibration and ratesetting, budget neutrality, and the impact analysis in the Addendum of this proposed rule.

Under the Bundled Payments for Care Improvement (BPCI) initiative, CMS would link payments for multiple services that patients receive during an episode of care. CMS is working in partnership with providers to develop and test models of bundling payments through the BPCI initiative. On August 23, 2011, CMS invited providers to apply to help develop and test four different models of bundling payments. For additional information, we refer readers to the CMS Web site at: *http://www.innovations.cms.gov/initiatives/Bundled-Payments/index.html*. We are providing below a brief overview of payments under each model. However, the BPCI initiative Request for Application and related information on the CMS Web site at *http://innovations.cms.gov/initiatives/bundled-payments/* provide more details of this initiative.

As described below and also in the Addendum to this proposed rule, we are generally proposing to include data from hospitals participating in the BPCI initiative and to treat these hospitals without regard to their participation in the BPCI initiative for the purposes of IPPS ratesetting.

Model 1

In Model 1, the episode of care is defined as the inpatient hospital services for the acute care hospital stay only. Applicants for this model were asked to propose discount percentages for various periods of the 3-year program, which would be applied to the IPPS operating MS–DRG payment for each participating hospital's MS–DRGs over the lifetime of the initiative. That is, for hospitals participating in Model 1, Medicare would continue to pay participating acute care hospitals under the IPPS. However, these payments to participating acute care hospitals would be at a reduced payment amount that reflects the applicable discount percentage for cases in all MS–DRGs for the specific period of the program. We note that an adjustment would be made such that payments for IME, DSH, and outliers would be calculated based on the nondiscounted MS–DRG operating IPPS payment amount and then paid, if applicable, in addition to the discounted MS–DRG operating IPPS payment. The minimum discount percentage that awardees are expected to offer would be phased in over time, with the discount percentage updated as frequently as every 6 months.

Model 2

In Model 2, the episode of care is defined as the inpatient acute care hospital stay for specific clinical conditions and a specified period of time following discharge (with a minimum episode length of at least 30 days following hospital discharge). The payment bundle for Model 2 would encompass all Medicare Part A payments for designated MS–DRGs, Part B professional services paid under the Medicare Physician Fee Schedule (MPFS) during the hospital stay, and related professional services furnished after discharge during the episode, ''related readmissions'' (as defined under the BPCI initiative), care by a postacute care provider such as an HHA, IRF, SNF, LTCH, and other related services furnished during the episode (that is, all Medicare Part A and Part B with the exception of hospice care). Applicants, which may be a Medicare supplier or provider, groups of such entities, or other organizations that bring together providers and suppliers to test the model, are asked to propose specific MS–DRG(s) for the clinical condition(s) to be tested in Model 2. Furthermore, the applicants are asked to propose the target price on an MS–DRG basis for the episode that includes a single rate of discount off of the expected Medicare payment (including hospital, postacute care, Medicare Part B professional services, and other services, as applicable) for all Model 2 beneficiaries discharged from the inpatient hospital stay with the specified MS–DRG(s). We note that, when proposing the target price, applicants are instructed to include IPPS outlier payments in their calculation; however, IPPS IME and DSH payments should be excluded from the target price. In Model 2, payments would be made at the usual fee-for-service payment rates to the participating providers through the regular claims processing system, after which the aggregate Medicare payment for the episode would be reconciled against the target price. If aggregate Medicare expenditures are less than the target price, the awardee would be paid the difference as a reconciliation payment. Conversely, if aggregate Medicare expenditures exceed the target price, CMS would recoup that amount from the awardee.

Model 3

In Model 3, the episode of care begins at initiation of postacute services at one of four postacute care providers (HHAs, IRFs, SNFs, and LTCHs) within 30 days after discharge from any acute care hospital for specific clinical conditions. As with the other three models, applicants may be one or more Medicare providers or supplier or other organization(s) bringing those entities together to test the model. Applicants are asked to propose an episode length that would extend to at least 30 days following initiation of care at an HHA, IRF, SNF, or LTCH. The payment bundle for Model 3 would encompass care by a postacute care provider, and other related services furnished during the episode, including Medicare Part B professional services paid under the MPFS, and inpatient hospital readmissions (as defined under the BPCI initiative). In contrast to Model 2, the payment bundle for Model 3 does not include services provided in the initial acute care hospital stay. We note that, while the episode is initiated at one of the four postacute care providers rather than at an acute care hospital, applicants are asked to specify the clinical condition(s) to be tested in Model 3 by proposing relevant MS–DRG(s). Therefore, applicable to all Model 3 beneficiaries discharged from any inpatient acute care hospital stay with the specified MS–DRG(s), applicants are to propose a target price on an MS–DRG basis for the episode that includes a single rate of discount off of the expected Medicare payment, which includes care by a postacute care provider, related Medicare Part B professional services paid under the MPFS, inpatient hospital readmissions, and other related services furnished during the episode. In Model 3, payments would be made at the usual fee-for-service payment rates to the participating providers through the regular claims processing process, after which the aggregate Medicare payment for the episode would be reconciled against the target price. Like Model 2, if aggregate Medicare expenditures are less than the target price, the awardee would be paid the difference as a reconciliation payment. Conversely, if

aggregate Medicare expenditures exceed the target price, CMS would recoup that amount from the awardee. We note that Model 3 does address payment for related hospital readmissions.

Model 4

In Model 4, the episode of care is defined as the acute care hospital stay and includes all ''related readmissions'' (as defined under the BPCI initiative). The payment bundle for Model 4 would encompass Medicare inpatient hospital services, Medicare Part B professional services paid under the MPFS furnished during the initial hospitalization, as well as hospital services and Medicare Part B professional services during any related readmissions. Applicants are asked to propose specific MS–DRG(s) for the clinical condition(s) to be tested in Model 4. Applicants for this model are asked to propose a target price for the episode that includes a single rate of discount off of expected Medicare payment (including both Medicare Part A hospital services and Part B professional services) for all beneficiaries discharged from the inpatient hospital stay with the specified MS–DRG(s).

In contrast to Models 2 and 3, where usual Medicare fee-for-service payments are made to all providers and reconciliation of Medicare spending against the target price for the episode is conducted retrospectively, under Model 4, hospitals would receive a prospectively established bundled payment for specified MS–DRGs. This payment would include both the MS–DRG payment for the hospital and a fixed payment amount for the Medicare Part B professional services anticipated to be furnished during the episode. That is, separate payment for providers' professional services furnished during the inpatient hospital stay would not be made. Participating Model 4 hospitals receiving payment would take responsibility for distributing payment to providers that would otherwise be paid separately. We note that IPPS IME and DSH payments to Model 4 hospitals would be calculated based on the nondiscounted base MS–DRG operating IPPS payment that would have been made in the absence of the model. Other applicable payment adjustors would also be calculated based on the base MS–DRG operating IPPS payment amount that would otherwise have applied to the case, as opposed to the prospectively established amount paid through this initiative, which would be higher as it includes payment for Part B services as well as the base MS–DRG payment. Under Model 4, no separate IPPS outlier payments would be made.

b. Proposed Treatment of Data From Hospitals Participating in the BPCI Initiative

As discussed above, acute care hospitals have the opportunity to apply and participate in the BPCI payment models described above. For Model 1 and Model 2, participating acute care hospitals would continue to receive an IPPS payment under section 1886(d) of the Act (subject to a predetermined discount for hospitals participating in Model 1). For Model 2, participating hospitals may also receive a reconciliation payment under the BPCI initiative (based on their predetermined target price). Under Model 3, services provided in the initial acute care hospital stay are not included; however, the model does address payment for possible hospital readmissions. Under Model 1, hospitals participate for all MS–DRGs, while, under Model 2, hospitals participate for only pre-selected MS–DRGs. We believe it is appropriate to include all applicable data from these subsection(d) hospitals in our IPPS payment modeling and ratesetting calculations because these hospitals are still receiving IPPS payments under section 1886(d) of the Act (in addition to, with respect to Model 2 hospitals, any reconciliation payment the hospital may receive under the BPCI initiative). Moreover, even if these hospitals were not receiving IPPS payments under section 1886(d) of the Act (and were participating in Models 1 and 2), the Secretary has the authority to make appropriate adjustments for payment amounts under section 1886(d)(5)(I)(i) of the Act to include all applicable data from these subsection(d) hospitals in our IPPS ratesetting calculations. We believe it is appropriate to use the Secretary's authority under section 1886(d)(5)(I)(i) of the Act to include all IPPS, short-term, acute care hospitals within the IPPS ratesetting calculations because excluding these hospitals would diminish the number of providers used to determine the IPPS rates, which could cause fluctuations in the IPPS rates and could produce instability to the IPPS rates. Therefore, because we believe it is appropriate to include all claims from hospitals participating within Models 1 and 2 within the IPPS ratesetting calculations, using the Secretary's authority under section 1886(d)(5)(I)(i) of the Act, we are proposing to include all applicable data from ''subsection (d)'' hospitals participating in Models 1 and 2 under the BPCI initiative in our IPPS payment modeling and ratesetting calculations (which includes recalibration of the MS–DRG weights, ratesetting, calculation of the budget neutrality factors, and the impact analysis). In essence, we would continue to treat these hospitals the same as prior fiscal years for purposes of the FY 2013 (and subsequent years) IPPS payment modeling and ratesetting process without regard to a hospital's participation within these two bundled payment models (that is, we would treat these hospitals as if they are not participating in Model 1 or Model 2 under the BPCI initiative).

In contrast to BPCI Models 1 and 2 (wherein participating IPPS hospitals would receive an IPPS payment under section 1886(d) of the Act, and, in the case of Model 2, may also receive a reconciliation payment under the BPCI initiative), IPPS hospitals participating in Model 4 would receive a predetermined bundled payment for Medicare Part A and Part B services for a pre-specified MS–DRG ''episode'' (and any ''related readmissions'' as defined under the BPCI initiative). These bundled payments are for certain pre-specified MS- DRG(s) episodes (not all cases) and would be made in accordance with the terms of the model, as authorized by section 1115A of the Act (these IPPS hospitals would also receive ''regular'' IPPS payments under section 1886(d) of the Act for those MS–DRGs not included in the bundling model). Similar to Models 1 and 2, we believe it is appropriate to keep all applicable data from these ''subsection (d)'' hospitals in our IPPS payment modeling and ratesetting calculations because the majority of Medicare payments these hospitals would receive would be IPPS payments under section 1886(d) of the Act (that is, payments for cases in MS–DRGs that are not included in the bundled payment model). Moreover, although these hospitals are not receiving payments under 1886(d) of the Act for the cases included in the prospective bundled payment under Model 4, the Secretary has the authority to make appropriate adjustments for payment amounts at section 1886(d)(5)(I)(i) of the Act to include all applicable data from these subsection(d) hospitals in our IPPS ratesetting calculations. We believe it is appropriate to use the Secretary's authority under section 1886(d)(5)(I)(i) of the Act to include all IPPS, short-term, acute care hospitals and their claims within the IPPS ratesetting calculations because excluding these hospitals would diminish the number of providers used to determine the IPPS rates, which could cause fluctuations in the IPPS rates and could produce

instability to the IPPS rates. Therefore, because we believe it is appropriate to include all claims from hospitals participating within Models 1 and 2 within the IPPS ratesetting calculations and use the Secretary's authority under section 1886(d)(5)(I)(i) of the Act to include those hospitals and claims, we also believe it is appropriate to include all applicable data from subsection (d) hospitals participating in Model 4 in our IPPS payment modeling and ratesetting calculations (which includes recalibration of the MS–DRG weights, ratesetting, calculation of the budget neutrality factors, and the impact analysis) and propose to do so. In essence, we would continue to treat these hospitals the same as prior fiscal years for purposes of the FY 2013 (and subsequent years) IPPS payment modeling and ratesetting process without regard to a hospital's participation within this bundled payment model (that is, we would treat these hospitals as if they are not participating in Model 4 under the BPCI initiative).

We note that Model 3 only addresses payments for related readmissions and postacute care services (rather than IPPS payments). Therefore, we believe it is not necessary to propose to address the treatment of any data for participating hospitals in Model 3.

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 at 42 CFR 412.87 implement these provisions and specify three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. Below we highlight some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria as well as other information. For a complete discussion on the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574).

Under the first criterion, as reflected in 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. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a 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) and FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 and 43814), we explained our policy regarding substantial similarity in detail.

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. Table 10 that was released with the FY 2012 IPPS/LTCH PPS final rule contains the final thresholds that will be used to evaluate applications for new technology add-on payments for FY 2013. We refer readers to the Web site *http://www.cms.gov/AcuteInpatientPPS/FR2012/list.asp#TopOfPage* for a complete viewing of Table 10 from the FY 2012 IPPS/LTCH PPS final rule.

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. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for complete information on this issue.

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

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 2014 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 2014, 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 2013 prior to publication of this FY 2013 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on November 18, 2011 (76 FR 71571 through 71572), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on February 14, 2012. 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 2013 new medical service and technology add-on payment applications before the publication of this FY 2013 proposed rule.

Approximately 70 individuals registered to attend the town hall meeting in person, while additional individuals listened over an open telephone line. Four of the five FY 2013

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 that were received by the due date of March 6, 2012, in our evaluation of the new technology add-on applications for FY 2013 in this proposed rule.

In response to the published notice and the new technology town hall meeting, we received written comments regarding applications for FY 2013 new technology add-on payments. We summarize these comments below 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 the issue of whether the FY 2013 new technology add-on applications met the ''substantial clinical improvement'' criterion.

Response: As explained above and in the **Federal Register** notice announcing the new technology town hall meeting (76 FR 71571), the purpose of the new technology town hall meeting was specifically to discuss the substantial clinical improvement criterion in regard to pending new technology applications for FY 2013. Therefore, we are not summarizing those comments in this proposed rule. Commenters are welcome to resubmit these comments in response to proposals presented in this proposed rule.

3. FY 2013 Status of Technology Approved for FY 2012 Add-On Payments: 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 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 principal 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.

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 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, for FY 2013, as of December 2012, the AutoLITT™ will have been on the market for 3 years, and would therefore no longer be considered ''new'' as of December 2012 nor be considered eligible for new technology add-on payments in FY 2013. However, we received information from the manufacturer that the market release date of the AutoLITT™ occurred after April 2010 (which occurs in the latter half of the fiscal year) and, therefore, it appears that the AutoLITT™ would still be considered ''new'' for FY 2013 and would still be eligible for new technology add-on payments in FY 2013. We note that we received this information in close proximity to the

publication of the proposed rule and anticipate receiving further information on the delayed market release date from the manufacturer and welcome public comment as well.

4. FY 2013 Applications for New Technology Add-On Payments

We received six applications for new technology add-on payments for FY 2013. However, two applicants withdrew their applications prior to the publication of this proposed rule.

a. Glucarpidase (Trade Brand Voraxaze®)

BTG International, Inc. submitted an application for new technology add-on payments for Glucarpidase (trade brand Voraxaze®) for FY 2013. Glucarpidase is used in the treatment of patients who have been diagnosed with toxic methotrexate (MTX) concentrations as a result of renal impairment. The administration of Glucarpidase causes a rapid and sustained reduction of toxic MTX concentrations.

Methotrexate (MTX) is a widely used anticancer agent. The administration of high-dose methotrexate (HDMTX) is an important component of the treatment provided to patients who have been diagnosed with various types of cancer. According to the applicant, HDMTX, in particular, is specifically used in the treatment of patients who have been diagnosed with osteosarcoma, acute lymphoblastic leukemia, non-Hodgkin's lymphoma, or primary CNS lymphoma. The applicant further stated that the administration of HDMTX can cause renal dysfunction. Renal dysfunction impairs the elimination of MTX, which in turn causes the levels of MTX to rise to the point of life-threatening toxicity.

The applicant maintains that there are not any currently FDA-approved pharmaceutical treatment options available to rapidly decrease MTX levels in patients who have been diagnosed with toxic MTX concentrations as a result of renal impairment. The applicant asserts that extracorporeal treatment options that are routinely employed to rapidly treat this condition, such as hemodialysis, hemodiafiltration, high-flux hemodialysis, charcoal hemoperfusion or hemofiltration, peritoneal dialysis, exchange transfusion, or plasma exchange, are invasive, may add excess morbidity to the treatment regimen, and have proven to have limited effects.[15] High flux hemodialysis is the most effective method of extracorporeal MTX removal, but this method requires 5 to 6 days of daily treatment (4 to 6 hours per session).[16] The risks associated with repeated hemodialysis procedures such as anemia, infection, and increased mortality, especially in neutropenic or thrombocytopenic patients, are significant and cause rebounds in MTX levels. The applicant maintains that other treatment options, such as the administration of leucovorin, hydration, and urinary alkalinization, also are commonly used to reduce harmful levels of MTX. However, these treatment options do not reduce toxic MTX concentrations in all patient populations.[17]

Voraxaze® is an orphan drug that was approved by the FDA on January 17, 2012. Beginning in 1993, certain patients could obtain expanded access for treatment use to Voraxaze® as an investigational drug. Since 2007, the applicant has been authorized to recover the costs of making Voraxaze® available through its expanded access program. We describe expanded access for treatment use of investigational drugs and authorization to recover certain costs of investigational drugs in more detail below. The applicant intends to make Voraxaze® available on the market in the United States as a commercial product to the larger population in April 2012.

With regard to newness, we are concerned that Voraxaze® may no longer be considered ''new''. Specifically, 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''. In addition, the regulations at § 412.87(b)(2) state 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 service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered 'new' under the criterion of this section.'' As we have indicated in the past, we generally believe that the newness period begins on the date that FDA approval is granted. The FDA approval date is typically the date when new technologies are available on the market and as a result begin to be reflected within the MS–DRGs cost data.

As noted above, Voraxaze® was approved by the FDA in January 2012. However, starting in 1993, certain patients were able to obtain access to Voraxaze® as an investigational drug through an expanded access program, and the applicant has been authorized to recover certain costs of making Voraxaze® available through its expanded access program since 2007. We discuss below in more detail whether the cost of Voraxaze® is already reflected within the MS–DRG relative weights.

To determine the date of newness for Voraxaze®, we believe it is appropriate to compare investigational drugs provided under the expanded access program to devices eligible for the Humanitarian Use Device (HUD) Program because these programs contain similarities to evaluate the newness criterion.

In prior final rules, we have evaluated and approved technologies with a Humanitarian Device Exemption (HDE) approval. In the FY 2010 IPPS/LTCH PPS final rule, we approved new technology add-on payments for the Spiration® IBV®, which received a HDE approval from the FDA on October 24, 2008, and had its first IRB approval on March 12, 2009 (74 FR 43754, 43819). Therefore, technologies with an HDE approval may be eligible for new technology add-on payments. In other words, we have concluded that HDE approval constitutes an FDA approval in the context of the newness criterion and would begin the newness period, subject to market availability.

There are separate processes and standards for providing expanded access to investigational drugs for treatment use and for the HUD Program. The term ''expanded access'' refers to the use of investigational drugs, or approved drugs where availability is limited by a risk evaluation or mitigation strategy, when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition. When the requirements in (FDA's regulations at) 21 CFR part 312, Subpart I are met, a patient or group of patients with a serious or immediately life-threatening disease or condition, and no comparable or satisfactory alternative therapy, may obtain expanded access to an investigational drug. When patients obtain expanded access to an unapproved investigational drug, the safety and effectiveness of the drug have

[15] Widemann *et al.,* [Cancer, 2004, and Vilay *et al.,*], Pharmacotherapy, Vol 30, January, 2010).

[16] Wall *et al.,* American Journal of Kidney Diseases, Vol. 28, No. 6, 1996.

[17] Pinedo *et al,* Cancer Research, 36, 4418–4424 December, 1976.

not been fully established, and the drug does not have formal FDA approval under a New Drug Application (NDA) or Biologics Licensing Application (BLA) for commercial marketing. Manufacturers may continue conducting clinical trials in parallel to the expanded access program in order to pursue formal market approval from the FDA under an NDA or BLA for commercial marketing. The FDA's Office of Orphan Products Development administers the HUD Program. A HUD is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year. To obtain approval for a HUD, a HDE application is submitted to FDA. A HDE application is similar in both form and content to a Premarket Approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. A HDE application must, however, contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. An approved HDE authorizes marketing of the HUD, however, an HDE approval requires that the device only be used in facilities that have established a local Institutional Review Board (IRB) to supervise clinical testing of devices, and that an IRB approve the use of the device to treat or diagnose the specific disease. Although HUDs can be marketed, they are subject to a general prohibition on profit; that is, they may not, except in narrow circumstances, be sold for an amount that exceeds the cost of research and development, fabrication and distribution.

Expanded access to investigational drugs and the HUD Program have similarities and differences that are relevant to the newness criterion. Both have limits on who is eligible to receive a drug or use a device. In addition, to satisfy the requirements for expanded access in FDA's regulations, and for a HDE to meet the standard for approval, a sponsor is not required to demonstrate effectiveness of the product at the same level as for approval of a PMA, NDA, or BLA. Expanded access to investigational drugs and the HUD Program differ in many ways, including that the HUD Program is for devices, and the expanded access programs provide access to drugs. In addition, under the HUD Program, the device is granted FDA approval for limited use. However, while FDA authorizes expanded access to an investigational drug, FDA does not approve the investigational drug when it authorizes expanded access.

This second difference is key to our interpretation of our policy to recognize a HDE approval as an FDA approval. We believe that the availability of a drug through the expanded access program would not constitute FDA approval in the context of the newness criterion because unapproved, investigational drugs made available to certain patients through the expanded access program do not receive FDA approval prior to enrollment in the program and cannot be marketed. In other words, we believe that for the purposes of evaluating whether a new technology meets the newness criterion, it may be appropriate not to consider the date when Voraxaze® became available to certain patients through the applicant's expanded access program as the date of market availability.

We note that cost recovery for investigational drugs is of concern with regard to the newness criterion. Although a sponsor (for example, a drug manufacturer) may not commercially distribute an investigational drug, in certain circumstances, a sponsor of a clinical trial or an expanded access program may receive authorization from FDA to charge for certain costs associated with making an investigational drug available. The applicant has been authorized to recover certain costs by making Voraxaze® available since 2007. As we stated earlier, once CMS has recalibrated the DRGs based on available data to reflect the costs of an otherwise new technology, that technology will no longer be considered ''new''' for the purposes of the new technology add-on payments. It is possible that a hospital may have submitted a claim to Medicare for the cost of Voraxaze® provided through the applicant's expanded access program. Therefore, it is also possible that the costs associated with this technology may already be reflected in some limited fashion in the data used to determine the MS–DRG relative weights. While these are possibilities, we have not in the past been confronted with a situation where an applicant has indicated that hospitals have sought cost recovery for their technology when the technology was available through the expanded access program. We also have not been confronted with a situation where an applicant has indicated that cost recovery was sought for technologies (that were not available via an expanded access program) during clinical trials. We note that our data do not distinguish charges for drugs by FDA approval status, and, therefore, we do not exclude from the relative weight calculation costs (as derived from charges) associated with investigational drugs if they are included by hospitals on a claim. Therefore, cost data for non-FDA approved technologies (that is, still involved in clinical trials) may be present in the relative weights on a very limited basis prior to FDA approval, regardless of whether a technology received new technology add-on payments.

We are inviting public comment regarding the issue of whether a drug is considered ''new'' for the purposes of new technology add-on payments starting with its availability in the expanded access program, and how that may differ from devices being considered ''new'' starting from the date the device received FDA approval under a HDE (subject to market availability or availability to Medicare beneficiaries) and specifically request comment on these considerations in the context of Voraxaze®. We also are inviting public comment on whether the costs of Voraxaze®, or more generally, any unapproved investigational drug for which cost recovery is authorized are already included in data used to determine relative weights, and how that influences the start of a newness period, if at all. In addition, we are inviting public comment regarding the market availability of Voraxaze® between its FDA approval date of January 17, 2012, and the market availability date according to the applicant of April 2012 and the reasons for the delay in availability.

The applicant submitted a request to the ICD–9–CM Coordination and Maintenance Committee for a new procedure code, which was discussed at the committee's March 2012 meeting. For further information regarding the code proposal, we refer readers to the following CMS Web site: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html*.

We are inviting public comment on whether or not Voraxaze® meets the newness criterion, especially in light of its reported availability date through the applicant's expanded access program, and the ability for the applicant to charge for certain costs associated with making an investigational drug available. In addition, we are inviting public comment on considerations that should be given in regard to the technology's delay in availability after FDA's approval was granted, in addition to the reason for the delay, as it relates to the newness criterion.

With respect to cost criterion, the applicant researched the 2009 Standard Analytic Inpatient File (SAF) for cases with a principal or secondary diagnosis of osteosarcoma (ICD–9–CM code series 170.xx), acute lymphoblastic leukemia (ICD–9–CM code series 204.0x), non-Hodgkin's lymphoma (ICD–9–CM code series 200.xx and 202.xx), or primary CNS lymphoma (ICD–9–CM code series 200.5x) with a corresponding ICD–9–CM procedure code for chemotherapy (99.25) that may be eligible for Voraxaze®, based on the product's approved indications. The applicant's search yielded potentially eligible cases within 249 MS–DRGs, of which 56 MS–DRGs captured 12 or more cases.

Using this universe of cases (249 MS–DRGs), the applicant added the additional costs of Voraxaze® to the case-weighted average standardized charge per case. Although the applicant submitted data related to the estimated cost of Voraxaze®, the applicant noted that the cost of the technology was proprietary information. According to the applicant, it did not convert the costs to charges for this analysis because of the technology's high cost. The applicant maintains that an average adult receiving treatment for one of the diagnoses above would require a minimum of four vials of Voraxaze®.

The applicant used the following multiple analysis of different subsets of MS–DRGs to compare the average case-weighted standardized charge per case to the average case-weighted threshold to determine that Voraxaze® met the cost criteria:

- The applicant found 12,324 eligible cases within 249 MS–DRGs, and determined a case-weighted average standardized charge per case of $87,582 (which includes the cost of Voraxaze®) and a case-weighted threshold of $39,216. The applicant maintains that Voraxaze® meets the cost criterion because the case-weighted average standardized charge per case exceeds the case-weighted threshold.
- The applicant excluded those MS–DRGs that had fewer than 11 cases, which resulted in 12,134 eligible cases within 56 MS–DRGs. The applicant determined a case-weighted average standardized charge per case of $84,039 (which includes the cost of Voraxaze®) and a case-weighted threshold of $37,195. The applicant maintains that Voraxaze® meets the cost criterion because the case-weighted average standardized charge per case exceeds the case-weighted threshold.
- The applicant analyzed the 20 MS–DRGs that contained the highest number of cases and, based on the 20 cases they stated they found, determined a case-weighted average standardized charge per case of $80,400 (which includes the cost of Voraxaze®) and a case-weighted threshold of $34,990. The applicant maintains that Voraxaze® meets the cost criterion because the case-weighted average standardized charge per case exceeds the case-weighted threshold.

We are inviting public comment on whether or not Voraxaze® meets the cost criterion. Specifically, we welcome public comment on the methodologies used in the applicant's analysis, including (1) the methods used to identify the eligible cases used in the cost analysis of this technology, especially if there are cases that should be excluded from the analysis because of clinical reasons, and if there are other ways to identify cases for which this technology may be appropriate, and (2) the appropriateness of not converting the costs to charges for the purposes of this analysis and what would be an accurate and appropriate CCR for this technology.

With regard to substantial clinical improvement, the applicant maintains that Voraxaze® is a clinical improvement compared to current treatment options because it is less time intensive, allows certain patient populations to avoid risks associated with current treatment options, and has characteristics that allows it to reduce MTX concentrations more effectively. As noted above, the applicant maintains that current treatment options for renal impairment as a result of toxic MTX concentrations are limited to extracorporeal methods that are time-intensive and could subject patients in certain populations to harm from the associated risks. The applicant states that the administration of Voraxaze® to patients who have been diagnosed with HDMTX-induced renal dysfunction metabolizes circulating MTX to the inactive metabolite DAMPA. The applicant asserts that this characteristic action of the technology represents a substantial clinical improvement over current treatment options available to patients who have toxic MTX concentrations in a more effective, and rapid way, and provides protection to eligible patient populations against potential harm associated with current treatment options.

In addition, the applicant provided the results from a study of 23 patients diagnosed with MTX-induced renal dysfunction treated with Voraxaze®. During this study, the applicant reported that the administration of Voraxaze® lowered toxic MTX concentrations in patients within 15 minutes after the administration by more than 98 percent. Because the administration of Voraxaze® could metabolize both leucovorin and its active metabolite, 5-mTHF, these patients were also administered Thymidine, a drug used to enhance the treatment for patients with high levels of MTX. The applicant notes that the combination of Voraxaze® and Thymidine rescue was well tolerated by the 23 patients studied, and MTX-related toxicities were reduced from severe to mild to moderate. The range of age of these 23 patients was 19 to 94 years old. The applicant asserts that the types of health conditions treated with HDMTX, such as acute lymphoblastic leukemia, osteosarcoma, central nervous system (CNS) lymphoma, and leptomeningeal cancer, tend to occur within the Medicare population and cites research that states ''HD–MTX-induced renal failure with persistence of toxic blood MTX levels is a rare but life threatening complication that occurs more frequently in adults, particularly those with advanced age and CNS lymphoma.'' [18] When these malignancies arise which require treatment with HDMTX, HDMTX-induced renal failure with persistent toxic MTX levels is a complication that occurs more frequently in adults. The applicant asserts that the administration of Voraxaze® has been shown to be well-tolerated by older adult patients, while achieving similar reduction rates in younger patient populations who have been diagnosed with toxic MTX concentrations and treated with Voraxaze®.[19] The applicant also provided additional published peer-reviewed articles [20,21,22,23,24,25] relevant to their application to support their

[18] Schwartz, Borner *et al.,* The Oncologist, December 2007.

[19] Schwartz, Borner *et al.*, The Oncologist, December 2007.

[20] Levy CC, Goldman P. The enzymatic hydrolysis of methotrexate and folic acid. J Biol Chem. 1967; 242:2993–2998.

[21] Minton NP, Atkinson T, Sherwood RF. Molecular cloning of the Pseudomonas carboxypeptidase G2 gene and its expression in Escherichia coli and Pseudomonas putida. J Bacteriol. 1983; 156: 1222–1227.

[22] Widemann BC, Balis FM, Kim A, *et al.* Glucarpidase, leucovorin and thymidine for high-dose methotrexate induced renal dysfunction. Clinical and pharmacologic factors affecting outcome. J Clin Oncology 2010; 28:1–8.

[23] Patterson DM, Lee SM. Glucarpidase following high-dose methotrexate: Update on development. Expert Opin Biol Ther. 2010;10(1):105–111.

[24] Phillips M, Smith W, Balan G, *et al.* Pharmacokinetics of glucarpidase in subjects with normal and impaired renal function. J Clin Pharmacol 2008; 48:279–284.

[25] Bleyer WA. Methotrexate: Clinical pharmacology, current status and therapeutic guidelines. Cancer Treat Rev. 1977;4:87–101.

assertion that they meet the substantial clinical improvement criteria.

We are inviting public comment on whether or not Voraxaze® meets the criterion of representing a substantial clinical improvement for Medicare beneficiaries.

b. DIFICID™ (Fidaxomicin) Tablets

Optimer Pharmaceuticals, Inc. submitted an application for new technology add-on payments for FY 2013 for the use of DIFICID™ (Fidaxomicin) tablets. The applicant asserts that Fidaxomicin is a major clinical advancement in the options available to treat *Clostridium difficile*-associated diarrhea (CDAD).

Clostridium difficile (*C. Diff.*) is a bacterium that can cause infection with symptoms that range from diarrhea to life-threatening inflammation of the colon, and is also commonly referred to as CDAD. The symptoms associated with CDAD can be treated by stopping administration of an antibiotic because often antibiotics can alter the native intestinal microflora and thus trigger CDAD. For mild cases of CDAD, this step may be sufficient to relieve the associated symptoms. However, many patients who have been diagnosed with more severe cases of CDAD require further treatment. Further treatment options include prescribing antibiotics such as Metronidazole or Vancomycin, prescribing probiotics administered in conjunction with antibiotics, and performing surgery using a fecal transplant to restore healthy intestinal bacteria by placing donor stool in the colon. According to the applicant, about one-fourth of the patients diagnosed with CDAD experience a recurrence of these associated symptoms.

As indicated on the labeling submitted to the FDA, the applicant noted that Fidaxomicin is taken twice a day as a daily dosage (200 mg tablet twice daily = 400 mg per day) as an oral antibiotic. The applicant asserts that Fidaxomicin provides potent bactericidal activity against *C. Diff.,* and moderate bactericidal activity against certain other gram-positive organisms, such as enterococcus and staphylococcus. Unlike other antibiotics used to treat CDAD, the applicant noted that the effects of Fidaxomicin preserve bacteroides organisms in the fecal flora. These are markers of normal anaerobic microflora. The applicant asserts that this helps prevent pathogen introduction or persistence, which potentially inhibits the re-emergence of *C. Diff.,* and reduces the likelihood of overgrowths as a result of vancomycin-resistant Enterococcus (VRE). Because of this narrow spectrum of activity, the applicant asserts that Fidaxomicin does not alter this native intestinal microflora.[26]

With regard to the newness criterion, Fidaxomicin was approved by the FDA on May 27, 2011, for the treatment of CDAD in adult patients, 18 years of age and older. Fidaxomicin was commercially available on the market within 7 weeks after the FDA's approval was granted. Currently, there are not any ICD–9–CM diagnosis or procedure codes that exist to uniquely identify the use of Fidaxomicin, or any oral drug, as a procedure. Optimer has submitted a request to the ICD–9–CM Coordination and Maintenance Committee for a new ICD–9–CM procedure code, which was discussed at the committee's meeting on March 5, 2012. For further information regarding the code proposal, we refer readers to the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html.*

We believe that under our current new technology add-on payment policy, eligibility for consideration for new technology add-on payments is limited to new technologies associated with procedures described by ICD–9–CM codes. In the FY 2002 IPPS final rule, we establish the framework for our current policy (66 FR 46907 through 46915). The discussion of technologies in that rule focuses on those technologies identifiable by ICD–9–CM codes. We also discuss in response to comments the feasibility and appropriateness of HCPCS codes and V-codes. Similar to ICD–9–CM codes, HCPCS codes are also a procedure-based system and identify procedures. We noted in that rule that V-codes would not be appropriate to use for identification of new technology because they are not a substitute for procedure coding. Volume 3 of ICD–9–CM contains codes that describe inpatient procedures (65 FR 50325). In other words, we have not considered drugs that are only taken orally to be eligible for consideration for new technology add-on payments, because there is no procedure associated with these drugs and, therefore, no ICD–9–CM code(s).

This interpretation is also consistent with other Medicare payment policies. For example, when drugs taken orally are given as part of an outpatient encounter, they would likely be considered self-administered drugs under the Hospital Outpatient Prospective Payment System (OPPS). If a Medicare beneficiary who has outpatient status were to be provided a self-administered drug by a hospital or wholly-owned or wholly-operated entity of that hospital and that beneficiary were subsequently admitted to that hospital for a related reason within three days, the hospital may not include these self-administered drugs on the inpatient bill (under the 3-day payment window policy), because self-administered drugs are not covered under the OPPS. However, they would be required to include nondiagnostic services related to admission and all other diagnostic services on the inpatient bill (under the 3-day payment window).

We are inviting public comment on our interpretation of our policy regarding drugs that are only self-administered for consideration for new technology add-on payments. Further, we are inviting public comment on whether or not Fidaxomicin meets the newness criterion.

With regard to the cost criterion, Optimer researched the FY 2010 MedPAR file for cases that would be eligible for treatment with Fidaxomicin to determine it if would qualify for the cost criterion for new technology add-on payments. Based on its analysis, the applicant identified cases in which a patient had been diagnosed with CDAD by searching the MedPAR file for claims that included ICD–9–CM diagnosis code 008.45 (Intestinal infection due to *Clostridium difficile*) as a principal diagnosis or secondary diagnosis. Optimer provided three examples of how the results of the analyses of different MS–DRGs demonstrate that it meets the cost criterion.

Under the first analysis, the applicant researched the FY 2010 MedPAR file for cases that included ICD–9–CM diagnosis code 008.45 as a principal or secondary diagnosis across all MS–DRGs. The applicant found 162,310 cases within 536 MS–DRGs, and determined a case-weighted average standardized charge per case (excluding charges for the cost of Fidaxomicin) of $50,136. Using a factor of 6.5 percent to inflate the charges to 2012 rates based on the Medical Consumer Price Index (CPI), the applicant determined a case-weighted standardized charge per case that equals $53,394. The applicant then added the charges related to the technology to the inflated charges. The applicant then determined a final case-weighted average standardized charge per case of $58,994, which exceeds the

[26] Koo, Garey *et al.* Future novel therapeutic agents for Clostridium difficile infection. Expert Opin Investig Drugs, 2010;19(7):825–836. Tannock, Munro *et al.,* A new macrocyclic antibiotic, fidaxomicin (OPT–80), causes less alteration to the bowel microbiota of Clostridium difficile-infected patients than does vancomycin. Microbiology. 2010 Nov;156(Pt 11):3354–9.

case-weighted threshold of $43,673. Because the final case-weighted average standardized charge per case for the applicable MS–DRGs exceeds the case-weighted threshold amount in this first analysis, the applicant maintains that Fidaxomicin meets the cost criterion for new technology add-on payments.

Under the second analysis, the applicant researched the FY 2010 MedPAR file for cases that included ICD–9–CM diagnosis code 008.45 only as a principal diagnosis, which mapped to MS–DRGs 371 (Major Gastrointestinal Disorders and Peritoneal Infections with MCC), 372 (Major Gastrointestinal Disorders and Peritoneal Infections with CC), and 373 (Major Gastrointestinal Disorders and Peritoneal Infections without CC/MCC). The applicant found 55,410 cases, and determined a case-weighted average standardized charge per case (excluding charges for the cost of Fidaxomicin) of $28,007. Using a factor of 6.5 percent to inflate the charges to 2012 rates based on the Medical CPI, the applicant determined a case-weighted standardized charge per case that equals $29,828. The applicant then added the charges related to the drug to the inflated charges. The applicant then determined a final case-weighted average standardized charge per case of $35,428, which exceeds the case-weighted threshold of $34,730. Because the final case-weighted average standardized charge per case for the applicable MS–DRGs exceeds the case-weighted threshold amount in this second analysis, the applicant maintains that Fidaxomicin meets the cost criterion for new technology add-on payments.

Under the third analysis, the applicant again researched the FY 2010 MedPAR file for cases that included ICD–9–CM diagnosis code 008.45 as a principal or secondary diagnosis across all MS–DRGs. The applicant then narrowed the results of the analysis to include only the top 37 MS–DRGs (in volume of cases), which accounted for 75 percent of all cases. The applicant's methodology resulted in 121,748 cases, and the applicant determined a case-weighted average standardized charge per case (excluding charges for the cost of Fidaxomicin) of $45,523. Using a factor of 6.5 percent to inflate the charges to 2012 rates based on the Medical CPI, the applicant determined a case-weighted standardized charge per case that equals $48,482. The applicant then added the charges related to the drug to the inflated charges. The applicant then determined a final case-weighted average standardized charge per case of $54,082, which exceeds the case-weighted threshold of $42,452. Because the final case-weighted average standardized charge per case for the applicable MS–DRGs exceeds the case-weighted threshold amount in this third analysis, the applicant maintains that Fidaxomicin meets the cost criterion for new technology add-on payments.

In the three analyses discussed above, the applicant submitted data related to the estimated cost and charge of the drug (using a charge markup). However, the applicant has not released the cost of the technology, asserting that it is proprietary information. The applicant converted the cost of the technology to a charge using a charge markup (a factor of 6.5 percent based on the Medical CPI) that represented a 10-day dosage.

We are concerned that these analyses do not take into account situations in which patients would be prescribed Fidaxomicin later in the duration of their inpatient stay, and may finish the course of Fidaxomicin sometime after being discharged from the hospital. In addition, as discussed above, if Fidaxomicin is prescribed and self-administered during the 3-day period prior to admission to an IPPS hospital for a related encounter, we do not believe that this service is payable under the OPPS, nor that it can be included on the inpatient claim submitted to Medicare because of the 3-day payment window policy. Therefore, it may not be appropriate to include in the applicant's calculations the full charges related to Fidaxomicin and the corresponding proprietary charges for the 10-day dose. In addition, we believe that it is necessary for the applicant to adjust its estimates to remove from the MedPAR file's claims for the charges that describe other types of treatment options such as Vancomycin, since use of these treatments would preclude use of Fidaxomicin. Furthermore, to identify the cases that may be eligible for the technology's use, the applicant researched and analyzed claims that included ICD–9–CM diagnosis code 008.45 as the principal diagnosis or as the principal or secondary diagnosis. We are concerned that this baseline for eligible cases may not represent the appropriate universe of cases, such as if all MS–DRGs were considered or if a subset of MS–DRGs were considered.

We are inviting public comment on whether or not Fidaxomicin meets the cost criterion. In addition, we are inviting public comment on the methodologies used by the applicant in its analyses, in particular the assumptions made about the dosage in developing the cost analysis. We also are interested in comments about the applicant's selection of claims with an ICD–9–CM diagnosis code 008.45 as the principal diagnosis or secondary diagnosis, and whether those cases accurately represent the Medicare population that may benefit from the technology's use.

With regard to the substantial clinical improvement criterion, the applicant maintains that Fidaxomicin represents a substantial clinical improvement to the treatment options currently available. According to the applicant, Fidaxomicin represents the first major clinical advancement in the treatment options available to address CDAD in more than 25 years, and it is one of only two agents indicated by the FDA to treat this condition. The applicant notes that reports from its clinical trials show that a higher proportion of patients achieve positive clinical response to treatment with Fidaxomicin as opposed to treatment with Vancomycin. The applicant reported that these patients did not experience recurrences of associated symptoms for at least 25 days after the end of treatment. The applicant asserts that Fidaxomicin has longer acting antimicrobial activity and inhibits spore production in *C. difficile* in vitro. The applicant stated that *C. difficile* cells produce spores when exposed to air; therefore, transmission of infection occurs even when the cells themselves are killed.

The applicant reported on two randomized, double-blinded trials [27,28]. A non-inferiority design was utilized to demonstrate the efficacy of administering Fidaxomicin (200 mg twice daily for 10 days) compared to administering Vancomycin (125 mg four times daily for 10 days) to adult patients diagnosed with CDAD. The demographic profile and baseline CDAD characteristics of the subjects enrolled in both trials were similar. These patients had a median age of 64 years, were mainly white (90 percent), female (58 percent), and inpatients (63 percent).

The applicant reported that the primary efficacy endpoint (for both trials) was the clinical response rate at

[27] Pivotal trial 101.1.C.003:

Thomas J. Louie, M.D., Mark A. Miller, M.D., Kathleen M. Mullane, D.O., Karl Weiss, M.D., Arnold Lentnek, M.D., Yoav Golan, M.D., Sherwood Gorbach, M.D., Pamela Sears, Ph.D., and Youe-Kong Shue, Ph.D. for the OPT–80–003 Clinical Study Group. *Fidaxomicin versus Vancomycin for Clostridium difficile Infection. N Engl J Med* 2011; 364:422–431 February 3, 2011. *Attached reference: 12_LouieNEJM2011.pdf.*

[28] Crook D, Weiss K, Comely O, Miller M, Esposito R, Gorbach 8. Randomized Clinical Trial (RCT) in *Clostridium difficile* Infection (CDI) Confirms Equivalent Cure Rate and Lower Recurrence Rate of Fidaxomicin (FDX) versus Vancomycin (VCN). 20th European Congress of Clinical Microbiology and Infectious Diseases; April 10–13, 2010; Vienna, Austria.

the end of therapy, based upon improvement in diarrhea or other symptoms such that, in the investigator's judgment, further CDAD treatment was not needed. An additional efficacy endpoint was sustained clinical response 25 days after the end of treatment. Sustained response was only evaluated for patients who were clinical successes at the end of treatment. Sustained response was defined as clinical response at the end of treatment, and survival without proven or suspected reoccurrence of a diagnosis of CDAD beyond 25 days after the end of treatment. The results for clinical response at the end of treatment in both trials, which the applicant submitted in the table below, indicate that the effects of administering Fidaxomicin is noninferior to the effects of administering Vancomycin based on the 95 percent confidence interval (CI) lower limit being greater than the non-inferiority margin of −10 percent.

The applicant stated that the results for sustained clinical response at the end of the follow-up period, also shown in the table below, indicate that the effects of administering Fidaxomicin is superior to the effects of administering Vancomycin on this endpoint. Because clinical success at the end of treatment and mortality rates were similar across treatment arms (approximately 6 percent in each group), the applicant determined that the differences in sustained clinical response were due to lower rates of proven or suspected reoccurrence of diagnoses of CDAD in patients during the follow-up period. In addition, the applicant asserts that the effects of administering Fidaxomicin has minimal impact on normal gut flora due to its limited specificity, and could be associated with a lower risk of acquisition of VRE if used as a treatment option instead of administering Vancomycin.

CLINICAL RESPONSE RATES AT END-OF-THERAPY AND SUSTAINED RESPONSE AT 25 DAYS POST-THERAPY

	Clinical response at end of treatment			Sustained response at follow-up		
	FIDAXOMICIN % (N)	Vancomycin % (N)	Difference (95% CI)	FIDAXOMICIN % (N)	Vancomycin % (N)	Difference (95% CI)
Trial 1	88% (N = 289)	86% (N = 307)	2.6% (−2.9%, 8.0%)	70% (N = 289)	57% (N = 307)	12.7% (4.4%, 20.9%)
Trial 2	88% (N = 253)	87% (N = 256)	1.0% (−4.8%, 6.8%)	72% (N = 253)	57% (N = 256)	14.6% (5.8%, 23.3%)

Based on the analysis described above, the applicant asserts Fidaxomicin meets the substantial clinical improvement criterion as a treatment option with the potential to decrease hospitalizations and physician office visits, as well as to improve the quality of life for patients who have been diagnosed with CDAD.

We are concerned that this technology may not offer a substantial clinical improvement compared to other effective treatment alternatives already available in the treatment of patients who have been diagnosed with CDAD. In addition, although the applicant maintains that there is no evidence of significant clinical resistance developing with the use of this drug, we are still concerned about the long-term possibility that patients may develop resistance to this drug since the applicant provided no data to substantiate its claim. We are inviting public comment on whether or not Fidaxomicin meets the substantial clinical improvement criterion based on the analysis and results presented by the applicant.

c. Zilver® PTX® Drug Eluting Stent

Cook® Medical submitted an application for new technology add-on payments for the Zilver® PTX® Drug Eluting Stent (Zilver® PTX®) for FY 2013. The Zilver® PTX® is intended for use in the treatment of peripheral artery disease (PAD) of the above–the-knee femoropopliteal arteries (superficial femoral arteries). According to the applicant, the stent is percutaneously inserted into the artery(s), usually by accessing the common femoral artery in the groin. The applicant states that an introducer catheter is inserted over the wire guide and into the target vessel where the lesion will first be treated with an angioplasty balloon to prepare the vessel for stenting. The applicant indicates that the stent is self-expanding, made of nitinol (nickel titanium), and is coated with the drug Paclitaxel. Paclitaxel is a drug approved for use as an anticancer agent and for use with coronary stents to reduce the risk of renarrowing of the coronary arteries after stenting procedures.

The manufacturer maintains that there are currently no FDA approved drug-eluting stents used for superficial femoral arteries. The applicant expects to receive FDA approval for the stent in the second quarter of 2012. The technology is currently described by ICD–9–CM procedure code 00.60 (Insertion of drug-eluting stent(s) of the superficial femoral artery). We are inviting public comment regarding how the Zilver® PTX® meets the newness criterion.

With regard to the cost criterion, the applicant believes that cases of superficial femoral arteries typically map to MS–DRGs 252 (Other Vascular Procedures with MCC), 253 (Other Vascular Procedures with CC), and 254 (Other Vascular Procedures without CC/MCC). The applicant searched the FY 2009 MedPAR file for cases with a procedure code of 39.90 (Insertion of non-drug-eluting peripheral vessel stents) in combination with a diagnosis code of 440.20 (Atherosclerosis of the extremities, unspecified), 440.21 (Atherosclerosis of the extremities, with intermittent claudication), 440.22 (Atherosclerosis of the extremities with rest pain), 440.23 (Atherosclerosis of the extremities with ulceration), and 440.24 (Atherosclerosis of the extremities with gangrene). The applicant found 7,144 cases (or 24.4 percent of all cases) in MS–DRG 252; 9,146 cases (or 31.2 percent of all cases) in MS–DRG 253; and 13,012 cases (or 44.4 percent of all cases) in MS–DRG 254. The average charge per case was $78,765 for MS–DRG 252, $63,758 for MS–DRG 253, and $47,586 for MS–DRG 254, equating to a case-weighted average charge per case of $60,236.

The case-weighted average charge per case above does not include charges related to the Zilver® PTX®; therefore, it is first necessary to remove the amount of charges related to the nondrug-eluting peripheral vessel stents and replace them with charges related to the Zilver® PTX®. The applicant used two methodologies to remove the charges of the nondrug-eluting peripheral vessel stents and replace them with charges related to the Zilver® PTX®. Although the applicant submitted data related to the estimated cost of the nondrug-eluting peripheral vessel stents and the Zilver® PTX®, the applicant noted that the cost of these devices was proprietary information.

Under the first methodology, the applicant determined the amount of

stents per case based on the following ICD–9–CM codes on each claim: 00.45 (Insertion of one vascular stent), 00.46 (Insertion of two vascular stents), 00.47 (Insertion of three vascular stents) and 00.48 (Insertion of four or more vascular stents). If a claim had a code of 00.48, the applicant assumed a maximum of four stents per case. The applicant multiplied the amount of stents used per case by the average market price for nondrug-eluting peripheral vessel stents and then converted the cost of the stents used per case to a charge by dividing the results by the national average CCR of 0.329 for supplies and equipment (76 FR 51571). The applicant removed the appropriate amount of charges per case and then standardized the charges per case. Because the applicant used FY 2009 MedPAR data, it was necessary to inflate the charges from FY 2009 to FY 2012. Using data from the U.S. Department of Labor Bureau of Labor Statistics Consumer Price Index, the applicant inflated the average standardized charge per case with an inflation factor of 6 percent. To determine the amount of Zilver® PTX® stents per case, instead of using the amount of stents used per case based on the ICD–9–CM codes above, the applicant used an average of 1.9 stents per case based on the Zilver® PTX® Global Registry Clinical Study.[29] The applicant believed that it is appropriate to use data from the clinical study (to determine the average amount of stents used per case) rather than the actual data from the claims because the length of a nondrug-eluting peripheral vessel stent typically ranges from 80mm to 120 mm, while the length of the Zilver® PTX® is 80 mm (which could cause a variance in the actual amount of stents used per case when using the Zilver® PTX®). Similar to above, the applicant multiplied the average of 1.9 stents used per case by the future market price for the Zilver® PTX® and then converted the cost of the stents used per claim to a charge by dividing the results by the national average CCR of 0.329 for supplies and equipment. The applicant then added the amount of charges related to the Zilver® PTX® to the inflated average standardized charge per case and determined a final case-weighted average standardized charge per case of $60,014. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS–DRGs 252, 253, and 254 was $52,293 (all calculations above were performed using unrounded numbers). Because the case-weighted average standardized charge per case for the applicable MS–DRGs exceed the case-weighted threshold amount, the applicant maintains that the Zilver® PTX® meets the cost criterion.

The second methodology was similar to the first methodology described above, but the applicant used hospital-specific CCRs from the FY 2009 IPPS impact file to convert the cost of the nondrug-eluting peripheral vessel stents and the cost of the Zilver® PTX® to charges. In summary, the applicant determined the amount of nondrug-eluting peripheral vessel stents used per case based on the ICD–9–CM codes on each claim (as discussed above). The applicant multiplied the amount of stents used per case by the average market price for nondrug-eluting peripheral vessel stents and then converted the cost of the stents used per case to a charge by dividing by the hospital-specific CCR (from the FY 2009 IPPS impact file). The applicant removed the appropriate amount of charges per case and then standardized the charges per case. Similar to the step described above, because the applicant used FY 2009 MedPAR data, it was necessary to inflate the charges from FY 2009 to FY 2012. Using data from the Bureau of Labor Statistics Consumer Price Index, the applicant inflated the average standardized charge per case with an inflation factor of 6 percent. To determine the amount of Zilver® PTX® stents per case, instead of using the amount of stents used per case based on the ICD–9–CM codes above, the applicant used an average of 1.9 stents per case based on the Zilver® PTX® Global Registry Clinical Study (because of the reason stated in the first methodology). The applicant then multiplied the average of 1.9 stents used per case by the future market price for the Zilver® PTX® and then converted the cost of the stents used per claim to a charge by dividing the results by the hospital-specific CCR (from the FY 2009 IPPS impact file). The applicant then added the amount of charges related to the Zilver® PTX® to the inflated average standardized charge per case and determined a final case-weighted average standardized charge per case of $60,339. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS–DRGs 252, 253, and 254 was $52,293 (all calculations above were performed using unrounded numbers). Because the case-weighted average standardized charge per case for the applicable MS–DRGs exceed the case-weighted threshold amount, the applicant maintains that the Zilver® PTX® would meet the cost criterion.

We are inviting public comment on whether or not the Zilver® PTX® meets the cost criterion. Additionally, we are inviting public comment on the methodologies used by the applicant in its analysis, including its assumptions regarding the types of cases in which this technology could potentially be used, the number of stents required for each case, and the CCRs used in the cost calculation.

In an effort to demonstrate that the technology meets the substantial clinical improvement criterion, the applicant shared several findings from the clinical trial data. The applicant stated that current treatment options for patients who have been diagnosed with PAD includes angioplasty, bare metal stenting, bypass graft and endarterectomy. The applicant asserts that the Zilver® PTX® meets the substantial clinical improvement because it decreases the recurrence of symptoms arising from restenotic SFA lesions, the rate of subsequent diagnostic or therapeutic interventions required to address restenotic lesions, and the number of future hospitalizations.

The applicant cited a 480-patient, multicenter, multinational randomized controlled trial that compared the Zilver® PTX® to balloon angioplasty; an additional component of the study allowed a direct comparison of the Zilver® PTX® to a bare (uncoated) metal Zilver® stent. The primary safety endpoint of the randomized controlled study was ''Event-Free Survival'' (EFS), defined as ''freedom from the major adverse events of death, target lesion revascularization, target limb ischemia requiring surgical intervention or surgical repair of the target vessel, and freedom of worsening systems as described by the Rutherford classification by 2 classes or to class 5 or 6.'' The primary effectiveness endpoint was primary patency (defined as a less than 50 percent renarrowing).

The applicant noted that the Zilver® PTX® had an EFS of 90.4 percent compared to balloon angioplasty, which had an EFS of 83.9 percent, demonstrating that the Zilver® PTX® is as safe or safer than balloon angioplasty. In addition, the applicant noted that the Zilver® PTX® demonstrated a 50-percent reduction in restenosis rates compared to angioplasty and a 20-percent reduction compared to bare metal stents. The 12-month patency rate

[29] Dake, M.D., Ansel, G.M., Jaff, M.R., Ohki, T., Saxon, R.R., Smouse, H.B., Zeller, T., Roubin, G.S., Burket, M.W., Khatib, Y., Snyder, S.A., Ragheb, A.O., White, J.K., Machan, L.S.(2011), Paclitaxel-eluting stents show superiority to balloon angioplasty and bare metal stents in femoropopliteal disease: twelve-month zilver PTX randomized study results. Circulation Cardiovascular Interventions, published online September 27, 2011, 495–504.

for the Zilver® PTX® was 83.1 percent, which compared favorably to the balloon angioplasty patency rate of 32.8 percent. In the provisional stenting arm of the study, which allowed a direct comparison of the Zilver® PTX® and a bare metal stent, the Zilver® PTX® primary patency exceeded the bare metal stent patency by nearly 20 percent (89.9 percent versus 73.0 percent). The applicant stated that these differences are significant, as they result in a substantial clinical improvement compared to angioplasty and bare metal stenting, with patients being spared a recurrence of their leg pain and the need to be admitted to the hospital for repeat procedures on these treated lesions.

The applicant also cited a prospective, multicenter, multinational, 787-patient single arm study on the Zilver® PTX® that demonstrated similar safety and effectiveness results consistent with those from the pivotal randomized controlled study above. The applicant cited an EFS for the Zilver® PTX® of 89.0 percent and an 86.2 percent primary patency rate. The applicant stated that these results confirm the safety and effectiveness of the Zilver® PTX®, and compare favorably to current results for angioplasty and bare metal stenting. The applicant added that these results also demonstrate a 67 to 81 percent relative reduction in Target Lesion Revascularization (the need to retreat an already treated lesion that has restenosed, resulting in a recurrence of symptoms) rates compared to recently published results of contemporary bare metal stents.[30]

We are inviting public comment regarding whether the Zilver® PTX® meets the substantial clinical improvement criterion.

d. Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft

Cook® Medical submitted an application for new technology add-on payments for the Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft (Zenith® F. Graft) for FY 2013. The applicant stated that the current treatment for patients who have had an AAA is an endovascular graft. The applicant explained that the Zenith® F. Graft is an implantable device designed to treat patients who have an AAA and who are anatomically unsuitable for treatment with currently approved AAA endovascular grafts because of the length of the infrarenal aortic neck. The applicant noted that, currently, an AAA is treated through an open surgical repair or medical management for those patients not eligible for currently approved AAA endovascular grafts.

The applicant stated that the Zenith® F. Graft is custom-made for each patient. It is a modular system consisting of three components: a two-part main body graft and one iliac leg. The two-part main body of the graft consists of a proximal tubular graft and a distal bifurcated graft body. The proximal body graft contains precisely located holes (fenestrations) and/or cut-outs from the proximal margin (scallops) of the polyester graft material along with a bare proximal stent with barbs to provide fixation. The iliac leg component, which couples with the main bifurcated body, completes the basic fenestrated endograft.

With respect to newness, the applicant stated that FDA approval for the use of the Zenith® F. Graft was granted on April 4, 2012. The technology is described by ICD–9–CM procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta), which became effective October 1, 2011. While procedure code 39.78 maps to MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without MCC/CC, respectively), the applicant believes that MS–DRGs 237 and 238 (Major Cardiovascular Procedures with MCC and without MCC, respectively) would be a more appropriate assignment for procedure code 39.78. (We note that in section III.G.3.b. of this preamble, we discuss our response to the request for consideration of MS–DRGs 237 and 238 as a more appropriate assignment for procedure code 39.78.) We are inviting public comment regarding whether the Zenith® F. Graft meets the newness criterion for new technology add-on payment.

With regard to the cost criterion, the applicant used clinical trial data and three separate analyses of FY 2010 MedPAR data to demonstrate that the Zenith® F. Graft meets the cost criteria. The clinical trial data[31] was based on 173 claims (all Medicare patients except one patient). The applicant found that, of the 173 cases, 35 cases (or 20.2 percent of all cases) mapped to MS–DRG 252, 86 cases (or 49.7 percent of all cases) mapped to MS–DRG 253, and 52 cases (or 30.1 percent of all cases) mapped to MS–DRG 254, equating to a case-weighted average charge per case of $87,733.

The applicant noted that the investigational devices (the bare metal renal stents that are used in the procedure and the Zenith® F. Graft) were sold to the trial sites at reduced prices. Therefore, the average charge per case cited above contains reduced charges for the investigational devices rather than commercial charges. As a result, the applicant believes it is necessary to remove the reduced charges for the investigational devices and replace them with commercial charges, in order to determine the cost of the investigational devices for each of the three analyses. Although the applicant submitted data related to the estimated cost of the investigational devices, the applicant noted that the cost of these devices was proprietary information.

To remove the reduced charges for the investigational devices, the applicant searched the clinical trial claims data and removed those charges with a revenue code of 0624 (investigational device exempt). Because the claims data for the clinical trial ranged from 2002 to 2010, it was necessary to inflate the charges. Using data from the U.S. Department of Labor Bureau of Labor Statistics (BLS) Consumer Price Index, the applicant applied an inflation factor to the claim charges ranging from 3 percent to 27 percent, depending on the year of the claim. After inflating the charges, the applicant then added the commercial charges of the investigational devices to the inflated charge per case. To determine the amount of commercial charges related to the investigational devices, the applicant divided the cost of the investigational devices by the hospital-specific CCR from the FY 2012 IPPS Final Rule Impact File. After adding the charges of the investigational devices to the inflated charges, the applicant then standardized the charges on each claim. As a result, the applicant determined a final case-weighted average standardized charge per case of $122,821. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS–DRGs 252, 253, and 254 was $53,869 (all calculations above were performed using unrounded numbers). Because the final case-weighted average standardized charge per case for the applicable MS–DRGs exceeds the case-weighted threshold amount, the applicant maintains that the Zenith® F.

[30] Dake, M. D., Scheinert, D., Tepe, G., Tessarek, J., Fanelli, F., Bosiers, M., *et al.* (2011). Nitinol stents with polymer-free paclitaxel coating for lesions in the superficial femoral and popliteal arteries above the knee: Twelve-month safety and effectiveness results from the zilver PTX single-arm clinical study. *Journal of Endovascular Therapy, 18(5),* 613–623.

[31] Evaluation of the Safety and Effectiveness of the Zenith(R) Fenestrated AAA Endovascular Graft, Zenith Fenestrated AAA Endovascular Graft Pivotal Study, Clinicaltrials.gov: Identifier NCT00875563 and a Physician Sponsored IDE.

Graft meets the cost criterion for new technology add-on payment.

We note that, in addition to the analysis above, the applicant conducted a similar cost analysis using drug eluting renal stents instead of bare metal renal stents. The applicant noted that the price of drug eluting renal stents exceeds the price of bare metal renal stents by approximately $2,200 per stent. Therefore, the applicant asserted that if the price of drug eluting renal stents is more expensive than bare metal renal stents and the Zenith® F. Graft meets the cost criteria with bare metal renal stents, the Zenith® F. Graft also meets the cost criteria when the applicant uses drug eluting renal stents in its analysis.

As mentioned above, the applicant conducted three separate analyses using FY 2010 MedPAR data to identify cases eligible for the Zenith® F. Graft to demonstrate that it meets the cost criterion. Cases of endovascular implantation of branching or fenestrated graft(s) in the aorta are coded with procedure code 39.78, which currently map to MS–DRGs 252, 253, and 254. Because procedure code 39.78 was effective October 1, 2011, the applicant noted that it was unable to conduct a MedPAR data analysis with claims that contained a procedure code of 39.78. Therefore, in order to identify cases eligible for the Zenith® F. Graft prior to October 1, 2011, the applicant searched the MedPAR file for the following three scenarios. The first analysis searched the FY 2010 MedPAR file for cases with procedure code 39.71 (Endovascular implantation of graft in abdominal aorta) in combination with a diagnosis code of 441.4 (Abdominal aneurysm without mention of rupture). The applicant conducted this analysis using MS–DRGs 237 and 238 rather than MS–DRGs 252, 253, and 254 because procedure code 39.71 maps to MS–DRGs 237 and 238. The applicant found 1,679 cases (or 9.1 percent of all cases) in MS–DRG 237 and 16,793 cases (or 90.9 percent of all cases) in MS–DRG 238. The average charge per case was $122,252 for MS–DRG 237 and $76,883 for MS–DRG 238, equating to a case-weighted average charge per case of $81,006.

The applicant noted that these MedPAR claims data included charges for the existing stent graft but did not include charges for the Zenith® F. Graft. Therefore, the applicant stated that it was first necessary to remove the amount of charges related to the existing stent graft and replace them with charges for the Zenith® F. Graft. Although the applicant submitted data related to the estimated cost of the existing stent graft and the Zenith® F. Graft, the applicant noted that the cost of these devices was proprietary information.

To determine the amount of charges for the existing stent graft, the applicant divided the costs for the existing stent graft by the national average CCR of 0.329 for supplies and equipment (76 FR 51571). The applicant removed the appropriate amount of charges per case from the average charge per case. Because the applicant used FY 2010 MedPAR data, it was necessary to inflate the charges from FY 2010 to FY 2012. Using data from the BLS' Consumer Price Index, the applicant inflated the case-weighted average standardized charge per case with an inflation factor of 4 percent. The applicant then determined the amount of charges for the Zenith® F. Graft by dividing the costs of the Zenith® F. Graft by the national average CCR of 0.329 for supplies. The applicant then added the amount of charges related to the Zenith® F. Graft to the inflated charges and then standardized the charges. The applicant determined a final case-weighted average standardized charge per case of $80,509. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS–DRGs 237and 238 was $72,512 (all calculations above were performed using unrounded numbers). Because the final case-weighted average standardized charge per case for the applicable MS–DRGs exceeds the case-weighted threshold amount under this first analysis, the applicant maintains that the Zenith® F. Graft meets the cost criterion for new technology add-on payment. The applicant noted that the FY 2013 Table 10 thresholds for MS–DRGs 237 and 238 are much higher than the FY 2013 Table 10 thresholds for MS–DRGs 252, 253, and 254. Therefore, the applicant believes that if the final case-weighted average standardized charge per case exceeds the case-weighted threshold for MS–DRGs 237 and 238, it would exceed any case-weighted threshold for MS–DRGs 252, 253, and 254.

For their second analysis, the applicant searched the FY 2010 MedPAR file for cases with procedure code 38.44 (Resection of vessel with replacement, aorta) in combination with a diagnosis code of 441.4. Similar to the first analysis, the applicant conducted this analysis using MS–DRGs 237 and 238 rather than MS–DRGs 252, 253, and 254 because procedure code 38.44 maps to MS–DRGs 237 and 238. The applicant found 1,310 cases (or 37.9 percent of all cases) in MS–DRG 237 and 2,145 cases (or 62.1 percent of all cases) in MS–DRG 238. The average charge per case was $110,708 for MS–DRG 237 and $64,095 for MS–DRG 238, equating to a case-weighted average charge per case of $81,769.

The next steps of the applicant's second analysis were similar to the steps in the first analysis. The applicant noted that the MedPAR claims data included charges for the vascular graft for open procedures but did not include charges for the Zenith® F. Graft. Therefore, the applicant indicated that it was first necessary to remove the amount of charges related to the vascular graft for open procedures and replace them with charges for the Zenith® F. Graft. Although the applicant submitted data related to the estimated cost of the vascular graft for open procedures and the Zenith® F. Graft, the applicant noted that the cost of these devices was proprietary information.

To determine the amount of charges for the vascular graft for open procedures, the applicant divided the costs for the vascular graft for open procedures by the national average CCR of 0.329 for supplies and equipment (76 FR 51571). The applicant removed the appropriate amount of charges per case from the average charge per case. Similar to the first analysis, the applicant inflated the case-weighted average charge per case with an inflation factor of 4 percent (based on data from the BLS' Consumer Price Index). The applicant then determined the amount of charges for the Zenith® F. Graft by dividing the costs of the Zenith® F. Graft by the national average CCR of 0.329 for supplies. The applicant then added the amount of charges related to the Zenith® F. Graft to the inflated charges and then standardized the charges. The applicant determined a final case-weighted average standardized charge per case of $118,774. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS–DRGs 237 and 238 was $81,776 (all calculations above were performed using unrounded numbers). Because the final case-weighted average standardized charge per case for the applicable MS–DRGs exceeds the case-weighted threshold amount in this second analysis, the applicant maintains that the Zenith® F. Graft meets the cost criterion for new technology add-on payments. As discussed above, the applicant noted that the FY 2013 Table 10 thresholds for MS–DRGs 237 and 238 are much higher ($101,728 for MS–DRG 237 and $69,591 for MS–DRG 238) than the FY 2013 Table 10 thresholds for MS–DRGs 252, 253, and 254 ($60,619 for MS–DRG 252, $56,719 for MS–DRG 253 and $44,611 for MS–DRG 254).

Therefore, the applicant believes that if the final case-weighted average standardized charge per case exceeds the case-weighted threshold for MS–DRGs 237 and 238, it would exceed any case-weighted threshold for MS–DRGs 252, 253, and 254.

While the applicant removed charges for the vascular graft for open procedures, we are concerned that the applicant did not remove charges for other services such as extra operating room time and other possible charges that would be incurred during an open procedure but would possibly not be incurred during cases when the Zenith® F. Graft is implanted.

The third analysis was a combination of the first and second analyses discussed above. The applicant searched the FY 2010 MedPAR file for cases with a procedure code of 38.44 or 39.71 in combination with a diagnosis code of 441.4. Similar to the first and second analyses, the applicant conducted this analysis using MS–DRGs 237 and 238 rather than MS–DRGs 252, 253, and 254 because both procedure codes map to MS–DRGs 237 and 238. The applicant found 2,981 cases (or 13.6 percent of all cases) in MS–DRG 237 and 18,928 cases (or 86.4 percent of all cases) in MS–DRG 238. The applicant removed those cases that had both procedure codes 38.44 and 39.71 on the claim. The average charge per case was $116,826 for MS–DRG 237 and $75,298 for MS–DRG 238, equating to a case-weighted average charge per case of $80,948.

The applicant noted that the MedPAR claims data included charges for the existing stent graft or vascular graft for open procedures but did not include charges for the Zenith® F. Graft. Therefore, the applicant stated that it was first necessary to remove the amount of charges related to the existing stent graft or vascular graft for open procedures and replace them with charges for the Zenith® F. Graft. Similar to the first and second analyses, to determine the amount of charges for the existing stent graft or vascular graft for open procedures, the applicant divided the costs for these devices by the national average CCR of 0.329 for supplies and equipment (76 FR 51571). The applicant removed the appropriate amount of charges per case from the average charge per case. The applicant inflated the case-weighted average standardized charge per case with an inflation factor of 4 percent (based on data from the BLS' Consumer Price Index). The applicant then determined the amount of charges for the Zenith® F. Graft by dividing the costs of the Zenith® F. Graft by the national average CCR of 0.329 for supplies. The applicant then added the amount of charges related to the Zenith® F. Graft to the inflated charges and then standardized the charges. As a result, the applicant determined a final case-weighted average standardized charge per case of $86,081. Using the FY 2013 Table 10 thresholds, the case-weighted threshold for MS–DRGs 237 and 238 was $73,964 (all calculations above were performed using unrounded numbers). Because the final case-weighted average standardized charge per case for the applicable MS–DRGs exceeds the case-weighted threshold amount, the applicant maintains that the Zenith® F. Graft meets the cost criterion for new technology add-on payment. As discussed above, the applicant noted that the FY 2013 Table 10 thresholds for MS–DRGs 237 and 238 are much higher than the FY 2013 Table 10 thresholds for MS–DRGs 252, 253, and 254. The applicant believes that if the final case-weighted average standardized charge per case exceeds the case-weighted threshold for MS–DRGs 237–238, it would exceed any case-weighted threshold for MS–DRGs 252, 253, and 254.

Similar to our concerns with the second analysis, we are concerned that for this third analysis the applicant did not remove charges for other services such as extra operating room time and other possible charges that would be incurred during an open procedure, but would possibly not be incurred during cases when the Zenith® F. Graft is implanted.

We appreciate the multiple analyses of the FY 2010 MedPAR data provided by the applicant and are inviting public comment on whether or not the Zenith® F. Graft meets the cost criterion for new technology add-on payments. In addition, we are inviting public comment on the methodologies used by the applicant, specifically on whether and the degree to which the second and third analyses may contain charges not relevant to the final case-weighted standardized charge per case determined by the applicant.

The applicant maintains that the technology also meets the substantial clinical improvement criterion. The applicant first explained that current treatment for those patients who are not eligible for standard endovascular AAA devices is an open repair. The applicant referenced data from a published series [32] that demonstrated an open repair can lead to a high risk of morbidity and increased mortality. The applicant added that an open procedure requires suprarenal aortic cross-clamping.[33] The applicant also noted that there is a high risk of blood loss during an open procedure and the de-branching of vessels increases the level of surgical risk. The applicant further noted that 30 to 40 percent of patients who have an infrarenal AAA cannot be treated with current commercial devices because of anatomical reasons (for example, insufficient neck length to achieve graft adequate seal). The applicant added that use of standard endografts in patients with neck lengths less than 10 mm can result in a fourfold increase in an endoleak.[34]

The applicant also stated that the intended use of the Zenith® F. Graft differs from standard AAA endovascular grafts in that the fenestrated device provides physicians the ability to treat patients who have infrarenal aortic neck lengths as short as 4 mm, where standard endovascular AAA devices require an infrarenal aortic neck length of at least 10 to 15 mm. Therefore, the applicant believes that the Zenith® F. Graft offers an additional AAA repair option to those patients who have limited surgical treatment options (for example, if short infrarenal neck lengths make the patients at too high a risk to be candidates for open surgical repair).

The applicant also stated, for patients who have AAAs and short infrarenal neck lengths, the Zenith® F. Graft offers a less invasive treatment option than open surgical repair. The applicant referred to several sources of literature to support the following endpoints for fenestrated endovascular aortic repair (EVAR) versus open repair of the juxtarenal AAA relative to open repair of the juxtarenal AAA: Reduced peri-operative mortality (2.4 percent (range: 0 to 5.7 percent)) [35,36,37,38,39,40,41,42,43]

[32] Wilderman, M. *et al.* Fenestrated Grafts or Debranching Procedures for Complex Abdominal Aortic Aneurysms. Perspectives in Vascular Surgery and Endovascular Therapy, March 2009; 21(1): 13–18.

[33] Jongkind V, Yeung K, *et al.* Juxtarenal aortic aneurysm repair. Journal of Vascular Surgery 2010 Sept; 29(3) 760–767.

[34] Amiot, S., *et al.,* Fenestrated endovascular grafting: The French multicentre experience. Eur J Vasc Endovasc Surg, 2010. 39(5): p. 537–44.

[35] Nordon, I.M., *et al.,* Modern treatment of juxtarenal abdominal aortic aneurysms with fenestrated endografting and open repair—a systematic review. Eur J Vasc Endovasc Surg, 2009. 38(1): p. 35–41

[36] Verhoeven, E.L., *et al.,* Fenestrated stent grafting for short-necked and juxtarenal abdominal aortic aneurysm: An 8-year single-centre experience. Eur J Vasc Endovasc Surg, 2010. 39(5): p. 529–36.

[37] Chisci E, Kristmundsson T, de Donato G, *et al.* The AAA with a challenging neck: Outcome of open versus endovascular repair with standard and fenestrated stent-grafts. J Endovasc Ther 2009;16:137–146.

Continued

reported for fenestrated EVAR repairs versus 2.9 percent (range 0 to 7.4 percent)[44,45] reported for open repair of juxtarenal AAA);[46] reduced morbidity by reducing renal failure requiring permanent dialysis (1.9 percent (pooled average) for fenestrated EVAR repairs versus 3.4 percent reported for open repair of juxtarenal AAA); shorter hospital stay and less operative blood loss to open repair. The applicant maintains that fenestrated EVAR repair results in an average length of stay of 3.5 days, compared to 14.2 days for open repair of juxtarenal AAA, and blood loss of 537 ml, compared to 2586 ml for open repair of juxtarenal AAA.

We note that the information provided by the applicant to evaluate substantial clinical improvement compares this technology to open surgical repair. We are concerned that the applicant does not present publicly available information comparing the technology to medical management, which the applicant mentions as another method for treating patients anatomically unsuited for currently approved AAA endovascular grafts. In these comparisons, we are also concerned that information regarding the longevity of the Zenith® F. Graft as well as long-term complications and secondary interventions or reinterventions has not been presented. In terms of the data presented by the applicant, we are concerned that these clinical study data were nonrandomized, did not differentiate between patients by infrarenal neck length and/or suitability for other endovascular grafts, and were of noninferiority. We are inviting public comment on whether or not the Zenith® F. Graft 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 2013 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 2013 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 2013 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, 2012 (the FY 2013 wage index) appears under section III.F. of this preamble.

In response to concerns frequently expressed by providers and other relevant parties that the current wage index system does not effectively reflect the true variation in labor costs for a large cross-section of hospitals, two studies were undertaken by the Department. First, section 3137(b) of the Affordable Care Act required the Secretary to submit to Congress a report that includes a plan to comprehensively reform the Medicare wage index applied under section 1886(d) of the Act. In developing the plan, the Secretary was directed to take into consideration the goals for reforming the wage index that were set forth by the Medicare Payment Advisory Commission (MedPAC) in its June 2007 report entitled ''Report to Congress: Promoting Greater Efficiency in Medicare'' and to ''consult with relevant affected parties.'' Second, the Secretary commissioned the Institute of Medicine (IOM) to ''evaluate hospital and physician geographic payment adjustments, the validity of the adjustment factors, measures and methodologies used in those factors, and sources of data used in those factors.'' Reports on both of these studies recently have been released. We refer readers to section IX.B. of this preamble for summaries of the studies, their findings, and recommendations on reforming the wage index system.

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 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). We also discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582) that, in 2013, OMB plans to announce new area delineations based on new standards adopted in 2010 (75 FR 37246) and the

[38] Amiot, S., *et al.,* Fenestrated endovascular grafting: The French multicentre experience. Eur J Vasc Endovasc Surg, 2010. 39(5): p. 537–44.

[39] Kristmundsson T, Sonesson B, Malina M, *et al.* Fenestrated endovascular repair for juxtarenal aortic pathology. J Vasc Surg 2009;49:568–574.

[40] Beck AW, Bos WT, Vourliotakis G, *et al.* Fenestrated and branched endograft repair of juxtarenal aneurysms after previous open aortic reconstruction. J Vasc Surg 2009;49:1387–1394.

[41] Tambyraja, A.L., *et al.,* Fenestrated aortic endografts for juxtarenal aortic aneurysm: Medium term outcomes. Eur J Vasc Endovasc Surg, 2011. 42(1): p. 54–8.

[42] Unpublished results, Evaluation of the Safety and Effectiveness of the Zenith(R) Fenestrated AAA Endovascular Graft, Zenith Fenestrated AAA Endovascular Graft Pivotal Study, Clinicaltrials.gov identifier NCT00875563.

[43] Unpublished results, British Society of Endovascular Therapy-sponsored GlobalStar Collaborative Study.

[44] Jongkind V, Yeung K, *et al.* Juxtarenal aortic aneurysm repair. *J. Vasc. Surg.* 2010 Sept; 29(3) 760–767.

[45] Landry G, Lau I, Liem T, Mitchell E, Moneta G.. Open abdominal aortic aneurysm repair in the endovascular era: Effect of clamp site on outcomes. Arch. Surg., 144 (9) Sep. 2009, 811–6.

2010 Census of Population and Housing data. For the FY 2013 wage index, to be effective October 1, 2012 and before the availability of OMB's new area delineations, we are proposing to use the same labor market areas that we used for the FY 2012 wage index (76 FR 51581).

C. Worksheet S–3 Wage Data for the FY 2013 Proposed Wage Index

The FY 2013 proposed wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2009 (the FY 2012 wage indices were based on data from cost reporting periods beginning during FY 2008).

1. Included Categories of Costs

The FY 2013 proposed 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 pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590) and other deferred compensation costs.

2. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2012, the proposed wage index for FY 2013 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 2013 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).

3. 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.

D. Verification of Worksheet S–3 Wage Data

The wage data for the FY 2013 proposed 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, 2008, and before October 1, 2009. For wage index purposes, we refer to cost reports during this period as the ''FY 2009 cost report,'' the ''FY 2009 wage data,'' or the ''FY 2009 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 wage index includes FY 2009 data submitted to us as of March 2, 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 FY 2013 proposed wage index, we identified and excluded 32 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 intend to include some of these providers in the FY 2013 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 11, 2012. 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 2013 IPPS final rule.

In constructing the FY 2013 proposed wage index, we included the wage data for facilities that were IPPS hospitals in FY 2009, 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 7 hospitals that converted to CAH status between February 15, 2011, the cut-off date for CAH exclusion from the FY 2012 wage index, and February 14, 2012, the cut-off date for CAH exclusion from the FY 2013 wage index. After removing hospitals with aberrant data and hospitals that converted to CAH status, the proposed FY 2013 wage index is calculated based on 3,443 hospitals.

For the FY 2013 proposed wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located in the same manner we allotted such hospitals' data in the FY 2012 wage index (76 FR 51591). Table 2 containing the FY 2013 proposed wage index associated with this proposed rule (available on the CMS Web site) includes separate wage data for the campuses of four multicampus hospitals.

E. Method for Computing the Proposed FY 2013 Unadjusted Wage Index

The method used to compute the FY 2013 proposed wage index without an occupational mix adjustment follows the same methodology that we used to compute the FY 2012 final wage index without an occupational mix adjustment (76 FR 51591 through 51593).

As discussed in that final rule, in ''Step 5,'' for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2008, through April 15, 2010, for private industry hospital workers from the BLS' *Compensation and Working Conditions.* We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing any changes to the usage for FY 2013. 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
10/14/2008	11/15/2008	1.03003
11/14/2008	12/15/2008	1.02786
12/14/2008	01/15/2009	1.02582
01/14/2009	02/15/2009	1.02386
02/14/2009	03/15/2009	1.02199
03/14/2009	04/15/2009	1.02014
04/14/2009	05/15/2009	1.01826
05/14/2009	06/15/2009	1.01635
06/14/2009	07/15/2009	1.01446
07/14/2009	08/15/2009	1.01263
08/14/2009	09/15/2009	1.01086
09/14/2009	10/15/2009	1.00910
10/14/2009	11/15/2009	1.00728
11/14/2009	12/15/2009	1.00539
12/14/2009	01/15/2010	1.00352
01/14/2010	02/15/2010	1.00172
02/14/2010	03/15/2010	1.00000
03/14/2010	04/15/2010	0.99830

For example, the midpoint of a cost reporting period beginning January 1, 2009, and ending December 31, 2009, is June 30, 2009. An adjustment factor of 1.01446 would be applied to the wages of a hospital with such a cost reporting period.

Using the data as described above and in the FY 2012 IPPS–LTCH PPS final rule, the FY 2013 proposed national average hourly wage (unadjusted for occupational mix) is $37.4023. The proposed Puerto Rico overall average hourly wage (unadjusted for occupational mix) is $15.8467.

F. Proposed Occupational Mix Adjustment to the FY 2013 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 FY 2013 Proposed Occupational Mix Adjustment Based on the 2010 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.

As discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586), the FY 2013 proposed wage index is based on data collected on the new 2010 Medicare Wage Index Occupational Mix Survey (Form CMS–10079 (2010)). 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 were required to submit their completed 2010 surveys to their fiscal intermediaries/MACs by July 1, 2011. The preliminary, unaudited 2010 survey data was 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.

2. Calculation of the Proposed Occupational Mix Adjustment for FY 2013

For FY 2013, we are proposing to calculate the occupational mix adjustment factor using the same methodology that we used for the FY 2012 wage index (76 FR 51582 through 51586). As a result of applying this methodology, the FY 2013 proposed occupational mix adjusted national average hourly wage is $37.3721. The FY 2013 proposed occupational mix adjusted Puerto Rico-specific average hourly wage is $15.8838.

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 2013 wage index. For the FY 2010 survey, the response rate was 91.7 percent. In the FY 2013 proposed wage index established in this proposed rule, we applied proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586).

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 was effective beginning with the new 2010 occupational mix survey. We instructed fiscal intermediaries/MACs to begin gathering this information as part of the FY 2013 wage index desk review process. We will review these data for future analysis and consideration of potential penalties for noncompliant hospitals.

G. Analysis and Implementation of the Proposed Occupational Mix Adjustment and the Proposed FY 2013 Occupational Mix Adjusted Wage Index

1. Analysis of the Occupational Mix Adjustment and the Occupational Mix Adjusted Wage Index

As discussed in section III.F. of this preamble, for FY 2013, we are proposing to apply the occupational mix adjustment to 100 percent of the proposed FY 2013 wage index. We calculated the proposed occupational mix adjustment using data from the 2010 occupational mix survey data, using the methodology described in the FY 2012 IPPS–LTCH PPS final rule (76 FR 51582 through 51586).

Using the occupational mix survey data and applying the occupational mix adjustment to 100 percent of the FY 2013 wage index results in a proposed national average hourly wage of $37.3721 and a proposed Puerto-Rico specific average hourly wage of $15.8838. After excluding data of hospitals that either submitted aberrant data that failed critical edits, or that do not have FY 2009 Worksheet S–3, Parts II and III, cost report data for use in calculating the proposed FY 2013 wage index, we calculated the proposed FY 2013 wage index using the occupational mix survey data from 3,443 hospitals. Using the Worksheet S–3, Parts II and III, cost report data of 3,443 hospitals and occupational mix survey data from 3,157 hospitals represents a 91.7 percent survey response rate. The proposed FY 2013 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	37.362735568
National LPN and Surgical Technician	21.762566488
National Nurse Aide, Orderly, and Attendant	15.312800678
National Medical Assistant	17.240367808
National Nurse Category	31.807020884

The proposed national average hourly wage for the entire nurse category as computed in Step 5 of the occupational mix calculation is $31.807020884. 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 2010 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 43.34 percent, and the national percentage of hospital employees in the all other occupations category is 56.66 percent. At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 27.03 percent in one CBSA, to a high of 59.70 percent in another CBSA.

We also compared the FY 2013 wage data adjusted for occupational mix from the 2010 survey to the FY 2013 wage data adjusted for occupational mix from the 2007–2008 survey. This analysis illustrates the effect on area wage indices of using the 2010 survey data compared to the 2007–2008 survey data; that is, it shows whether hospitals' wage indices are increasing or decreasing under the current survey data as compared to the prior survey data. Our analysis shows that the FY 2013 wage index values for 190 (48.6 percent) urban areas and 18 (37.5 percent) rural areas will increase. Fifty (12.8 percent) urban areas will increase by 1 percent or more, and no urban areas will increase by 5 percent or more. Three (6.3 percent) rural areas will increase by 1 percent or more, and no rural areas will increase by 5 percent or more. However, the wage index values for 197 (50.4 percent) urban areas and 30 (62.5 percent) rural areas will decrease using the 2010 data. Sixty-four (16.4 percent) urban areas will decrease by 1 percent or more, and no urban areas will decrease by 5 percent or more. Three (6.3 percent) rural areas will decrease by 1 percent or more, and no rural areas will decrease by 5 percent or more. The largest positive impacts using the 2010 data compared to the 2007–2008 data are 4.37 percent for an urban area and 3.24 percent for a rural area. The largest negative impacts are 4.86 percent for an urban area and 2.28 percent for a rural area. Four urban areas and no rural areas will be unaffected. These results indicate that the wage indices of more CBSAs overall (51.7 percent) will be decreasing due to application of the 2010 occupational mix survey data as compared to the 2007–2008 survey data to the wage index. Further, a larger percentage of urban areas (48.6 percent) will benefit from the 2010 occupational mix survey as compared to the 2007–2008 survey than will rural areas (37.5 percent).

We compared the proposed FY 2013 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 207 (52.9 percent) urban areas and 32 (66.7 percent) rural areas would increase. One hundred seventeen (29.9 percent) urban areas would increase by 1 percent or more, and 3 (0.77 percent) urban areas would increase by 5 percent or more. Fourteen (29.2 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 184 (47.1 percent) urban areas and 15 (31.3 percent) rural areas would decrease. Eighty-five (21.7 percent) urban areas would decrease by 1 percent or more, and one urban area would decrease by 5 percent or more (0.26 percent). 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 6.71 percent for an urban area and 3.10 percent for a rural area. The largest negative impacts are 5.22 percent for an urban area and 3.10 percent for a rural area. No urban areas are unaffected, but one rural area is 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 (52.9 percent). While these results are more positive overall for rural areas than under the previous occupational mix adjustment that used survey data from 2007–2008, approximately one-third (31.3 percent) of rural CBSAs would still experience a decrease in their wage indices as a result of the occupational mix adjustment.

2. Application of the Rural, Imputed, and Frontier Floors

a. Rural Floor

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. This provision is referred to as the ''rural floor.'' Section 3141 of Public Law 111–148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor. In the FY 2013 proposed wage index associated with this proposed rule and available on the CMS Web site, 393 hospitals are receiving an increase in their FY 2013 proposed wage index due to the application of the rural floor.

b. Imputed Floor and Proposal for an Alternative, Temporary Methodology for Computing the Imputed Floor

In the FY 2005 IPPS final rule (69 FR 49109), we adopted the ''imputed floor'' policy as a temporary 3-year regulatory measure to address concerns from hospitals in all-urban States that have argued that they are disadvantaged by the absence of rural hospitals to set a wage index floor for those States. Since its initial implementation, we have extended the imputed floor policy three times, with the latest extension being set to expire on September 30, 2013 (we refer readers to the discussion in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593)). There are currently two all-urban States, New Jersey and Rhode Island, that have a range of wage indices assigned to hospitals in the State, including through reclassification or redesignation (we refer readers to discussions of geographic reclassifications and redesignations in section III.H. of this preamble). However, as we explain below, the current method for computing the imputed floor benefits only New Jersey, and not Rhode Island.

The current methodology for computing the imputed floor is contained in our regulations at 42 CFR 412.64(h)(4). In computing the imputed floor, we calculate the ratio of the lowest-to-highest CBSA wage index for each all-urban State (that is, New Jersey and Rhode Island) as well as the average of the ratios of lowest-to-highest CBSA wage indices of those all-urban States. We compare the State's own ratio to the average ratio and whichever is higher is multiplied by the highest CBSA wage index value in the State—the product of which establishes the imputed floor for the State. Rhode Island has only one CBSA (Providence-New Bedford-Fall River, RI–MA); therefore, Rhode Island's own ratio equals 1.0, and its imputed floor is equal to its original CBSA wage index value. Conversely, New Jersey has 10 CBSAs. As the average ratio of New Jersey and Rhode Island is higher than New Jersey's own ratio, the current methodology provides a benefit for New Jersey.

For the FY 2013 wage index, the final year of the extension of the imputed floor policy under § 412.64(h)(4), we are proposing an alternative, temporary methodology for computing the imputed floor wage index to address the concern that the current imputed floor methodology guarantees a benefit for one all-urban State with multiple wage indices but cannot benefit the other. This proposed alternative methodology for calculating the imputed floor would be established using empirical data from the application of the rural floor policy for FY 2013. Under this proposal, we would first determine the average percentage difference between the post-reclassified, pre-floor area wage index and the post-reclassified, rural floor wage index (without rural floor budget neutrality applied) for all CBSAs receiving the rural floor. (Table 4D associated with this proposed rule and available on the CMS Web site includes the CBSAs receiving a State's rural floor wage index.) The lowest post-reclassified wage index assigned to a hospital in an all-urban State having a range of such values would then be increased by this factor, the result of which would establish the State's alternative imputed floor. We are proposing to amend § 412.64(h)(4) to add new paragraphs (v)(A) and (B) to incorporate this proposed alternative methodology, and to make conforming references.

In addition, for the FY 2013 wage index, we are proposing no changes to the current imputed floor methodology at § 412.64(h)(4) and, therefore, no changes to the New Jersey imputed floor computation for FY 2013. Instead, for FY 2013, we are proposing a second, alternative methodology that would be used in cases where an all-urban State has a range of wage indices assigned to its hospitals, but the State cannot benefit from the methodology in existing § 412.64(h)(4). We intend to further evaluate the need, applicability, and methodology for the imputed floor before the September 30, 2013 expiration of the imputed floor policy and address these issues in the FY 2014 proposed rule.

The proposed wage index and impact tables associated with this FY 2013 proposed rule that are available on the CMS Web site include the application of the imputed floor policy at § 412.64(h)(4) and a national budget neutrality adjustment for the imputed floor. There are 29 providers in New Jersey that would receive an increase in their FY 2013 proposed wage index due to the imputed floor policy. The proposed wage index and impact tables for this proposed rule do not reflect the application of the proposed second alternative methodology for computing the imputed floor, which we anticipate would benefit four hospitals in Rhode Island.

c. Frontier Floor

Section 10324 of Public Law 111–148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000 (we refer readers to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160). Four States in the FY 2013 proposed wage index are being treated as frontier States: Montana, North Dakota, South Dakota, and Wyoming; 51 providers in these States are receiving the frontier floor value of 1.0000 in the FY 2013 proposed wage index associated with this proposed rule. Although Nevada is also, by definition, a frontier State and was assigned a frontier floor value of 1.0000 for FY 2012, its FY 2013 proposed rural floor value of 1.0293 is greater and, therefore, is the State's proposed minimum wage index for FY 2013.

The areas affected by the rural, imputed, and frontier floor policies for the FY 2013 proposed wage index are identified in Table 4D associated with this proposed rule and available on the CMS Web site.

3. Proposed FY 2013 Wage Index Tables

The proposed wage index values for FY 2013 (except those for hospitals receiving wage index adjustments under section 1886(d)(13) of the Act), included in Tables 4A, 4B, 4C, and 4F, available on the CMS Web site, include the proposed occupational mix adjustment, geographic reclassification or redesignation as discussed in section III.H. of this preamble, and the application of the rural, imputed, and frontier State floors as discussed in section III.G.2. of this preamble.

Tables 3A and 3B, available on the CMS Web site, list the 3-year average hourly wage for each labor market area before the redesignation or reclassification of hospitals based on FYs 2007, 2008, and 2009 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 available on the CMS Web site, includes the adjusted average hourly wage for each hospital from the FY 2007 and FY 2008 cost reporting periods, as well as the FY 2009 period used to calculate the proposed FY 2013 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 available on the CMS Web site, include the proposed occupational mix adjustment. The proposed wage index values in Tables 4A, 4B, 4C, and 4D also

include the proposed national rural and imputed floor budget neutrality adjustment. The proposed wage index values in Table 2 also include the proposed outmigration adjustment for eligible hospitals.

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

1. General Policies and Effects of Reclassification and Redesignation

Under section 1886(d)(10) of the Act, the 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).) The general policies for reclassifications and redesignations that we are proposing for FY 2013, and the policies for the effects of hospitals' reclassifications and redesignations on the wage index, are the same as those discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596). Also, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under 42 CFR 412.103. Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification pursuant to 42 CFR 412.103.

2. FY 2013 MGCRB Reclassifications

a. FY 2013 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 regulations under 42 CFR 412.230 through 412.280.

At the time this proposed rule was constructed, the MGCRB had completed its review of FY 2013 reclassification requests. Based on such reviews, there were 238 hospitals approved for wage index reclassifications by the MGCRB for FY 2013. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2013, hospitals reclassified during FY 2011 or FY 2012 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications. There were 277 hospitals approved for wage index reclassifications in FY 2011, and 255 hospitals approved for wage index reclassifications in FY 2012. Of all of the hospitals approved for reclassification for FY 2011, FY 2012, and FY 2013, based upon the review at the time of this proposed rule, 770 hospitals are in a reclassification status for FY 2013.

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. For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to 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 2013 will be incorporated into the wage index values published in the FY 2013 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 2014

Applications for FY 2014 reclassifications are due to the MGCRB by September 4, 2012 (the first working day of September 2012). 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 2012, via the Internet on the CMS 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.

3. 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. The FY 2013 chart with the listing of the rural counties containing the hospitals designated as urban under section 1886(d)(8)(B) of the Act is available via the Internet on the CMS Web site.

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

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 associated with this proposed rule (available on the CMS Web site) 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 FY 2013 proposed rule. (We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51598 through 51599) for the procedural rules and requirements for a hospital that is redesignated under section 1886(d)(8)(B) of the Act and seeking reclassification under the MGCRB, as well as our policy of measuring the urban area, exclusive of the Lugar County, for purposes of meeting proximity requirements.) 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.)

5. 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 2012 notice, CMS–1442–N, which went on public display at the Office of the Federal Register on April 19, 2012, and was published in the **Federal Register** on April 20, 2012. The most recent extension of the provision was included in section 302 of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112–78), as amended by section 3001 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96), which extends certain section 508 reclassifications and special exception wage indices for a 6-month period during FY 2012, from October 1, 2011 through March 31, 2012. As of the drafting of this proposed rule, section 508 reclassifications and certain special exceptions have not been extended for FY 2013.

6. Waiving Lugar Redesignation for the Out-Migration Adjustment

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS, 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 adopted a minor procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within the requisite number of days from the publication of the proposed rule [47]) 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. Thus, under the 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 the required period (generally 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.

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600) for a detailed discussion of the policy and process for waiving Lugar status for the out-migration adjustment.

I. Proposed FY 2013 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. The proposed FY 2013 out-migration adjustment is based on the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment (we refer readers to a full discussion of the adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602)). Table 4J, available via the Internet on the CMS Web site, lists the out-migration adjustments for the FY 2013 proposed wage index.

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 2013 wage index were made available on October 4, 2011, 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 notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and the scheduling of the Hospital Open Door forums at the CMS Web site at: *http://www.cms.hhs.gov/OpenDoorForums/*.

In a memorandum dated September 29, 2011, 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, 2011 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 5, 2011. 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 September 29, 2011 memorandum referenced above.

In the September 29, 2011 memorandum, we also specified that a hospital requesting revisions to its occupational mix survey data was to copy its record(s) from the CY 2010 occupational mix preliminary files posted to the CMS Web site in October, highlight the revised cells on its spreadsheet, and submit its spreadsheet(s) and complete

[47] Hospitals generally have 45 days from publication of the proposed rule to request an out-migration adjustment in lieu of the section 1886(d)(8) deemed urban status.

documentation to its fiscal intermediary/MAC no later than December 5, 2011.

The fiscal intermediaries/MACs notified the hospitals by mid-February 2012 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 2012. CMS published the proposed wage index public use files that included hospitals' revised wage index data on February 21, 2012. Hospitals had until March 5, 2012, 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' 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 were required to transmit any additional revisions resulting from the hospitals' reconsideration requests by April 11, 2012. 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 was April 18, 2012.

Hospitals should examine Table 2, which is listed in section VI. of the Addendum to this proposed rule and available on the CMS Web site at: *http://www.cms.gov*. 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 2009 data used to construct the proposed FY 2013 wage index. We note that the hospital average hourly wages shown in Table 2 only reflect changes made to a hospital's data that were transmitted to CMS by March 2012.

We will release the final wage index data public use files in early May 2012 on the Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp*. The May 2012 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 11, 2012). If, after reviewing the May 2012 final public use 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 4, 2012.

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.

After the release of the May 2012 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 11, 2012.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the February 21, 2012 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 4, 2012) will be incorporated into the final wage index in the FY 2013 IPPS/LTCH PPS final rule, which will be effective October 1, 2012.

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 2013 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 appeals 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 2012, 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 2013 wage index by August 2012, and the implementation of the FY 2013 wage index on October 1, 2012. 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 4, 2012, 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 4 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 4, 2012 deadline for the FY 2013 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 4, 2012 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 2013 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.'' Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share resulted in a higher payment.

In the FY 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 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 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 FY 2013 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 2013, we are proposing to continue to use a labor-related share of 68.8 percent for discharges occurring on or after October 1, 2012. 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, 2012. 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 2013 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 Decisions and Proposed Changes to the IPPS for Operating Costs and Graduate Medical Education (GME) Costs

A. Hospital Readmissions Reduction Program

1. Statutory Basis for the Hospital Readmissions 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 ''Hospital Readmissions 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.

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, ''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 the 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 are proposing policies to implement the statutory provisions related to the definition of ''base operating DRG payment amount'' in this 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 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 is addressed in detail in section IV.C.3.a. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51665 through 51666), 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).'' Section 1886(q)(5)(B) of the Act also requires the Secretary, beginning in FY 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 Hospital Readmissions 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 under

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 the FY 2012 IPPS/LTCH PPS final 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 public 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. Overview

As we stated in the FY 2012 IPPS/LTCH PPS final rule, 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.

As explained above, the payment adjustment factor set forth in section 1886(q) of the Act does not apply to discharges until FY 2013. Therefore, we elected to implement the Hospital Readmissions Reduction Program over a 2-year period, beginning in FY 2012. In the FY 2012 IPPS/LTCH PPS final rule, we addressed the issues of the selection of readmission measures and the calculation of the excess readmission ratio, which will be used, in part, to calculate the readmission adjustment factor. Specifically, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676), we addressed 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; 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 specifically addressed the following:

- Index hospitalizations;
- Risk adjustment;
- Risk standardized readmission rate;
- Data sources; and
- Exclusion of certain readmissions.

We are providing below a summary of the provisions of section 1886(q) of the Act that were finalized in the FY 2012 IPPS/LTCH PPS final rule.

Applicable conditions: In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51665 through 51666), we finalized the applicable conditions for the FY 2013 Hospital Readmissions Reduction Program as heart failure (HF), acute myocardial infarction (AMI), and pneumonia (PN). Section 1886(q)(5)(A) of the Act requires that the ''applicable conditions'' be conditions or procedures for which readmissions are ''high volume or high expenditure'' and that ''measures of such readmissions'' have been endorsed by the entity with a contract under section 1890(a) of the Act (currently National Quality Forum (NQF)) and such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge. In this proposed rule, we are proposing to codify this definition of ''applicable conditions'' in the regulations we are proposing at 42 CFR 412.152.

In the FY 2012 IPPS/LTCH PPS final rule, we discussed how each of the finalized ''applicable conditions'' for FY 2013 meets these statutory requirements. We noted that section 1886(q)(5)(B) of the Act allows for the Secretary to expand the conditions for the Hospital Readmissions Reduction Program starting in FY 2015.

Readmission: In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51666), we finalized a definition of ''readmission'' as occurring when a patient is discharged from an applicable hospital and then admitted to the same or another acute care hospital, that is, another applicable hospital, within a specified time period (30 days) from the date of discharge from the initial index hospitalization. In this proposed rule, we are proposing to codify this definition of ''readmission'' under the regulations we are proposing at 42 CFR 412.152. As also discussed in the FY 2012 IPPS/LTCH PPS final rule, only one readmission during the 30 days following the discharge from the initial hospitalization will count as a readmission for purposes of calculating the ratios set forth in section 1886(q)(3) of the Act. For any given patient, none of the subsequent readmissions he or she experiences within 30 days after discharge would be counted as a new ''index'' admission (that is, an admission evaluated for a subsequent readmission).

Measures for applicable conditions: As finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51666 and 51667), we will use three NQF-endorsed, hospital risk-standardized readmission measures for FY 2013, which are currently in the Hospital IQR Program: 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). The measures, as endorsed by the NQF, include the 30-day time window, risk-adjustment methodology, and exclusions for certain readmissions.

As finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673), we will 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.

Measure methodology: In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51668 through 51669), we finalized the methodology of the measures and are summarizing it briefly below.

Index hospitalizations included in the measure calculation: We finalized the definition of ''index hospital'' consistent with the NQF-endorsed definition. The measures define an index hospitalization as a hospitalization evaluated in the measure for a possible readmission within 30 days after discharge (that is, a hospitalization included in the measure calculation). The measures exclude as index hospitalizations any hospitalization for patients with an in-hospital death, without at least 30 days post-discharge enrollment in Medicare fee-for-service (FFS), discharged against medical advice, and under the age of 65.

Risk adjustment: The three measures, as endorsed by the NQF and finalized in the FY 2012 IPPS/LTCH PPS final rule, adjust for key factors that are clinically relevant and have strong relationships with the outcome (for example, patient demographic factors, patient coexisting 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 at the Web site: *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841*.

Data sources: The finalized measures use Medicare inpatient claims data for Medicare FFS patients 65 years and older to identify index hospitalizations and readmissions. For risk adjustment, the measures use Part A and Part B claims for the 12 months prior to the index hospitalization as well as index hospitalization claims.

Exclusion of certain readmissions: The NQF-endorsed measures of readmissions finalized in the FY 2012 IPPS/LTCH PPS final rule include exclusions of readmissions consistent with the statutory requirement that all measures exclude certain readmissions that are unrelated to the prior discharge, such as transfers to other acute care facilities and planned readmissions.

Minimum number of discharges for applicable conditions: Section 1886(q)(4)(C)(ii) of the Act allows the Secretary discretion to determine the minimum number of discharges for the applicable condition. We finalized a policy in the FY 2012 IPPS/LTCH PPS final rule that the minimum number of discharges for applicable conditions is 25 for each condition for the FY 2013 Hospital Readmissions Reduction Program.

Applicable period: Under 1886(q)(5)(D) of the Act, the Secretary has the authority to specify the applicable period with respect to a fiscal year. In the FY 2012 IPPS/LTCH PPS final rule, we finalized our policy to use 3 years worth of claims data to calculate the proposed readmission measures. Specifically, we finalized the policy to use claims data from July 1, 2008, to June 30, 2011, to calculate the excess readmission ratios and to calculate the FY 2013 Hospital Readmissions Reduction Program payment adjustment. As discussed in section IV.A.3.d. of this preamble, for the purpose of this proposed rule, the excess readmission ratios used to model our proposed methodology to calculate the Hospital Readmissions Reduction Program payment adjustment will be based on the 3-year time period of July 1, 2007 to June 30, 2010. For the final rule, we intend to use excess readmission ratios based on the applicable period of July 1, 2008 to June 30, 2011, as finalized in the FY 2012 IPPS/LTCH PPS final rule. In this proposed rule, we are proposing to codify the definition of ''applicable period'' under the regulations we are proposing at 42 CFR 412.152 as the 3-year period from which data are collected in order to calculate excess readmission ratios and adjustments for the fiscal year.

Excess Readmission Ratio calculation: In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673 through 51676), we finalized the excess readmission ratio pursuant to section 1886(q)(4)(C) of the Act. We established the excess readmission ratio as the risk-standardized readmission ratio from the NQF-endorsed measures. The ratio is calculated using hierarchical logistic regression. The method adjusts for variation across hospitals in how sick their patients are when admitted to the hospital (and therefore variation in hospital patients' readmission risk) as well as the variation in the number of patients that a hospital treats to reveal difference in quality. The method produces an adjusted actual (or ''predicted'') number in the numerator and an ''expected'' number in the denominator. The expected calculation is similar to that for logistic regression—it is the sum of all patients' expected probabilities of readmission, given their risk factors and the risk of readmission at an average hospital.

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. Mathematically, the numerator equation can be expressed as:

Numerator: Adjusted Actual Readmissions

Step 1:

Calculate each patient's predicted probability of readmission = $\frac{1}{1 + e^{-Z_a}}$

Z_a = hospital-specific effect + $X\beta$

intercept + risk-adjustment coefficients

Step 2:

To get the numerator result, add all patients' predicted probabilities of readmission

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 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. In summary, in the FY 2012 IPPS/LTCH PPS final rule, we defined the ''excess readmission ratio'' as the risk-standardized readmission ratio of the NQF-endorsed readmission measures. More in-depth detail surrounding the methodology of excess readmission ratio calculation can be accessed on the Web site at: *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069855841.*

In this proposed rule, we are proposing to codify the definition of ''excess readmission ratio'' under the regulations we are proposing at 42 CFR 412.152 as a hospital-specific ratio for each applicable condition for an applicable period, which is the ratio (but not less than 1.0) of (1) risk-adjusted readmissions based on actual readmissions for an applicable hospital for each applicable condition to (2) the risk-adjusted expected readmissions for the applicable hospital for the applicable condition.

3. FY 2013 Proposed Policies for the Hospital Readmissions Reduction Program

a. Overview

In this proposed rule, we are addressing the provisions in section 1886(q) of the Act that are related to the Hospital Readmissions Reduction Program payment adjustment, as well as any other provisions in section 1886(q) of the Act that were not addressed in the FY 2012 IPPS/LTCH PPS final rule that are effective for discharges beginning on or after October 1, 2012. Specifically, in this proposed rule, we are addressing section 1886(q) of the Act related to the following provisions:

- Base operating DRG payment amount, including policies for SCHs and MDHs and hospitals paid under section 1814(b) of the Act;
- Adjustment factor (both the ratio and floor adjustment factor);
- Aggregate payments for excess readmissions and aggregate payments for all discharges;
- Applicable hospital;
- Limitations on review;
- Reporting of hospital-specific information, including the process for hospitals to review and submit corrections.

We are proposing to establish a new Subpart I under 42 CFR Part 412 to incorporate the rules relating to the payment adjustments under the Hospital Readmissions Reduction Program.

b. Proposals Regarding Base Operating DRG Payment Amount, Including Special Rules for SCHs and MDHs and Hospitals Paid Under Section 1814 of the Act

(1) Proposed Definition of Base Operating DRG Payment Amount (Proposed § 412.152)

Under the Hospital Readmissions Reduction Program at section 1886(q) 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 an ''adjustment factor'' that accounts for excess readmissions for the hospital for the fiscal year, for discharges beginning on or after October 1, 2012. Specifically, 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. The ''base operating DRG payment amount'' is defined under section 1886(q)(2) of the Act 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) [of section 1886 of the Act] refer to outlier payments, indirect medical education (IME) payments, disproportionate share (DSH) payments, and low-volume hospital payments, respectively.

In general, ''the payment amount that would otherwise be made under subsection (d) * * * for a discharge'' (that is, the discharge payment amount made under section 1886(d) of the Act) determined without consideration of the adjustments to payments made under the Hospital VBP Program (section 1886(o) of the Act) or under the Hospital Readmissions Reduction Program (section 1886(q) of the Act) is the applicable average standardized amount adjusted for resource utilization by the applicable MS–DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index (and by the applicable cost-of-living adjustment (COLA) for hospitals located in Alaska and Hawaii), which is often

referred to as the ''wage-adjusted DRG operating payment.'' This payment amount may then be further adjusted if the hospital qualifies for an IME adjustment (under section 1886(d)(5)(B) of the Act), a DSH payment adjustment (under section 1886(d)(5)(F) of the Act), and/or a low-volume payment adjustment (under section 1886(d)(12) of the Act), or if the discharge qualifies for an outlier payment (under section 1886(d)(5)(A) of the Act). Furthermore, certain discharges may qualify for an additional payment for new medical services or technologies under section 1886(d)(5)(K) of the Act (often referred to as a ''new technology add-on payment'').

Consistent with section 1886(q)(2) of the Act, under the regulations we are proposing at 42 CFR 412.152, we would define the ''base operating DRG payment amount'' under the Hospital Readmissions Reduction Program as the wage-adjusted DRG operating payment plus any applicable new technology add-on payments. As required by the statute, the proposed definition of ''base operating DRG payment amount'' does not include adjustments or add-on payments for IME, DSH, outliers and low-volume hospitals provided for under sections 1886(d)(5)(B), (d)(5)(F), (d)(5)(A), and (d)(12) of the Act, respectively. Section 1886(q)(2) of the Act does not exclude new technology payments made under section 1886(d)(5)(K) of the Act; therefore, any payments made under section 1886(d)(5)(K) of the Act are included in the proposed definition of ''base operating DRG payment amount.'' In addition, under the regulations we are proposing at 42 CFR 412.152, we are proposing to define ''wage-adjusted DRG operating payment'' as the applicable average standardized amount adjusted for resource utilization by the applicable MS–DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index (and by the applicable COLA for hospitals located in Alaska and Hawaii). We are proposing that, under § 412.154(b)(1), to account for excess readmissions, an applicable hospital's base operating DRG payment amount is adjusted for each discharge occurring during the fiscal year. The payment adjustment for each discharge is determined by subtracting the product of the base operating DRG payment amount for such discharge by the hospital's admission payment adjustment factor for the fiscal year from the base operating DRG payment amount for such discharge.

Under this proposal, consistent with section 1886(q)(2)(B)(i) of the Act and proposed § 412.154(b)(2), for SCHs that receive payments based on their hospital-specific payment rate, we also are proposing to exclude the difference between the hospital's applicable hospital-specific payment rate and the Federal payment rate from the definition of ''base operating DRG payment amount.'' We note that, under the Hospital Readmissions Reduction Program at section 1886(q) of the Act, the proposed definition of ''base operating DRG payment amount'' would be used to calculate both the ''aggregate payments for excess readmissions'' and ''aggregate payments for all discharges'' under sections 1886(q)(4)(A) and (B) of the Act, which would then be used to determine the readmission adjustment factor that accounts for excess readmissions under section 1886(q)(3) of the Act (as discussed in greater detail in section IV.A.3.c. of this preamble), and would also be used to determine which payment amounts will be adjusted to account for excess readmissions. (We note that, as discussed in section IV.G. of this preamble, under current law, the MDH program expires at the end of FY 2012 (that is, the MDH program is currently only applicable to discharges occurring before October 1, 2012). Therefore, due to the expiration of the MDH program beginning with FY 2013, we are not including MDHs in the discussion of our proposals regarding the base operating DRG payment amount in this proposed rule.)

(2) Proposal on Special Rules for Certain Hospitals: Hospitals Paid Under Section 1814(b)(3) of the Act (Proposed § 412.154(d))

Although the definition of ''applicable hospital'' under section 1886(q)(5)(C) of the Act includes hospitals paid under section 1814(b)(3) of the Act (that is, certain Maryland hospitals), section 1886(q)(2)(B)(ii) of the Act allows the Secretary to exempt such hospitals from the Hospital Readmissions Reduction Program, provided that the State submits an annual report to the Secretary describing how a similar program to reduce hospital readmissions in that State achieves or surpasses the measured results in terms of health outcomes and cost savings established by Congress for the program as applied to ''subsection (d) hospitals.'' Accordingly, a program established by the State of Maryland that could serve to exempt the State from the Hospital Readmissions Reduction program would focus on those ''applicable'' Maryland hospitals operating under the ''waiver'' provided by section 1814(b)(3) of the Act, that is, those hospitals that would otherwise have been paid by Medicare under the IPPS, absent the provision.

In this proposed rule, we are proposing to establish criteria for evaluation of an annual report to CMS to determine whether Maryland should be exempted from the program each year. Accordingly, we would evaluate a report submitted by the State of Maryland documenting how its program that is described below meets those criteria. Based on the information in the report, we would determine whether or not Maryland's readmission program meets our criteria to be exempt from the Hospital Readmissions Reduction Program for FY 2013. We note that our proposed criteria to evaluate Maryland's program is for FY 2013, the first year of the program, and our evaluation criteria may change through notice-and-comment rulemaking as the Hospital Readmissions Reduction Program evolves. We are proposing to codify this requirement at § 412.154(d) of the regulations.

Based on preliminary discussions with the State, we understand that, effective July 1, 2011, Maryland has established the Admission-Readmission Revenue (ARR) Program. The State has described its program as a voluntary program for acute care hospitals, of which 30 out of the 46 acute care hospitals in the State are currently enrolled. Under the program, the State pays hospitals under a case-mix adjusted bundled payment per episode of care, where the episode of care is defined as the initial admission and any subsequent readmissions to the same hospital or linked hospital system that occur within 30 days of the original discharge. According to the State, an initial admission with no readmissions provides the hospital with the same weight as an initial admission with multiple readmissions. Therefore, hospitals receive a financial reward for decreased readmissions (as determined through the case mix adjusted, episode of care weights). Unlike the Hospital Readmissions Reduction Program under section 1886(q) of the Act, which is currently based on measures for three conditions (HF, AMI, and PN) for the Medicare FFS population and only adjusts the IPPS operating payments, Maryland's program applies to all conditions for all patients. In addition, while the Hospital Readmissions Reduction Program considers a readmission to be a subsequent admission to either the original acute care hospital from where the patient was initially discharged or an admission to another acute care hospital, currently Maryland only tracks readmissions to the same acute care hospital (or linked

hospital system) from which the patient was originally discharged. The State has noted that, under its ARR program, the readmission rates for the hospitals participating in the ARR program for the first quarter of its fiscal year compared to the first quarter of its previous fiscal year decreased from 9.86 percent to 8.96 percent.

We are proposing to evaluate Maryland's ARR program based on whether the State can demonstrate that cost savings under its program achieve or exceed the savings to the Medicare program due to the Hospital Readmissions Reduction Program under section 1886(q) of the Act. We also are proposing to evaluate whether Maryland's program can demonstrate similar results in reducing unnecessary readmissions among hospitals in the State, as described in more detail below. With specific regard to Maryland's demonstration of cost savings, we are proposing to evaluate whether Maryland's ARR program can demonstrate savings to the Medicare program that are at least similar to those expected under the Hospital Readmissions Reduction Program. As discussed later in this proposed rule, we estimate that, under the Hospital Readmissions Reduction Program, for FY 2013, Medicare IPPS operating payments will decrease by approximately $300 million (or 0.3 percent) of total Medicare IPPS operating payments. Maryland has indicated that it believes it can achieve comparable savings because it intends to reduce the rate update factor for all hospitals by 0.3 percent, regardless of a hospital's performance on readmissions.

In addition, we plan to propose in future rulemaking to evaluate whether Maryland's ARR program can meet or exceed health outcomes that we expect to improve under the Hospital Readmissions Reduction Program. Because the Hospital Readmissions Reduction Program is not effective until October 1, 2012, we do not yet have measured health outcomes against which we can evaluate Maryland's ARR program. However, we intend to have outcomes data in the future with which to evaluate Maryland's ARR program. We anticipate that, under the Hospital Readmissions Reduction Program, hospitals will experience a reduction in unnecessary readmissions. Therefore, in future rulemaking, we intend to propose to evaluate whether Maryland's ARR program can demonstrate similar decreases in potential preventable readmissions among hospitals in the State. Furthermore, we are proposing that the State's annual report and request for exemption from the Hospital Readmissions Reduction Program must be resubmitted and reconsidered annually in accordance with the statute and as proposed at § 412.154(d)(2).

Based on preliminary information provided by Maryland, the State believes that its program can meet our evaluation criteria and demonstrate that its program achieves or surpasses the measured results in terms of health outcomes and cost savings. We are reviewing whether the Maryland's ARR program, which currently cannot monitor readmissions to other hospitals and a financial reward for hospitals that reduce within-hospital readmissions and provides a 0.3 percent reduction to the annual rate update to account for comparable savings to the Hospital Readmissions Reduction Program, meets the criteria to exempt Maryland hospitals from the Hospital Readmissions Reduction Program. We welcome public comments on whether the Maryland ARR program meets the requirements for exemption from the Hospital Readmissions Reduction Program set forth in section 1886(q)(2)(B)(ii) of the Act.

For the purposes of modeling the impacts of this proposal in this proposed rule, we have modeled under the assumption that Maryland hospitals will not have Hospital Readmission Reduction Program adjustment factors applied to them. Although the adjustment factors do not apply to these hospitals under our models, Maryland hospitals have excess readmission ratios, consistent with the definition of excess readmission ratio. Any readmission to a Maryland hospital from a subsection(d) hospital in another State is still considered a readmission for purposes of the original hospital in another State. This is consistent with the definition of readmissions in section 1886(q)(5)(E) of the Act, which includes admissions to the same or another ''applicable hospital.'' As discussed above, we interpret the definition of ''applicable hospital'' under section 1886(q)(5)(C) of the Act includes both subsection (d) hospitals and hospitals paid under section 1814(b)(3) of the Act that would, absent the provisions of section 1814(b)(3) of the Act, be paid under subsection (d).

c. Proposals Regarding Adjustment Factor (Both the Ratio and Floor Adjustment Factor) (Proposed § 412.154(c))

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. Specifically, it states that the ratio is ''equal to 1 minus the ratio of—(i) the aggregate payments for excess readmissions * * *; and (ii) the aggregate payments for all discharges. * * *'' We are proposing to codify the calculation of this ratio at § 412.154(c)(1) of the regulations. Section 1886(q)(3)(C) of the Act specifies 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. We are proposing to codify the floor adjustment factor at § 412.154(c)(2) of the regulations.

For FY 2013, under proposed § 412.154(c), we are proposing that an applicable hospital would receive an adjustment factor that is either the greater of the ratio described in section IV.A.3.d. of this preamble or a floor adjustment factor of 0.99. We are proposing that the ratio would be rounded to the fourth decimal place, consistent with the calculation of other IPPS payment adjustments such as the wage index, DSH adjustment, and the IME adjustment. In other words, a hospital included in this program can have an adjustment factor that is between 1.0 and 0.9900 for FY 2013. Consistent with section 1886(q)(3) of the Act, under proposed § 412.154(c), we are proposing that, for FY 2013, the hospital will receive an adjustment factor under the Hospital Readmissions Reduction Program that is the greater of the ratio or the floor of 0.99. Consistent with this proposal, under the regulations we are proposing at 42 CFR 412.152, we are proposing to define the ''floor adjustment factor'' as the value that the readmissions adjustment factor cannot be less than for a given fiscal year. As noted above, the floor adjustment factor is set at 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years.

d. Proposals Regarding Aggregate Payments for Excess Readmissions and Aggregate Payments for All Discharges (Proposed § 412.152)

As discussed earlier, section 1886(q)(3)(B) of the Act specifies the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program. 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 * * *.'' In this section, we set forth

proposals to define aggregate payments for excess readmissions and aggregate payments for all discharges, as well as a methodology for calculating the numerator of the ratio (aggregate payments for excess readmissions) and the denominator of the ratio (aggregate payments for all discharges).

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 ''for a hospital for an applicable period, 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.'' We are proposing to include this definition of ''aggregate payments for excess readmissions'' under the regulations we are proposing at 42 CFR 412.152.

The ''excess readmission ratio'' is a hospital-specific ratio calculated for 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. The methodology for the calculation of the excess readmission ratio was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673). ''Aggregate payments for excess readmissions'' is the numerator of the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program.

The term ''aggregate payments for all discharges'' is defined at section 1886(q)(4)(B) of the Act as ''for a hospital for an applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period.'' ''Aggregate payments for all discharges'' is the denominator of the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program. We are proposing to include this definition of ''aggregate payments for all discharges'' under the regulations we are proposing at § 412.152.

As discussed above, when calculating the numerator (aggregate payments for excess readmission), CMS determines the base operating DRG for the applicable period. ''Aggregate payments for excess readmissions'' (the numerator) is defined 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.''

We discussed above our proposed definition of ''base operating DRG payment amount.'' When determining the base operating DRG payment amount for an individual hospital for such applicable period for such condition, we are proposing to use Medicare inpatient claims from the MedPAR file with discharge dates that are within the same applicable period that was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671) to calculate the excess readmission ratio. We are proposing to use MedPAR claims data as our data source for determining aggregate payments for excess readmissions and aggregate payments for all discharges, as this data source is consistent with the claims data source used in IPPS rulemaking in order to determine IPPS rates. For FY 2013, we are proposing to use data from MedPAR claims with discharge dates that are on or after July 1, 2008, and no later than June 30, 2011, the applicable period finalized in the FY 2012 IPPS/LTCH PPS final rule. We are proposing to use the update of the MedPAR file for each Federal fiscal year, which is updated 6 months after the end of each Federal fiscal year within the applicable period, as our data source (that is, the March updates of the respective Federal fiscal year MedPAR files for the final rules, as described in greater detail below). These are the same MedPAR files that are used in the annual IPPS rulemaking for each Federal fiscal year.

For the purposes of this proposed rule, for FY 2013, we are proposing to use the March 2009 update of the FY 2008 MedPAR file to identify claims within FY 2008 with discharges dates that are on or after July 1, 2008, the March 2010 update of the FY 2009 MedPAR file to identify claims within FY 2009, the March 2011 update of the FY 2010 MedPAR file to identify claims within FY 2010, and the December 2011 update of the FY 2011 MedPAR file to identify claims within FY 2011 with discharge dates no later than June 30, 2011. However, for the FY 2013 IPPS/LTCH PPS final rule, we plan to use the March 2012 update of the FY 2011 MedPAR file to identify claims within FY 2011, as these would be the most recently available FY 2011 claims data used for FY 2013 rulemaking. These MedPAR data files are used each year in other areas of the IPPS, including calculating the IPPS relative weights, budget neutrality factors, outlier thresholds, and the standardized amount. Accordingly, we believe it is appropriate to use these same data files for the purpose of calculating the readmission adjustment factors. The FY 2008 through FY 2011 MedPAR data files can be purchased from CMS. These files allow the public to verify the readmission adjustment factors. Interested individuals may order these files through the Web site at: *http://www.cms.hhs.gov/LimitedDataSets/* by clicking on the MedPAR Limited Data Set (LDS)-Hospital (National). This Web page describes the files and provides directions and further detailed instructions for how to order the data sets. 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 and Medicaid Services, RDDC Account, Accounting Division, P.O Box 7520, Baltimore, MD 21207–0520.

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

We note that, in this proposed rule, we are proposing to determine aggregate payments for excess readmissions and aggregate payments for all discharges using data from MedPAR claims with discharge dates that are on or after July 1, 2008, and no later than June 30, 2011, which is the applicable period finalized in the FY 2012 IPPS/LTCH PPS final rule. However, in this proposed rule, for the purposes of modeling, we are using excess readmission ratios based on an older performance period of July 1, 2007 to June 30, 2010. For the final rule, we intend to use both the excess readmission ratios and MedPAR claims data to calculate aggregate payments for excess readmissions and aggregate payments for all discharges based on the applicable period finalized in the FY 2012 IPPS/LTCH PPS final rule (July 1, 2008 to June 30, 2011).

In order to identify the admissions for each condition for an individual hospital for calculating the aggregate payments for excess readmissions, we are proposing to identify each applicable condition using the same ICD–9–CM codes used to identify applicable conditions to calculate the excess readmission ratios. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51669), in our discussion of the methodology of the readmissions measures, we stated that we identify eligible hospitalizations and readmissions of Medicare patients discharged from an applicable hospital having a principal diagnosis for the measured condition in an applicable period. 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 Web site at: *http://www.QualityNet.org* > Hospital-Inpatient > Readmission Measures > methodologies.

In order to identify the applicable conditions to calculate the aggregate payments for excess readmissions, we are proposing to identify the claim as an applicable condition if the ICD–9–CM code for that condition is listed as the principal diagnosis on the claim, consistent with the methodology to identify conditions to calculate the excess readmission ratio. Furthermore, we are proposing to only identify Medicare FFS claims that meet the criteria (that is, claims paid for under Part C, Medicare Advantage, would not be included in this calculation), consistent with the methodology to calculate excess readmission ratios based on readmissions for Medicare FFS patients. The tables below list the ICD–9–CM codes we are proposing to use to identify each applicable condition to calculate the aggregate payments for excess readmissions under this proposal. These ICD–9–CM codes will also be used to identify the applicable conditions to calculate the excess readmission ratios, consistent with our policy finalized in the FY 2012 IPPS/LTCH PPS final rule.

ICD–9–CM CODES TO IDENTIFY PNEUMONIA CASES

ICD–9–CM Code	Description of code
480.0	Pneumonia due to adenovirus.
480.1	Pneumonia due to respiratory syncytial virus.
480.2	Pneumonia due to parainfluenza virus.
480.3	Pneumonia due to SARS-associated coronavirus.
480.8	Viral pneumonia: pneumonia due to other virus not elsewhere classified.
480.9	Viral pneumonia unspecified.
481	Pneumococcal pneumonia [streptococcus pneumoniae pneumonia].
482.0	Pneumonia due to klebsiella pneumoniae.
482.1	Pneumonia due to pseudomonas.
482.2	Pneumonia due to hemophilus influenzae [h. influenzae].
482.30	Pneumonia due to streptococcus unspecified.
482.31	Pneumonia due to streptococcus group a.
482.32	Pneumonia due to streptococcus group b.
482.39	Pneumonia due to other streptococcus.
482.40	Pneumonia due to staphylococcus unspecified.
482.41	Pneumonia due to staphylococcus aureus.
482.42	Methicillin Resistant Pneumonia due to Staphylococcus Aureus.
482.49	Other staphylococcus pneumonia.
482.81	Pneumonia due to anaerobes.
482.82	Pneumonia due to escherichia coli [e.coli].
482.83	Pneumonia due to other gram-negative bacteria.
482.84	Pneumonia due to legionnaires' disease.
482.89	Pneumonia due to other specified bacteria.
482.9	Bacterial pneumonia unspecified.
483.0	Pneumonia due to mycoplasma pneumoniae.
483.1	Pneumonia due to chlamydia.
483.8	Pneumonia due to other specified organism.
485	Bronchopneumonia organism unspecified.
486	Pneumonia organism unspecified.
487.0	Influenza with pneumonia.
488.11	Influenza due to identified novel H1N1 influenza virus with pneumonia.

ICD–9–CM CODES TO IDENTIFY HEART FAILURE CASES

ICD–9–CM Code	Code description
402.01	Hypertensive heart disease, malignant, with heart failure.
402.11	Hypertensive heart disease, benign, with heart failure.
402.91	Hypertensive heart disease, unspecified, with heart failure.
404.01	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified.
404.03	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage V or end stage renal disease.
404.11	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified.
404.13	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified failure and chronic kidney disease stage V or end stage renal disease.

ICD–9–CM CODES TO IDENTIFY HEART FAILURE CASES—Continued

ICD–9–CM Code	Code description
404.91	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease heart failure and with chronic kidney disease stage I through stage IV, or unspecified.
404.93	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease.
428.xx	Heart Failure.

ICD–9–CM CODES TO IDENTIFY ACUTE MYOCARDIAL INFARCTION CASES

ICD–9–CM Code	Description of Code
410.00	AMI (anterolateral wall)—episode of care unspecified.
410.01	AMI (anterolateral wall)—initial episode of care.
410.10	AMI (other anterior wall)—episode of care unspecified.
410.11	AMI (other anterior wall)—initial episode of care.
410.20	AMI (inferolateral wall)—episode of care unspecified.
410.21	AMI (inferolateral wall)—initial episode of care.
410.30	AMI (inferoposterior wall)—episode of care unspecified.
410.31	AMI (inferoposterior wall)—initial episode of care.
410.40	AMI (other inferior wall)—episode of care unspecified.
410.41	AMI (other inferior wall)—initial episode of care.
410.50	AMI (other lateral wall)—episode of care unspecified.
410.51	AMI (other lateral wall)—initial episode of care.
410.60	AMI (true posterior wall)—episode of care unspecified.
410.61	AMI (true posterior wall)—initial episode of care.
410.70	AMI (subendocardial)—episode of care unspecified.
410.71	AMI (subendocardial)—initial episode of care.
410.80	AMI (other specified site)—episode of care unspecified.
410.81	AMI (other specified site)—initial episode of care.
410.90	AMI (unspecified site)—episode of care unspecified.
410.91	AMI (unspecified site)—initial episode of care.

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 (d)(5)(A), (d)(5)(B), (d)(5)(F), and (d)(12) of section 1886 refer to outlier payments, IME payments, DSH payments, and payments for low-volume hospitals, respectively.

As discussed earlier in section IV.A.3.b.(1) of this preamble, we are proposing to define ''base operating DRG payment amount'' under the Hospital Readmissions Reduction Program as the wage-adjusted DRG operating payment plus any new technology add-on payments. Thus, in order to calculate the base operating DRG payment amount for such condition for such hospital, we are proposing to identify the base operating DRG payment amount for such conditions based on the payment amounts in the MedPAR files on the claims identified to meet those conditions based on their ICD–9–CM code.

As discussed in section IV.A.3.b. of this preamble, applicable hospitals in the Hospital Readmissions Reduction Program include SCHs and current MDHs (whose status is set to expire at the end of FY 2012), as these hospitals meet the definition of subsection (d) hospitals. SCHs are paid in the interim (prior to cost report settlement) on a claim-by-claim basis at the amount that is the higher of the payment based on the hospital-specific rate or the IPPS Federal rate based on the standardized amount. At cost report settlement, the fiscal intermediary or MAC determines whether the hospital would receive higher IPPS payments in the aggregate using the hospital-specific rate (on all claims) or the Federal rate (on all claims). MDHs are paid the sum of the Federal payment amount plus 75 percent of the amount by which their hospital-specific rate exceeds the Federal payment amount. Although MDH status is to expire beginning in FY 2013, because we are using historical data to determine the base operating DRG payments to calculate adjustment factor, the payments reflected on claims for current MDHs may be based on the hospital-specific rate. For SCHs and current MDHs, we are proposing to model their base operating DRG payment amount as they would have been paid under the Federal standardized amount, rather than using the information on the claim (which may represent a payment either made under the hospital-specific rate or the Federal rate) so that their payments are consistent with our proposed definition of base operating DRG payment. As such, the payment difference between the payment made under the hospital-specific rate and the payment made under the Federal rate is not included in the base operating DRG amount to determine the readmission adjustment factor; that is, it is neither included in the numerator of the aggregate dollars for excess readmissions nor in the denominator of the aggregate dollars for all discharges.

As discussed earlier, we are proposing to use data from the MedPAR files that contain claims from the 3-year applicable period of July 1, 2008, to June 30, 2011, for FY 2013 to calculate aggregate payments for excess readmissions (the numerator of the ratio). To calculate aggregate payments for excess readmissions, we are proposing to calculate the base operating DRG payment amounts for all the claims in the 3-year applicable period that list each applicable

condition as the principal diagnosis (as described above). Once we have calculated the base operating DRG payment amounts for all the claims that list each condition as the principal diagnosis, we are proposing to add up the base operating DRG payment amounts by each condition, resulting in three summed amounts, one amount for each of the three applicable conditions. We then are proposing to multiply each amount for each condition by their respective excess readmission ratio minus 1. The methodology for the calculation of the excess readmission ratio was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673). We are proposing that the excess readmission ratios for each condition used to calculate the numerator of this ratio are excess readmission ratios that have gone through the proposed review and correction process described later in this proposed rule. Each product in this computation represents the payment for excess readmissions for that condition. We are proposing to then sum the resulting products, which represent a hospital's proposed ''aggregate payments for excess readmissions'' (the numerator of the ratio).

If a hospital has an excess readmission ratio that is greater than 1 for a condition, that hospital has performed, with respect to readmissions for that applicable condition, worse than the average hospital with similar patients. As such, it will have aggregate payments for excess readmissions. If a hospital has an excess readmission ratio that is less than (or equal) to one, that hospital has performed better (or on average), with respect to readmissions for that applicable condition, than an average hospital with similar patients. As such, that hospital would not be considered to have ''aggregate payments'' for excess readmissions, and its payments would not be reduced under section 1886(q) of the Act. As described in section 1886(q)(4)(C) of the Act, and finalized in the FY 2012 IPPS/LTCH PPS final rule, the excess readmission ratio used cannot be less than 1 because the hospital will not have aggregate payments for excess readmissions and will not be subject to a readmission payment adjustment, as the hospital will have performed better than average. Because this calculation is performed separately for the three conditions, a hospital's excess readmission ratio must be less than or equal to 1 on each measure to avoid aggregate payments for excess readmissions.

Section 1886(q)(4)(B) of the Act defines ''aggregate payments for all discharges'' (the denominator of the ratio) as ''for a hospital for an applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period.'' We are proposing to use the same MedPAR files to calculate the denominator as we are proposing to use to calculate the numerator, for the 3-year applicable period of July 1, 2008 to June 30, 2011, for FY 2013. We are proposing to calculate base operating DRG payments in the same manner as we calculate base operating DRG payments for the numerator. We are proposing to sum the base operating DRG payment amounts for all Medicare FFS claims for such hospital during the 3-year applicable period. We also are proposing that we would model base operating DRG payment amount for SCHs and current MDHs as they would have been paid under the Federal standardized amount, rather than using the information on the claim (as described above).

We are proposing that the ratio described in section 1886(q)(3)(B) of the Act is 1 minus the ratio of the numerator and denominator described above. In addition, we are proposing that the readmission adjustment for an applicable hospital is the higher of this ratio under section 1886(q)(3)(B) of the Act or the floor of 0.99 for FY 2013. Consistent with this proposal, under the regulations we are proposing at 42 CFR 412.152, we are proposing to define ''readmissions adjustment factor'' as equal to the greater of: (i) 1 minus the ratio of the aggregate payments for excess readmissions to aggregate payments for all discharges or (ii) the floor adjustment factor.

For this proposed rule, for the purpose of modeling the proposed aggregate payments for excess readmissions and the proposed readmissions adjustment factors, we are using excess readmission ratios for the applicable hospitals from the 3-year period of July 1, 2007 to June 30, 2010, because the underlying data from this period have already been available to the public on the Hospital Compare Web site (as of July 2011). The data from the 3-year applicable period for FY 2013 of July 1, 2008 to June 30, 2011, have not been through the review and correct process required by section 1886(q)(6) of the Act (as discussed below). For the final rule, we intend to use excess readmission ratios based on discharges for the finalized applicable period of July 1, 2008 to June 30, 2011, to calculate the aggregate payments for excess readmissions and, ultimately, to calculate the readmission adjustment factors. Applicable hospitals will have had the opportunity to review and correct these data before they are made public under our proposal set forth below regarding the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act.

Formulas To Calculate the Readmission Adjustment Factor

Aggregate payments for excess readmissions = [sum of base operating DRG payments for AMI × (Excess Readmission Ratio for AMI–1)] + [sum of base operating DRG payments for HF × (Excess Readmission Ratio for HF–1)] + [sum of base operating DRG payments for PN × (Excess Readmission Ratio for PN–1)].

Aggregate payments for all discharges = sum of base operating DRG payments for all discharges.

Ratio = 1 − (Aggregate payments for excess readmissions/Aggregate payments for all discharges).

Readmissions Adjustment Factor for FY 2013 is the higher of the ratio or 0.99.

*Based on claims data from July 1, 2008 to June 30, 2011 for FY 2013.

During the FY 2012 IPPS rulemaking cycle, we received public comments expressing concern that hospitals that treat a larger proportion of patients of lower socioeconomic circumstances may have higher readmission rates and could be unfairly penalized under the Hospital Readmissions Reduction Program. The table below shows, based on the excess readmission ratios and the proposed methodology to calculate the readmissions adjustment factor discussed in this proposed rule, the estimated distribution of the readmission adjustment factors among hospitals ranked by their DSH patient percentage (DPP). The DPP is used as a proxy for low-income patients and is the sum of the hospital's Medicare fraction and Medicaid fraction. The Medicare fraction is computed by dividing the number of a hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days. The DPP is used to determine a hospital's Medicare DSH payment adjustment. Thus, hospitals with higher

percentages of Medicare patients entitled to SSI and higher percentages of Medicaid patients have higher DPPs. In the table, the hospitals are ranked by their estimated DPP and categorized into deciles. The table shows the number of hospitals within each decile that are subject to no proposed readmission payment adjustment, the −1 percent floor readmission payment adjustment, and a readmission payment adjustment that is less than the −1 percent floor. We are inviting public comment on this analysis.

DISTRIBUTION OF HOSPITALS READMISSION ADJUSTMENT FACTOR BY DSH PATIENT PERCENTAGE (DPP)

Decile	Number of hospitals	Payment adjustment of less than −1 percent	−1 Percent floor adjustment	No readmission adjustment factor
Lowest DPP	339	156	38	145
Second	339	164	57	118
Third	339	168	44	127
Fourth	339	170	48	121
Fifth	339	182	42	115
Sixth	339	171	43	125
Seventh	339	187	44	108
Eighth	339	182	43	114
Ninth	339	179	58	102
Highest DPP	342	185	61	96
Total	3,393	1,744	478	1,171

In addition, we have examined the estimated distribution of the proposed readmission adjustment factor based on the excess readmission ratios in this proposed rule (determined using the 2007–2010 data discussed above). The table below shows the number and percentage of hospitals ranked by the percent reduction received under the Hospital Readmissions Reduction Program. The table shows that about 71 percent of hospitals would receive either no adjustment or a readmission adjustment factor that would reduce their base operating DRG payments by less than 0.5 percent.

DISTRIBUTION OF READMISSION ADJUSTMENT FACTORS

Percent reduction	Number of hospitals	Percent of hospitals
No Adjustment	1,171	34.5
Up to −.09 Percent	347	10.2
−0.1 Percent to −0.19 Percent	280	8.3
−0.20 Percent to −0.29 Percent	228	6.7
−0.30 Percent to −0.39 Percent	196	5.8
−0.40 Percent to −0.49 Percent	180	5.3
−0.50 Percent to −0.59 Percent	129	3.8
−0.60 Percent to −0.69 Percent	118	3.5
−0.70 Percent to −0.79 Percent	110	3.2
−0.80 Percent to −0.89 Percent	77	2.3
−0.90 Percent to −0.99 Percent	76	2.2
−1.0 Percent	481	14.2
Total	3,393	100.0

e. Proposals Regarding Applicable Hospitals

An ''applicable hospital,'' is defined at section 1886(q)(5)(C) of the Act as (1) ''a subsection(d) hospital or (2) a hospital that is paid under section 1814(b)(3).'' Specifically, hospitals subject to the Hospital Readmissions Reduction Program are hospitals paid under the IPPS and hospitals paid under the authority of section 1814(b)(3) of the Act. We are interpreting this reference to section 1814(b)(3) of the Act to mean those Maryland hospitals that are paid under section 1814(b)(3) of the Act and that, absent the ''waiver'' specified by section 1814(b)(3) of the Act, would have been paid under the IPPS. 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 fifty States or the District of Columbia.'' The term subsection (d) hospital does not include hospitals located in the Territories or hospitals located in Puerto Rico. Section 1886(d)(9)(A) of the Act separately defines a ''subsection(d) Puerto Rico hospital'' as a hospital that is located in Puerto Rico and that ''would be a subsection(d) hospital * * * if it were located in one of the 50 States.'' Therefore, Puerto Rico hospitals are not considered applicable hospitals under the Hospital Readmissions Reduction Program. Indian Health Services hospitals enrolled as a Medicare provider meet the definition of a subsection (d) hospital and, therefore, are considered an applicable hospital under the Hospital Readmissions Reduction Program, even if they are not paid under the IPPS. In addition, hospitals that are SCHs and current MDHs, although they may be paid under a hospital-specific rate instead of under the Federal rate under the IPPS, are subsection (d) hospitals and, therefore, are included in the definition of an applicable hospital

under the Hospital Readmissions Reduction Program.

A subsection (d) hospital as defined in section 1886(d)(1)(B) of the Act does not include hospitals and hospital units excluded from the IPPS, such as LTCHs, cancer hospitals, children's hospitals, IRFs, and IPFs, and, therefore, these hospitals are not considered ''applicable hospitals.'' CAHs are not ''applicable hospitals'' because they do not meet the definition of a ''subsection (d) hospital,'' as they are separately defined under section 1886(mm) of the Act and are paid under a reasonable cost methodology under section 1814(l) of the Act. Consistent with the statute, therefore, we are proposing to define ''applicable hospital'' under the regulations at 42 CFR 412.152 to include both (1) subsection (d) hospitals, that is, hospitals paid under the IPPS and (2) hospitals in Maryland that are paid under section 1814(b)(3) of the Act and that, absent the ''waiver'' specified by section 1814(b)(3) of the Act, would have been paid under the IPPS.

The term ''applicable hospital'' is also referenced in the definition of readmission in section 1886(q)(5)(E) of the Act, which 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.'' In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51666), we finalized the definition of readmission as ''occurring when a patient is discharged from the applicable hospital 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.'' Furthermore, we finalized the time period specified for these readmission measures as 30 days. With our proposal to define an applicable hospital as a subsection (d) hospital or certain Maryland hospitals described above, we also are proposing to refine the definition of readmission to only include admissions and readmissions occurring from an applicable hospital (that is, a subsection (d) hospital or certain Maryland hospitals) to the same or another applicable hospital (again, a subsection (d) hospital or certain Maryland hospitals) (proposed § 412.152). Accordingly, excess readmission ratios calculated for the purpose of the Hospital Readmissions Reduction Program would include only admissions and readmissions to ''applicable hospitals.''

We note that because the Hospital Readmissions Reduction Program only includes admissions and readmissions to ''applicable hospitals'' to calculate the excess readmission ratios used under section 1886(q) of the Act, these excess readmission ratios will differ from the readmission rates reported on Hospital Compare for the purpose of the Hospital IQR Program. The excess readmission ratios for the purpose of the Hospital IQR Program were determined based on admissions and readmissions to all hospitals, not just hospitals specified in sections 1886(d) and 1814(b)(3) of the Act. Therefore, as discussed above, the excess readmission ratios used in this proposed rule will use a subset of the claims used to calculate the readmission rates reported on Hospital Compare for the purpose of the Hospital IQR Program and would be limited to admissions and readmissions to ''applicable hospitals'' and are based on the period of June 30, 2007 to July 1, 2010. In this proposed rule, we are using these excess readmission ratios, as they are based on the most recent data available and will allow the public to replicate our methodology to understand how the readmission adjustment factor is calculated. We believe that the differences between these proposed excess readmission ratios and those excess readmission ratios currently published on Hospital Compare under the Hospital IQR Program are minimal, and we believe that it is helpful for hospitals to see the impact of our proposed methodology to calculate the readmission adjustment using excess readmission ratios calculated under our methodology finalized in the FY 2012 IPPS/LTCH PPS final rule. For the final rule, we intend to use excess readmission ratios based on the applicable period of June 30, 2008 to July 1, 2011, as finalized in the FY 2012 IPPS/LTCH PPS final rule, and hospitals will have the opportunity to review and correct their data related to their excess readmission ratios prior to the publication of those excess readmission ratios.

We are specifically inviting public comment on our readmissions proposal, including our proposed definition of base operating DRG payment, our proposed methodology to calculate the readmission adjustment factor, the minimum number of cases, and our proposed definition of applicable hospital.

4. Limitations on Review (Proposed § 412.154(e))

Section 1886(q)(7) of the Act provides that there will be no administrative or judicial review under section 1869 of the Act, under section 1878 of the Act, or otherwise for any of the following:

- The determination of base operating DRG payment amounts.
- The methodology for determining the adjustment factor, including the excess readmissions ratio, aggregate payments for excess readmissions, and aggregate payments for all discharges, and applicable periods and applicable conditions.

We are proposing to include under proposed § 412.154(e) that the provisions listed above will not be subject to administrative or judicial review, consistent with section 1886(q)(7) of the Act. We note that section 1886(q)(6) of the Act requires that the Secretary ''make information available to the public regarding readmissions rates of each subsection (d) hospital under the [Hospital Readmissions Reduction Program]'' and also 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.'' Our proposal for reporting hospital-specific information, including a hospital's opportunity to review and submit corrections, consistent with section 1886(q)(7) of the Act, is discussed below.

5. Reporting Hospital-Specific Information, Including Opportunity To Review and Submit Corrections (Proposed § 412.154(f))

Section 1886(q)(6)(A) of the Act requires the Secretary to ''make information available to the public regarding readmissions rates of each subsection (d) hospital under the [Hospital Readmissions Reduction Program]''. Section 1886(q)(6)(B) of the Act also 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.'' In addition, section 1886(q)(6)(C) of the Act requires the Secretary to post the hospital-specific readmission information for each subsection (d) hospital on the Hospital Compare Web site in an easily understood format.

For purposes of the Hospital Readmissions Reduction Program for FY 2013, we will calculate excess readmission ratios for each of the three conditions, AMI, HF, and PN, using the previously finalized 3-year applicable period for the FY 2013 payment determination that spans from July 1, 2008 through June 30, 2011 (76 FR 51671), data sources, and the minimum number of discharges previously finalized in the FY 2012 IPPS/LTCH

PPS final rule for each applicable hospital (76 FR 51671 through 51672). We intend to make these excess readmission ratios available to the public, consistent with the requirements of section 1886(q)(6)(B) of the Act, as part of the FY 2013 rulemaking process, in addition to posting this information on the Hospital Compare Web site in a subsequent release.

In the FY 2012 IPPS/LTCH PPS final rule, we indicated that we would provide hospitals an opportunity to review and submit corrections using a process similar to what is currently used for posting results on Hospital Compare. We currently provide hospitals with the data elements necessary to verify the accuracy of their readmission rates for the Hospital IQR Program prior to posting their rates on Hospital Compare. Because we believe it is important to provide hospitals with relevant information available to hospitals for assessing payment impacts for purposes of the Hospital Readmissions Reduction Program, we plan to make the excess readmission ratios used for the Hospital Readmissions Reduction Program adjustment factor calculation available during the rulemaking cycle. As a result, the timeline and details of this process must accommodate the rulemaking timeline in addition to posting on Hospital Compare. We are proposing below the details regarding the process for hospitals to review and submit corrections to their excess readmission ratios prior to making this information available to the public in rulemaking and on Hospital Compare.

For FY 2013, we are proposing to deliver confidential reports and accompanying confidential discharge-level information to applicable hospitals as defined in section IV.A.2. of this preamble, which contain their excess readmission ratios for the three applicable conditions by June 20, 2012. These reports will be delivered in hospitals' secure QualityNet accounts. The information in the confidential reports and accompanying confidential discharge-level information would be calculated using the claims information we had available approximately 90 days after the last discharge date in the applicable period, which is when we would create the data extract for the calculations (we discuss this practice in more detail later).

The discharge-level information accompanying the excess readmission ratios would include the risk-factors for the discharges that factor into the calculation of the excess readmission ratio, as well as information about the readmissions associated with these discharges (such as dates, provider numbers, and diagnosis upon readmission). Our intent in providing this information is twofold: (1) To facilitate hospitals' verification of the excess readmission ratio calculations we provide during the review and correction period based upon the information CMS had available at the time our data extract was created; and (2) to facilitate hospitals' quality improvement efforts with respect to readmissions.

We are proposing to provide hospitals with a period of 30 days to review and submit corrections for their excess readmission ratios for the Hospital Readmissions Reduction Program. This 30-day period would begin the day hospitals' confidential reports and accompanying discharge-level information are posted to their QualityNet accounts. Based on previous experience with public reporting of measures under the Hospital IQR program, including the 30-day risk standardized readmission rates, we believe this 30-day period would allow enough time for hospitals to review their data and notify CMS of calculation errors, and for CMS to incorporate appropriate corrections to the excess readmission ratio calculations prior to the publication of the final rule, at which time the excess readmission ratios would be made available to the public in a table to be cited in the final rule and available via the Internet on the CMS Web site. During the review and correction period, hospitals should notify CMS of suspected errors in their excess readmission ratio calculations using the technical assistance contact information provided in their confidential reports.

The review and correction process we are proposing for the excess readmission ratios above would not allow hospitals to submit additional corrections related to the underlying claims data we used to calculate the ratios, or allow hospitals to add new claims to the data extract we used to calculate the ratios. This is because it is necessary to take a static ''snapshot'' of the claims in order to perform the calculations. For purposes of this program, we would calculate the excess readmission ratios using a static snapshot (data extract) taken at the conclusion of the 90 day period following the last date of discharge used in the applicable period. We recognize that under our current timely claims filing policy, hospitals have up to one year from the date of discharge to submit a claim to CMS. However, in using claims data to calculate measures for this program, we are proposing to create data extracts using claims in CMS' Common Working File (CWF) 90 days after the last discharge date in the applicable period which we will use for the calculations. For example, if the last discharge date in the applicable period for a measure is June 30, 2011, we would create the data extract on September 30, 2011, and use that data to calculate the ratios for that applicable period. Hospitals would then receive the excess readmission ratio calculations in their confidential reports and accompanying discharge-level information and they would have an opportunity to review and submit corrections for the calculations. As we stated above, hospitals would not be able to submit corrections to the underlying data that were extracted on September 30, 2011, and would also not be able to add claims to the data set. Therefore, we would consider hospitals' claims data to be complete for purposes of calculating the excess readmission ratios for the Hospital Readmissions Reduction Program at the conclusion of the 90-day period following the last date of discharge used in the applicable period.

We considered a number of factors in determining that a 90-day ''run-out'' period is appropriate for purposes of calculating claims based measures. First, we seek to provide timely quality data to hospitals for the purpose of quality improvement and to the public for the purpose of transparency. Next, we seek to make payment adjustments to hospitals based on their performance on measures as close in time to the performance period as possible. Finally, with respect to claims-based measures, we seek to have as complete a data set as possible, recognizing that hospitals have up to one year from the date of discharge to submit a claim under CMS' timely claims filing policy.

After the data extract is created, it takes several months to incorporate other data needed for the calculations (particularly in the case of risk-adjusted, and/or episode-based measures). We then need to generate and check the calculations, as well as program, populate, and deliver the confidential reports and accompanying data to be delivered to hospitals. We also are aware that hospitals would prefer to receive the calculations to be used for the Hospital Readmissions Reduction Program as soon as possible. Because several months lead time is necessary after acquiring the data to generate these claims-based calculations, if we were to delay our data extraction point to 12 months after the last date of the last discharge in the applicable period, we would not be able to deliver the calculations to hospitals sooner than 18 to 24 months after the last discharge

date. We believe this would create an unacceptably long delay both for hospitals and for CMS to deliver timely calculations to hospitals for quality improvement and transparency, and ultimately timely readmission adjustment factors for purposes of this program. Therefore, we are proposing to extract the data needed to calculate the excess readmission ratios for this program 90 days after the last date of discharge for the applicable period so that we can balance the need to provide timely program information to hospitals with the need to calculate the claims-based measures using as complete a data set as possible.

During the 30-day review and correction process for the excess readmission ratios, if a subsection (d) hospital suspects that such discrepancies exist in the CMS application of the measures' methodology, it should notify CMS during the review and correction period using the technical support contacts provided in the hospital's confidential report. We would investigate the validity of each submitted correction and notify hospitals of the results. If we confirm that we made an error in creating the data extract or in calculating the excess readmission ratios, we would strive to correct the calculations, issue new confidential reports to subsection (d) hospitals, and then publicly report the corrected excess readmission ratios through the rulemaking process, and subsequently on Hospital Compare. However, if the errors take more time than anticipated to correct, not allowing for publication of the corrected ratios in the final rule, we would notify hospitals in the final rule that corrected ratios will be made available after the final rule through delivery of confidential reports followed by a second 30-day review and correction period, subsequent publication, and posting on Hospital Compare. In addition, we are proposing that any corrections to a hospital's excess readmission ratios would then be used to recalculate a hospital's ratio under section 1886(q)(4)(B) of the Act in order to determine the hospital's adjustment factor in accordance with section 1886(q)(3) of the Act.

We believe that this proposed process would fulfill the statutory requirements at section 1886(q)(6)(A), section 1886(q)(6)(B), and section 1886(q)(6)(C) of the Act. We further believe that the proposed process would allow hospitals to review and correct their excess readmission ratios. We note that, under the proposed process, hospitals would retain the ability to submit new claims and corrections to submitted claims for payment purposes in line with CMS' timely claims filing policies. However, we emphasize that the administrative claims data used to calculate the excess readmission ratios reflect the state of the claims at the time of extraction from CMS' Common Working File. Under the proposed process, a hospital's opportunity to submit corrections to the calculation of the excess readmission ratios ends at the conclusion of the review and correction period. We welcome public comments on the proposed review and corrections process for the Hospital Readmissions Reduction Program.

B. Sole Community Hospitals (SCHs) (§ 412.92)

1. Background

Section 1886(d)(5)(D)(iii) of the Act defines a sole community hospital (SCH) in part 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 inpatient hospital services reasonably available to Medicare beneficiaries. The regulations at 42 CFR 412.92 set forth the criteria that a hospital must meet to be classified as a SCH. For more information on SCHs, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (74 FR 43894 through 463897).

2. Clarification of Regulations Regarding Duration of Classification (Proposed § 412.92(b)(3)(iv))

The regulations at § 412.92(b)(2) and (b)(3) address the effective dates of a classification as an SCH and the duration of this classification. Currently, a hospital's SCH classification status remains in effect without the need for reapproval unless there is a change in the circumstances under which the classification was approved. Section 412.92(b)(3) requires a hospital to notify the fiscal intermediary (or MAC) within 30 days of when a change occurs that could affect its classification as an SCH. Specifically, the regulations require an SCH to notify its fiscal intermediary or MAC if any of the following changes specified in § 412.92(b)(3)(ii) (A) through (E) occur:

- The opening of a new hospital in its service area.
- The opening of a new road between itself and a like provider within 35 miles.
- An increase in the number of beds to more than 50, if the hospital qualifies as an SCH under § 412.92(a)(1)(ii).
- Its geographic classification changes.
- Any changes to the driving conditions that result in a decrease in the amount of travel time between itself and a like provider if the hospital qualifies as an SCH under § 412.92(a)(3).

As discussed in the FY 2007 IPPS final rule (71 FR 48060), in the context of CMS becoming aware of several hospitals that had been paid based on SCH status, even after the original circumstances that led to the classification changed, CMS determined that an SCH's classification status would end 30 days after CMS notifies the SCH that it no longer meets the requirements to be classified as an SCH. However, if a hospital does not report when any one of the changes listed above occurs, CMS will cancel the hospital's SCH classification effective with the date that the hospital no longer met the criteria for SCH classification, subject to the reopening rules at 42 CFR 405.1885 (§ 412.92(a)(3)(i)).

For any change that is not listed under § 412.92(b)(3)(ii)(A) through (E) that affects an SCH's classification status, CMS requires a hospital to report that change to the fiscal intermediary or MAC only if it ''becomes aware'' of the change. If a hospital does not report a change, other than those listed under § 412.92(b)(3)(ii)(A) through (E), and it becomes known to CMS that the hospital had knowledge of that change, CMS will cancel the hospital's SCH classification effective with the date the hospital became aware of the event. Specifically, § 412.92(b)(3)(iii) states that ''a sole community hospital must report to the fiscal intermediary if it *becomes aware of any change* that would affect its classification as a sole community hospital beyond the events listed in paragraph (b)(3)(ii) of this section within 30 days of the event. If CMS determines that a sole community hospital has failed to comply with this requirement, CMS will cancel the hospital's classification as a sole community hospital effective with the date the hospital *became aware of the event* that resulted in the sole community hospital no longer meeting the criteria for such classification, consistent with the provisions of § 405.1885 of this chapter.'' (Emphasis added.)

It has come to our attention that the existing regulations only address a situation where an SCH no longer meets the requirements to be classified as an SCH. The existing language at § 412.92(b)(3)(iii) only refers to a hospital becoming aware of a ''change,'' because it deals specifically with a situation where a hospital was

appropriately classified as an SCH because it had previously met the requirements to become an SCH. However, the regulations do not explicitly address the situation where a hospital never met the requirements to be classified as an SCH, but was incorrectly classified as an SCH. We believe that the regulations need to be clarified to state explicitly our current authority that if a determination is subsequently made that, in fact, a hospital did not ever qualify as an SCH, the withdrawal of SCH status could be made retroactively to revoke the SCH status for the entire time period, consistent with the reopening rules at § 405.1885.

We continue to believe that any factor or information, not only a change or an event, that could affect a hospital's SCH classification status, must be reported by the SCH to its fiscal intermediary or MAC. Accordingly, we are proposing to revise the regulations by adding a new paragraph (b)(3)(iv) to § 412.92 to clarify our current authority that if CMS determines that the hospital was incorrectly classified as an SCH, SCH status could be cancelled retroactively, consistent with the provisions at § 405.1885.

3. Proposed Change to Effective Date of Classification for MDHs Applying for SCH Status Upon the Expiration of the MDH Program (Proposed § 412.92(b)(2)(v))

Under existing regulations at § 412.92(b)(2), a SCH's status is generally effective 30 days after CMS's written notification of approval. It has come to our attention that there may be a number of hospitals currently classified as MDHs under § 412.108 of the regulations that intend to apply for classification as SCHs upon the expiration of the MDH program provision on September 30, 2012. Those hospitals may be reluctant to apply for SCH classification status well before the expiration of their MDH status because they would prefer to maintain their MDH status for as long as possible. Conversely, if those hospitals were to wait to apply for SCH classification status after expiration of their MDH status, they could experience a financial hardship if there were a delay in the approval for SCH classification status. In order to facilitate a seamless transition for hospitals that are currently classified as MDHs and that will qualify as SCHs, we are proposing to add an exception to the effective dates of SCH classification by adding a new paragraph (v) under § 412.92(b)(2). We are proposing that, for any MDH that applies for SCH classification status at least 30 days prior to the expiration of the MDH program provision and requests that SCH classification status be effective with the expiration of the MDH program provision, and the MDH is approved for SCH classification status, the effective date of the hospital's classification as an SCH would be the day following the expiration date of the MDH program provision (that is, October 1, 2012). For example, Hospital A is an MDH that would like to maintain its MDH status for as long as possible and be classified as an SCH only after its MDH status expires. In order to seamlessly transition from MDH status to SCH status, Hospital A must apply for SCH status prior to September 1, 2012, and must request that, if approved, SCH classification status be effective with the expiration of the MDH program provision. If CMS determines that Hospital A qualifies for SCH status, the effective date of its SCH classification will be October 1, 2012.

C. Rural Referral Centers (RRCs): Annual Update to Case-Mix Index (CMI) and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center (RRC). RRCs receive some special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs 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 2013 includes data from all urban hospitals nationwide, and the proposed regional values for FY 2013 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 2011 (October 1, 2010 through September 30, 2011), and include bills

posted to CMS' records through December 2011.

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, 2012, they must have a CMI value for FY 2011 that is at least—

- 1.5378; 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)	1.3085
2. Middle Atlantic (PA, NJ, NY)	1.3739
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.4647
4. East North Central (IL, IN, MI, OH, WI)	1.4557
5. East South Central (AL, KY, MS, TN)	1.4025
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.4734
7. West South Central (AR, LA, OK, TX)	1.5861
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.6132
9. Pacific (AK, CA, HI, OR, WA)	1.5156

The preceding numbers will be revised in the FY 2013 final rule to the extent required to reflect the updated FY 2011 MedPAR file, which will contain data from additional bills received through March 2012.

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 would normally propose to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2010 (that is, October 1, 2009 through September 30, 2010), which would normally be the latest cost report data available at the time of the development of this proposed rule. However, due to a transition in our data system, in lieu of a full year of FY 2010 cost report data, we needed to use a combination of FY 2009 and FY 2010 cost report data in order to create a full fiscal year of cost report data for this analysis. Due to CMS' transition to a new cost reporting form effective for cost reporting periods beginning on or after May 1, 2010, cost reports with fiscal year begin dates of May 1, 2010 through September 30, 2010 were not accessible on our system for analysis at the time of the development of this proposed rule. Therefore, in order to have a complete fiscal year of cost report data, we utilized FY 2009 cost report data for providers with fiscal years beginning on or after May 1, 2010 and by September 30, 2010, in addition to the FY 2010 cost report data for providers with fiscal years beginning on or after October 1, 2009 and before May 1, 2010.

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, 2012, must have, as the number of discharges for its cost reporting period that began during FY 2010 (based on a combination of FY 2009 and FY 2010 cost report data as explained in the preceding paragraph), 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)	8,159
2. Middle Atlantic (PA, NJ, NY)	11,448
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	11,728
4. East North Central (IL, IN, MI, OH, WI)	8,833
5. East South Central (AL, KY, MS, TN)	7,234
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	8,129
7. West South Central (AR, LA, OK, TX)	6,253
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	9,347
9. Pacific (AK, CA, HI, OR, WA)	8,745

These numbers will be revised in the FY 2013 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, 2012, the hospital would be required to have at least 3,000 discharges for its cost reporting period that began during FY 2010 (based on a combination of FY 2009 and FY 2010 cost report data as explained earlier in this section).

D. Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Expiration of the Affordable Care Act Provision for FYs 2011 and 2012

For FYs 2011 and 2012, the Affordable Care Act expanded the definition of low-volume hospital and modified the methodology for determining the payment adjustment for hospitals meeting that definition. Beginning with FY 2013, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act. We discuss the proposed payment policies for FY 2013 in section IV.D.4. of this preamble.

2. 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 total 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.

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, regardless of payer (that is, not only 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. Section 1886(d)(12)(B)(iii) of the Act limits the applicable percentage increase 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 multivariate analyses supported the existing low-volume adjustment implemented in FY 2005. Therefore, the low-volume adjustment of an additional 25 percent continues to be provided for qualifying hospitals with less than 200 discharges.

3. Affordable Care Act Provisions for FYs 2011 and 2012

Sections 3125 and 10314 of the Affordable Care Act amended section 1886(d)(12) of the Act, modifying the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals, effective only for discharges occurring during FYs 2011 and 2012. Beginning with FY 2013, the preexisting low-volume hospital qualifying criteria and payment adjustment, as implemented in FY 2005, will resume.

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 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.''

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414), we revised our regulations at 42 CFR 412.101 to reflect the changes to the qualifying criteria and the payment adjustment for low-volume hospitals according to the provisions of the Affordable Care Act. In addition to changing the regulations to conform them to the Affordable Care Act changes, we also defined, at § 412.101(a), the term ''road miles'' to mean ''miles'' as defined at § 412.92(c)(i). The definition of ''road miles'' continues to apply even after the Affordable Care Act provisions expire at the end of FY 2012. 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, in that same final rule, we discussed the process for requesting and obtaining the low-volume hospital payment adjustment (75 FR 50240).

4. Proposed Payment Adjustment for FY 2013 and Subsequent Fiscal Years

In accordance with section 1886(d)(12) of the Act, beginning with FY 2013, the low-volume hospital definition and payment adjustment methodology will revert back to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act. Therefore, effective for FY 2013 and subsequent years, in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year. As discussed above, the statute specifies that a low-volume hospital must have less than 800 discharges during the fiscal year. However, as required by section 1886(d)(12)(B)(i) of the Act and as discussed above, the Secretary has developed an empirically justifiable payment adjustment based on the relationship, for IPPS hospitals with less than 800 discharges, between the

additional incremental costs (if any) that are associated with a particular number of discharges. 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 for low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. (Under the policy we established in that same final rule, hospitals with between 200 and 799 discharges do not receive a low-volume hospital adjustment.)

As described above, for FYs 2005 through 2010 and FY 2013 and subsequent years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges. The hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year (§ 412.101(b)(2)(i)). We use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. We note that, for FYs 2011 and 2012, CMS used the most recently available MedPAR data to determine the hospital's Medicare discharges because only Medicare discharges were used to determine if a hospital met the discharge criterion for those years.

For FY 2013 and for subsequent fiscal years, in addition to a discharge criterion, the eligibility for the low-volume payment adjustment is also dependent upon the hospital meeting the mileage criterion specified at § 412.101(b)(2)(i). Specifically, to meet the mileage criterion to qualify for the low-volume payment adjustment for FY 2013 and subsequent fiscal years, a hospital must be located more than 25 road miles from the nearest ''subsection (d) hospital.'' As mentioned above, we define, at § 412.101(a), the term ''road miles'' to mean ''miles'' as defined at § 412.92(c)(i) (75 FR 30238 through 50275 and 50414).

As discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 30238 through 50275 and 50414), we discussed the process for requesting and obtaining the low-volume hospital payment adjustment. 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. 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.

In order to receive a low-volume hospital payment adjustment 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. In addition, the fiscal intermediary or MAC will refer to the hospital's most recently submitted cost report to determine whether or not the hospital meets the discharge criterion. A hospital should refer to its most recently submitted cost report for total discharges (Medicare and non-Medicare) in order to decide whether or not to apply for low-volume hospital status for a particular fiscal year. As noted previously, a hospital must continue to meet the qualifying criterion at § 412.101(b)(2)(i) as a low-volume hospital (that is, the discharge criterion and the mileage criterion) in order to receive the payment adjustment in that year; that is, low-volume hospital status is not based on a ''one-time'' qualification.

In order to be a low-volume hospital in FY 2013 and subsequent fiscal years, in accordance with our previously established procedure, a hospital must make its request for low-volume hospital status in writing to its fiscal intermediary or MAC by September 1 immediately preceding the start of the Federal fiscal year for which the hospital is applying for low-volume hospital status in order for the 25 percent low-volume add-on payment adjustment to be applied to payments for its discharges for the fiscal year beginning on or after October 1 immediately following the request (that is, the start of the Federal fiscal year). For a hospital whose request for low-volume hospital status is received after September 1, if the fiscal intermediary or MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the fiscal intermediary or MAC will apply the 25 percent low-volume add-on payment adjustment to determine payment for the hospital's discharges for the fiscal year, effective prospectively within 30 days of the date of the fiscal intermediary's or MAC's low-volume status determination.

Specifically, for FY 2013, a hospital must make its request for low-volume hospital status in writing to its fiscal intermediary or MAC by September 1, 2012, in order for the 25 percent low-volume add-on payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2012 (through September 30, 2013). If a hospital's request for low-volume hospital status for FY 2013 is received after September 1, 2012, and if the fiscal intermediary or MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the fiscal intermediary or MAC will apply the 25 percent low-volume add-on payment adjustment to determine the payment for the hospital's FY 2013 discharges, effective prospectively within 30 days of the date of the fiscal intermediary's or MAC's low-volume status determination. For additional information on our established application process for the low-volume hospital payment adjustment, we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 20574 through 20575), Transmittal 2060 (Change Request 7134; October 1, 2010), and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680).

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414), in addition to implementing the Affordable Care Act provisions affecting low-volume hospitals for FYs 2011 and 2012, we also implemented changes to the regulations at 42 CFR 412.101 to conform them to the statutory requirements to require that, beginning with FY 2013, the low-volume hospital qualifying criteria and payment adjustment methodology will return to that which was in effect prior to the amendments made by the Affordable Care Act (that is, the low-volume hospital payment policy in effect for FYs 2005 through 2010). Therefore, no further revisions to the policy or to the

regulations at § 412.101 are required to conform them to the statutory requirement that the low-volume hospital policy in effect prior to the Affordable Care Act returns for FY 2013 and subsequent years.

E. Indirect Medical Education (IME) Payment Adjustment (§ 412.105)

1. IME Adjustment Factor for FY 2013

Under the IPPS, an additional payment amount is made to 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 payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B) of the Act states that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2013, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2013 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.

2. Clarification and Proposal Regarding Timely Filing Requirements Under Fee-for-Service Medicare

a. IME and Direct GME

The Balanced Budget Act of 1997 (Pub. L. 105–33) amended sections 1886(d) and 1886(h) of the Act by adding paragraphs (d)(11) and (h)(3)(D), respectively, to establish payment provisions for IME and direct GME costs to hospitals providing services to Medicare + Choice (now Medicare Advantage) enrollees. Sections 1886(d)(11) and 1886(h)(3)(D) of the Act specify that the Secretary shall provide for an ''additional payment amount'' for services furnished to individuals who are enrolled in a Medicare Advantage plan under Medicare Part C. To implement sections 1886(d)(11) and 1886(h)(3)(D) of the Act, we issued two final rules in the Federal Register that specifically addressed IME and direct GME payments to teaching hospitals for services provided to Medicare Advantage enrollees (the FY 1997 IPPS final rule (62 FR 46003) and the FY 1998 IPPS final rule (63 FR 26341)). Subsequent to the FY 1998 IPPS final rule, we (then HCFA) issued a Program Memorandum (PM), A–98–21, in July 1998, which outlined fiscal intermediary and standard system changes needed to process requests for IME and direct GME supplemental payments for services provided to Medicare Advantage enrollees. The PM explained that hospitals must submit their Medicare claims to the fiscal intermediary in UB–92 format in order for the standard system to process the claims so that hospitals may be paid the supplemental IME and direct GME payments for services provided to Medicare Advantage enrollees. It was always our intent that the claims filing requirements under 42 CFR Part 424, including the time limits at 42 CFR 424.44, fully applied to these claims submissions.

Existing § 424.44 of the regulations contains the time limits for filing all Medicare claims. In this proposed rule, we are clarifying again that the regulations governing time limits for filing claims at § 424.44 apply to claims submitted for IME and direct GME payments associated with services provided to Medicare Advantage enrollees. The process that was established by PM A–98–21 is within the same framework of the preexisting methodology for submitting claims under Medicare Part A. Therefore, because IME and direct GME payments for services provided to Medicare Advantage enrollees are also made under Medicare Part A, the same timely filing requirements that apply to other Part A claims for payments also apply to claims for IME and direct GME payments for services provided to Managed Advantage enrollees. In this proposed rule, we are clarifying once again that when hospitals submit claims for services provided to Medicare Advantage enrollees for additional IME and direct GME payments, the hospitals must comply with the regulations governing time limits for filing claims at § 424.44.

b. Nursing and Allied Health Education

Section 541 of the Balanced Budget Refinement Act (BBRA) of 1999 (Pub. L. 106–113) further amended section 1886 of the Act by adding subsection (l) to provide for additional payments to hospitals that operate nursing or allied health education programs and incur costs associated with services provided to Medicare+Choice (now Medicare Advantage) enrollees. Section 512 of the Benefits Improvement and Protection Act (BIPA) (Pub. L. 106–554) changed the formula for determining the additional payment amount paid to hospitals that operate nursing or allied health education programs and incur costs for services provided to Medicare+Choice (now Medicare Advantage) enrollees. We issued several PMs (Transmittals A–00–86 on November 22, 2000, and A–03–043 on May 23, 2003) to implement section 541 of the BBRA and section 512 of the BIPA. We also issued related Transmittal A–03–007 on February 3, 2003, and Transmittal A–03–045 on May 30, 2003, to instruct hospitals that operate a nursing or allied health education program and that qualify for additional payment related to services provided to Medicare Advantage enrollees to also submit those claims for processing as no-pay bills in the UB–92 format. These transmittals also instructed hospitals that are not paid under the IPPS, hospitals with rehabilitation and psychiatric units, and hospitals that operate approved nursing or allied health education programs (but may not have approved GME residency programs) to submit claims for services provided to Medicare Advantage enrollees to their fiscal intermediary in UB–92 format with specific condition codes present. In this proposed rule, we also are clarifying that the regulations governing the time limits for filing claims at § 424.44 also apply to claims submitted for nursing or allied health education program payments for services provided to Medicare Advantage enrollees.

c. Disproportionate Share Hospital (DSH) Payments

On July 20, 2007, we issued Change Request 5647 instructing applicable hospitals to submit no pay bills for their Medicare Advantage patients for FY 2007 forward in order for these days to be captured in the DSH calculation. Because we issued this request in the middle of FY 2007, we later believed it was appropriate to extend the deadline for submission of FY 2007 and FY 2008 no pay Medicare Advantage bills to August 31, 2010.

In this proposed rule, we are proposing to adopt a policy that hospitals that are required to submit no pay bills for services furnished on a prepaid capitation basis by a Medicare Advantage organization, or through cost settlement with either a health maintenance organization (HMO), a competitive medical plan (CMP), a health care prepayment plan (HCPP), or a demonstration, for the purpose of calculating the DSH patient percentage (DPP) must also do so within the time limits for filing claims specified at § 424.44. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50282), we

changed our methodology for calculating the SSI fraction of the DSH adjustment, in part, by using claims information that is updated 15 months after the close of each Federal fiscal year. We believed that allowing for a 15-month run-out period would more closely align the timing of the match process with the requirements for the timely submission of claims. As we stated in that final rule, hospitals may not have an incentive to submit no pay bills in as timely a manner as they would for fee-for-service claims. In order to ensure that no pay claims are properly incorporated into the DSH calculation, in this proposed rule, we are proposing to extend our rules regarding the timely submission of claims to no pay bills submitted for the purposes of calculating the DPP.

To clarify our existing policy for hospitals to file timely claims in order to receive supplemental IME, direct GME and/or nursing or allied health education payments for Medicare Advantage enrollees and to propose that hospitals that are required to submit no pay bills for the purpose of calculating the DPP must also follow the time limits for filing claims, we are proposing to revise the regulations at § 424.30 to reflect these requirements.

3. Other Related Proposed Policy Changes

In sections IV.F. and IV.I of this preamble, we present other proposed policy changes relating to determining labor and delivery bed counts for purposes of the DSH payment adjustment and relating to determining FTE resident caps for direct GME and IME payment purposes that would have an effect on the IME payment adjustment.

F. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medical Education (IME) (§§ 412.105 and 412.106)

1. Background

For the most recent background discussion regarding the Medicare payment adjustment for subsection (d) hospitals that serve a significantly disproportionate number of low-income patients, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51681).

As we did in FY 2012 IPPS/LTCH PPS final rule, we are combining, under section IV.I.2. of this preamble, 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) because the underlying concepts are similar, and we believe they should generally be interpreted in a consistent manner for both purposes.

2. Proposed Policy Change Relating to Treatment of Labor and Delivery Beds in the Calculation of the Medicare DSH Payment Adjustment and the IME Payment Adjustment

a. Background

Medicare's policy with respect to the treatment of labor and delivery services in the calculation of the Medicare DSH payment adjustment has undergone a number of changes over the years. (We refer readers to the background discussion regarding these policy changes in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43899 through 43901)). The most recent change in policy was adopted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule. Prior to FY 2010, our policy was to exclude from the count of inpatient days for purposes of the Medicare DSH calculation labor and delivery patient days associated with beds used for ancillary labor and delivery services when the patient did not occupy a routine bed prior to occupying an ancillary labor and delivery bed. This policy applied whether the hospital maintained separate labor and delivery rooms and postpartum rooms, or whether it maintained ''maternity suites'' in which labor, delivery, and postpartum services all occurred in the same bed. However, in the latter case, patient days were counted proportionally based on the proportion of (routine/ancillary) services furnished. (We refer readers to the example provided in the FY 2004 IPPS final rule (68 FR 45420) that describes how routine and ancillary days are allocated under this policy.)

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule, we revised our regulations to include in the DPP of the Medicare DSH adjustment all patient days associated with patients occupying labor and delivery beds once the patient has been admitted to the hospital as an inpatient, regardless of whether the patient days are associated with patients who occupied a routine bed prior to occupying an ancillary labor and delivery bed. Our rationale for adopting this change was that the costs associated with labor and delivery patient days are generally payable under the IPPS. Although we adopted this change with respect to labor and delivery *patient* days, we did not make a similar change to our policy for counting hospital beds.

b. Proposed Policy Change

As we recently stated in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51682), our policy for counting hospital beds is to include bed days available for IPPS-level acute care hospital services. In the FY 2004 IPPS final rule (68 FR 45417), we stated that beds in a particular unit would be considered available for IPPS-level acute care services if the services furnished in that unit were generally payable under the IPPS. Moreover, as stated above, our policy for counting patient days with respect to the Medicare DSH payment adjustment is to include patient days in units that provide services that are generally payable under the IPPS. Under our current policy, the services furnished to a labor and delivery patient are considered to be generally payable under the IPPS (74 FR 43900).

We recognize that, under our current policy, while the services furnished to a labor and delivery patient are considered to be generally payable under the IPPS, under § 412.105(b)(4), the bed where the services are furnished is not considered to be available for IPPS-level care.

Upon further examination of our existing policies, we believe that if a patient day is counted because the services furnished are generally payable under the IPPS, the bed in which the services were furnished should also be considered to be available for IPPS-level care. Accordingly, we believe it is appropriate to extend our current approach of including labor and delivery patient days in the DPP of the Medicare DSH payment adjustment to our rules for counting hospital beds for purposes of both the IME payment adjustment and the Medicare DSH payment adjustment. Specifically, because we have described labor and delivery patient days as being generally payable under the IPPS (74 FR 43900), we believe that the bed in which such services are furnished should also be considered to be available for IPPS-level care, and should be included in the count of beds available for IPPS-level acute care hospital services. The rules for counting hospital beds for purposes of the IME payment adjustment are codified in the IME regulations at § 412.105(b), which are cross-referenced in § 412.106(a)(1)(i) for purposes of determining the DSH payment adjustment.

In light of the similar policy rationales for determining patient days in the calculation of the Medicare DSH payment adjustment, and for determining bed days for both the Medicare DSH payment adjustment and

IME payment adjustment, we are proposing to include labor and delivery bed days in the count of available beds used in the IME and DSH calculations. Moreover, our proposal to treat labor and delivery patient days and bed days consistently is consistent with our approach with respect to the observation, swing-bed, and hospice days, which are excluded from both the patient day count and the available bed count. Accordingly, we are proposing to revise the regulations at § 412.105(b)(4) to remove from the list of currently excluded beds those beds associated with ''ancillary labor/delivery services.'' We are proposing that this regulation change would be effective for cost reporting periods beginning on or after October 1, 2012.

As we noted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43900), our policy for counting labor and delivery patient days does not allow for the inclusion of days of labor and delivery patients who are not admitted to the hospital as inpatients. For example, if a woman presents at a hospital for labor and delivery services, but is determined by medical staff to be in false labor and is sent home without ever being admitted to the hospital as an inpatient, any days associated with such services furnished by the hospital would not be included in the DPP for purposes of the calculation of the Medicare DSH payment adjustment. For the same reason, days on which labor and delivery beds are used for such services also will be excluded from the count of available bed days.

G. Expiration of the Medicare-Dependent, Small Rural Hospital (MDH) Program (§ 412.108)

Under current law, separate special payment protections are provided to a Medicare-dependent, small rural hospital (MDH) under the IPPS through the end of FY 2012. (For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684.) The provisions for MDHs at section 1886(d)(5) of the Act expire at the end of FY 2012 (that is, with discharges occurring on September 30, 2012). As we discussed in the FY 2012 IPPS/LTCH PPS final rule, 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. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684), we did not make any additional changes to this regulatory text for FY 2012.

Because the MDH program is not authorized by statute beyond FY 2012, all hospitals that previously qualified for MDH status will no longer have MDH status and will be paid based on the Federal rate beginning in FY 2013. (We note that, in section IV.B.3. of this preamble, we are proposing to revise our SCH policies to allow MDHs to apply for SCH status and be paid as such under certain proposed conditions, following expiration of the MDH program.) For the FY 2013 impact of the expiration of the MDH program at the end of FY 2012, we refer readers to section I.G.2.j. of Appendix A to this proposed rule.

H. Proposed Changes in the Inpatient Hospital Update

1. FY 2013 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 is set by section 1886(b)(3)(B)(iv) of the Act as discussed further below.

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 2013 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 2012 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 2013 adjustment of 0.1 percentage point may result in the applicable percentage increase being less than zero.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment. For FY 2013, we are not proposing any change in our methodology for calculating and applying the MFP adjustment. Similar to the market basket increase, we are using the most recent data available for this proposed rule to compute the MFP adjustment. Using the methodology that we finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51690), based on the most recent data available for this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we based the proposed FY 2013 market basket update used to determine the applicable percentage increase for the IPPS on the IHS Global Insight, Inc. (IGI's) first quarter 2012 forecast of the FY 2006-based IPPS market basket rate-of-increase, which is estimated to be 3.0 percent. This proposed 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 most recent estimate of the MFP adjustment (the 10-year moving average of MFP for the period ending FY 2013) of 0.8 percent, which is calculated using the methodology described in the FY 2012 IPPS/LTCH

PPS final rule (76 FR 51690) and based on IGI's first quarter 2012 forecast. Following application of the MFP 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 discussed in section I. of the Addendum to this proposed rule).

Consistent with current law, and based on IGI's first quarter 2012 forecast of the FY 2013 market basket increase, we are proposing an applicable percentage increase to the FY 2013 operating standardized amount of 2.1 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 0.8 percentage point for economy-wide productivity (that is, the MFP adjustment) and less 0.1 percentage point) for hospitals in all areas, provided the hospital submits quality data under rules established in accordance with section 1886(b)(3)(B)(viii) of the Act in accordance with our rules. For hospitals that do not submit these quality data, we are proposing an applicable percentage increase to the operating standardized amount of 0.1 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent, less 2.0 percentage points for failure to submit quality data, less an adjustment of 0.8 percentage point for the MFP adjustment, and less an additional adjustment of 0.1 percentage point). Lastly, we also 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 2013 market basket update and MFP adjustment in the final rule.

We are proposing to revise the existing regulations at 42 CFR 412.64(d)(1)(iv) to reflect the current law for the FY 2013 update. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to revise paragraph (d)(1)(iv) to reflect the applicable percentage increase to the FY 2013 operating standardized amount as the percentage increase in the market basket index less an MFP adjustment and less an 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 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 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 of 2.1 percent for hospitals that submit quality data or 0.1 percent for hospitals that fail to submit quality data. For FY 2013, the regulations in §§ 412.73(c)(16), 412.75(d), 412.77(e) and 412.78(e) already contain provisions that set the update factor for SCHs 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 four regulatory provisions to reflect the FY 2013 update factor for the hospital-specific rates of SCHs.

We note that, as discussed in section IV.G. of this preamble, 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, the MDH program was to be in effect through the end of FY 2011 only. Absent additional legislation further extending the MDH program, the MDH program will expire for discharges beginning in FY 2013. Accordingly, we are not including MDHs in our proposal to update the hospital-specific rates for FY 2013.

2. FY 2013 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 Pub. L. 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 2.1 percent for FY 2013. The regulations at § 412.211(c) already 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. Therefore, it is not necessary for us to propose changes to the existing regulatory text.

I. Payment for Graduate Medical Education (GME) and Indirect Medical Education (IME) Costs (§§ 412.105, 413.75 Through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) and as currently implemented in the regulations at 42 CFR 413.75 through 413.83, establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). The base year PRA is updated annually for inflation. In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days.

Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the hospital inpatient prospective payment system (IPPS) for hospitals that have residents in an approved GME program, in order to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment are located at 42 CFR 412.105. The

hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital to the number of inpatient hospital beds.

The calculation of both direct GME and IME payments is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress, through the Balanced Budget Act of 1997 (Pub. L. 105–33), established a limit on the number of allopathic and osteopathic residents that a hospital may include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

The Affordable Care Act made a number of statutory changes relating to the determination of a hospital's FTE resident count for direct GME and IME payment purposes and the manner in which FTE resident limits are calculated and applied to hospitals under certain circumstances. Section 5503 of the Affordable Care Act added a new section 1886(h)(8) to the Act to provide for the reduction in FTE resident caps for direct GME under Medicare for certain hospitals training fewer residents than allowed by their caps, and to authorize the ''redistribution'' of the estimated number of excess FTE resident slots to other qualified hospitals. In addition, section 5503 amended section 1886(d)(5)(B)(v) of the Act to require the application of the section 1886(h)(8) of the Act provisions ''in the same manner'' to the IME FTE resident caps. The regulations implementing section 5503 of the Affordable Care Act were included in the November 24, 2010 final rule with comment period (75 FR 72263).

2. New Teaching Hospitals: Proposed Change in New Program Growth From 3 Years to 5 Years

Section 1886(h)(4)(H)(i) of the Act requires CMS to establish rules for calculating the direct GME caps of teaching hospitals training residents in new programs established on or after January 1, 1995. Under section 1886(d)(5)(B)(viii) of the Act, these rules also apply to the establishment of a hospital's IME cap. CMS implemented these statutory requirements in the August 29, 1997 **Federal Register** (62 FR 46005) and in the May 12, 1998 **Federal Register** (63 FR 26333). Generally, under existing regulations at 42 CFR 413.79(e)(1) and 42 CFR 412.105(f)(1)(vii), if a hospital did not train any allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, and it begins to participate in training residents in a new residency program (allopathic or osteopathic) on or after January 1, 1995, the hospital's unweighted FTE resident cap (which would otherwise be zero) may be adjusted based on the product of the highest number of FTE residents in any program year during the third year of the first new program, for all new residency training programs established during that 3-year period, and the minimum accredited length for each type of program. The number of FTE resident cap slots that a teaching hospital receives for each new program may not exceed the number of accredited slots that are available for each new program. Once a hospital's FTE resident cap is established, no subsequent cap adjustments may be made for new programs unless the teaching hospital is a rural hospital. A rural hospital's FTE resident caps may be adjusted for participation in subsequent new residency training programs. As a reminder, a hospital that did not train any allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, may only receive a permanent FTE resident cap adjustment for training residents in a truly ''new'' residency training program; no permanent cap adjustment would be given for training residents associated with an existing program. That is, if a hospital that did not train any allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, serves as a training site for residents in a program that exists or existed previously at another teaching hospital that remains open, that ''new'' teaching hospital does not receive a ''new program'' cap adjustment because it is not participating in training residents in a truly ''new'' program. However, it is possible for that hospital to receive a temporary cap adjustment if the new teaching hospital enters into a Medicare GME affiliation agreement with the existing teaching hospital as specified at 42 CFR 413.79(f) and 412.105(f)(1)(vi). (For a detailed discussion of the distinctions between a new residency program and an existing residency program, we refer readers to the August 27, 2009 final rule (74 FR 43908).)

As stated previously, the existing regulations provide for a 3-year period in which a new teaching hospital can ''grow'' its programs, for the purpose of establishing its FTE resident caps. This 3-year period, which we will refer to as the ''3-year window'' for ease of reference, starts when (typically a July 1) the new teaching hospital first begins to train residents in its first new program, and it ends when the third program year of that first new program ends. For example, assume residents begin training in a new program for the first time on July 1, 2012. The 3-year window begins on July 1, 2012, and ends on June 30, 2015, the end of the third program year of that (first) new program. At this point in time, regardless of the actual accredited length of the new program, or the number of new programs started, the new teaching hospital's FTE resident caps are established permanently and are effective beginning with the fourth program year from the date the first new program started (using the same example, this would be July 1, 2015).

The provider community has expressed concerns that 3 years do not provide for a sufficient amount of time for a hospital to ''grow'' its new residency programs and to establish FTE resident caps that are properly reflective of the number of FTE residents that it will actually train, once the programs are fully grown. Providers have explained that 3 years is an insufficient amount of time primarily because a period of 3 years is not compatible with program accreditation requirements, particularly in instances where the new teaching hospital wishes to start more than one new program. For example, we understand that a new teaching hospital may not begin all of its new programs at the same time because of accreditation prerequisites; rather, a new teaching hospital must wait until the first program is in place for a specified amount of time before it can begin training residents in a second or third program. This potential delay means that a new teaching hospital may not be able to sufficiently ''grow'' all of

its new programs by the end of the ''3-year window.'' We understand, for example, that the Accreditation Council for Graduate Medical Education (ACGME) requires that, for a hospital to sponsor an anesthesiology program, the hospital must sponsor or be affiliated with at least one internal medicine program and one general surgery program. Furthermore, we understand that the ACGME can require new residency training programs to pass through an ''initial'' accreditation period of up to 3 years until they can be granted ''continued'' accreditation. During this initial accreditation period, a hospital is not allowed to add any additional positions to its new program. Therefore, even if a hospital has plans to expand its new training program beyond the number of positions for which it is initially accredited, it may not be possible for the hospital to actually do so until this initial period has expired. Lastly, we have been made aware that providers may want to stagger the start dates for their residency training programs if they plan on training residents in several programs because they may want to gain some experience in residency training before they begin all of their new programs.

Given the concerns about new teaching hospitals having insufficient time to ''grow'' their new residency training programs and to establish an appropriately reflective permanent FTE resident cap within a 3-year window, we are proposing that a new teaching hospital will have 5 years, or a ''5-year window,'' in which to establish and grow new programs. At the end of the fifth program year of the first new program in which the new teaching hospital participates, the new teaching hospital's FTE resident caps would be determined, and set permanently, effective with the beginning of the sixth program year. We are proposing that this change would apply to new teaching hospitals that begin training residents in new programs for the first time on or after October 1, 2012. Although we understand that many residency training programs begin July 1 of the calendar year, consistent with the proposed effective date of the FY 2013 IPPS provisions in this proposed rule, we are proposing an effective date for this change of October 1, 2012. We are proposing to amend the regulations at § 413.79(e)(1) to state that if a new teaching hospital participates in training residents in a new program for the first time on or after October 1, 2012, the new teaching hospital's FTE resident cap may be adjusted based on the product of the highest number of FTE residents training in any program year during the fifth year of the first program's existence for all new residency training program(s) and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program. This proposed policy would apply to the establishment of a hospital's cap for both direct GME and IME payment purposes. The IME regulations at § 412.105(f)(1)(vii) refer to the direct GME regulations at § 413.79(e)(1) through (e)(4) for the rules for the establishment of a new teaching hospital's cap. As is required under existing regulations, the number of cap slots associated with each new program cannot exceed the number of accredited slots available to the hospital for that new program.

We note that we are not proposing to make any changes to regulations governing treatment of the rolling average and the intern and resident-to-bed (IRB) ratio for new programs. That is, new program FTE residents will continue to be exempt from the rolling average and the cap on the IRB ratio for the minimum accredited length for the specific type of residency training program. These exceptions are discussed in the regulations at §§ 412.105(a)(1)(i) through (a)(1)(ii) and 413.79(d)(5). The current cost report instructions for Worksheet E–4, Line 6 (current year unweighted allopathic and osteopathic FTE count) instruct hospitals to contact their Medicare contractor for instructions on how to complete that line if the hospital has a new program for which the period of years is less than or greater than 3 years. Similarly, in the case of this proposed policy where the exemption from the rolling average for a new program could expire prior to the hospital's cap being set in the sixth year of the first new program, we would encourage our Medicare contractors to contact us if they have questions on the method of reporting FTE resident counts that are subject to the rolling average but not subject to the cap.

We also are proposing to revise the regulations at § 413.79(e)(1)(i) that discuss the methodology used to calculate a new teaching hospital's cap adjustment for a new residency training program if residents training in the new program are rotating to more than one hospital during the 5-year window. This same methodology would apply to a rural teaching hospital because a rural teaching hospital can always receive a cap adjustment for starting a brand-new program. We are proposing to revise the regulations to specify that, in calculating the cap adjustment for each new program started within the 5-year window, we would look at the highest total number of FTE residents training in any program year during the fifth academic year of the first new program's existence at all participating hospitals involved and multiply that highest FTE resident count by the number of years in which residents are expected to complete the program, based on the minimum accredited length of the specific program. Furthermore, we are proposing that, for each new program started within the 5-year window, we would then take that product and multiply it by each hospital's ratio of the number of FTE residents in the new program training over the course of the 5-year period at each hospital to the total number FTE residents training at all participating hospitals over the course of the 5 years. We believe it is appropriate to propose to apportion the overall FTE cap among the hospitals participating in training residents in the new program based on the percentage of FTE residents each hospital trained over the course of the entire 5-year period, rather than the percentage of FTE residents each hospital trained only during the fifth academic year, because the trend of training over the entire 5-years may reflect more completely the patterns in the training in years subsequent to the fifth academic year. Otherwise, a hospital's FTE cap adjustment, which is permanent, may reflect too heavily the share of training time solely in the fifth academic year, which may or may not be beneficial to the hospital. We note that a hospital's cap adjustment could differ, depending on whether we look only at the fifth academic year of the first new program or look at every available year (up to 5 years) for which training occurred to calculate each hospital's share of the aggregate cap for a specific program.

In addition, we are proposing to revise the existing regulation text at § 413.79(e)(1)(i) to include the phrase ''the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program.'' This proposed language is consistent with our past, current, and proposed policy. We also note that § 413.79(e)(1) applies in instances where the residents in the new program train only at one hospital; § 413.79(e)(1)(i) applies when residents in the new program train at more than one hospital, regardless of whether each of those hospitals are new hospitals or existing teaching hospitals with previously established caps. The example below illustrates the proposed methodology of how we would calculate

a new teaching hospital's cap (or rural teaching hospital's cap) if we changed the cap-building period from 3 years to 5 years. In this example, as explained above, we are proposing that we would calculate the cap based on what is occurring at the new teaching hospital(s) during the fifth academic year of the new teaching hospital's first new program (or the fifth academic year of the rural teaching hospital's new residency training program). The provider community has requested that the cap-building period be increased from 3 years to 5 years. Therefore, we are proposing that we would only look at the training that is occurring during the fifth academic year of the first new program to calculate the aggregate cap adjustment. However, we would look at the FTE residents training at the hospital(s) during all 5 years to determine how we would distribute the aggregate cap adjustment among the participating hospitals.

Example: Hospital A is a hospital that becomes a new teaching hospital by training residents in a new family medicine program in academic year 1. Within its 5-year window, it also begins a new surgery program in academic year 4 of the first new program, the family medicine program. The family medicine program is accredited for 15 positions, 5 positions per year (the minimum accredited length of a family medicine program is 3 years). The surgery program is accredited for 20 positions, 4 positions per year (the minimum accredited length of a surgery program is 5 years). Residents in both the family medicine program and the surgery program also rotate to Hospital B. Hospital B is an existing teaching hospital (nonrural) with a cap that is already established; therefore, it will not receive any cap adjustments for training FTE residents in the new family medicine program or the new surgery program. However, because both of these programs are approved programs and FTE residents are training at Hospital B for part of the time, Hospital B can count the FTE residents training in the family medicine program and the surgery program at its facility if it has room under its caps to do so.

First, we will determine the cap adjustment that Hospital A will receive for training FTE residents in the family medicine program. The following table includes the allowable FTE resident counts in the family medicine program at both Hospital A and Hospital B during the 5-year window. These numbers are FTE resident counts because they reflect the share of training time spent at Hospital A and Hospital B, and also assume for this example that we have excluded some nonallowable time, such as the time residents spend training in didactic activities in a medical school lecture hall.

HOSPITAL A

Year 1	Year 2	Year 3	Year 4	Year 5
0.75 PGY 1	2.60 PGY 1	4.00 PGY 1	4.10 PGY 1	4.20 PGY 1.
0.00 PGY 2	2.80 PGY 2	3.40 PGY 2	3.40 PGY 2	3.70 PGY 2.
0.00 PGY 3	0.00 PGY 3	2.40 PGY 3	2.80 PGY 3	2.80 PGY 3.
Total 0.75	Total 5.40	Total 9.80	Total 10.30	Total 10.70.

Hospital A's 5 year total = 36.95.

HOSPITAL B

Year 1	Year 2	Year 3	Year 4	Year 5
3.75 PGY 1	2.20 PGY 1	0.90 PGY 1	0.80 PGY 1	0.60 PGY 1.
0.00 PGY 2	2.00 PGY 2	1.50 PGY 2	1.50 PGY 2	1.20 PGY 2.
0.00 PGY 3	0.00 PGY 3	2.40 PGY 3	2.00 PGY 3	2.00 PGY 3.
Total 3.75	Total 4.20	Total 4.80	Total 4.30	Total 3.80.

Hospital B's 5 year total = 20.85.

Total Hospital A and Hospital B over 5 years = 36.95 + 20.85 = 57.80 FTEs.

To calculate the cap adjustment for Hospital A with respect to the family medicine program, we need to take the highest number of FTE residents training in any program year in the program (that is, FTE residents training at both Hospital A and Hospital B) in the fifth academic year of the first new program (which is the family medicine program). If we add the PGY 1s, the PGY 2s, and the PGY 3s at both hospitals, in year 5, we see that we would use the total number of PGY 2s to calculate the FTE cap adjustment for the family medicine program, because the total number of PGY 2s at both hospitals is 4.90 FTEs (3.70 + 1.20), whereas the total number of PGY 1s and PGY 3s is only 4.80. We multiply 4.90 by the minimum accredited length of the family medicine program to get the total possible cap adjustment for the family medicine program (4.90 × 3 = 14.70). The cap adjustment that Hospital A receives for the family medicine program will be some number less than 14.70 based on the ratio of the number of FTEs in the new program training over the course of the 5-year period at Hospital A to the total number FTE residents training at both hospitals over the course of the 5 year period.

To determine this ratio, note that Hospital A's total FTE residents in the new family medicine program over the course of 5 years is the numerator, 36.95. The total FTE residents at Hospitals A and B in the new family medicine program over the course of 5 years is the denominator, 57.80 (that is, 36.95 + 20.85). The ratio of training that occurred at Hospital A is 36.95/57.80 = 0.64. Therefore, Hospital A's cap for its share of the family medicine program is 0.64 × 14.70, or 9.41. (If Hospital B had been eligible to receive a cap adjustment, its ratio of the cap would have been 0.36, that is, (20.85/57.80), and its share would have been 5.30 (0.36 × 14.70). If we add 9.41 to 5.30, we get 14.71 (we note that 14.71 is ''approximately'' equal to 14.70, the total cap determined for the entire family medicine program, with a slight difference due to rounding). Thus, we have ensured that, in assigning a cap of 9.41 to Hospital A on behalf of its family medicine program, the total allowable and accredited number of slots has not been exceeded).

Now we will determine the cap adjustment that Hospital A will receive for training FTE residents in the new

surgery program that began in year 4 of the first new program. The following tables include the allowable FTE resident counts in the surgery program at Hospital A and Hospital B, respectively, during the hospital's 5-year window. Again, assume we have excluded nonallowable time, such as time residents spent training in didactic activities in a medical school lecture hall.

HOSPITAL A

Year 1	Year 2	Year 3	Year 4	Year 5.
0.00 PGY 1	0.00 PGY 1	0.00 PGY 1	4.10 PGY 1	4.20 PGY 1.
0.00 PGY 2	0.00 PGY 2	0.00 PGY 2	0.00 PGY 2	2.70 PGY 2.
0.00 PGY 3	0.00 PGY 3	0.00 PGY 3	0.00 PGY 3	0.00 PGY 3.
0.00 PGY 4	0.00 PGY 4	0.00 PGY 4	0.00 PGY 4	0.00 PGY 4.
0.00 PGY 5.	0.00 PGY 5.	0.00 PGY 5.	0.00 PGY 5.	0.00 PGY 5.
Total 0.00	Total 0.00	Total 0.00	Total 4.10	Total 6.90.

Hospital A's 5 year total = 11.00.

HOSPITAL B

Year 1	Year 2	Year 3	Year 4	Year 5
0.00 PGY 1	0.00 PGY 1	0.00 PGY 1	1.70 PGY 1	0.60 PGY 1.
0.00 PGY 2	0.00 PGY 2	0.00 PGY 2	0.00 PGY 2	1.50 PGY 2.
0.00 PGY 3	0.00 PGY 3	0.00 PGY 3	0.00 PGY 3	0.00 PGY 3.
0.00 PGY 4	0.00 PGY 4	0.00 PGY 4	0.00 PGY 4	0.00 PGY 4.
0.00 PGY 5.	0.00 PGY 5.	0.00 PGY 5.	0.00 PGY 5.	0.00 PGY 5.
Total 0.00	Total 0.00	Total 0.00	Total 1.70	Total 2.10.

Hospital B's 5 year total = 3.80.

Total Hospital A and Hospital B over 5 years = 11.00 + 3.80 = 14.80 FTEs.

To calculate the cap adjustment for Hospital A with respect to the surgery program, we need to take the highest number of FTE residents training in the program (that is, FTE residents training at both Hospital A and Hospital B) in the fifth academic year of the first new program (which is the family medicine program). Because the surgery program only started in Year 4 of the family medicine program, there are only PGY 1s and PGY 2s training at both Hospitals A and B in year 5. If we add the PGY 1s and the PGY 2s at both hospitals in year 5, we see that we would use the total number of PGY 1s to calculate the FTE cap adjustment for the surgery program, because the total number of PGY 1s is 4.80 FTEs (4.20 + 0.60), whereas the total number of PGY 2s is only 4.20. We multiply 4.80 by the minimum accredited length of the surgery program to get the total possible cap adjustment for the surgery program ($4.80 \times 5 = 24.00$). However, because the surgery program is only accredited for 20 positions, the overall FTE resident cap associated with the surgery program that is to be apportioned between Hospital A and Hospital B is limited to a maximum of 20. In this instance, because the surgery program started in Year 4 of the family medicine program, and it only ''grew'' for 2 years, we only have 2 years of FTE resident counts to consider and not 5 years. Nevertheless, the cap adjustment that Hospital A receives for the surgery program will be some number less than 20 and is based on the ratio of the number of FTE residents in the new program training over the course of the 2-year period at Hospital A to the total number of FTEs training at both hospitals over the course of the 2-year period.

To determine this ratio, note that Hospital A's total FTE residents in the new surgery program over the course of 2 years is the numerator, 11.00. The total number of FTE residents at Hospitals A and B in the new surgery program over the course of 5 years is the denominator, 14.80 (that is, 11.00 + 3.80). The ratio of training that occurred at Hospital A is 11.00/14.80 = 0.74. Hospital A's cap for its share of the surgery program is $0.74 \times 20 = 14.80$. (If Hospital B had been eligible to receive a cap adjustment, its share of the cap would have been 5.20 ($(3.80/14.80) \times 20$) = 5.20. Thus, we have ensured that, in assigning a cap of 14.80 to Hospital A on behalf of its surgery program, the total allowable and accredited number of slots has not been exceeded).

Adding together the cap adjustment Hospital A receives for the new family medicine program and the cap adjustment it receives for the new surgery program, Hospital A's total permanent cap is 24.21 (9.41 + 14.80 = 24.21).

In summary, we are proposing to revise the regulations at § 413.79(e)(1) for the purposes of direct GME and, by reference, § 412.105(f)(1)(vii) for purposes of IME to state that if a hospital begins training residents in a new program for the first time on or after October 1, 2012, that hospital's caps may be adjusted based on the product of the highest number of FTE residents training in any program year during the fifth academic year of the first program's existence for all new residency training programs and the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program. The cap would be applied beginning with the sixth academic year of the first new program. We also are proposing conforming changes throughout paragraph (e)(1) of § 413.79 to correspond with the proposed change to increase the length of the cap-building period from 3 to 5 years. In addition, we are proposing to change the regulation text at § 413.79(e)(1)(i) to reflect a methodology to calculate a new teaching hospital's cap adjustment if the residents in the new training program are training at more than one hospital. We are proposing that these changes would be effective for a hospital that begins training residents for the first time on or

after October 1, 2012. Lastly, we are making a clarification to the existing regulation text at § 413.79(e)(1)(i) to insert the missing phrase ''and the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program.'' This change is consistent with our past, current, and proposed policy.

3. Clarification Related to 5-Year Period Following Implementation of Reductions and Increases to Hospitals' FTE Resident Caps for GME Payment Purposes Under Section 5503 of the Affordable Care Act

As previously discussed, in an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress instituted a cap on the number of allopathic and osteopathic residents a hospital is allowed to count for direct GME and IME purposes. Some hospitals have trained a number of allopathic and osteopathic residents in excess of their FTE resident caps, while other hospitals are training a number of allopathic and osteopathic residents at some level below their FTE resident caps. Section 5503 of the Affordable Care Act added a new section 1886(h)(8) to the Act to provide for reductions in the statutory FTE resident caps for direct GME payment purposes under Medicare for certain hospitals that are training allopathic and osteopathic residents at a level below their FTE resident caps, and to authorize a ''redistribution'' to certain hospitals of the estimated number of FTE resident slots resulting from the reductions. Section 5503 of the Affordable Care Act also amended section 1886(d)(5)(B)(v) of the Act to require application of the provisions of section 1886(h)(8) of the Act ''in the same manner'' to the FTE resident caps for IME payment purposes.

Section 1886(h)(8)(A)(i) of the Act provides that, effective for portions of cost reporting periods occurring on or after July 1, 2011, a hospital's FTE resident cap will be reduced by 65 percent of the difference between the hospital's ''otherwise applicable resident limit'' and its ''reference resident level,'' if its ''reference resident level'' is less than its ''otherwise applicable resident limit'' (as defined at section 1886(h)(8)(H) of the Act). (We refer readers to the November 24, 2010 final rule with comment period (75 FR 72155 through 72161) for a discussion of these terms.) Section 1886(h)(8)(A)(ii) of the Act and the November 24, 2010 final rule with comment period (75 FR 72147) describe which hospitals are exempt from a cap reduction under section 5503 of the Affordable Care Act, including rural hospitals with fewer than 250 acute care inpatient beds.

Under section 1886(h)(8)(B) of the Act, the Secretary is authorized to increase the FTE resident caps for certain categories of hospitals for portions of cost reporting periods occurring on or after July 1, 2011, in the aggregate, by a number that does not exceed the estimated overall reduction in FTE resident caps for all hospitals under section 1886(h)(8)(A) of the Act. In determining which hospitals will receive an increase in their FTE resident caps, sections 1886(h)(8)(C) through 1886(h)(8)(E) of the Act direct us to do all of the following:

- Take into account the demonstrated likelihood of the hospital filling the additional positions within the first three cost reporting periods beginning on or after July 1, 2011.
- Take into account whether the hospital has an accredited rural training track program.
- Distribute 70 percent of the resident slots to hospitals located in States with resident-to-population ratios in the lowest quartile.
- Distribute 30 percent of the resident slots to hospitals located in a State, a territory of the United States, or the District of Columbia that are among the top 10 States, territories, or the District in terms of the ratio of the total population living in an area designated as a health professional shortage area (HSPA), as of March 23, 2010, to the total population, and/or to hospitals located in rural areas.

A comprehensive description of the rules implementing the cap slot redistribution under section 1886(h)(8) of the Act can be found in the November 24, 2010 final rule with comment period (75 FR 72168). Section 1886(h)(8)(B)(ii) of the Act, as added by section 5503(a)(4) of the Affordable Care Act, specifies that a hospital that receives an increase in its cap shall ensure, during the 5-year period beginning on the date of such increase (July 1, 2011), that certain requirements, referred to as the primary care average and the 75-percent threshold, are met in order to retain those slots. Otherwise, section 1886(h)(8)(B)(iii)(I) of the Act authorizes the Secretary to reduce the FTE resident caps of the hospital by the same number of FTE residents by which the hospital's FTE resident caps were increased if the hospital fails to meet either requirement; and section 1886(h)(8)(B)(iii)(II) of the Act authorizes the Secretary to redistribute those positions.

Specifically, section 1886(h)(8)(B)(ii) of the Act states, ''* * * a hospital that receives an increase in the otherwise applicable resident limit under this subparagraph shall ensure, during the 5-year period beginning on the date of such increase, that—

(I) The number of full-time equivalent primary care residents, as defined in paragraph (5)(H) (as determined by the Secretary), excluding any additional positions under subclause (II), is not less than the average number of fulltime equivalent primary care residents (as so determined) during the 3 most recent cost reporting periods ending prior to the date of enactment of this paragraph; and

(II) Not less than 75 percent of the positions attributable to such increase are in a primary care or general surgery residency (as determined by the Secretary).

The Secretary may determine whether a hospital has met the requirements under this clause during such 5-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 5-year period.''

In a case where the Secretary determines that a hospital did not meet the requirements in a cost reporting year during the 5-year time period, section 1886(h)(8)(B)(iii) of the Act states that ''* * * the Secretary shall—

(I) Reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was increased under this paragraph; and

(II) Provide for the distribution of positions attributable to such reduction in accordance with the requirements of this paragraph.''

In the November 24, 2010 final rule with comment period (75 FR 72195 through 72203), we stated that the ''5-year period beginning on the date of such increase'' is July 1, 2011 through June 30, 2016, and we provided a detailed discussion of what the two requirements under sections 1886(h)(8)(B)(ii)(I) and 1886(h)(8)(B)(ii)(II) of the Act entail. In that final rule, we noted that section 1886(h)(8)(B)(ii) of the Act allows the Secretary to ''determine whether a hospital has met the requirements * * * during such 5-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 5-year period,'' and section 1886(h)(8)(B)(iii) of the Act instructs the Secretary to ''reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was increased * * *.'' We also explained that we believe the Secretary has the discretion to consider a hospital's performance over more than one year or

to review each year during the 5 years independently in determining whether or not a hospital is in compliance with the primary care average and the 75-percent threshold, as required (75 FR 72196 and 72197 and 72200 and 72201). We emphasized that it is within CMS' and the Medicare contractors' authority to adjust a hospital's IME and direct GME payments as early as it is feasible within a cost report's submission and review cycle, and that we need not wait until final settlement to do so. We further stated in the November 24, 2010 final rule with comment period implementing section 5503 that ''We also understand that we should consider that hospitals might not immediately fill all the slots they receive, particularly because they are only required to demonstrate the likelihood of filling the slots within the first three cost reporting periods beginning on or after July 1, 2011'' (75 FR 72197). However, we gave an example that indicated that, of the section 5503 FTE slots that the hospital does begin to use, 75 percent of those slots must be in primary care or general surgery.

Since we awarded the section 5503 slots pursuant to section 1886(h)(8) of the Act, we have received questions from hospitals asking if and how CMS would enforce the primary care average and the 75-percent threshold requirements under sections 1886(h)(8)(B)(ii)(I) and 1886(h)(8)(B)(ii)(II) of the Act if a hospital does not use any of its section 5503 slots until year 4 or year 5 of the 5-year period, or if a hospital does not use any of the section 5503 slots until after expiration of the 5-year period. We have informed hospitals that the 75-percent threshold requirement applies once the hospital starts using any of the section 5503 slots, and the 3-year primary care average requirement applies immediately on July 1, 2011, regardless of whether or not the hospital begins to use its additional section 5503 slots in year 1 of the 5-year period. This is because the 3-year primary care average test applies to the hospital's pre-section 5503 resident complement as well, and not exclusively to the additional FTE residents associated with slots awarded under section 5503.

In determining which hospitals applying for slots under section 5503 will receive slots, section 1886(h)(8)(C)(i) of the Act specifies that the Secretary shall take into account the demonstrated likelihood of the hospital filling the slots within the first three cost reporting periods beginning on or after July 1, 2011. Hospitals included evidence supporting the demonstrated likelihood stipulation in their applications and we took that into consideration in awarding slots under section 5503. We believe that it is inappropriate and in direct conflict with a base consideration in the awarding of slots under section 5503 for hospitals to refrain from using their section 5503 slots until after the initial 3 years after the slots have been awarded in an attempt to circumvent the primary care average or the 75-percent threshold requirements, or both.

As stated in the November 14, 2010 final rule, CMS reserves the right to assess as many times as necessary in the 5-year period whether a hospital is meeting the required criteria. The agency also may remove the slots awarded to a hospital at any point during the 5-year period (75 FR 72196 and 72197 and 72200 and 72201). Because a statutorily directed criterion for consideration in awarding slots under section 5503 included the requirement that hospitals applying for slots demonstrate the likelihood of filling the slots within the first three cost reporting periods beginning on or after July 1, 2011, and we relied on that information in awarding slots, we believe it is reasonable to expect that hospitals that received slots under section 5503 should begin to use their slots within the first three 12-month cost reporting periods beginning on or after July 1, 2011, of the 5-year period in order to give full effect to the requirements under section 1886(h)(8)(B)(ii) of the Act. Therefore, we are proposing that a hospital must fill *at least half* of its section 5503 slots, IME and direct GME respectively, in at least one of the following timeframes, or lose its section 5503 slots: (A) in its first 12-month cost reporting period of the 5-year period; and/or (B) in its second 12-month cost reporting period of the 5-year period; and/or (C) in its third 12-month cost reporting period of the 5-year period. For example, Hospital A and Hospital B both have June 30 fiscal year ends (FYEs), and they received 10 slots under section 5503. In its FYE June 30, 2012, Hospital A filled 8 slots. In its FYE June 30, 2013, Hospital A filled 0 slots. In its FYE June 30, 2014, Hospital A filled 5 slots. However, Hospital B, in its FYEs June 30, 2012, 2013, and 2014, only filled 3 slots respectively in each of the 3 years. Hospital A would have complied with our proposed requirement, because it filled at least half of its section 5503 slots in either its first, and/or second, and/or its third 12-month cost reporting period during the 5-year period. Hospital B would not have complied with our proposed requirement because in neither its first, second, or third 12-month cost reporting period had it filled at least 5 (half of 10) slots.

We are proposing to interpret that a hospital's failure to use slots awarded under section 5503 in a timely manner to also be a failure to meet the 75-percent threshold. We believe that we have the authority to interpret section 1886(h)(8)(B)(ii) of the Act in such a manner and to propose this requirement because section 1886(h)(8)(B)(ii) of the Act allows the Secretary to ''* * * determine whether a hospital has met the requirements under this clause during such 5-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 5-year period.'' We are reiterating that the 75-percent threshold applies in the instance where a hospital *uses less than half, or any amount,* of its slots prior to its third 12-month cost reporting period during the 5-year period (75 FR 72197). In other words, the 75-percent threshold applies throughout the 5-year period, as long as the hospital is using some amount of its section 5503 slots in the respective cost reporting period. If a hospital is using some of its section 5503 slots in a cost reporting period, the 75-percent threshold would be enforced; if a hospital is not using any of its section 5503 slots in a cost reporting period, the 75-percent threshold would not be enforced. However, as stated earlier, we are proposing that a hospital must use its section 5503 slots no later than the hospital's third 12-month cost reporting period (and that at least half of its section 5503 slots must be used in either the first, or second, or third 12-month cost reporting period).

We note that we did not specify that a hospital must use at least half of its section 5503 slots in its third 12-month cost reporting period of the 5-year period in the November 24, 2010 final rule with comment period because the possibility that a hospital might not begin to use its section 5503 slots for several years only came to our attention after July 1, 2011, in response to questions raised by hospitals. Furthermore, given the huge demand for these slots (to the extent that we ran out of slots during the redistribution process and were unable to award any slots to hospitals in qualifying, but lower ranking, States), and that the slots were slated to be distributed in States where there was an acute need for additional residents (that is, as sections 1886(h)(8)(D) and 1886(h)(8)(E) of the Act specify, to States with resident-to-population ratios in the lowest quartile, and to States that are among the top 10 in terms of the HPSA population to total

population ratios), we did not expect that hospitals that received section 5503 slots would not be able to make almost immediate use of the slots. Consequently, given the presumed huge need for these slots in the States where Congress directed that they be awarded, we believe it is appropriate to use our authority to reasonably ensure that those slots awarded are used in compliance with section 5503 (hence, the proposals in this proposed rule), and, if not, are able to be redistributed to other hospitals in need of slots as Congress intended.

Section 1886(h)(8)(B)(iii) of the Act states that if the Secretary determines that a hospital does not meet either the primary care average or the 75-percent threshold, ''the Secretary shall (I) reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was increased under this paragraph; and (II) provide for the distribution of positions attributable to such reduction in accordance with the requirements of this paragraph.'' Accordingly, we are exercising the broad authority that the Secretary is given to determine whether the requirements at section 1886(h)(8)(B)(ii) of the Act are met by proposing that if a hospital fails to fill at least half of its section 5503 slots, IME and direct GME respectively, in its first 12-month cost reporting period of the 5-year period, and/or in its second 12-month cost reporting period, and/or in its third 12-month cost reporting period of the 5-year period, this would mean failure to meet the 75-percent threshold. In the case of such failure, CMS would instruct the Medicare contractor after audit to permanently remove all of the hospital's section 5503 slots from the earliest cost reporting period that is subject to reopening and in which it would be determined that the hospital did not meet the requirements (in accordance with existing § 413.79(n)(2)(iii), which is proposed to be redesignated as § 413.79(n)(2)(iv) in this proposed rule), even if the hospital had used at least half of its section 5503 slots in its fourth or subsequent cost reporting year of the 5-year period. Thus, as part of the Medicare contractors' reviews of the hospitals that received section 5503 slots, we are proposing that the Medicare contractors would determine whether a hospital filled at least half of its section 5503 slots in its first 12-month cost reporting period of the 5-year period, *and/or* in its second 12-month cost reporting period, *and/or* in its third 12-month cost reporting period of the 5-year period. We believe it is appropriate to remove the slots from a hospital that has not filled at least half of its slots in any 12-month cost reporting year prior to and including the third 12-month cost reporting period so that these slots may be redistributed to other hospitals that may have greater success in filling the slots and that are located in States that are described in sections 1886(h)(8)((D) and 1886(h)(8)(E) of the Act.

We note that, as explained in the November 24, 2010 final rule with comment period, the start and end of each year of the 5-year period depend on the fiscal year begin date of each hospital's cost reporting periods. Hospitals with fiscal year begin dates of July 1 will have five 12-month cost reporting periods starting on July 1, 2011, and ending on June 30, 2016, while hospitals with fiscal year begin dates of other than July 1 will have a partial cost reporting period that includes July 1, 2011, four 12-month cost reporting periods, and another partial cost reporting period that includes June 30, 2016 (75 FR 72197). For example, if Hospital A has a June 30 fiscal year end, its third 12-month cost reporting period of the 5-year period would be July 1, 2013, to June 30, 2014, and Hospital A must fill *at least half* of its section 5503 slots, IME and direct GME respectively, in its first 12-month cost reporting period of the 5-year period, *and/or* in its second 12-month cost reporting period, *and/or* in its third 12-month cost reporting period of the 5-year period. If Hospital B has a September 30 fiscal year end, its cost reporting periods occurring during July 1, 2011 through June 30, 2016 are as follows:

Year 1—July 1, 2011–September 30, 2011

Year 2—October 1, 2011–September 30, 2012

Year 3—October 1, 2012–September 30, 2013

Year 4—October 1, 2013–September 30, 2014

Year 5—October 1, 2014–September 30, 2015

Year 6—October 1, 2015–June 30, 2016

Hospital B's third 12-month cost reporting period would be October 1, 2013, to September 30, 2014, and Hospital B must fill at least half of its section 5503 slots, IME and direct GME, respectively, in its first 12-month cost reporting period of the 5-year period, and/or in its second 12-month cost reporting period, and/or in its third 12-month cost reporting period of the 5-year period. As explained in the November 24, 2010 final rule with comment period (75 FR 72197), if hospitals have other than a June 30 fiscal year end, for their cost reports that include July 1, 2011 and June 30, 2016 respectively, we will consider whether the hospital meets the primary care average and the 75-percent threshold requirements based on an annualized FTE count. Also, if during the period of July 1, 2011 through June 30, 2016, hospitals, for whatever reason, actually have less than 12-month cost reports, we would consider on a case-by-case basis which cost reports we would evaluate for purposes of meeting the proposed requirement of filling at least half of the section 5503 slots in its first, second, and/or third cost reporting period. As under existing policy, if the hospital does begin to fill its section 5503 slots but fails to meet the 75-percent threshold, the Medicare contractor would also remove the section 5503 slots, effective with the earliest year that the 75-percent threshold is not met.

Lastly, considering again that hospitals that received section 5503 slots had to demonstrate the likelihood of filling the slots within the first three cost reporting periods beginning on or after July 1, 2011, we are proposing to require that hospitals that received section 5503 slots must fill all of the slots they received in their final cost reporting period beginning during the timeframe of July 1, 2011 through June 30, 2016 (IME and direct GME respectively), or lose all of their section 5503 slots after June 30, 2016. As stated above, we consider it to be appropriate to remove the slots from a hospital that has not filled at least half of its slots in any 12-month cost reporting period prior to and including the third 12-month cost reporting period, so that these slots may be redistributed to other hospitals that otherwise qualified to receive slots, but did not receive them because the available slots were granted to higher ranking hospitals. We also are interested in commenters' recommendations regarding alternative approaches to encouraging compliance with the 3-year primary care average requirement and the 75-percent threshold.

In summary, we are proposing that a hospital must fill at least half of its section 5503 slots, IME and direct GME respectively, in at least one of the following timeframes or lose its section 5503 slots: (A) in its first 12-month cost reporting period of the 5-year period; and/or (B) in its second 12-month cost reporting period of the 5-year period; and/or (C) in its third 12-month cost reporting period of the 5-year period. We are proposing to enforce the 75-percent threshold test once the hospital begins to use its section 5503 slots,

which we are proposing must be no later than the hospital's third 12-month cost reporting period (and that at least half of its section 5503 slots must be used in either the first, or second, or third 12-month cost reporting period). In addition, we are proposing that a hospital does not meet the 75-percent threshold if it fails to fill at least half of its section 5503 slots, IME and direct GME, respectively, in one or a combination of the first three 12-month cost reporting period of the 5-year period, and upon that basis, CMS would instruct the Medicare contractor, after audit, to permanently remove all of the hospital's section 5503 slots from the earliest cost reporting period that is subject to reopening and in which it would be determined that the hospital did not meet the requirements (in accordance with existing § 413.79(n)(2)(iii), which is proposed to be redesignated as § 413.79(n)(2)(iv) in this proposed rule), even if the hospital had used at least half of its section 5503 slots in its fourth or subsequent cost reporting year of the 5-year period. Thus, as part of the Medicare contractors' reviews of the hospitals that received section 5503 slots, we are proposing that the Medicare contractors would determine whether a hospital filled at least half of its section 5503 slots in its first 12-month cost reporting period of the 5-year period, and/or in its second 12-month cost reporting period, and/or in its third 12-month cost reporting period of the 5-year period. Lastly, we are proposing to require that a hospital that received section 5503 slots must fill all of the slots it received in their final cost reporting period beginning during the timeframe of July 1, 2011 through June 30, 2016 (IME and direct GME respectively), or lose all of its section 5503 slots after June 30, 2016.

We are proposing that these requirements would be effective for a hospital's third 12-month cost reporting period occurring during the 5-year period of July 1, 2011 through June 30, 2016. For example, for hospitals with a June 30 fiscal year end, this would be July 1, 2013 through June 30, 2014. For hospitals with a September 30 fiscal year end, this would be October 1, 2013 through September 30, 2014. For hospitals with a December 31 fiscal year end, this would be January 1, 2014 through December 31, 2014. We are proposing to make appropriate changes to the regulations text at § 413.79(n)(2) to incorporate our proposals. The IME regulations regarding section 5503 slots that are at existing § 412.105(f)(1)(iv)(C)(2) reference the direct GME regulations text at § 413.79(n) and would not require amendments.

4. Preservation of Resident Cap Positions From Closed Hospitals (Section 5506 of the Affordable Care Act)

a. Background

Under existing regulations at § 413.79(h) for direct GME and § 412.105(f)(1)(ix) for IME, a hospital that is training FTE residents at or in excess of its FTE resident caps and takes in residents displaced by the closure of another teaching hospital may receive a temporary increase to its FTE residents caps so that it may receive direct GME and IME payment associated with those displaced FTE residents. However, those temporary FTE resident caps are associated with those specific displaced FTE residents, and the temporary caps expire as those displaced residents complete their training program. Thus, in the past, if a teaching hospital closed, its direct GME and IME FTE resident cap slots would be ''lost,'' because those cap slots are associated with a specific hospital's Medicare provider agreement, which would be retired upon the hospital's closure. Section 5506 of the Affordable Care Act addressed that situation by amending section 1886(h)(4)(H) of the Act to add a new clause (vi) that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria up to the number of the closed hospital's FTE resident caps. The Secretary is directed to ensure that the total number of FTE resident cap slots distributed shall be equal to the amount of slots in the closed hospital's direct GME and IME FTE resident caps, respectively. Under existing regulations at § 489.52 and § 413.79(h), ''closure of a hospital'' means the hospital terminates its Medicare provider agreement. As finalized in the November 24, 2010 final rule with comment period (75 FR 72213), we also specified that the FTE resident cap slots of the hospital that closed no longer exist as part of any other hospital's permanent FTE resident cap.

Section 1886(h)(4)(H)(vi)(II) of the Act, as added by section 5506(a) of the Affordable Care Act, specifies that the Secretary shall distribute the FTE cap increases in the following priority order, ''with preference given within each category to hospitals that are members of the same affiliated group'' (as defined by the Secretary) as the closed hospital:

- First, to hospitals located in the same core-based statistical area (CBSA) as, or in a CBSA contiguous to, the hospital that closed.
- Second, to hospitals located in the same State as the closed hospital.
- Third, to hospitals located in the same region of the country as the hospital that closed.
- Fourth, only if the slots are not able to be fully distributed under the third priority group, to qualifying hospitals in accordance with the criteria established under section 5503 (''Distribution of Additional Residency Positions'') of the Affordable Care Act.

For a detailed discussion on these ranking categories, we refer readers to the November 24, 2010 final rule with comment period (75 FR 72214 and 72215). In the November 24, 2010 final rule with comment period (75 FR 72212 through 72240), we also finalized the following Ranking Criteria:

☐ *Ranking Criterion One.* The applying hospital is requesting the increase in its FTE resident cap(s) because it is assuming (or assumed) an entire program (or programs) from the hospital that closed, and the applying hospital is continuing to operate the program(s) exactly as it had been operated by the hospital that closed (that is, same residents, possibly the same program director, and possibly the same (or many of the same) teaching staff).

☐ *Ranking Criterion Two.* The applying hospital was listed as a participant of a Medicare GME affiliated group on the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed, and under the terms of that Medicare GME affiliation agreement, the applying hospital *received* slots from the hospital that closed, and the applying hospital will use the additional slots to continue to train at least the number of FTE residents it had trained under the terms of the Medicare GME affiliation agreement. If the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed was with a hospital that itself has closed or is closing, preference would be given to an applying hospital that was listed as a participant in the next most recent Medicare GME affiliation agreement (but not one which was entered into more than 5 years prior to the hospital's closure) of which the first closed hospital was a member before the hospital closed, and that applying hospital received slots from the closed hospital under the terms of that affiliation agreement.

□ *Ranking Criterion Three.* The applying hospital took in residents displaced by the closure of the hospital, but is not assuming an entire program or programs, and will use the additional slots to continue training residents in the same programs as the displaced residents, even after those displaced residents complete their training (that is, the applying hospital is permanently expanding its own existing programs).

□ *Ranking Criterion Four.* The applying hospital does not fit into Ranking Criteria One, Two, or Three, and will use additional slots to establish a new or expand an existing geriatrics residency program.

□ *Ranking Criterion Five:* Applying hospital does not meet Ranking Criterion One, Two, or Three, is located in a HPSA, and will use all the additional slots to establish or expand a primary care or general surgery residency program.

□ *Ranking Criterion Six:* Applying hospital does not meet Ranking Criterion One, Two, or Three, is not located in a HPSA, and will use all the additional slots to establish or expand a primary care or general surgery residency program.

□ *Ranking Criterion Seven:* Applying hospital seeks the slots for purposes that do not fit into any of the above ranking criteria.

In determining which hospitals should receive the slots associated with the closed hospital, in addition to considering the ranking categories and criteria listed above, section 1886(h)(4)(H)(vi) of the Act, as added by section 5506(a) of the Affordable Care Act, states that the Secretary may only award slots to an applying hospital ''if the Secretary determines that the hospital has demonstrated a likelihood of filling the positions made available under this clause within 3 years.'' ''Within 3 years'' means within the 3 academic years immediately following the application deadline to receive slots after a particular hospital closes (75 FR 72224). For example, where the application deadline is April 1, 2011, the immediately following academic year is July 1, 2011; therefore, hospitals must demonstrate the likelihood of filling their slots by June 30, 2014.

Finally, section 5506(d) of the Affordable Care Act specifies that ''the Secretary shall give consideration to the effect of the amendments made by this section on any temporary adjustment to a hospital's FTE cap under § 413.79(h) * * * (as in effect on the date of enactment of this Act) in order to ensure that there is no duplication of FTE slots * * *.'' In distributing slots permanently under section 5506, we need to be cognizant of the number of FTE residents for whom a temporary FTE cap adjustment was provided under existing regulations at § 413.79(h), and when those residents will complete their training, at which point the temporary slot associated with those displaced residents would be available for permanent redistribution.

b. Proposed Change in Amount of Time Provided for Submitting Applications Under Section 5506 of the Affordable Care Act

In the August 3, 2010 proposed rule (75 FR 46422), we proposed to establish an application process for hospitals to apply to CMS to receive an increase in FTE caps based on slots from closed hospitals. Section 5506 of the Affordable Care Act did not specify an application deadline for hospitals to request an increase to their caps when a hospital closes. With respect to the first application process, which applied to all teaching hospital closures between March 23, 2008, and August 3, 2010, we established an application deadline of April 1, 2011. For future teaching hospital closures, we finalized a policy whereby we would inform the public through an appropriate medium that increases to hospitals' FTE resident caps are available for distribution due to the closure of a teaching hospital, and the application deadline would be 4 months following the issuance of that notice to the public (75 FR 72215).

Some representatives of the provider community have commented that providing hospitals with 4 months following the announcement of a teaching hospital closure to apply for slots under section 5506 is longer than necessary. They asserted that such a long application period unnecessarily delays CMS' review of applications and the resulting distribution of resident cap slots from closed hospitals to the applicants. The provider representatives suggested that perhaps a 2-month application window is sufficient and is more practical.

We have considered the suggestion of the provider representatives, and after our initial experience in implementing section 5506 of the Affordable Care Act, we agree that 4 months may be more time than is needed for hospitals to properly prepare and submit section 5506 applications to CMS. Accordingly, as recommended, we are proposing to set the application deadline for future section 5506 applications to be 60 days following CMS' public notice of a hospital's closure and the availability of resident cap slots increases. We believe that reducing the application submission timeframe from 4 months to 60 days will shorten the entire process for awarding FTE resident cap slots from closed hospitals considerably.

c. Proposed Change to the Ranking Criteria Under Section 5506

In the November 24, 2010 final rule with comment period (75 FR 72223), we finalized the Ranking Criteria within each of the three first statutory priority categories (that is, same or contiguous CBSAs, same State, and same region) to be used to rank applications. For each application, we assigned slots based on Ranking Criteria, with Ranking Criterion One being the highest ranking and Ranking Criterion Seven being the lowest. For a complete list of the Ranking Criteria, we refer readers to section IV.I.4.a. of this preamble, which discusses the background for preservation of resident cap positions from closed hospitals under section 5506 of the Affordable Care Act. For a detailed discussion of the ranking categories, we refer readers to the November 24, 2010 final rule with comment period (75 FR 72212 through 72240).

After reviewing applications from the first section 5506 application process (those applications that were due to CMS on April 1, 2011), we observed that the overwhelming majority of applications fell under Ranking Criterion Seven, that is, the applying hospital seeks the slots for purposes that do not fit into any of Ranking Criterion One through Ranking Criterion Six. These applications included applications from hospitals that applied for FTE cap slots for *both* primary care and/or general surgery and for nonprimary care specialties as well as applications for general cap relief. The sheer number of applications we received under Ranking Criterion Seven was indicative of a need to further prioritize among the applicants that would have qualified under Ranking Criterion Seven. Therefore, we are proposing to replace current Ranking Criterion Seven with the two separate proposed Ranking Criteria listed below. We note that we are not proposing to make any changes to Ranking Criteria One through Six. We are proposing the following two criteria to replace existing Ranking Criterion Seven:

- *Proposed Ranking Criterion Seven:* The program does not meet Ranking Criterion One through Six, and the slots for which the hospital is applying are for a primary care or a general surgery program, but the hospital is also applying for slots under Ranking Criterion Eight.
- *Proposed Ranking Criterion Eight:* Applying hospital seeks the slots for

purposes that do not fit into any of the above ranking criteria.

Our proposal to modify Ranking Criterion Seven is consistent with current Medicare policy goals to increase residency training in primary care and general surgery, because we are proposing to give a higher ranking to those applications from hospitals applying for primary care and general surgery FTE cap slots, as well as nonprimary care programs. Under the current Ranking Criteria, when a hospital applies for additional FTE cap slots for primary care and/or general surgery as well as nonprimary care programs, we do not distinguish between the primary care/general surgery and nonprimary care applications. Therefore, because the hospital would be applying for nonprimary program(s), all the hospital's applications would fall under proposed Ranking Criterion Seven. Under this proposal, although the hospital's application that requests FTE cap slots for primary care/general surgery would qualify for proposed Ranking Criterion Seven, the application for nonprimary care/general surgery would be classified as proposed Ranking Criterion Eight.

Following is an example of how the proposed Ranking Criteria Seven and Eight would be assigned:

Hospital A applies for slots from closed Hospital B. Hospital A is seeking to expand its internal medicine and dermatology programs. Under the current ranking system, both of Hospital A's applications would receive consideration under Ranking Criterion Seven. That is, the internal medicine application is ranked equally with the dermatology application even though internal medicine is a primary care specialty. Under the proposed change to the Ranking Criteria, Hospital A's internal medicine program would receive consideration under proposed Ranking Criterion Seven while the dermatology program would receive consideration under proposed Ranking Criterion Eight.

d. Effective Dates of Slots Awarded Under Section 5506

As stated previously, section 5506(d) of the Affordable Care Act instructs the Secretary, in pertinent part, ''* * * to ensure that there is no duplication of FTE slots. * * *'' Accordingly, in distributing slots permanently under section 5506, we need to be cognizant of the number of FTE residents for whom a temporary FTE cap adjustment was provided under existing regulations at § 413.79(h), when those residents will complete their training, and at which point the temporary slots associated with those displaced residents would be available for permanent redistribution. With that in mind, in the first distribution of section 5506 cap slots from hospitals that closed between March 23, 2008, and August 3, 2010, we used the following several effective dates based on the ranking criterion under which a hospital applied:

- Date of hospital closure. This effective date could have applied to Ranking Criterion Two. It also could have applied to Ranking Criteria One and Three if there were no temporary cap adjustments given for any displaced FTE residents.
- Cost reporting period following date of hospital closure. This effective date could have been used for awarding slots to hospitals that were training displaced FTE residents and qualified for Ranking Criterion One or Ranking Criterion Three because they were taking over an entire program or part of a program from a closed hospital and had received a temporary cap adjustment to train those displaced residents under 42 CFR 413.79(h).
- July 1 effective date. This effective date, which could have been retroactive, could have been used for awarding slots to hospitals that qualified under Ranking Criteria Four through Seven where there were temporary cap adjustments made for displaced FTE residents that completed training in a program on a specific June 30.
- Date of award announcement (January 30, 2012). This effective date could have applied to hospitals that qualified under Ranking Criteria Four through Seven either where there were no temporary cap increases under 42 CFR 413.79(h), or where there were temporary cap increases but those slots associated with the temporary cap increases were already accounted for. That is, displaced FTE residents graduated prior to a specific July 1, and, therefore, the cap slots associated with these FTE residents had already been permanently assigned that specific July 1, but the closed hospital still had remaining cap slots available for permanent assignment.

Based on comments we have received from hospitals that were involved in the initial phase of section 5506 implementation (hospitals that applied for cap slots from hospitals that closed between March 23, 2008 and August 3, 2010), we believe we need to clarify certain existing policies and propose a change to the effective dates associated with several ranking criteria.

First, we are clarifying the effective date of slots awarded under section 5506 with respect to Ranking Criterion Two. Ranking Criterion Two applies to hospitals that participated in a Medicare GME affiliation agreement with the closed hospital (but not one that was entered into more than 5 years prior to the hospital's closure), received slots from the closed hospital as part of the affiliation agreement, and will use any additional awarded slots to continue to train at least the same number of FTE resident slots it trained as part of the affiliation agreement. For hospitals that qualify for additional slots under Ranking Criterion Two, we award the 5506 slots effective on a permanent basis with the date of the hospital's closure. However, for hospitals that qualify under Ranking Criteria One and Three and are already receiving temporary cap adjustments for displaced FTE residents under 42 CFR 413.79(h), we award the 5506 slots effective on a permanent basis with the cost reporting period following the date of the hospital's closure. Because these hospitals are already receiving temporary cap adjustments for their portion of their cost reporting period following the closure, for administrative ease, slots became permanent due to the section 5506 award effective with the cost reporting period following the date of the hospital's closure. However, this policy, applicable to hospitals that qualify under Ranking Criterion One or Three, is not appropriate for hospitals that qualify under Ranking Criterion Two and that participated in a Medicare GME affiliation agreement with the closed hospital and received cap slots from the closed hospital as part of that affiliation agreement. This policy is not appropriate because, in this case, there were no displaced FTE residents from the Medicare GME affiliation agreement and, therefore, the hospital did not receive a temporary cap adjustment. For example, if Hospital A received slots from Hospital B as part of an affiliation agreement so that FTE residents could train at Hospital A and Hospital B closes, Hospital A lost the cap adjustment it received from Hospital B as part of the affiliation agreement as of the date of the hospital's closure, and a temporary cap adjustment under 42 CFR 413.79(h) is not available to Hospital A. In this case, no FTE residents are displaced.

In this proposed rule, we are clarifying that, for hospitals qualifying under Ranking Criterion Two that are awarded cap slots from the closed hospital, the award is effective with the date of the hospital's closure. This effective date allows a hospital applying under Ranking Criterion Two to receive funding for training the additional FTE

residents it was training as part of the Medicare GME affiliation agreement with the closed hospital immediately after the closure, without having to wait until the following cost reporting period to receive that cap adjustment. We note that, under existing regulations at 42 CFR 413.79(d), additional FTEs that a hospital receives under the terms of a Medicare GME affiliation agreement are subject to the 3-year rolling average. Therefore, hospitals that receive permanent assignment of FTE resident cap slots under Ranking Criterion Two do not receive an exemption from the rolling average. With regard to the IME intern and resident-to-bed (IRB) ratio, the existing regulations at 42 CFR 412.105(a)(1)(i) indicate that the numerator of the prior year IRB ratio may be adjusted to reflect FTEs added under a Medicare GME affiliation agreement. The affiliation agreement would terminate when the hospital closes. Thus, on the cost report of the hospital that receives slots under Ranking Criterion Two, the prior year numerator of the IRB ratio would only be adjusted to reflect the *portion* of the affiliated FTEs that the hospital received *prior* to the other hospital's closure and the termination of the affiliation agreement.

We also are clarifying that when there are *no* temporary cap adjustments for displaced FTE residents from hospitals that closed, and an applying hospital qualifies under Ranking Criterion One or Ranking Criterion Three, the FTE resident cap slots are awarded effective with the date of the hospital's closure. This was indicated in the November 24, 2010 final rule with comment period (75 FR 72225), but we understand, based on comments received after the initial phase of section 5506 slot awards, that this policy was not clearly understood. These slots are also immediately included in applying the rolling average and IRB ratio cap.

We are proposing to change the effective date of an award of additional FTE caps for hospitals that qualify under Ranking Criterion Four through proposed Ranking Criterion Eight where temporary caps were given for displaced FTE residents (we refer readers to section IV.I.4.b. of this preamble for a discussion of proposed Ranking Criteria Seven and Eight). As a general matter, hospitals that apply under Ranking Criterion Four through proposed Ranking Criterion Eight are applying either to establish or expand a program or to seek cap relief. We do not believe that, when a hospital receives additional cap slots to establish or expand a residency training program, we need to award the cap slots retroactively to a previous July 1 effective date. Rather, the awarded cap slots are to be used on a prospective basis to allow hospitals to expand current programs or establish new ones. We understand that if a hospital is applying for cap relief under proposed Ranking Criterion Eight (current Ranking Criterion Seven), the hospital would want its cap slots awarded retroactively to the date of the hospital's closure or the July 1 after a specific displaced resident has graduated if that date is prior to the date of the award announcement. However, we do not believe such a policy is consistent with the spirit of the BBA caps. Furthermore, the purpose of section 5506 is for hospitals to receive slots from the closed hospital to facilitate the continuity of the closed hospital's programs and to promote stability in the number of physicians in a community. The proposed Ranking Criterion Eight of section 5506 does not serve to encourage the continuity of the closed hospital's programs; it merely provides Medicare funding for a certain amount of slots in excess of the BBA caps. Accordingly, we believe that hospitals applying for cap relief under proposed Ranking Criterion Eight should only receive their permanent cap slots effective on a prospective basis. Therefore, while under the initial section 5506 application process, it was possible for an applying hospital that qualified under Ranking Criteria Four through Seven to receive slots retroactive to the July 1 after a specific displaced FTE resident's graduation date, we are proposing that, for hospitals that qualify under Ranking Criteria Four through Eight for cap slots from a closed hospital even where there were temporary caps given for displaced FTE residents, the applying hospitals would receive the permanent FTE cap slots effective no earlier than the date of the award announcement. That is, if an applying hospital that qualified under Ranking Criterion Four through proposed Ranking Criterion Eight receives cap slots associated with a displaced FTE resident and that resident graduated prior to the date of the award announcement, the earliest the applying hospital could receive the permanent cap adjustment would be the date of the award announcement. If a hospital qualified under Ranking Criterion Four through proposed Ranking Criterion Eight, and the only available cap slots are temporarily being used to train displaced FTE residents that are expected to graduate *after* the date of the award, the applying hospital will receive the permanent slots effective the July 1 *after* those displaced FTE residents complete their training. For example, if a hospital closed January 1, 2012, and the section 5506 slot awards were announced May 1, 2013, but residents displaced from the closed hospital did not complete their training until June 30, 2013, the applying hospital will receive section 5506 slots for those displaced residents effective July 1, 2013, following the completion of training of those displaced residents. We are not proposing to change the effective date of section 5506 awards for applying hospitals that qualify under Ranking Criterion Four through proposed Ranking Criterion Eight where there were no temporary caps given for displaced residents; as described in the November 24, 2010 final rule with comment period (75 FR 72227), those applying hospitals will continue to receive their section 5506 cap slots effective with the date of the award announcement.

Alternatively, another option to consider for the effective date of Ranking Criteria Four through proposed Ranking Criterion Seven, which are ranking criteria associated with either starting a program or expanding a program, would be to award the slots in accordance with when the hospital actually needs the slots, as asserted in the hospital's section 5506 application. (The proposed effective date for proposed Ranking Criterion Eight would still be no earlier than the date of the award announcement.) For example, assume a hospital applies under Ranking Criterion Five to expand an internal medicine program by nine positions. As described in its section 5506 application, the hospital plans that expansion to occur beginning on July 1, 2012, and at that time, the hospital would add three residents, and on July 1, 2013, the hospital would add another three residents, and then on July 1, 2014, the hospital would add the last three internal medicine residents. Therefore, the effective date of three slots could be July 1, 2012, the effective date of three additional slots would be July 1, 2013, and the effective date of the last three slots would be July 1, 2014. We are interested in receiving public comments on this policy alternative. We would still propose that the effective date for proposed Ranking Criterion Eight would be no earlier than date of the award.

Thus far, we have clarified when various effective dates have been used (that is, the date of closure, or the cost reporting period following the date of the closure, or a July 1 date), and we have proposed a change to the effective date of Ranking Criteria Four through proposed Ranking Criterion Eight when

temporary cap adjustments for displaced residents were given (to be no earlier than the date of the award announcement). However, due to concerns expressed by recipients of slots under the first round of section 5506, particularly regarding the interaction with the rolling average as the retroactive section 5506 slots become effective, we are soliciting public comments on alternative approaches to implementing section 5506. While bearing in mind that section 5506(d) of the Affordable Care Act instructs the Secretary ''* * * to ensure that there is no duplication of FTE slots * * *,'' we would be interested in public comments regarding whether to either make the effective dates prospective for all section 5506 slots awarded under all ranking criteria, or, in certain instances such as when slots are awarded under Ranking Criteria One or Three, make the effective dates of the section 5506 slots seamless with the expiration of applicable temporary cap adjustments under § 413.79(h). We also are soliciting public comments on whether the regulatory temporary cap adjustment for residents displaced from closed hospitals under § 413.79(h) is still necessary and appropriate, now that there is a provision in the statute that addresses permanent reassignment of slots from closed teaching hospitals. Alternatively, we would be interested in comments regarding whether the regulatory temporary cap adjustment for displaced residents under § 413.79(h) should be preserved, but the exemption from the rolling average for those displaced FTE residents should be eliminated. These options should be considered by commenters not only in the context of section 5506 slots that have already been assigned, but also in the context of future teaching hospital closures, and how previously awarded section 5506 slots that have not as yet been filled might interact with eligibility for temporary cap adjustments for additional displaced residents in the future.

e. Clarification of Relationship Between Ranking Criteria One, Two, and Three

In the November 24, 2010 final rule with comment period, as part of the response to a comment we received requesting that the order of Ranking Criterion One (regarding an applicant hospital that assumes an entire program from a closed hospital) and Ranking Criterion Two (regarding an applicant hospital that received slots under the terms of a Medicare GME affiliation agreement from a closed hospital) be switched, we stated:

Furthermore, the commenter need not be concerned that hospitals that would fit into Ranking Criterion Two would be at a disadvantage and deprived of their fair share of slots to hospitals that would fit under Ranking Criterion One. In fact, Ranking Criteria One and Two are *not* competing with each other, and hospitals fitting into each category would get their 'fair' share of slots. For example, assume a hospital with an FTE resident cap of 100 closes. Hospital A assumes the entire programs in which 80 FTE residents were training when the hospital closed. Hospital B had been receiving 20 FTE slots from the closed hospital under the terms of a Medicare GME affiliation agreement. Hospital A applies for 80 slots under Ranking Criterion One and, all other things being equal, is awarded 80 slots. Hospital A could apply for more than 80 slots, but it could only receive consideration under Ranking Criterion One for a maximum of 80 slots. Therefore, 20 slots would remain for Hospital B to apply for and receive under Ranking Criterion Two. Accordingly, we do not believe it is necessary to reorder Ranking Criteria One and Two (75 FR 72218).

We have recently been made aware that it may not always be true that Ranking Criteria One, Two, and even Three are not competing with each other. For example, in the case where the closed hospital was training residents in excess of its FTE resident caps, it is possible for hospitals to apply under Ranking Criteria One, Two, and/or Three for more slots than are available. However, under the policy expressed in the response quoted above from the November 24, 2010 final rule with comment period, because a hospital that takes over an entire program from the closed hospital is ranked under Ranking Criterion One, and a hospital that received slots from a Medicare GME affiliation agreement from the closed hospital is ranked under Ranking Criterion Two, all the slots could be assigned to the hospital under Ranking Criterion One, leaving no slots for hospitals ranked under Ranking Criterion Two or Three. (We note that in the first round of section 5506 awards associated with hospitals that closed between March 23, 2008, and August 3, 2010, this turned out *not* to be a concern because even in the case where a closed hospital was training residents in excess of its FTE caps at the time of closure, there were no applicants for the slots that simultaneously qualified under Ranking Criteria One, Two, and/or Three). For example, a hospital that closed has an FTE resident cap of 10, but when it closed, it was training 15 FTEs in an internal medicine program. Hospital A assumes at least 90 percent of the internal medicine program; that is, the ''entire'' program (a hospital that takes on 90 percent of the residents training in a particular program at the closed hospital within 5 years prior to the hospital's closure or at the time of the hospital's closure would be deemed to have assumed an ''entire'' program (75 FR 72218)). Ninety percent of the internal medicine program is 13.5 FTEs. Because Hospital A took over the ''entire'' internal medicine program, it applies for slots under Ranking Criterion One. Hospital B applies under Ranking Criterion Three because it assumes the other 10 percent of the program, or 1.5 FTEs. However, because the closed hospital's FTE resident cap was limited to 10, it would seem that all 10 slots would be assigned to Hospital A under Ranking Criterion One, leaving no slots for Hospital B under Ranking Criterion Three. Conversely, if Ranking Criteria One and Three were ranked as equals, the 10 slots could be prorated so that both Hospital A and Hospital B each receive a ''fair'' share.

Another example might be one in which a closed hospital that was training residents in excess of its FTE resident cap of 10 ''lent'' 2 of those 10 cap slots to Hospital C under the terms of a Medicare GME affiliation agreement. Although under the terms of the Medicare GME affiliation agreement, the hospital's FTE resident cap was reduced from 10 to 8, the hospital actually trained 9 FTEs, and continued to do so until it closed. Hospital D then assumes the 9 FTEs, or the entirety of the program that remained at the closed hospital when it closed. Again, one policy approach would be to rank the ranking criteria in descending order, and assign all 10 slots to Hospital D since Hospital D qualifies under Ranking Criterion One. Alternatively, another policy approach would be to treat Ranking Criteria One and Two as equals, and then a prorata share of the 10 slots could be given each to Hospital C and Hospital D.

After consideration of these scenarios, we believe that in the case where the closed hospital was training residents in excess of its FTE resident caps, prorating among hospitals that qualify under Ranking Criteria One, Two, and Three is not warranted. This is because we believe that a hospital that assumes an entire program from the closed hospital should be ranked highest, as it has taken the boldest step to ensuring the continuity of the closed hospital's program. As we explained first in the August 3, 2010 proposed rule (75 FR 46423) and again in the November 24, 2010 final rule with comment period (75 FR 72218), ''We note that we are proposing this ranking criterion regarding affiliated hospitals as second, after the first ranking criterion regarding applying hospitals that assume an entire

program or programs from the closed hospital because, even though section 5506 of the Affordable Care Act directs the Secretary to give preference to members of the same affiliated group, we believe that a hospital that assumes the responsibility for an entire program or programs demonstrates a commitment to maintain the programs to an even greater degree than does a hospital that was affiliated with the hospital that closed and may only be maintaining a portion of the residency program or programs.'' Similarly, we believe that because section 5506 of the Affordable Care Act does give preference to members of the same affiliated group as the closed hospital, hospitals qualifying for Ranking Criterion Two should receive slots first before hospitals qualifying for slots under Ranking Criterion Three. While we would encourage a hospital to assume a part of a closed hospital's program if it does not have the capacity to assume the entire program, such a hospital would be ranked under Ranking Criterion Three, still receiving preference before all hospitals that did not necessarily have any relationship with the closed hospital and that qualify under Ranking Criteria Four and below. As we stated in the November 24, 2010 final rule with comment period (75 FR 72226), ''we would still assign the slots to hospitals qualifying under Ranking Criteria One, Two, and Three in descending order.'' Therefore, in the instance where a closed hospital is training residents in excess of its FTE resident caps when it closes, we are clarifying that we would not prorate a closed hospital's FTE resident caps among applicant hospitals that qualify under Ranking Criteria One, Two, and Three.

f. Proposed Modifications to the Section 5506 CMS Evaluation Form

We are proposing to make numerous changes to the Section 5506 CMS Evaluation Form. Most of the changes are not substantive, but are intended to clarify the requirements on the form, and therefore, we will not list them each individually. There are several proposed changes that are more substantive, and we will enumerate those. First, we are proposing to change the name of the CMS Evaluation Form to the CMS Application Form. We believe this is a more appropriate name, as it is the form used by hospitals to apply for slots under section 5506. Second, there are several instances on the proposed CMS Application Form where we prompt the applicant to specify whether the application is for a particular program, or for general cap relief, or for slots associated with a Medicare GME affiliation agreement with the closed hospital (which we did not do on the preceding form). Third, we are clarifying the titles of the Demonstrated Likelihood Criteria (DLC). Specifically, the proposed title for Demonstrated Likelihood Criterion 1 is ''Establishing a New Residency Program'', the proposed title for Demonstrated Likelihood Criterion 2 is ''Taking Over All or Part of an Existing Residency Program from the Closed Hospital, or Expanding an Existing Residency Program,'' the proposed title for Demonstrated Likelihood Criterion 3 is ''Receiving Slots for General Cap Relief,'' and the proposed title for Demonstrated Likelihood Criterion 4 is ''Receiving Slots by Virtue of Medicare GME Affiliated Group Agreement with Closed Hospital.'' Fourth, we are proposing to add a category under Demonstrated Likelihood Criterion 2 stating that if the hospital currently has unfilled positions in a residency program that have previously been approved by the ACGME, AOA, or the ABMS, and the hospital is now seeking to fill those positions, the hospital must attach documentation clearly showing its current number of approved positions, and its current number of filled positions (as proof of the unfilled positions). Fifth, we are proposing to change the wording in Ranking Criteria 4, 5, and 6, respectively, from ''The applying hospital does not meet ranking criteria 1, 2, or 3'' to ''The program does not meet ranking criterion 1, 2, or 3'' because the latter is more accurate. That is, it is possible for a hospital to qualify under Ranking Criterion 1, 2, or 3 for a particular program, and also to apply for slots separately under Ranking Criterion 4, 5, or 6 for a different program. Sixth, we are proposing to add a new Ranking Criterion 7: *The program does not meet ranking criteria 1 through 6, and the slots for which the hospital is applying are for a primary care or a general surgery program, but the hospital is also applying for slots under Ranking Criterion Eight.* We also are renumbering what had been the previous Ranking Criterion 7 to be the proposed Ranking Criterion 8.

Following is the proposed revised section 5506 CMS Application Form:

CMS Application Form

As Part of the Application for the Increase in a Hospital's FTE Cap(s) under Section 5506 of the Affordable Care Act: Preservation of FTE Cap Slots from Teaching Hospitals that Close

Directions: Please fill out the information below for each residency program for which the applicant hospital intends to use the increase in its FTE cap(s). If the hospital is applying for general FTE cap relief (an increase in the hospital's FTE cap(s) in recognition of already training residents in excess of the hospital's cap(s)), that application must be submitted separately from an individual program request. If the hospital is applying for slots associated with a Medicare GME affiliation agreement with a hospital that closed, that application must also be submitted separately from an individual program request.

NAME OF HOSPITAL:

MEDICARE PROVIDER NUMBER:

NAME OF MEDICARE CONTRACTOR:

CORE-BASED STATISTICAL AREA (CBSA in which the hospital is physically located—write the 5 digit code here):

COUNTY NAME (in which the hospital is physically located):

Complete the following, as applicable:

1. Name of Specialty Training Program:

2. General FTE Cap Relief:

3. Medicare GME Affiliated Group:

(Check one):

☐ Allopathic Program

☐ Osteopathic Program

NUMBER OF FTE SLOTS REQUESTED FOR SPECIFIC PROGRAM (OR HOSPITAL OVERALL IF SEEKING GENERAL CAP RELIEF OR SLOTS ASSOCIATED WITH A MEDICATE GME AFFILIATED GROUP) AT YOUR HOSPITAL:

Direct GME: _____ IME: _____

Section A: Demonstrated Likelihood Criteria (DLC) of Filling the FTE Slots

The applicant hospital must provide documentation to demonstrate the likelihood of filling requested slots under section 5506 within the 3 academic years immediately following the application deadline to receive slots after a particular hospital closes. *Please indicate the specific use for which you are requesting an increase in your hospital's FTE cap(s). If you are requesting an increase in the hospital's FTE cap(s) for a combination of DLC1, DLC2, or DLC3, you must complete a separate CMS Application Form for each DLC and specify the distinct*

criterion from the list below within each Form.

Demonstrated Likelihood Criterion 1: Establishing a New Residency Program

The hospital does not have sufficient room under its direct GME FTE cap or IME FTE cap, or both, and will establish a new residency program in the specialty. **(The hospital must check at least one of the following.)**

☐ Application for approval of the new residency program has been submitted to the ACGME, AOA or the ABMS **(The hospital must attach a copy.)**

☐ The hospital has submitted an institutional review document or program information form concerning the new program in an application for approval of the new program. **(The hospital must attach a copy.)**

☐ The hospital has received written correspondence from the ACGME, AOA or ABMS acknowledging receipt of the application for the new program, or other types of communication from the accrediting bodies concerning the new program approval process (such as notification of site visit). **(The hospital must attach a copy.)**

☐ The hospital has other documentation demonstrating that it has made a commitment to start a new program **(The hospital must attach a copy.)**

Demonstrated Likelihood Criterion 2: Taking Over All or Part of an Existing Residency Program From the Closed Hospital, or Expanding an Existing Residency Program

The hospital does not have sufficient room under its direct GME FTE cap or IME FTE cap, or both, and a) has permanently taken over the closed hospital's entire residency program, or b) is permanently expanding its own previously established and approved residency program resulting from taking over part of a residency program from the closed hospital, or c) is permanently expanding its own existing residency program. **(The hospital must check at least one of the following.)**

☐ Application for approval to take over the closed hospital's residency program has been submitted to the ACGME, AOA, or the ABMS, or approval has been received from the ACGME, AOA, or the ABMS. **(The hospital must attach a copy.)**

☐ Application for approval of an expansion of the number of approved positions in its residency program resulting from taking over part of a residency program from the closed hospital has been submitted to the ACGME, AOA or the ABMS, or approval has been received from the ACGME, AOA, or the ABMS. **(The hospital must attach a copy.)**

☐ Application for approval of an expansion of the number of approved positions in its residency program has been submitted to the ACGME, AOA or the ABMS, or approval has been received from the ACGME, AOA, or the ABMS. **(The hospital must attach a copy.)**

☐ The hospital currently has unfilled positions in its residency program that have previously been approved by the ACGME, AOA, or the ABMS, and is now seeking to fill those positions. **(The hospital must attach documentation clearly showing its current number of approved positions, and its current number of filled positions).**

☐ The hospital has submitted an institutional review document or program information form concerning the program in an application for approval of an expansion to the program **(The hospital must attach a copy).**

Demonstrated Likelihood Criterion 3: Receiving Slots for General Cap Relief

☐ The hospital does not have sufficient room under its direct GME FTE cap or IME cap, or both, and is seeking an increase in its FTE cap(s) for general cap relief for residents that it is already training.

Demonstrated Likelihood Criterion 4: Receiving Slots by Virtue of Medicare GME Affiliated Group Agreement with Closed Hospital

☐ The hospital was listed as a participant of a Medicare GME affiliated group on the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed, and under the terms of that Medicare GME affiliation agreement, the applying hospital *received* slots from the hospital that closed, and the applying hospital will use the additional slots to continue to train at least the number of FTE residents it had trained under the terms of the Medicare GME affiliation agreement. If the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed was with a hospital that itself has closed or is closing, the applying hospital was listed as a participant in the next most recent Medicare GME affiliation agreement (but not one which was entered into more than 5 years prior to the hospital's closure) of which the first closed hospital was a member before the hospital closed, and that applying hospital *received* slots from the closed hospital under the terms of that affiliation agreement. **(Copies of EACH of the following must be attached.)**

- Copies of the recent Medicare GME affiliation agreement of which the applying hospital and the closed hospital were a member of before the hospital closed.
- Copies of the most recent accreditation letters for all of the hospital's training programs in which the hospital had a shared rotational arrangement (as defined at § 413.75(b)) with the closed hospital.

Section B. Level Priority Category

(Place an "X" in the appropriate box that is applicable to the level priority category that describes the applicant hospital.)

☐ First, to hospitals located in the same core-based statistical area (CBSA) as, or in a CBSA contiguous to, the hospital that closed.

☐ Second, to hospitals located in the same State as the closed hospital.

☐ Third, to hospitals located in the same region as the hospital that closed.

☐ Fourth, if the slots have not yet been fully distributed, to qualifying hospitals in accordance with the criteria established under section 5503, "Distribution of Additional Residency Positions"

Section C. Evaluation Criteria

(Place an "X" in the box for each criterion that is appropriate for the applicant hospital and for the program for which the increase in the FTE cap is requested.)

☐ Ranking Criterion One. *The applying hospital is requesting the increase in its FTE resident cap(s) because it is assuming (or assumed) an entire program (or programs) from the hospital that closed, and the applying hospital is continuing to operate the program (s) exactly as it had been operated by the hospital that closed (that is, same residents, possibly the same program director, and possibly the same (or many of the same) teaching staff).*

☐ Ranking Criterion Two. *The applying hospital was listed as a participant of a Medicare GME affiliated group on the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed, and under the terms of that Medicare GME affiliation agreement, the applying hospital received slots from the hospital that closed, and the applying hospital will use the additional slots to continue to train at least the number of FTE residents it had trained under the terms of the Medicare GME affiliation agreement. If the most recent Medicare*

GME affiliation agreement of which the closed hospital was a member before the hospital closed was with a hospital that itself has closed or is closing, preference would be given to an applying hospital that was listed as a participant in the next most recent Medicare GME affiliation agreement (but not one which was entered into more than 5 years prior to the hospital's closure) of which the first closed hospital was a member before the hospital closed, and that applying hospital received slots from the closed hospital under the terms of that affiliation agreement.

☐ Ranking Criterion Three. *The applying hospital took in residents displaced by the closure of the hospital, but is not assuming an entire program or programs, and will use the additional slots to continue training residents in the same programs as the displaced residents, even after those displaced residents complete their training (that is, the applying hospital is permanently expanding its own existing programs).*

☐ Ranking Criterion Four. *The program does not meet Ranking Criteria 1, 2, or 3, and the applying hospital will use additional slots to establish a new or expand an existing geriatrics residency program.*

☐ Ranking Criterion Five: *The program does not meet Ranking Criteria 1 through 4, the applying hospital is located in a HPSA, and will use all the additional slots to establish or expand a primary care or general surgery residency program.*

☐ Ranking Criterion Six: *The program does not meet Ranking Criteria 1 through 5, and the applying hospital is not located in a HPSA, and will use all the additional slots to establish or expand a primary care or general surgery residency program.*

☐ Ranking Criterion Seven: *The program does not meet Ranking Criteria 1 through 6, and the slots for which the hospital is applying are for a primary care or a general surgery program, but the hospital is also applying for slots under Ranking Criterion Eight.*

☐ Ranking Criterion Eight: *The applying hospital seeks the slots for purposes that do not fit into any of the above ranking criteria.*

Application Process and CMS Central Office and Regional Office Mailing Addresses for Receiving Increases in FTE Resident Caps

In order for hospitals to be considered for increases in their FTE resident caps, each qualifying hospital must submit a timely application. The following information must be submitted on applications to receive an increase in FTE resident caps:

- The name and Medicare provider number, and Medicare contractor (to which the hospital submits its cost report) of the hospital.
- The total number of requested FTE resident slots for direct GME or IME, or both.
- A completed copy of the CMS Application Form for each residency program for which the hospital intends to use the requested increase in FTE residents.
- Source documentation to support the assertions made by the hospital on the CMS Application Form.
- FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report. (If the CMS Form 2552–96 is applicable, include copies of Worksheets E, Part A, E–3, Part IV, and if a hospital received an increase to its FTE cap(s) under section 422 of the MMA, a copy of E–3, Part VI. If the CMS Form 2552–10 is applicable, include copies of Worksheets E, Part A, and E–4).
- An attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, of the following information:

''I hereby certify that I understand that misrepresentation or falsification of any information contained in this application may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under federal law. Furthermore, I understand that if services identified in this application were provided or procured through payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result. I also certify that, to the best of my knowledge and belief, it is a true, correct, and complete application prepared from the books and records of the hospital in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding Medicare payment to hospitals for the training of interns and residents.''

J. Proposed Changes to the Reporting Requirements for Pension Costs for Medicare Cost-Finding Purposes

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51693 through 51697), we finalized our policy for reporting costs of qualified defined benefit pension plans for Medicare cost-finding purposes. Specifically, beginning with cost reporting periods on or after October 1, 2011, a provider's pension cost for cost-finding purposes equals the cash basis contribution deposits plus any carry forward contributions, subject to a limitation. Providers with current contributions and carry forward contributions in excess of the limit may request approval of excess contributions, which will be reviewed on a case-by-case basis. Some or all of the excess contributions will be approved, as applicable, if it is determined that all or a portion of the excess contribution(s) are reasonable and necessary. To the extent that approval is granted, that portion of the excess is allowable as current period pension costs. We refer readers to the FY 2012 IPPS/LTCH PPS final rule for full details on this policy.

In addition to finalizing this new policy in the FY 2012 IPPS/LTCH PPS final rule, we stated that we intended to make future amendments to conform existing regulations to this final policy (76 FR 51693). The existing regulations at 42 CFR 413.24 and 413.100 specify that pension costs of qualified defined benefit plans are reported on an accrual basis of accounting method. Sections 413.24 and 413.100 provide that revenue is reported in the period in which it is earned, regardless of when it is collected and expenses are reported in the period in which they are incurred, regardless of when it is paid. For Medicare payment purposes, the costs are generally allowable in the year in which the costs are accrued and claimed, subject to specific exceptions. Furthermore, for accrued costs to be recognized for Medicare payment in the year of the accrual, the requirements must be met with respect to the liquidation of related liabilities. Therefore, to conform these two existing regulations to the final policy we adopted in the FY 2012 IPPS/LTCH PPS final rule with regard to pension costs for Medicare cost-finding purposes, we are proposing to amend the general cost reporting rules under §§ 413.24 and 413.100 to note the exception for recognizing actual pension contributions funded during the cost reporting period on a cash basis. We also plan to revise section 2305.2 of the Provider Reimbursement Manual to reflect this policy change.

K. Rural Community Hospital Demonstration Program

1. Background

Section 410A(a) of Public Law 108–173 required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing ''rural community hospitals'' to furnish covered inpatient hospital services to Medicare

beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Section 410A(a)(4) of Public Law 108–173 specified 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: 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).

CMS originally solicited applicants for the demonstration in May 2004; 13 hospitals began participation with cost report years beginning on or after October 1, 2004. In 2005, 4 of these 13 hospitals withdrew from the program and converted to CAH status. This left nine hospitals participating at that time. In 2008, we announced a solicitation for up to six 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 payment methodology with the hospital's first cost reporting period starting on or after July 1, 2008. At that time, 13 hospitals were participating in the demonstration.

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.) In CY 2011, one hospital that was among the original set of hospitals that participated in the demonstration withdrew from the demonstration. These actions left 7 of the originally participating hospitals (that is, hospitals that were selected to participate in either 2004 or 2008), participating in the demonstration program as of June 1, 2011.

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. Further, the Affordable Care Act requires, 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 to 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 Public Law 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 Pub. L. 108–173, as added by section 3123(a) of the Affordable Care Act and as further amended by section 10313 of such 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 that 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. We determined that each of these new hospitals would begin participating in the demonstration with its first cost reporting period beginning on or after April 1, 2011.

Three of these 19 hospitals declined participation prior to the start of the cost report periods for which they would have begun the demonstration. In addition to the 7 hospitals that were selected in either 2004 or 2008 and that are still participating, the new selection led to a total of 23 hospitals in the demonstration.

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 eight 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 FYs 2005 through 2012 IPPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, and 76 FR 51698, 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 2013 national IPPS rates.

In general terms, in each of these previous years, we used available cost reports for the participating hospitals to derive an estimate of the additional costs attributable for the demonstration. We used finalized, or settled, cost reports, as available, and ''as submitted'' cost reports for hospitals for which finalized cost reports were not available. Annual market basket percentage increase amounts provided by the CMS Office of the Actuary reflecting the growth in the prices of inputs for inpatient hospitals were applied to these cost amounts. An annual update factor provided by the CMS Office of the Actuary reflecting growth in the volume of inpatient operating services was also applied. For the budget neutrality calculations in the IPPS final rules for FYs 2005 through 2011, the annual volume adjustment applied was 2 percent; for the IPPS final rule for FY 2012, it was 3 percent. For a detailed discussion of our budget neutrality offset calculations, we refer readers to the IPPS final rule applicable to the fiscal year involved.

In general, for FYs 2005 through 2009, we based the budget neutrality offset estimate on the estimated cost of the demonstration in an earlier given year. For these periods, we derived that estimated cost by subtracting the estimated amount that would otherwise be paid without the demonstration in an earlier given year from the estimated amount for the same year that would be paid under the demonstration under the reasonable cost-based methodology authorized by section 410A of Public Law 108–173. (The reasonable cost-based methodology authorized by section 410A of Pub. L. 108–173, and as later amended by Pub. L. 111–148, as applicable to the year, is hereafter referred to as the ''reasonable cost methodology.'' We refer readers to section 410A(b) and (g)(4) of Pub. L. 108–173 and Pub. L. 111–148.) (We ascertained the estimated amount that would be paid in an earlier given year under the reasonable cost methodology and the estimated amount that would otherwise be paid without the demonstration in an earlier given year from ''as submitted'' cost reports that were submitted by the hospitals prior to the inception of the demonstration.) We then updated the estimated cost described above to the current year by multiplying it by the market basket percentage increases applicable to the years involved and the applicable annual volume adjustments. For the FY 2010 IPPS final rule, data from finalized cost reports reflecting the participating hospitals' experience under the demonstration were available. Specifically, the finalized cost reports for the first 2 years of the demonstration, that is, cost reports for cost reporting years beginning in FYs 2005 and 2006 (CYs 2004, 2005, and 2006) were available. These data showed that the actual costs of the demonstration for these years exceeded the amounts originally estimated in the respective final rules for the budget neutrality adjustment. In the FY 2010 IPPS/LTCH PPS final rule, we included in the budget neutrality offset amount an amount in addition to the estimate of the demonstration costs in that fiscal year. This additional amount was based on the amount that the costs of the demonstration for FYs 2005 and 2006 exceeded the budget neutrality offset amounts finalized in the IPPS rules applicable for those years.

Following upon the FY 2010 IPPS/LTCH PPS final rule, we have continued to propose a methodology for calculating the budget neutrality offset amount to account for both the estimated demonstration costs in the upcoming fiscal year and an amount by which the actual demonstration costs corresponding to an earlier, given year (which would be known once we have finalized cost reports for that year) exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule. However, we note that on account of a delay affecting the settlement process for cost reports for IPPS hospitals occurring on a larger scale than merely for the demonstration, we have been unable to finalize this component of the budget neutrality offset amount accounting for the amount by which the actual demonstration costs in a given year exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule for cost reports of demonstration hospitals dating to those beginning in FY 2007. (For only a small fraction of the hospitals that have participated in the demonstration from FY 2007 to FY 2010 have cost reports been finalized in any year, making the overall calculation of this component of the budget neutrality impossible at this time for any given year.)

2. Proposed FY 2013 Budget Neutrality Offset Amount

We revisited the issue of which cost reports to propose to use for calculating the FY 2013 budget neutrality offset amount. Although we used finalized cost reports where available for the FYs 2010, 2011, and 2012 IPPS/LTCH PPS final rules, for FY 2013, we are proposing to use the ''as submitted'' cost report for each hospital participating in the demonstration for the cost report period ending in CY 2010 in estimating the costs of the demonstration. We believe a way to streamline our methodology for calculating the budget neutrality offset amount would be to use cost reports all with the same status (that is, only ''as submitted'' cost reports as opposed to a mix of ''as submitted'' and ''settled'' cost reports) from the same time period for all hospitals participating in the demonstration (as opposed to varying cost reports of statuses from varying years for the various hospitals as has been done previously). Therefore, because ''as submitted'' cost reports ending in CY 2010 are the most recent complete set of cost reports for all demonstration hospitals, we are proposing to use these cost reports for our budget neutrality offset estimate. Further, because ''as submitted'' cost reports ending in CY 2010 are recent available cost reports, we believe they would be an accurate predictor of the costs of the

demonstration in FY 2013 because they give us a recent picture of the participating hospitals' costs.

In revisiting the issue of which data sets to propose to use in the budget neutrality offset amount calculation, we also revisited the methodology for calculating the budget neutrality offset amount. In this proposed rule, we are proposing changes to that methodology in an effort to further improve and refine it. We note that the proposed methodology varies, in part, from that finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51698 through 51707). Specifically, in proposing refinements to the methodology, we would simplify the calculation so that it includes only a few steps. In addition, we are proposing to incorporate different update factors (the market basket percentage increase and the applicable percentage increase, as applicable, to several years of data as opposed to solely using the market basket percentage increase) for the calculation of the budget neutrality offset amount. As explained in greater detail below, we believe this approach would maximize the precision of our calculation because we believe it would more closely replicate payments made with and without the demonstration.

We note that, although we are proposing changes to certain aspects of the budget neutrality offset amount calculation, several core components of the methodology would remain unchanged. For example, we are continuing to propose to include in the budget neutrality offset amount the estimate of the demonstration costs for the upcoming fiscal year and the amount by which the actual demonstration costs corresponding to an earlier given year (which would be known once we have finalized cost reports for that year) exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule).

The proposed methodology for calculating the estimated FY 2013 demonstration cost for the 23 currently participating hospitals is as follows:

Step 1: For each of the 23 participating hospitals, we are proposing to identify the general reasonable cost amount calculated under the reasonable cost methodology for covered inpatient hospital services (as indicated on the ''as submitted'' cost report for the hospital's cost reporting period ending in CY 2010) in FY 2010. The general reasonable cost amount calculated under the reasonable cost methodology for any applicable year is hereafter referred to as the ''reasonable cost amount.''

Because section 410A of Public Law 108–173 stipulates swing-bed services are to be included among the covered inpatient hospital services for which the demonstration payment methodology applies, we also are proposing to include the cost of these services, as reported on the cost reports for the hospitals that provide swing-bed services, within the general total estimated FY 2010 reasonable cost amount for covered inpatient hospitals services under the demonstration. As indicated above, we are proposing to use ''as submitted'' cost reports for the hospital's cost reporting period ending in CY 2010 for this calculation.

We are proposing to sum the two above-referenced amounts to calculate the general total estimated FY 2010 reasonable cost amount for covered inpatient hospital services for all 23 hospitals.

We are proposing to multiply this sum (that is, the general total estimated FY 2010 reasonable cost amount for covered inpatient hospital services for all 23 hospitals) by the FYs 2011 through 2013 IPPS market basket percentage increases, which were formulated by the CMS Office of the Actuary. In this proposed rule, the current estimate of the FY 2013 IPPS market basket percentage increase provided by the CMS Office of the Actuary is indicated in section IV.H.1. of this preamble.) We also are proposing to then multiply the product of the general total estimated FY 2010 reasonable cost amount for all 23 hospitals and the market basket percentage increases applicable to the years involved by a 3-percent annual volume adjustment for the years 2011 through 2013—the result would be the general total estimated FY 2013 reasonable cost amount for covered inpatient hospital services for all 23 hospitals.

We are proposing to apply the IPPS market basket percentage increases applicable for FYs 2011 through 2013 to the FY 2010 reasonable cost amount described above to model the estimated FY 2013 reasonable cost amount under the demonstration. We are proposing to use the IPPS market basket percentage increases because we believe that these update factors appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology for the years involved. The 3-percent annual volume adjustment was stipulated last year by the CMS Office of the Actuary and is proposed because it is intended to accurately reflect the tendency of hospitals' inpatient caseloads to increase. We acknowledge the possibility that inpatient caseloads for small hospitals may fluctuate, and are proposing to incorporate into the estimate of demonstration costs a factor to allow for a potential increase in inpatient hospital services.

Step 2: For each of the 23 hospitals, we are proposing to identify the general estimated amount that would otherwise be paid in FY 2010 under applicable Medicare payment methodologies for covered inpatient hospital services (as indicated on the ''as submitted'' cost report for cost reporting periods ending in CY 2010) if the demonstration was not implemented. Similarly, as in Step 1, for the hospitals that provide swing-bed services, we are proposing to identify the estimated amount that generally would otherwise be paid for these services (as indicated on the ''as submitted'' cost report for cost reporting periods ending in CY 2010) and include it in the total FY 2010 general estimated amount that would otherwise be paid for covered inpatient hospital services without the demonstration. We are proposing to sum these two amounts in order to calculate the estimated FY 2010 total payments that generally would otherwise be paid for covered inpatient hospital services for all 23 hospitals without the demonstration.

We are proposing to multiply the above amount (that is, the estimated FY 2010 total payments that generally would otherwise be paid for covered inpatient hospital services for all 23 hospitals without the demonstration) by the FYs 2011 through 2013 IPPS applicable percentage increases and the proposed 3 percent annual volume adjustment for FYs 2011 through 2013—the result would be the general total estimated FY 2013 costs that would be paid without the demonstration for covered inpatient hospital services to the 23 participating hospitals. In this proposed rule, the current estimate of the FY 2013 IPPS applicable percentage increase is 2.1 percent. This methodology differs from Step 1, in which we are proposing to apply the market basket percentage increases to the sum of the hospitals' general total FY 2010 estimated reasonable cost amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate factors to update the estimated amounts that generally would otherwise be paid without the demonstration. This is because IPPS payments would constitute the majority of payments that would otherwise be made without the demonstration and the applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates.

Hospitals participating in the demonstration would be participating under the IPPS payment methodology if they were not in the demonstration. We note that such use of the applicable percentage increase would represent a shift from formulations in previous years of the budget neutrality offset amount. In this FY 2013 proposed rule, we are trying to increase the precision of the different nature of the projections that we are proposing for estimating the reasonable cost amounts and the estimated payments that would otherwise be paid without the demonstration.

Step 3: We are proposing to subtract the amount derived in Step 2 (representing the sum of estimated amounts that generally would otherwise be paid to the 23 hospitals for covered inpatient hospital services for FY 2013 if the demonstration was not implemented) from the amount derived in Step 1 (representing the sum of the estimated reasonable cost amount that generally would be paid under the demonstration to all 23 hospitals for covered inpatient hospital services for FY 2013). We are proposing that the resulting difference would be the amount for which an adjustment to the national IPPS rates would be calculated.

For this proposed rule, the resulting difference is $35,077,708. For this FY 2013 IPPS/LTCH PPS proposed rule, this amount is the estimated amount for which an adjustment to the national IPPS rates is being calculated. This estimated amount is based on the specific assumptions identified regarding the data sources that are used, that is, ''as submitted'' recently available cost reports. We note that if updated data become available prior to the FY 2013 final rule, we are proposing to use them to the extent appropriate to estimate the costs of the demonstration program in FY 2013. Therefore, this estimated budget neutrality offset amount may change in the final rule depending on the availability of updated data. Similar to previous years, we are proposing that if settled cost reports for all of the demonstration hospitals that participated in the applicable fiscal year (FY 2007, 2008, 2009, or 2010) are available prior to the FY 2013 IPPS/LTCH PPS final rule, we will include in the budget neutrality offset amount any additional amounts by which the final settled costs of the demonstration for the year (FY 2007, 2008, 2009, or 2010) exceeded the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule. (The final settled costs of the demonstration for a year would be calculated by subtracting the total amount that would otherwise be paid under the applicable Medicare payment systems without the demonstration for the year from the amount paid to those hospitals under the reasonable cost methodology for such year.)

L. Hospital Routine Services Furnished Under Arrangements

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51711 through 51714), we included a provision that limits the circumstances under which a hospital may furnish services to Medicare beneficiaries ''under arrangement.'' Under the revised policy, therapeutic and diagnostic services are the only services that may be furnished under arrangements outside of the hospital to Medicare beneficiaries. ''Routine services'' (that is, bed, board, and nursing and other related services) must be furnished by the hospital. Under this revised policy, routine services furnished to Medicare beneficiaries as inpatients of the hospital are considered services furnished by the hospital. If these services are furnished outside of the hospital, the services are considered to be furnished ''under arrangement.''

We have become aware that a number of affected hospitals need additional time to restructure existing arrangements and establish necessary operational protocols to comply with the requirement that therapeutic and diagnostic services are the only services that may be furnished outside of the hospital to Medicare beneficiaries ''under arrangement,'' and that ''routine services'' must be furnished by the hospital. While we still believe that our policy is correct and consistent with the statutory language, we also believe that because a number of hospitals are actively pursuing compliance (often building construction or restructuring is involved), it is appropriate to postpone the effective date of this requirement to give hospitals additional time to comply with the provision.

Therefore, we are proposing to change the implementation date of this requirement to be effective for cost reporting periods beginning on or after October 1, 2013. We expect that, during FY 2013, hospitals will complete the work needed to ensure compliance with the new requirement. Beginning with a hospital's FY 2014 cost reporting period, we expect that all hospitals would be in full compliance with the revised policy for services furnished under arrangement. We will continue to work with affected hospitals to communicate the requirement established by this provision, and to provide continued guidance regarding compliance with the provision.

M. Proposed Technical Change

In an interim final rule that appeared in the November 27, 2007 **Federal Register** (72 FR 66895 through 66897), we made changes to the regulations governing the application of the emergency Medicare GME affiliation agreement rules in order to address the needs of hospitals located in the section 1135 emergency area in the aftermath of Hurricane Katrina and Rita. In that rule, we changed the length of emergency affiliation agreements from 3 years to 5 years under 42 CFR 413.79(f)(7) (then § 413.79(f)(6)); that is, we specified that the emergency Medicare GME affiliation agreement must terminate no later than the conclusion of 4 academic years following the academic year during which the section 1135 emergency period began. However, we inadvertently did not make a conforming change to 42 CFR 413.79(f)(7)(i)(B). We are proposing to change the regulatory text specified § 413.79(f)(7)(i)(B) to make it consistent with the regulatory text under § 413.79(f)(7).

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. The IPPS for capital-related costs was initially implemented 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, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF)) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at § 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under §§ 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, as noted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725 and 51804), FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Finally, under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, § 412.300(b) of the regulations defines a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS a new hospital is paid 85 percent of its 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 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. 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. Capital IPPS payments to hospitals located in Puerto Rico are computed based on a blend of 25 percent of the capital IPPS Puerto Rico rate and 75 percent of the capital IPPS Federal rate. For additional details on capital IPPS payments to hospitals located in Puerto Rico, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

C. Proposed Changes in the Documentation and Coding Adjustment for FY 2013

1. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), 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 2009 IPPS final rule with comment period (73 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).)

For the FY 2011 IPPS/LTCH PPS proposed and final rules, 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. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50355), we implemented an additional 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. Consistent with past practice, this −2.9 percent adjustment was applied in a cumulative manner, which yielded a combined effect of −4.4 percent. (For additional information on our estimate of the 5.4 percent cumulative documentation effect under the MS–DRG system for FYs 2008 and 2009 and the additional −2.9 percent documentation and coding adjustment applied to the national capital Federal rate in FY 2011, we refer readers to the

FY 2011 IPPS/LTCH PPS proposed rule (75 FR 24014) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50355)).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51727), we made an additional −1.0 percent adjustment to the national capital Federal rate to account for the remainder of the 5.4 percent estimate of the cumulative effect of documentation and coding changes under the MS–DRG system that occurred during FYs 2008 and 2009. Consistent with past practice, this −1.0 percent adjustment was applied in a cumulative manner, which yielded a combined effect of −5.4 percent.

2. Prospective Documentation and Coding Adjustment to the National Capital Federal Rate for FY 2013 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 in those years absent the change to the MS–DRGs. 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 noted 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 the estimated 5.4 percent documentation and coding effect of documentation and coding changes under the MS–DRG system for FYs 2008 and 2009 (that is, −0.6 percent in FY 2008, −0.9 percent in FY 2009, −2.9 percent in FY 2011, and −1.0 in FY 2012).

As discussed in greater detail in section II.D.10. of this preamble, we believe it is appropriate to analyze claims data from FY 2010 to determine whether any additional adjustment would be required to ensure that the adoption of MS–DRGs was implemented in a budget neutral manner. Specifically, for this proposed rule, we analyzed FY 2010 data on claims paid through December 2011 using our existing methodology (as described in section II.D.4. of this preamble). Based on this analysis, our actuaries determined that implementation of the MS–DRG system resulted in a 6.2 percent change in case-mix due to documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2010. This is an estimated additional 0.8 percentage point increase over the 5.4 percent reduction currently applied to the national capital Federal rate.

Therefore, 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 consistent with our proposal for the operating IPPS standardized amounts (discussed in section II.D.5. of this preamble), we are proposing to reduce the national capital Federal rate in FY 2013 by an additional 0.8 percent to account for the remainder of the cumulative effect of the estimated changes in documentation and coding under the MS–DRG system that did not reflect an increase in case-mix severity in FY 2010. Furthermore, consistent with the documentation and coding adjustments we have made in the past, we are proposing to leave the proposed −0.8 percent adjustment in place for FY 2013 and subsequent fiscal years to account for the effect those years. As explained above, this proposed −0.8 percent adjustment accounts for the remainder of our current estimate of the cumulative effect of documentation and coding changes under the MS–DRG system that occurred during FYs 2008, 2009, and 2010 of 6.2 percent minus the existing cumulative adjustment already applied to the national capital Federal rate of −5.4 percent. We note that this proposed adjustment only adjusts the national capital Federal rate prospectively. It does not attempt to recoup any excess payments that have resulted in FYs 2010, 2011, and 2012 as a result of this additional effect of documentation and coding in those years.

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. We also explained that we continue to believe that an adjustment for such increases 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, 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 the −2.6 percent adjustment will remain 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. Therefore, the −2.6 percent adjustment to the capital

Puerto Rico-specific rate made in FY 2011 reflects the entire amount of our estimate at that time 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.

As discussed above, for this proposed rule, we analyzed FY 2010 data on claims paid through December 2011 using our existing methodology to determine if any additional adjustment for the effects of documentation and coding that did not reflect real changes in case-mix is warranted. Based on this analysis (which is described in greater detail in section II.D.10. of this preamble), we found no significant additional effect of documentation and coding that would warrant any additional adjustment. Therefore, we are not proposing any additional adjustment to the capital Puerto Rico-specific rate for FY 2013 for the effect of documentation and coding that did not reflect real changes in case-mix.

D. Proposed Changes for Annual Update for FY 2013

The annual update to the capital IPPS Federal and Puerto Rico-specific rates, as provided for at § 412.308(c), proposed for FY 2013 is discussed in section III. of the Addendum to this proposed rule.

VI. Proposed Changes for Hospitals Excluded From the IPPS

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 2013 rate-of-increase percentage to be applied to the target amount for cancer and children's hospitals and RNHCIs would be the FY 2013 percentage increase in the IPPS operating market basket. For this proposed rule, the FY 2013 percentage increase in the IPPS operating market basket is currently estimated to be 3.0 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 2013, 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.

We are proposing to use the FY 2006-based IPPS operating market basket to update the target amounts for children's and cancer hospitals and RNHCIs for FY 2013. Therefore, based on IHS Global Insight, Inc.'s 2012 first quarter forecast, with historical data through the 2011 fourth quarter, the current estimate of the IPPS operating market basket update for FY 2013 is 3.0 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 2013.

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 2013. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

VII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2013

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 from payments under the TEFRA System to payments under the LTCH PPS. 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).

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51733 through 51743) for a chronological summary of the main legislative and regulatory developments affecting the LTCH PPS through the annual update cycles prior to this FY 2013 rulemaking cycle.

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 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 short-stay outlier (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 health care 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 2013

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.)

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 2013, we are not proposing to create or delete any MS–DRGs, and as such we would continue to have a total of 751 MS–DRG groupings for FY 2013. 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).) Consistent with our existing methodology, we also are proposing to account for adjustments to payments for 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 continue 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 methodology to adjust the 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 nine and six, respectively. However, for claims submitted on the 5010 format beginning January 1, 2011, we increased 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. In prior rules published in the **Federal Register** (for example, section II.G.11. of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50122 through 50128)), we discussed the implementation date for the conversion to the ICD–10–CM and ICD–10–PCS coding systems. We refer readers to section II.G.9. 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 one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication 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 2013

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, 2012, through September 30, 2013 (FY 2013) consistent with the changes to specific MS–DRG classifications presented in section II.G. of this preamble (that is, proposed GROUPER Version 30.0). Therefore, the proposed MS–LTC–DRGs for FY 2013 presented in this proposed rule are the same as the proposed MS–DRGs that are being proposed for use under the IPPS for FY 2013. In addition, because the proposed MS–LTC–DRGs for FY 2013 are the same as the proposed MS–DRGs for FY 2013, the other changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under proposed Version 30.0 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 2013.

3. Development of the Proposed FY 2013 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 our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity, the basic methodology for developing the proposed FY 2013 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). (For additional details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550).) 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 calculated 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 2013

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 (72 FR 26882 through 26884). Consistent with § 412.517(b), we are proposing to continue to apply our established 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 proposed annual update to the MS–LTC–DRG classifications and relative weights for FY 2013 are based on the FY 2012 MS–LTC–DRG classifications and relative weights established in Table 11 listed in section VI. of the Addendum to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51813).

c. Data

In this proposed rule, to calculate the proposed MS–LTC–DRG relative weights for FY 2013, we are proposing to obtain total charges from FY 2011 Medicare LTCH bill data from the December 2011 update of the FY 2011 MedPAR file, which are the best available data at this time, and to use the proposed Version 30.0 of the GROUPER to classify LTCH cases. Consistent with our existing methodology, we also are proposing that if more recent data become available, we would use those data and the finalized Version 30.0 of the GROUPER in establishing the FY 2013 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. Furthermore, consistent with our historical practice, we are proposing to continue to exclude Medicare Advantage (Part C) claims, which are now included in the MedPAR files, in the calculations for the relative weights under the LTCH PPS that are used to determine payments for Medicare fee-for-service claims. Specifically, under this proposal, we are not using 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). Accordingly, in the development of the proposed FY 2013 MS–LTC–DRG relative weights in this proposed rule, we are proposing to exclude the data of 14 all-inclusive rate providers and the 2 LTCHs that are paid in accordance with demonstration projects that had claims in the December 2011 update of the FY 2011 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 treatment of infections 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 2013. We believe this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this proposed methodology, we 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, under this proposal, we would continue to standardize charges for each case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in section VII.B.3.g. (Step 3) of this preamble) 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. Proposed Treatment of Severity Levels in Developing the 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 are 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 the treatment of severity levels in determining the proposed MS–LTC–DRG relative weights for FY 2013. (We provide in-depth discussions of our 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 this preamble.)

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 2013 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 2013 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, for purposes of determining the proposed FY 2013 MS–LTC–DRG relative weights, we are proposing to continue to employ the quintile methodology for proposed low-volume MS–LTC–DRGs, such that we group the proposed ''low-volume MS–LTC–DRGs'' (that is, proposed MS–LTC–DRGs that 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 2013 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 2011 update of the FY 2011 MedPAR file, we identified 307 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 61 proposed MS–LTC–DRGs (307/5 = 61 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 184th proposed low-volume MS–LTC–DRG in the sorted list is closer to the average charge of the 185th proposed low-volume MS–LTC–DRG (assigned to Quintile 4) than to the average charge of the 183rd proposed low-volume MS–LTC–DRG (assigned to Quintile 3), we are proposing to assign it to Quintile 4 (such that Quintile 4 contains 62 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 61 MS–LTC–DRGs (Quintiles 1, 2, and 3) and the other 2 low-volume quintiles contain 62 MS–LTC–DRGs (Quintiles 4 and 5). 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 quintiles for MS–LTC–DRGs for FY 2013.

Accordingly, in order to determine the proposed FY 2013 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 Table 13A (listed in section VI. of the Addendum to this proposed rule and available via the Internet) was used in determining the proposed FY 2013 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 this preamble. 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 made 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 most recent 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 2013 MS–LTC–DRG Relative Weights

In this proposed rule, we are proposing to determine the FY 2013 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, to determine the proposed FY 2013 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 2013 relative weights by first removing statistical outliers and cases with a length of stay of 7 days or less (Steps 1 and 2 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 7 days or less (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 2013 MS–LTC–DRG relative weights. We note that, as we discussed 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 December 2011 update of the FY 2011 MedPAR file.

Step 1—Remove statistical outliers.

The first step in the calculation of the proposed FY 2013 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 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 2013 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 2013 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 2013 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 2013 MS–LTC–DRG relative weights would lower the proposed FY 2013 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 2013 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, we are proposing to calculate the FY 2013 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 2013 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. These LTCHs' hospital-specific relative charge values (from above) are then multiplied by these hospital-specific case-mix indexes. These hospital-specific case-mix adjusted relative charge values are then used to calculate a new set of proposed MS–LTC–DRG relative weights across all LTCHs. This iterative process is continued until there is convergence between the weights produced at adjacent steps, for example, when the maximum difference is less than 0.0001.

Step 5—Determine a proposed FY 2013 relative weight for MS–LTC–DRGs with no LTCH cases.

As we stated above, we are proposing to determine the proposed FY 2013 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 2011 update of the FY 2011 MedPAR file for this proposed rule). Using these data, we identified the proposed MS–LTC–DRGs for which there are 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 2011 and, therefore, no charge data are available for these proposed MS–LTC–DRGs. Thus, in the process of determining the proposed MS–LTC–DRG relative weights, we are 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 2013 relative weights for the proposed MS–LTC–DRGs with no LTCH cases in the December 2011 update of the FY 2011 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 is assigned the same relative weight (and average length of stay) of the proposed MS–LTC–DRG to which it is cross-walked (as described in greater detail below).

Of the 751 proposed MS–LTC–DRGs for FY 2013, we identified 213 proposed MS–LTC–DRGs for which there are 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 213 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 538 (751 − 213 = 538) proposed MS–LTC–DRGs for which we are able to determine proposed relative weights based on FY 2011 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 213 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 are LTCH cases in the December 2011 update of the FY 2011 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 is cross-walked in order to assign an appropriate proposed relative weight for the proposed no-volume MS–LTC–DRGs in FY 2013. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the proposed no-volume MS–LTC–DRGs in FY 2013, 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 2013. We note that if the proposed cross-walked MS–LTC–DRG had 25 cases or more, its proposed relative weight, which is calculated using the proposed methodology described in Steps 1 through 4 above, is 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, is 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 2013. (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 2013 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 2013 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 2013 provided in Table 13B.

Example: There are no cases in the FY 2011 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 Cerebrovascular Disorders with MCC) is 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 0.8135 for FY 2013 to MS–LTC–DRG 61 (Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via 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 used 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 2013, 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 2013 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 increases (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 2013 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 2013 MS–LTC–DRG relative weights in this proposed rule by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet.

Step 7— Calculate the proposed FY 2013 budget neutrality factor.

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881 and 26882).)

The MS–LTC–DRG classifications and relative weights are updated annually based on the most recent available LTCH claims data to reflect changes in relative LTCH resource use (§ 412.517(a) in conjunction with § 412.503). 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 2013 based on the most recent available LTCH data, and to apply a budget neutrality adjustment in determining the proposed FY 2013 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, for FY 2013, we are proposing 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 2013 (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 2011) and grouped them using the proposed FY 2013 GROUPER (Version 30.0) and the proposed recalibrated FY 2013 MS–LTC–DRG relative weights (determined in steps 1 through 6 of the Steps for Determining the Proposed FY 2013 MS–LTC–DRG Relative Weights above) to calculate the average CMI; (1.b.) we grouped the same LTCH claims data (FY 2011) using the FY 2012 GROUPER (Version 29.0) and FY 2012 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 2012 (determined in Step 1.b.) by the average proposed CMI for FY 2013 (determined in Step 1.a.). In determining the proposed MS–LTC–DRG relative weights for FY 2013, each proposed recalibrated MS–LTC–DRG relative weight was multiplied by 1.12393 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produced proposed ''normalized relative weights.''

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 2013 MS–LTC–DRG classifications and relative weights) are equal to estimated aggregate LTCH PPS payments before reclassification and recalibration (that is, the FY 2012 MS–LTC–DRG classifications and relative weights). Accordingly, consistent with our existing methodology, we are proposing to use FY 2011 discharge data to simulate payments and compare estimated aggregate LTCH PPS payments using the FY 2012 MS–LTC–DRGs and relative weights to estimate aggregate LTCH PPS payments using the proposed FY 2013 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 2013 in the final rule.

For this proposed rule, we are proposing to determine the proposed FY 2013 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 2013 and proposed GROUPER Version 30.0 (as described above); (2.b.) we simulated estimated total LTCH PPS payments using the FY 2012 GROUPER (Version 29.0) and the FY 2012 MS–LTC–DRG relative weights in Table 11 of the Addendum to the FY 2012 IPPS/LTCH PPS final rule available on the Internet (76 FR 51813); 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 2012 GROUPER (Version 29.0) and the FY 2012 MS–LTC–DRG relative weights (determined in Step 2.b.) by the estimated total LTCH PPS payments using the proposed FY 2013 GROUPER (Version 30.0) and the proposed normalized MS–LTC–DRG relative weights for FY 2013 (determined in Step 2.a.). In determining the proposed FY 2013 MS–LTC–DRG relative weights, each proposed normalized relative weight was multiplied by a budget neutrality factor of 0.9881603 (determined in Step 2.c.) in the second step of the proposed budget neutrality methodology to determine the proposed budget neutral FY 2013 relative weight for each proposed MS–LTC–DRG.

Accordingly, in determining the proposed FY 2013 MS–LTC–DRG relative weights in this proposed rule, consistent with our existing methodology, we are proposing to apply a normalization factor of 1.12393 and a budget neutrality factor of 0.9881603 (computed as described above). Table 11, which is listed in section 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, five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)), and the proposed ''IPPS Comparable Thresholds'' (used in determining SSO payments under § 412.529(c)(3)), for FY 2013. The proposed FY 2013 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 1.12393 and the proposed budget neutrality factor of 0.9881603.

C. Proposed Use of a LTCH-Specific Market Basket 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. Those types of hospitals are not paid under a PPS. Also, the FY 2002 cost structures for cancer and children's hospitals are noticeably different from the cost structures for 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 only reflects the cost structures for LTCHs. However, as we discussed in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43967 through 43968), we were in the process of conducting further research to assist us in understanding the underlying reasons for the variations in costs and cost structures between freestanding IRFs and hospital-based IRFs, as well as between freestanding IPFs and hospital-based IPFs. At this time, we remain unable to sufficiently explain the observed differences in costs and cost structures between hospital-based IRFs and freestanding IRFs and between hospital-based IPFs and freestanding IPFs.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51756), we finalized the rebasing and revising of the FY 2002-based RPL market basket by creating and implementing an FY 2008-based RPL market basket. We also discussed that we were 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 could be used to update payments under both the IPF and IRF payment systems. We continue our research in this area. The other market basket would be a stand-alone LTCH market basket. We stated that, depending on the outcome of our research, we may propose a stand-alone LTCH market basket in the next LTCH PPS update cycle. We received several public comments in response to the FY 2012 proposed rule, all of which supported deriving a stand-alone LTCH market basket (76 FR 51756 through 51757).

As we routinely do, we have revisited the issue of the market basket used in the LTCH PPS. We previously did not estimate stand-alone market baskets for IRFs, IPFs, and LTCHs because of small sample sizes for freestanding facilities and the data concerns associated with the hospital-based facilities. Although we continue to do research in this area, at this time, we believe it is appropriate to move forward with a proposal to create a LTCH-specific market basket. This is because we believe we have sufficiently robust data to create such a market basket, and no longer need to rely on the cost report data from IPPS hospitals or from IRFs, IPFs, and LTCHs combined. Specifically, over the last several years, the number of LTCH facilities submitting a Medicare cost report has increased, helping to address concerns regarding the size of the available pool of facilities. The completeness and quality of the Medicare cost reports that we have been evaluating over the last several years have improved as well. Therefore, consistent with our intention to use the latest available and complete cost report data, we believe that it would be appropriate to create a market basket that would specifically reflect the cost structures of LTCHs based on Medicare cost report data for FY 2009, which are for cost reporting periods beginning on and after October 1, 2008, and before October 1, 2009. We are proposing to use data from cost reports beginning in FY 2009 because these data are the latest available complete data and, therefore, we believe it will enable us to accurately calculate cost weights that specifically reflect the cost structures of LTCHs. As a result, in this FY 2013 proposed rule, we are proposing to create a LTCH-specific market basket based solely on Medicare cost report data from LTCHs of which the majority of the reports are settled. In the following discussion, we provide an overview of the proposed market basket and describe the methodologies we are proposing to use for determining the operating and capital portions of the proposed FY 2009-based LTCH-specific market basket.

2. Overview of the Proposed FY 2009-Based LTCH-Specific Market Basket

The proposed FY 2009-based LTCH-specific 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 (that is, intensity) of goods and services 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 2009 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 weights'' or ''expenditure weights.'' Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost 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 that 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 Development of a LTCH-Specific Market Basket

We are inviting public comments on our proposed methodology, discussed below, for deriving a LTCH-specific market basket.

a. Development of Cost Categories

(1) Medicare Cost Reports

The proposed FY 2009-based LTCH-specific market basket consists of several major cost categories derived from the FY 2009 LTCH Medicare cost reports as described previously, including wages and salaries, employee benefits, contract labor, pharmaceuticals, professional liability insurance, capital, and a residual. These FY 2009 Medicare cost reports are for cost reporting periods beginning on and after October 1, 2008, and before October 1, 2009. We are proposing to use FY 2009 as the base year because we believe that the FY 2009 Medicare cost reports represent the most recent, complete set of Medicare cost report data available for LTCHs.

Medicare cost report data include costs for all patients, including Medicare, Medicaid, and private payer. Because our goal is to measure cost shares for facilities that serve Medicare beneficiaries, and are reflective of case-mix and practice patterns associated with providing services to Medicare beneficiaries in LTCHs, we are proposing to limit our selection of Medicare cost reports to those from LTCHs 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. Similar to our methodology for the FY 2008-based RPL market basket, we are proposing to use the cost reports submitted by LTCHs 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 2008-based RPL market basket and generally includes those LTCHs with Medicare average length of stay within approximately 5 days of the facility average length of stay of the hospital.

Using this set of Medicare cost reports, we then calculated cost weights for six cost categories, and a residual category as represented by all other costs, directly from the FY 2009 Medicare cost reports submitted by LTCHs (found in Table VII.C–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 2009-based LTCH-specific market basket cost weights.

The methodology used to develop the proposed FY 2009-based LTCH-specific market basket cost weights is generally the same methodology used to develop the FY 2008-based RPL market basket cost weights, with the exception of the employee benefits and contract labor cost weights. For the FY 2008-based RPL market basket, there was an issue with obtaining data specifically for employee benefits and contract labor from the set of FY 2008 Medicare cost reports, as IRFs, IPFs, and LTCHs were not required to complete the Medicare cost report worksheet from which these data were collected (Worksheet S3, Parts II and III). As a result, only a proportion of the total number of IRFs, IPFs, and LTCHs reported data for employee benefits and contract labor; therefore, we developed these cost weights for the FY 2008-based RPL market basket using data obtained from IPPS Medicare cost reports. However, when we reviewed LTCH Medicare cost reports for FY 2009, we found that a greater proportion of LTCHs submitted data for employee benefits and contract labor (approximately 40 percent of LTCHs, whose total costs account for approximately 50 percent of total costs for all LTCHs, submitted a cost report) compared to the proportion of IRFs and IPFs that submitted these data. We believe that it is better to use the LTCH-specific cost report data whenever possible to further our goal to create a market basket that represents the cost structures of LTCHs serving Medicare beneficiaries. Therefore, we are proposing to use the LTCH-specific cost reports to derive the employee benefits and contract labor cost weights for the proposed FY 2009-based LTCH-specific market basket, as opposed to using the IPPS Medicare cost reports as a proxy, as was done for the FY 2008-based RPL market basket.

TABLE VII.C–1—PROPOSED MAJOR COST CATEGORIES AND THEIR RESPECTIVE COST WEIGHTS AS CALCULATED DIRECTLY FROM FY 2009 MEDICARE COST REPORTS

Major cost categories	Proposed FY 2009-based LTCH-specific market basket cost weights obtained from Medicare cost reports (percent)
Wages and Salaries	40.407
Employee Benefits	6.984
Contract Labor	6.947
Professional Liability Insurance (Malpractice)	0.830
Pharmaceuticals	8.877
Capital	9.829
All Other (Residual)	26.126

(2) Other Data Sources

In addition to the data from Medicare cost reports submitted by LTCHs, the other data source we are proposing to use to develop the proposed FY 2009-based LTCH-specific market basket cost weights is the 2002 Benchmark Input-Output (I–O) Tables created by the Bureau of Economic Analysis (BEA), U.S. Department of Commerce. We are proposing to use the 2002 BEA Benchmark I–O data to disaggregate the ''All Other (Residual)'' cost category (26.126 percent) into more detailed hospital expenditure category shares. We note that we use these data to derive most of the CMS market baskets, including the FY 2008-based RPL and

FY 2006-based IPPS market baskets. The BEA Benchmark I–O accounts provide the most detailed information on the goods and services purchased by an industry, which allows for a more detailed disaggregation of expenses in the market basket for which we can then proxy the appropriate price inflation.

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 detailed set of data that are derived from the 2002 Economic Census. We used the 2002 BEA Benchmark I–O data for the FY 2008-based RPL market basket. Because BEA has not released new Benchmark I–O data, and we believe the data to be comprehensive and complete as indicated above, we are proposing to use the 2002 Benchmark I–O data in the proposed FY 2009-based LTCH-specific market basket.

Instead of using the less detailed Annual I–O data, we aged the 2002 Benchmark I–O data forward to 2009. 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, telephone services would represent 10 percent of the ''All Other'' cost category of the LTCH-specific market basket.

b. Cost Category Computation

As stated previously, for the proposed FY 2009-based LTCH-specific market basket, we are proposing to use data from the Medicare cost reports submitted by LTCHs to derive six major cost categories. The six major categories are: Wages and Salaries, Employee Benefits, Contract Labor, Professional Liability Insurance, Pharmaceuticals, and Capital, as shown above in Table VII.C–1. These represent the most detailed cost categories available from the Medicare cost reports, and, as stated above, in order to further disaggregate expenses, we then utilize the Benchmark I–O data. This is the same methodology used to derive most of the CMS market baskets, including the FY 2008-based RPL and FY 2006-based IPPS market baskets. The proposed FY 2009-based LTCH market basket includes the same major cost categories that were included in the FY 2008-based RPL market basket (76 FR 51758), and two additional categories, Employee Benefits and Contract Labor.

c. Selection of Price Proxies

After computing the FY 2009 cost weights for the proposed LTCH 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 2009-based LTCH 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 PPIs better reflect the actual price changes encountered by hospitals. For example, we are proposing to 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 are proposing to 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 are proposing to use CPIs only if an appropriate PPI is not available, or if the expenditures are more like 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 proposed to be 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. We believe the proposed PPIs, CPIs, and ECIs selected meet these criteria.

Table VII.C–2 below sets forth the proposed FY 2009-based LTCH-specific market basket, including the cost categories and their respective weights and price proxies. For comparison purposes, the corresponding FY 2008-based RPL market basket cost weights also are listed. For example, ''Wages and Salaries'' are 46.330 percent of total costs in the proposed FY 2009-based LTCH-specific market basket compared to 49.447 percent for the FY 2008-based RPL market basket. ''Employee Benefits'' are 8.008 percent in the proposed FY 2009-based LTCH-specific market basket compared to 12.831 percent for the FY 2008-based RPL market basket. As a result, compensation costs (wages and salaries plus employee benefits) for the proposed FY 2009-based LTCH market basket are 54.338 percent of total costs compared to 62.278 percent for the FY 2008-based RPL market basket. We note that the ''Wages and Salaries'' cost weight contained in Table VII.C–2 (46.330 percent) differs from that contained in Table VII.C–1 (40.407 percent). We attribute this difference to our allocation of the ''Contract Labor'' cost weight obtained from the Medicare cost reports (6.947 percent) proportionately across the ''Wages and Salaries'' and ''Employee Benefits'' cost weights obtained from the Medicare cost reports.

Following Table VII.C–2 is a summary of the proxies we are proposing to use for the operating portion of the proposed FY 2009-based LTCH-specific market basket. We note that the proxies we are proposing for the operating portion of the proposed FY 2009-based LTCH-specific market basket are the same as those used for the FY 2008-based RPL market basket. Because these proposed 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 2008-based RPL market basket, we refer readers to the discussion in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51759). The price proxies proposed for the capital portion of the proposed FY 2009-based LTCH market basket are the same as those used for the FY 2008-based RPL market basket (prior to any vintage weighting), as described in the

FY 2012 IPPS/LTCH PPS final rule (75 FR 51765), and as described in more detail in the capital methodology section in section VII.C.3.d. of the preamble of this proposed rule.

TABLE VII.C–2—PROPOSED FY 2009-BASED LTCH-SPECIFIC MARKET BASKET COST CATEGORIES, COST WEIGHTS, AND PRICE PROXIES COMPARED TO FY 2008-BASED RPL MARKET BASKET COST WEIGHTS

Cost categories	Proposed FY 2009-based LTCH-specific market basket cost weights	FY 2008-based RPL market basket cost weights	Proposed FY 2009-based LTCH market basket price proxies
1. Compensation	54.338	62.278	
A. Wages and Salaries [1]	46.330	49.447	ECI for Wages and Salaries, Civilian Hospital Workers.
B. Employee Benefits [1]	8.008	12.831	ECI for Benefits, Civilian Hospital Workers.
2. Utilities	1.751	1.578	
A. Electricity	1.367	1.125	PPI for Commercial Electric Power.
B. Fuel, Oil, and Gasoline	0.281	0.371	PPI for Petroleum Refineries.
C. Water and Sewage	0.103	0.082	CPI–U for Water and Sewerage Maintenance.
3. Professional Liability Insurance	0.830	0.764	CMS Hospital Professional Liability Insurance Premium Index.
4. All Other Products and Services	33.252	26.988	
A. All Other Products	19.531	15.574	
(1.) Pharmaceuticals	8.877	6.514	PPI for Pharmaceutical Preparations for Human Use (Prescriptions).
(2.) Food: Direct Purchases	3.409	2.959	PPI for Processed Foods and Feeds.
(3.) Food: Contract Services	0.478	0.392	CPI–U for Food Away From Home.
(4.) Chemicals [2]	1.275	1.100	Blend of Chemical PPIs.
(5.) Medical Instruments	2.141	1.795	PPI for Medical, Surgical, and Personal Aid Devices.
(6.) Rubber and Plastics	1.329	1.131	PPI for Rubber and Plastic Products.
(7.) Paper and Printing Products	1.226	1.021	PPI for Converted Paper and Paperboard Products.
(8.) Apparel	0.250	0.210	PPI for Apparel.
(9.) Machinery and Equipment	0.127	0.106	PPI for Machinery and Equipment.
(10.) Miscellaneous Products	0.419	0.346	PPI for Finished Goods less Food and Energy.
B. All Other Services	13.721	11.414	
(1.) Labor-Related Services	5.349	4.681	
(a.) Professional Fees: Labor-Related	2.256	2.114	ECI for Compensation for Professional and Related Occupations.
(b.) Administrative and Business Support Services	0.508	0.422	ECI for Compensation for Office and Administrative Services.
(c.) All Other: Labor-Related Services	2.585	2.145	ECI for Compensation for Private Service Occupations.
(2.) Nonlabor-Related Services	8.372	6.733	
(a.) Professional Fees: Nonlabor-Related	5.332	4.211	ECI for Compensation for Professional and Related Occupations.
(b.) Financial Services	1.013	0.853	ECI for Compensation for Financial Activities.
(c.) Telephone Services	0.501	0.416	CPI–U for Telephone Services.
(d.) Postage	0.779	0.630	CPI–U for Postage.
(e.) All Other: Nonlabor-Related Services	0.747	0.623	CPI–U for All Items less Food and Energy.
5. Capital-Related Costs	9.829	8.392	
A. Depreciation	5.707	5.519	
(1.) Building and Fixed Equipment	3.838	3.286	BEA chained price index for Nonresidential Construction for Hospitals and Special Care Facilities—vintage weighted (20 years).
(2.) Movable Equipment	1.869	2.233	PPI for Machinery and Equipment—vintage weighted (8 years).
B. Interest Costs	2.434	1.954	
(1.) Government/Nonprofit	0.702	0.653	Average yield on Domestic Municipal Bonds (Bond Buyer 20 bonds)—vintage-weighted (20 years).
(2.) For Profit	1.732	1.301	Average yield on Moody's Aaa Bonds—vintage-weighted (20 years).
C. Other Capital-Related Costs	1.688	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 Gas Manufacturing, 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 the FY 2012 IPPS/LTCH final rule (76 FR 51761).

(1) Wages and Salaries

We are proposing to use the ECI for Wages and Salaries for Hospital Workers (All Civilian) (BLS series code CIU1026220000000I) to measure the price growth of this cost category.

(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.

(3) Electricity

We are proposing to use the PPI for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category.

(4) Fuel, Oil, and Gasoline

We are proposing to use the PPI for Petroleum Refineries (BLS series code PCU324110324110) to measure the price growth of this cost category. We are proposing this proxy based on the same reasons set forth in the FY 2012 IPPS/LTCH final rule when this proxy was adopted for use in the FY 2008-based RPL market basket (76 FR 51761).

(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.

(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).

(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.

(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.

(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.

(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). We are proposing to use this blended index based on the reasons as set forth in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51761) when this proxy was adopted for use in the FY 2008-based RPL market basket.

(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. We are proposing to use this index based on the reasons as set forth in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51761 through 51762) when this proxy was adopted for use in the FY 2008-based RPL market basket.

(12) Rubber and Plastics

We are proposing to use the PPI for Rubber and Plastic Products (BLS series code WPU07) to measure the price growth of this cost category.

(13) 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.

(14) Apparel

We are proposing to use the PPI for Apparel (BLS series code WPU0381) to measure the price growth of this cost category.

(15) 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.

(16) 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.

(17) Professional Fees: Labor-Related

We are proposing to use the ECI for Compensation for Professional and Related Occupations (Private Industry) (BLS series code CIS2020000120000I) to measure the price growth of this category. It includes occupations such as legal, accounting, and engineering services.

(18) 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. We believe this compensation index appropriately reflects the changing price of labor associated with the provision of Administrative and Business Support Services.

(19) 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.

(20) Professional Fees: Nonlabor-Related

We are proposing to use the ECI for Compensation for Professional and Related Occupations (Private Industry) (BLS series code CIS2020000120000I) 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.

(21) 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. We believe that this compensation index appropriately reflects the changing price of labor associated with the provision of Financial Services.

(22) 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.

(23) Postage

We are proposing to use the CPI for Postage (BLS series code CUUR0000SEEC01) to measure the price growth of this cost category.

(24) 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. We believe that using the CPI for All Items Less Food and Energy avoids double counting of changes in food and energy prices as they are already captured elsewhere in the market basket.

d. Proposed Methodology for the Capital Portion of the Proposed FY 2009-Based LTCH-Specific Market Basket

In order to ensure consistency in the proposed FY 2009-based LTCH-specific market basket, we are proposing to calculate the capital-related cost weights using the same set of FY 2009 Medicare cost reports used to develop the operating cost weights with the same length-of-stay edit as applied when calculating the operating cost weights as described in section VII.C.3.a. of this preamble. The resulting proposed capital weight for the FY 2009 base year is 9.829 percent. We then separated the total capital cost weight into more detailed cost categories.

From the Medicare cost reports, we are able to derive cost weights for depreciation, interest, lease, and other capital-related expenses. Lease expenses are unique in that they are not broken out as a separate cost category in the proposed LTCH-specific market basket, but rather are proportionally distributed among the cost categories of Depreciation, Interest, and Other Capital-Related, 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 2008-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-related, not including lease expenses. This is the same method that was applied in the FY 2008-based RPL market basket.

Depreciation contains two subcategories: (1) Building and Fixed Equipment (or Fixed Assets); and (2) Movable Equipment. In the FY 2008-based RPL market basket, we disaggregated total depreciation expenses into Building and Fixed Equipment and Movable Equipment, using depreciation data from the FY 2008 Medicare cost reports for freestanding IRFs, freestanding IPFs, and LTCHs. Based on FY 2009 LTCH Medicare cost report data, we have determined that depreciation costs for building and fixed equipment account for 42 percent of total depreciation costs, while depreciation costs for movable equipment account for 58 percent of total depreciation costs. As mentioned above, we are proposing to allocate lease expenses among the ''Depreciation,'' ''Interest,'' and ''Other Capital'' cost categories. We determined that leasing building and fixed equipment expenses account for 80 percent of total leasing expenses, while leasing movable equipment expenses account for 20 percent of total leasing expenses. We are proposing to sum the depreciation and leasing expenses for building and fixed equipment together, as well as sum the depreciation and leasing expenses for movable equipment. This results in the final building and fixed equipment depreciation cost weight (after leasing costs are included) being 67 percent of total depreciation costs and the movable equipment depreciation cost weight (after leasing costs are included) being 33 percent of total depreciation costs. We note that total leasing costs account for approximately one-half of total capital expenses.

The total ''Interest'' cost category is split between government/nonprofit interest and for-profit interest. The FY 2008-based RPL market basket allocated 33 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 67 percent of the ''Interest'' cost weight was allocated to for-profit interest and was proxied by the average yield on Moody's Aaa bonds (76 FR 51760). This was based on the FY 2008 Medicare cost report data on interest expenses for government/nonprofit and for-profit freestanding IRFs, freestanding IPFs, and LTCHs. For the proposed FY 2009-based LTCH-specific market basket, we are proposing to use the FY 2009 Medicare cost report data on interest expenses for government/nonprofit and for-profit LTCHs. Based on these data, we calculated a proposed 29/71 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 LTCHs.

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 2009-based LTCH-specific 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 vintage weights to compute vintage-weighted price changes associated with depreciation and interest expense.

Vintage weights are an integral part of the proposed FY 2009-based LTCH-specific 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. 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 2009-based LTCH 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, the AHA does provide a consistent database of total expenses back to 1963. Consequently, 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 2009.

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 2008-based RPL market basket, we used FY 2008 Medicare cost reports for IPPS hospitals to determine the

expected life of building and fixed equipment and movable equipment (76 FR 51763). The FY 2008-based RPL market basket was based on an expected average life of building and fixed equipment of 26 years and an expected average life of movable equipment of 11 years, which were both calculated using data for IPPS hospitals. 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 the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. Following a similar method to what was applied for the FY 2008-based RPL market basket, we are proposing to use the average expected life of building and fixed equipment to be equal to 20 years, and the average expected life of movable equipment to be 8 years. These expected lives are calculated using a 3-year average of data from Medicare cost reports for LTCHs for FY 2007 through FY 2009. We believe that using LTCH-specific data to calculate the expected lives of assets best reflects the cost structures of LTCH facilities.

We also are proposing to use the ''Building and Fixed Equipment'' and ''Movable Equipment'' cost weights derived from FY 2009 Medicare cost reports for 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's asset costs from the current year's 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. This is the same proxy used for the FY 2008-based RPL market basket. Because building and fixed equipment have an expected average life of 20 years, the vintage weights for building and fixed equipment are deemed to represent the average purchase pattern of building and fixed equipment over 20-year periods. With real building and fixed equipment purchase estimates available from 2009 back to 1963, we averaged twenty-seven 20-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 20-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 20-year period. This calculation is done for each year in the 20-year period, and for each of the twenty-seven 20-year periods. We used the average of each year across the twenty-seven 20-year periods to determine the average building and fixed equipment vintage weights for the proposed FY 2009-based LTCH-specific 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 2008-based RPL market basket. Based on our determination that movable equipment has an expected average life of 8 years, the vintage weights for movable equipment represent the average expenditure for movable equipment over an 8-year period. With real movable equipment purchase estimates available from 2009 back to 1963, thirty-nine 8-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 8-year period are calculated by dividing the real movable capital purchase amount for any given year by the total amount of purchases in the 8-year period. This calculation was done for each year in the 8-year period and for each of the thirty-nine 8-year periods. We used the average of each year across the thirty-nine 8-year periods to determine the average movable equipment vintage weights for the proposed FY 2009-based LTCH-specific 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 (including, but not limited to, mortgages and bonds). We are proposing that the vintage weights for interest should represent the average purchase pattern of total equipment over 20-year periods, which is the average useful life of building and fixed equipment as calculated using the LTCH Medicare cost report data. We believe vintage weights for interest should represent the average useful life of buildings and fixed equipment because, based on previous research described in the FY 1997 IPPS final rule (61 FR 46198), the expected life of hospital debt instruments and the expected life of buildings and fixed equipment are similar. With nominal total equipment purchase estimates available from 2009 back to 1963, twenty-seven 20-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 20-year period are calculated by dividing the nominal total capital purchase amount for any given year by the total amount of purchases in the 20-year period. This calculation is done for each year in the 20-year period and for each of the twenty-seven 20-year periods. We used the average of each year across the twenty-seven 20-year periods to determine the average interest vintage weights for the proposed FY 2009-based LTCH-specific market basket. The vintage weights for the capital portion of the FY 2008-based RPL market basket and the proposed FY 2009-based LTCH-specific market basket are presented in Table VII.C–4 below.

TABLE VII.C–4—FY 2008 RPL AND PROPOSED FY 2009 LTCH VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES

Year	Building and fixed equipment		Movable equipment		Interest	
	FY 2008 26 years	FY 2009 20 years	FY 2008 11 years	FY 2009 8 years	FY 2008 26 years	FY 2009 20 years
1	0.021	0.034	0.071	0.102	0.010	0.021
2	0.023	0.037	0.075	0.108	0.012	0.024
3	0.025	0.039	0.080	0.114	0.014	0.026
4	0.027	0.042	0.083	0.123	0.016	0.029
5	0.028	0.043	0.085	0.129	0.018	0.032
6	0.030	0.045	0.089	0.134	0.020	0.035
7	0.031	0.046	0.092	0.142	0.021	0.037
8	0.033	0.047	0.098	0.149	0.024	0.040
9	0.035	0.049	0.103	.....	0.026	0.043
10	0.037	0.051	0.109	.....	0.029	0.047
11	0.039	0.053	0.116	.....	0.033	0.050
12	0.041	0.053	.....	.....	0.035	0.053
13	0.042	0.053	.....	.....	0.038	0.055
14	0.043	0.054	.....	.....	0.041	0.059
15	0.044	0.055	.....	.....	0.043	0.062
16	0.045	0.057	.....	.....	0.046	0.068
17	0.046	0.059	.....	.....	0.049	0.073
18	0.047	0.059	.....	.....	0.052	0.077
19	0.047	0.061	.....	.....	0.053	0.082
20	0.045	0.062	.....	.....	0.053	0.086
21	0.045	.....	.....	.....	0.055	.....
22	0.045	.....	.....	.....	0.056	.....
23	0.046	.....	.....	.....	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.

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 (prior to any vintage weighting) for the capital portion of the proposed FY 2009-based LTCH market basket that were used in the FY 2008-based RPL market. 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, as shown in Table VII.C–2 above, are the same as those used for the FY 2008-based RPL market basket, as described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51765), as well as 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). The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table VII.C–4 is applied to the most recent data point. We have provided on the CMS Web site an example of how the vintage weighting price proxies are calculated, using example vintage weights and example price indices. The example can be found at the following link: *http://www.cms.gov/Medicare ProgramRatesStats/05_Market BasketResearch.asp#TopOfPage* in the zip file titled ''Weight Calculations as described in the IPPS FY 2010 Proposed Rule''.

e. Proposed FY 2013 Market Basket Update for LTCHs

For FY 2013 (that is, October 1, 2012, through September 30, 2013), we are proposing to use an estimate of the proposed FY 2009-based LTCH-specific market basket to update payments to LTCHs based on the best available data. Consistent with historical practice, we estimate the LTCH 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 2012 forecast with history through the fourth quarter of 2011, the projected market basket update for FY 2013 is 3.0 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 3.0 percent for FY 2013. Furthermore, because the proposed FY 2013 annual update is based on the most recent market basket estimate for the 12-month period (currently 3.0 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 2013 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 2.1 percent to the LTCH PPS standard Federal rate for FY 2013 under proposed § 412.523(c)(3)(viii) of the regulations.)

Using the current FY 2008-based RPL market basket and IGI's first quarter 2012 forecast for the market basket components, the FY 2013 market basket update would be 3.0 percent (before taking into account any statutory adjustment). Table VII.C–5 below compares the FY 2008-based RPL market basket and the proposed FY

2009-based LTCH-specific market basket percent changes.

TABLE VII.C–5—FY 2008-BASED RPL MARKET BASKET AND PROPOSED FY 2009-BASED LTCH MARKET BASKET PERCENT CHANGES; FY 2008 THROUGH FY 2015

Fiscal year (FY)	FY 2008-based RPL market basket index percent change	Proposed FY 2009-based LTCH market basket index percent change
Historical data:		
FY 2008	3.7	3.9
FY 2009	2.7	2.8
FY 2010	2.2	2.2
FY 2011	2.5	2.6
Average 2008–2011	2.8	2.9
Forecast:		
FY 2012	2.4	2.5
FY 2013	3.0	3.0
FY 2014	3.1	3.1
FY 2015	3.2	3.1
Average 2012–2015	2.9	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 2012 forecast.

For FY 2013, the proposed FY 2009-based LTCH-specific market basket update (as measured by percentage increase) is currently forecasted to be the same as the market basket update based on the FY 2008-based RPL market basket at 3.0 percent. The lower total compensation weight in the proposed FY 2009-based LTCH-specific market basket (54.338 percent) relative to the FY 2008-based RPL market basket (62.278 percent), absent other factors, would have resulted in a slightly lower market basket update for FY 2013 using the proposed FY 2009-based LTCH market basket. However, this impact is partially offset by the impact of the larger cost weights associated with the Pharmaceuticals and All Other Services cost categories. The net effect of these offsetting factors is that the market basket update is currently forecasted to be the same for FY 2013 based on the current FY 2008-based RPL market basket and the proposed FY 2009-based LTCH-specific market basket. As stated above, we are proposing that if more recent data (such as a revised IGI forecast) are subsequently available, we would use such data, if appropriate, to determine the FY 2013 annual update in the final rule.

f. Proposed FY 2013 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. As discussed in more detail below and similar to the FY 2008-based RPL market basket and FY 2006 IPPS market basket (74 FR 43850), 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. 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, and a portion of the Capital-Related cost weight. These are the same cost categories that were proposed and adopted in the FY 2012 labor-related share using the FY 2008-based RPL market basket, as we continue to believe these categories meet our criteria of being labor-intensive and whose costs vary with the local labor market. For a more detailed discussion of the selection of cost categories for inclusion in the FY 2012 labor-related share, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766). We note that, similar to the FY 2008-based RPL market basket and as described above, the wages and salaries and benefit cost weights reflect allocated contract labor costs.

For the FY 2008-based RPL market basket rebasing, in an effort to more accurately determine the share of professional fees for services such as accounting and auditing services, engineering services, legal services, and management and consulting services that should be included in the labor-related share, we obtained data from a survey of IPPS hospitals regarding the proportion of those fees that go to companies that are located beyond their own local labor market. The results from this survey were then used to separate a portion of the Professional Fees cost category into labor-related and nonlabor-related costs. These results and our allocation methodology are discussed in more detail in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766). For the proposed FY 2009-based LTCH-specific market basket, we are proposing to apply these survey results using this same methodology to separate the Professional Fees category into Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories. We believe using the survey results serves as an appropriate proxy for the purchasing patterns of professional services for LTCHs as they also are providers of institutional care.

In addition to the professional services listed above, we also are proposing to classify expenses under NAICS 55, Management of Companies and Enterprises, into the Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories, as was done for the FY 2008-based RPL

market basket. The NAICS 55 industry is mostly comprised of corporate, subsidiary, and regional managing offices (otherwise referred to as home offices). As stated above, we classify a cost category as labor-related and include it in the labor-related share if the cost category is labor-intensive and if its costs vary with the local labor market. We believe many of the costs associated with NAICS 55 are labor-intensive and vary with the local labor market. However, data indicate that not all LTCHs with home offices have home offices located in their local labor market. Therefore, we are proposing to include in the labor-related share only a proportion of the NAICS 55 expenses based on the methodology described below.

For the FY 2008-based RPL market basket, we used 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) and determined 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). For a detailed discussion of this analysis, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51767).

For the proposed FY 2009-based LTCH-specific market basket, we conducted a similar analysis of home office data. However, instead of using data on freestanding IRF, freestanding IPF, and LTCHs, we began with the initial set of LTCH Medicare cost reports that were used to derive the cost weights for the proposed FY 2009-based LTCH-specific market basket. For consistency, we believe it is important for our analysis on home office data to be conducted on the same LTCHs used to derive the proposed FY 2009 LTCH market basket cost weights.

The Medicare cost report requires a hospital to report information regarding their home office provider. Approximately 82 percent of LTCHs reported some type of home office information on their Medicare cost report for FY 2009 (for example, home office number, city, state, zip code, or name). For the majority of these providers, we were able to identify in which MSA the LTCH's home office was located using the HOMER database and the Medicare cost reports. We then compared the home office MSA with the MSA in which the LTCH was located.

We found that 13 percent of the LTCHs with home offices had those home offices located in the same MSA as their facilities. We then concluded that these providers were located in the same local labor market as their home office. As a result, we are proposing to apportion the NAICS 55 expense data by this percentage. Thus, we are proposing to classify 13 percent of these costs into the ''Professional Fees: Labor-related Services'' cost category and the remaining 87 percent into the ''Professional Fees: Nonlabor-related Services'' cost category.

Using this proposed method and the IGI forecast for the first quarter 2012 of the proposed FY 2009-based LTCH-specific market basket, the proposed LTCH labor-related share for FY 2013 would be the sum of the FY 2013 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 2012 forecast of the proposed FY 2009-based LTCH-specific market basket. Table VII.C–6 below shows the proposed FY 2013 relative importance labor-related share using the proposed FY 2009-based LTCH-specific market basket and the FY 2012 relative importance labor-related share using the FY 2008-based RPL market basket.

TABLE VII.C–6—COMPARISON OF THE FY 2012 RELATIVE IMPORTANCE LABOR-RELATED SHARE BASED ON THE FY 2008-BASED RPL MARKET BASKET AND THE PROPOSED FY 2013 RELATIVE IMPORTANCE LABOR-RELATED SHARE BASED ON THE PROPOSED FY 2009-BASED LTCH MARKET BASKET

	FY 2012 relative importance labor-related share [1]	Proposed FY 2013 relative importance labor-related share [2]
Wages and Salaries	48.984	45.604
Employee Benefits	12.998	8.143
Professional Fees: Labor-Related	2.072	2.216
Administrative and Business Support Services	0.416	0.502
All Other: Labor-Related Services	2.094	2.513
Subtotal	66.564	58.978
Labor-Related Portion of Capital Costs (46%)	3.635	4.239
Total Labor-Related Share	70.199	63.217

[1] Published in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51767) and based on the second quarter 2011 IGI forecast.
[2] Based on the first quarter 2012 IGI forecast.

The proposed labor-related share for FY 2013 is the sum of the proposed FY 2013 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 2009) and FY 2013. The sum of the proposed relative importance for FY 2013 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 58.978 percent, as shown in Table VII.C–6 above. We are proposing that the portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the FY 2008-based RPL market basket. Because the relative importance for capital-related costs would be 9.216 percent of the proposed FY 2009-based LTCH-specific market basket in FY 2013, we are proposing to take 46 percent of 9.216 percent to determine the proposed labor-related share of capital-related costs for FY 2013 (.46 * 9.216). The result would be 4.239 percent, which we are proposing to add to 58.978 percent for the operating cost amount to determine the total proposed labor-related share for FY

2013. Thus, the labor-related share that we are proposing to use for the LTCH PPS in FY 2013 would be 63.217 percent. This proposed labor-related share is determined using the same methodology as employed in calculating all previous LTCH labor-related shares.

D. Proposed Changes to the LTCH Payment Rates for FY 2013 and Other Proposed Changes to the LTCH PPS for FY 2013

1. Overview of Development of the LTCH Payment Rates

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 2013, that is, effective for LTCH discharges occurring on or after October 1, 2012 through September 30, 2013.

For further details on the development of the FY 2003 standard Federal rate when the LTCH PPS was initially implemented, 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); FY 2011 IPPS/LTCH PPS final rule (75 FR 50443 through 50444); and FY 2012 IPPS/LTCH PPS final rule (76 FR 51769 through 51773).

The proposed update to the LTCH PPS standard Federal rate for FY 2013 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 2013 are discussed below. Furthermore, as discussed in section VII.E.4. of this preamble, for FY 2013, in addition to the proposed update factor, we are proposing to make a one-time prospective adjustment to the standard Federal rate for FY 2013 so that the effect of any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years under existing § 412.523(d)(3) (this adjustment would not apply to payments made for discharges occurring on or before December 28, 2012, consistent with the statute). Furthermore, as discussed in section V.A. of the Addendum of this proposed rule, we are proposing to make an adjustment to the standard Federal rate to account for the estimated effect of the proposed changes to the area wage level adjustment for FY 2013 on estimated aggregate LTCH PPS payments, in accordance with § 412.523(d)(4).

2. Proposed FY 2013 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. As discussed in section VII.C. of this preamble, we are proposing to adopt the newly created FY 2009-based LTCH-specific market basket for use under the LTCH PPS beginning in FY 2013. For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to section VII.C.1. of this preamble.

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the standard Federal rate and refers to the timeframes associated with such adjustments as a ''rate year.'' (The adjustments are discussed in more detail in section VII.D.2.b. of this preamble.) We note that because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 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.

b. Revision of Certain Market Basket Updates as Required by the Affordable Care Act

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'') 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 discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51770 through 51771), section 1886(b)(3)(B)(xi)(II) of the Act defines the MFP adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (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). As discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51691 through 51692 and 51771), we proposed and finalized 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. Therefore, the MFP adjustment that is 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 they are both based on a fiscal year. As we established in that same final rule, the MFP adjustment is derived using a projection of MFP that is currently produced by IHS Global Insight, Inc. We established our methodology for calculating and applying the MFP adjustment in determining any annual update to the LTCH PPS standard Federal rate in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51772). In this proposed rule, we are not proposing to change our methodology

for calculating and applying the MFP adjustment to determine the annual update to the LTCH PPS standard Federal rate for FY 2013. (For details on the development of the MFP, including our finalized methodology for calculating and applying the MFP adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692).)

c. Proposed Market Basket Under the LTCH PPS for FY 2013

As discussed above in section VII.C. of this preamble, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we are proposing to adopt a newly created FY 2009-based LTCH-specific market basket for use under the LTCH PPS beginning in FY 2013 because we believe it appropriately reflects the cost structure of LTCHs. The proposed FY 2009-based LTCH-specific market basket is based solely on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of only LTCHs.

d. Proposed Annual Market Basket Update for LTCHs for FY 2013

Consistent with our historical practice, we are proposing to estimate the proposed market basket update and the proposed MFP adjustment based on IGI's forecast using the most recent available data. As discussed in section VII.C.3.e. of this preamble, based on IGI's first quarter 2012 forecast, the proposed FY 2013 full market basket estimate for the LTCH PPS using the proposed FY 2009-based LTCH-specific market basket is 3.0 percent. Using our established methodology for determining the MFP adjustment (discussed in section VII.D.2.b. of this preamble), the current estimate of the proposed MFP adjustment for FY 2013 based on IGI's first quarter 2012 forecast is 0.8 percent. Consistent with our historical practice of using the best available data, we are proposing that if more recent data become available to determine the market basket estimate or the MFP adjustment, we would use such data for the final rule, if appropriate.

For FY 2013, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the standard Federal rate be reduced by the productivity adjustment (''the MFP adjustment'') described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, we are proposing to reduce the full FY 2013 market basket update by the FY 2013 MFP adjustment. To determine the market basket update for LTCHs for FY 2013, as reduced by the MFP adjustment, consistent with the approach we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771), we are proposing to subtract the FY 2013 MFP adjustment from the FY 2013 market basket update. Furthermore, sections 1886(m)(3)(A)(ii) and 1886(m)(4)(C) of the Act requires that any annual update to the standard Federal rate for FY 2013 be reduced by the ''other adjustment'' described in paragraph (4), which is 0.1 percentage point for FY 2013. Therefore, following application of the productivity adjustment, we are proposing to reduce the adjusted market basket update (that is, the full market basket increase less the MFP adjustment) by the ''other adjustment'' specified by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act.

In this proposed rule, in accordance with the statute, we are proposing to reduce the proposed FY 2013 full market basket estimate of 3.0 percent (based on the first quarter 2012 forecast of the proposed FY 2009-based LTCH-specific market basket) by the proposed FY 2013 MFP adjustment (that is, the 10-year moving average of MFP for the period ending FY 2013, as described in section VII.D.2.b. of the preamble of this proposed rule) of 0.8 percentage point (based on IGI's first quarter 2012 forecast). Following application of the proposed productivity adjustment, the proposed adjusted market basket update of 2.2 percent (3.0 percent minus 0.8 percentage point) 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, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we are proposing to establish an annual market basket update under the LTCH PPS for FY 2013 of 2.1 percent (that is, the most recent estimate of the proposed LTCH PPS market basket update at this time of 3.0 percent less the proposed MFP adjustment of 0.8 percentage point 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 (ix), which would specify that the standard Federal rate for FY 2013 is the standard Federal rate for the previous LTCH PPS year updated by 2.1 percent, and as further adjusted, as appropriate, as described in § 412.523(d). In addition, proposed § 412.523(c)(3)(ix)(B) would specify that, with respect to discharges occurring on or after October 1, 2012, and before December 29, 2012, payments are based on the standard Federal rate in proposed § 412.523(c)(3)(ix)(A) without regard to the one-time prospective adjustment provided for under proposed § 412.523(d)(3)(iii). As stated above, consistent with our historical practice of using the most recent available data, we are proposing that if more recent data become 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 2013. (We note that we are proposing to adjust the FY 2013 standard Federal rate by a one-time prospective adjustment under proposed § 412.523(d)(3) (discussed in section VII.E.4. of this preamble) and a proposed area wage level budget neutrality factor in accordance with § 412.523(d)(4) (discussed in section V.B.5. of the Addendum of this proposed rule).)

3. Proposed LTCH PPS Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), we established a cost-of-living adjustment (COLA) for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States (67 FR 56022). Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal 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.

Historically, we have 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. As we discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51809), we did not believe it was appropriate to use either the 2010 or 2011 reduced factors to adjust the nonlabor-related portion of the standard Federal rate for LTCHs in Alaska and Hawaii for Medicare payment purposes.

Therefore, we established in that same final rule that, for FY 2012, we continued to use the same COLA factors (published by OPM) that we used to adjust payments in FY 2011 (which were 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 it was appropriate to use ''frozen'' COLA factors to adjust payments in FY 2012 while we explored alternatives for updating the COLA adjustment in the future because we believe those COLA factors appropriately adjusted the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska ad Hawaii, consistent with § 412.523(b) (76 FR 51809). In this proposed rule, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to continue to use the same ''frozen'' COLA factors used in FY 2012 for FY 2013 and to update the COLA factors for Alaska and Hawaii, beginning in FY 2014, based on a comparison of the growth in the consumer price indices (CPIs) for Anchorage, Alaska and Honolulu, Hawaii relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). Specifically, in FY 2014, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we would update the COLA factors published by OPM that we used to adjust payments in FY 2011 (which are based on OPM's 2009 COLA factors) as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay. Because the BLS publishes CPI data only for the cities of Anchorage and Honolulu, we are proposing to use a comparison of the relative growth in the overall CPI for those cities to update the COLA adjustment factors for all areas in Alaska and Hawaii, respectively. We believe that the relative price differences between these cities and the United States are appropriate proxies for the relative price differences of the ''other areas'' of Alaska and Hawaii.

The BLS publishes the CPI for All Items for Anchorage, Honolulu, and for the average U.S. city. However, we are proposing to create reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. The current composition of the CPI for All Items for all the respective areas is approximately 40 percent commodities and 60 percent services. However, the IPPS nonlabor-related share is comprised of approximately 60 percent commodities and 40 percent services. Therefore, we are proposing to create reweighted indexes for Anchorage, Honolulu, and the average U.S. city using the respective CPI commodities index and CPI services index using the approximate 60/40 share obtained from the IPPS market basket. We believe that proposing to use the underlying composition of the IPPS market basket nonlabor-related share to reweighted CPIs for each of the respective areas is an appropriate proxy for determining the COLA adjustments for LTCHs because both LTCHs and IPPS hospitals are required to meet the same certification criteria set forth in section 1861(e) of the Act to participate as a hospital in the Medicare program and generally experience similar nonlabor-related costs for providing inpatient hospital services. We also note that the composition of the proposed nonlabor-related share of the propose LTCH-specific market basket is not significantly different from the approximate 60/40 share obtained from the IPPS market basket.

We believe this proposed methodology is appropriate because we would be able to continue updating COLA adjustments for hospitals located in Alaska and Hawaii using the relative price differences as a proxy for relative cost differences. We believe this is an appropriate alternative methodology given the discontinuation of COLA factors from OPM. We note that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent, and since the inception of the LTCH PPS, we have exercised our discretionary authority to adjust payments to LTCHs located in Alaska and Hawaii by incorporating this cap. Consistent with our existing policy, our proposed approach for FY 2014 would continue to use such a cap, as our proposal is based on OPM's COLA factors (updated by the proposed methodology described above). We note that this proposal is consistent with the proposal we are making for IPPS hospitals discussed in section II.B.2. of the Addendum to this proposed rule.

Lastly, we are proposing to update the COLA factors using this proposed methodology every 4 years (beginning in FY 2014), consistent with the proposal for updating the COLA factors under the IPPS discussed in section II.B.2. of the Addendum to this proposed rule. Under the IPPS, we are proposing to update the COLA factors every 4 years (beginning of FY 2014) concurrently with the update to the labor-related share of the IPPS market basket. The labor-related share of the IPPS market basket currently is not scheduled to be updated until FY 2014. At the time of development of the FY 2014 proposed rule, we expect to have CPI data available through 2012. Therefore, the proposed FY 2014 COLA factors for Alaska and Hawaii would be based on the 2009 OPM COLA factors updated through 2012 by the comparison of the growth in the CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city.

In this proposed rule, for FY 2013, 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 the same COLA factors used to adjust payments in FY 2012 (which are based on OPM's 2009 COLA factors) by multiplying the nonlabor-related portion of the standard Federal payment rate by the proposed factors listed in the chart shown in section V.C. of the Addendum to this proposed rule. We believe that these proposed COLA factors would appropriately adjust the nonlabor-related portion of the standard Federal rate in FY 2013 for LTCHs located in Alaska and Hawaii, consistent with § 412.523(b).

E. Expiration of Certain Payment Rules for LTCH Services and the Moratorium on the Establishment of Certain Hospitals and Facilities and the Increase in Number of Beds in LTCHs and LTCH Satellite Facilities

1. Background

Moratoria on the implementation of certain LTCH payment policies and on the development of new LTCHs and LTCH satellite facilities and on bed increases in existing LTCHs and LTCH satellite facilities established under sections 114(c) and (d) of the MMSEA (Pub. L. 110–173) as amended by section 4302 of the ARRA (Pub. L. 111–5) and further amended by sections 3106 and 10312 of the Affordable Care Act are set to expire during CY 2012, under current law.

The moratoria established by these provisions delayed the full implementation of the following policies for 5 years beginning at various times in CY 2007:

- The full application of the ''25-percent payment adjustment threshold'' to certain LTCHs, including hospitals-within-hospitals (HwHs) and LTCH satellite facilities for cost reporting periods beginning on or after July 1, 2007, and before July 1, 2012, or cost reporting periods beginning on or after October 1, 2007, and before October 1,

2012, as applicable under the regulations at §§ 412.534 and 412.536.

• The inclusion of an ''IPPS comparable'' option for payment determinations under the short stay outlier (SSO) adjustment at § 412.529 of the regulations for LTCH discharges occurring on or after December 29, 2007, but prior to December 29, 2012.

• The application of any one-time prospective adjustment to the LTCH PPS standard Federal rate provided for in § 412.523(d)(3) of the regulations from December 29, 2007, until December 29, 2012.

• In general, the development of new LTCHs and LTCH satellite facilities, or increases in the number of beds in existing LTCHs and LTCH satellite facilities from December 29, 2007, and ending December 28, 2012, unless one of the specified exceptions to the particular moratorium was met. (We refer readers to the May 22, 2008 interim final rule with comment period for the MMSEA (73 FR 29699, 29704 through 29707, 29709), the interim final rule for the ARRA (74 FR 43990 through 43992, and 43997), and the finalizing of the ACA changes in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50399 through 50400, and 50416) for a complete description of this moratorium.)

In this proposed rule, we are proposing to extend the existing delay of the full implementation of the 25-percent payment adjustment threshold for an additional year; that is, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013, as applicable. We also are proposing to make a one-time prospective adjustment to the standard Federal rate under § 412.523(d)(3) of the regulations. We are proposing to phase in this proposed one-time prospective adjustment to the standard Federal rate over a 3-year period, beginning in FY 2013; however, consistent with the statute, this proposed adjustment would not apply to payments made for discharges occurring on or before December 28, 2012. We are not proposing to make any changes to the SSO policy as it currently exists in the regulations at § 412.529. Accordingly, consistent with the existing regulations at § 412.529(c)(3), for SSO discharges occurring on or after December 29, 2012, the ''IPPS comparable'' option at § 412.529(c)(3)(i)(D) would apply to payment determinations as appropriate for certain short stay cases. The moratoria on the development of new LTCHs or LTCH satellite facilities and on an increase in the number of beds in existing LTCHs or LTCH satellite facilities mandated by section 114(d) of the MMSEA, as amended by section 4302(b) of the ARRA and further amended by section 3106 and 10312 of the Affordable Care Act, are set to expire on December 29, 2012, under current law. As discussed later in this section, we are supportive of a statutory extension of these moratoria as we anticipate potential payment policy changes to the LTCH PPS as a result of CMS' research initiatives.

2. The 25-Percent Payment Adjustment Threshold

We are proposing to provide a 1-year extension (that is, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013) on the moratorium on the application of the 25-percent payment adjustment threshold policy as provided by section 144(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(c) and 10312(a) of the Affordable Care Act. Therefore, we are proposing to revise §§ 412.534 and 412.536 of the regulations to reflect this proposed extension. Specifically, we are proposing to change ''2012'' to ''2013'' in §§ 412.534(c)(1)(i) and (ii), (c)(2)(1), (d)(1) and (2), and (e)(1) and (2) to incorporate this proposed change. In addition, we are proposing to revise the headings at §§ 412.534(c)(3), (d)(3), and (e)(3), and make conforming changes to (h)(4) and (5) and § 412.536(a)(2) to reflect this proposed 1-year extension. This proposed 1-year extension would continue the existing statutory exemption of grandfathered HwHs and freestanding LTCHs from the 25-percent payment adjustment threshold and the continued statutory increase in the percentage threshold to 50 or 75 percent, as applicable, for those LTCHs and LTCH satellite facilities presently so affected. For a detailed description of the moratorium on the ''25-percent threshold'' policy, we refer readers to the May 22, 2008 interim final rule with comment period (73 FR 29699 through 29704) and the interim final rule with comment period for the ARRA (74 FR 43990 through 43992).

Although we are proposing to extend the moratorium relating to the application of the 25-percent payment adjustment threshold policy for cost reporting period beginning on or after October 1, 2012, and before October 1, 2013, this moratorium will expire for certain classes of LTCHs prior to the effective date of the proposed extension. Specifically, under existing regulations, the moratoria on the ''25-percent threshold'' payment adjustment policies set forth in §§ 412.534(h) and 412.536 for a LTCH described in § 412.23(e)(2)(i) that meets the criteria in § 412.22(f) and a satellite facility of a LTCH described under § 412.22(h)(3)(i) (that is, a grandfathered HwH and a grandfathered LTCH satellite facility, respectively), and the moratoria on the ''25 percent threshold'' policies set forth in § 412.536 for a ''freestanding'' LTCH as described in § 412.23(e)(5) will expire beginning with discharges occurring in cost reporting periods beginning on or after July 1, 2012. In addition, under existing regulations, the moratorium on the ''25-percent threshold'' policies set forth in §§ 412.534(h) and 412.536 expire beginning with discharges occurring in cost reporting periods beginning on or after July 1, 2012, for a LTCH or a LTCH satellite facility that, as of December 29, 2007, was co-located with an entity that is a provider-based, off-campus location of a subsection (d) hospital which did not provide services payable under section 1886(d) of the Act at the off-campus location. Therefore, under our proposed policy, there will be a period during which the above-described LTCHs and LTCH satellite facilities must comply with §§ 412.534 and 412.536 before becoming subject to the moratoria again. The period during which the above-described LTCHs and LTCH satellite facilities would comply with §§ 412.534 and 412.536 would be for discharges occurring in cost reporting periods beginning on or after July 1, 2012, and before July 1, 2013. Then, for discharges occurring in cost reporting periods beginning on or after July 1, 2013, and before July 1, 2014, the above-described LTCHs and LTCH satellite facilities would be under the proposed extension of the moratorium. We note that, if our proposal is finalized, the proposed policy would be effective prospectively, consistent with the prospective nature of the FY 2013 rulemaking.

We are proposing a 1-year extension in the delay of the full application of the 25-percent payment adjustment threshold policy because we believe, based on recent research as explained in greater detail below, that we could be in a position within the near future to propose revisions to our payment policies that could render the 25-percent payment adjustment threshold policy unnecessary. In light of this potential result, we believe it is prudent to avoid requiring LTCHs (or CMS payment processing systems) to retool in order to implement the full reinstatement of the policy for what could be a relatively short period of time.

We originally instituted the 25-percent payment adjustment threshold policy for co-located LTCHs and LTCH satellite facilities in the FY 2005 IPPS

final rule (69 FR 49191 through 49214), and expanded it to all ''subclause I'' LTCHs in RY 2008 (72 FR 26919 through 26944) because our data and medical reviews revealed a strong pattern of correlations between growing numbers of patient discharges from IPPS hospitals to onsite or neighboring LTCHs after shorter lengths of stay at the IPPS hospitals and significant and increasing costs to the Medicare program. Our concern was that such patient shifting by providers could be financially, rather than clinically, motivated and that many LTCHs, in effect, were functioning as long-stay units of IPPS hospitals, a configuration not permitted under the governing statute. Section 1886(d)(1)(B) of the Act provides for an exclusion of LTCHs from the IPPS for acute care hospitals. While the statute provides for an exclusion for psychiatric units and rehabilitation units, it does not provide for an exclusion for long-term care units. Our goal was to ''challenge'' this otherwise unrestricted flow of patients from one provider to the other which we believed was resulting in two Medicare payments, one to the IPPS hospital and one to the LTCH, for what often could be understood as one episode of care. The policy was aimed at altering both the financial benefits accruing to the providers and the resulting increasing costs to the Medicare program by establishing a percentage threshold for patient shifting beyond which a payment adjustment would be applied to the LTCH discharge. The policy did not include patients who had been a high-cost outlier case at the IPPS hospital prior to discharge to the LTCH in the calculation of the percentage threshold. The attainment of high-cost outlier status serves as a ''benchmark,'' which we believe indicates that there has not been a premature discharge from the IPPS hospital.

In addition, in several reports to the Congress (June 2003, Chapter 5; June 2004, Chapter 5; and March 2011, Chapter 10), MedPAC recommended the development of patient-level and facility-level criteria for LTCHs. It was MedPAC's belief that developing facility-level criteria would standardize the level and delivery of services provided by all LTCHs and that applying patient-level criteria would limit the type of beneficiaries admitted. The criteria would target the particular subgroup of beneficiaries who could derive the most clinical benefit from the long-stay and specialized hospital-level treatment at LTCHs while justifying the high Medicare payments in light of concerns about cost effectiveness and the program's commitment to value-based purchasing decisions (MedPAC's Report to Congress, June 2004, p. 128 through 131).

MedPAC's March 2011 Report to Congress (page 238) included the following statement:

> Previous research by the Commission found that the type of patients long-term care hospitals (LTCHs) treat are often cared for in alternative settings, such as acute care hospitals and skilled nursing facilities (SNFs) (Medicare Payment Advisory Commission 2004). The Commission found that Medicare pays more for patients using LTCHs than for similar patients using other settings; however the payment difference narrowed considerably if LTCH care was targeted to the most severely ill patients. The Commission has therefore argued that, while LTCHs appear to have value for very sick patients, they are too expensive to be used for patients who could be treated in less intensive settings.

Since MedPAC's 2004 recommendations for the development of patient-level and facility-level criteria for LTCHs, CMS has awarded research contracts for the purposes of exploring the feasibility of such criteria as a basis for ''ensuring that appropriate patients are treated in long-term care hospitals'' (MedPAC's March 2011 Report to Congress, p. 238). Specifically, in response to MedPAC's 2004 recommendation for the development of patient-level and facility-level criteria, CMS awarded research contracts to Research Triangle International, Inc. (RTI). Summaries of work done by RTI have been published in rules issued in the **Federal Register** for FY 2007 (71 FR 27884 through 27885), for FY 2008 (72 FR 4884 through 4886), and FY 2009 (73 FR 5374 through 5377). Reports on the research are posted on the Web site at: *http://www.cms.gov/LongTermCareHospitalPPS/02a_RTIReports.asp#TopOfPage.* As these researchers discovered, developing LTCH-specific patient-level criteria has been extremely difficult. This is because patients fitting the profile of LTCH patients (clinically complex, with multiple acute and chronic conditions) are far more likely to be treated in IPPS hospitals nationwide than they are in LTCHs, with over 3,500 general acute care hospitals as compared to approximately 440 LTCHs and with the number of LTCHs highly concentrated in some areas and nonexistent in others.

More recently, during the last 2 years, CMS has been engaged with contractors in two projects that appear to be moving toward addressing the concerns and perhaps realizing the goals that MedPAC articulated in its recommendations, quoted above. We believe that, within the near future, we could potentially be in a position to recommend revisions to our payment policies that could render the 25-percent payment adjustment threshold policy unnecessary. We are also aware that the LTCH industry has requested legislators to, among other things, forestall the reinstatement of the full implementation of the 25-percent payment adjustment threshold policy at this time. In acknowledgement of hopeful research outcomes as well as concerns raised by the industry, we are proposing a 1-year extension (that is, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013) of the existing moratoria on the full application of the 25-percent payment adjustment threshold policy as provided by section 144(c) of the MMSEA as amended by section 4302(a) of the ARRA and section 3106(c) and 10312(a) of the Affordable Care Act.

3. The ''IPPS Comparable Per Diem Amount'' Payment Option for Very Short Stays Under the Short-Stay Outlier (SSO) Policy

Prior to the enactment of section 114(c)(3) of the MMSEA, for LTCH short stay outlier (SSO) cases with a covered length of stay that was equal to or less than one standard deviation from the geometric average length of stay for the same MS–DRG under the IPPS (that is, the ''IPPS comparable threshold''), the SSO payment adjustment determination included an additional option, the ''IPPS comparable amount per diem amount'' (72 FR 26906). This policy was implemented in our regulations at § 412.529(c)(3)(i) in the RY 2008 LTCH PPS final rule (72 FR 26904 through 26908).

Section 114(c)(3) of the MMSEA as amended by section 3106(a) of the Affordable Care Act provided a 5-year moratorium from the application of the ''IPPS comparable amount'' option under the SSO payment adjustment, which is scheduled to expire for discharges beginning on or after December 29, 2012 (75 FR 50399 through 50400). With the expiration of the moratorium, payment for an SSO discharge occurring on or after December 29, 2012, the Medicare payment will be based on the least of the following:

- 100 percent of the estimated cost of the case.
- 120 percent of the MS–LTC–DRG specific per diem amount multiplied by the covered length of stay of the particular case.
- The full MS–LTC–DRG per diem amount.

• Comparing the covered length of stay for as an SSO case and the ''IPPS comparable threshold,'' one of the following:

1. The blend of the 120 percent of the MS–LTC–DRG specific per diem amount (specified in § 412.529(d)(1)) and an amount comparable to the IPPS per diem amount (specified in § 412.529(d)(4)), for cases where the covered length of stay for an SSO case is greater than the ''IPPS comparable threshold'' (as specified under § 412.529(c)(3)(ii)).

2. An amount comparable to the IPPS comparable per diem amount (specified in § 412.529(d)(4)), if the covered length of stay for an SSO case is equal to or less than one standard deviation from the geometric average length of stay for the same MS–DRG under the IPPS (the ''IPPS comparable threshold''), as specified under § 412.529(d)(4).

For a comprehensive discussion of the SSO policy, including the payment for very short stays under the SSO policy, we refer readers to the May 6, 2008 interim final rule with comment period (73 FR 24874 through 24881).

The proposed FY 2013 ''IPPS comparable thresholds'' (that is, one standard deviation from the geometric average length of stay for the same MS–DRG under the IPPS used in determining SSO payments for discharges occurring on or after December 29, 2012, under § 412.529(c)(3) of the regulations are provided in Table 11, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet.

Technical change. With the expiration of the moratorium on the application of the ''IPPS comparable per diem amount'' option at § 412.529(c)(3)(i)(D) to the determination of the payment adjustment under the SSO policy, described above, we are proposing to make a technical change to the regulation text at § 412.529(d)(4)(i)(C) in order to clarify the application of our policy. Specifically, at § 412.529(d)(4)(i)(C), we are proposing to remove the following introductory phrase that appears at the beginning of the paragraph: ''For purposes of the blend amount described in paragraph (c)(2)(iv) of this section,'' so that the provision of the paragraph is not limited only to the ''blend amount'' option under the SSO policy at § 412.529(c)(2)(iv), but is also applicable to the ''IPPS comparable per diem amount'' option at § 412.529(c)(3)(i)(D). We are proposing to clarify this policy by revising the language of paragraph (d)(4)(i)(C) to read as follows:

''(C) The payment amount specified under paragraph (d)(4)(i)(B) of this section may not exceed the full amount comparable to what would otherwise be paid under the hospital inpatient prospective payment system determined under paragraph (d)(4)(i)(A) of this section.''

We are proposing this technical correction in order to clarify that, payment for a case based solely on the ''IPPS comparable per diem amount'' described at § 412.529(d)(4) is calculated in the same way that it is calculated when payment for a case will be based on the ''blend amount'' (under § 412.529(c)(2)(iv)) of the ''IPPS comparable per diem amount'' and the ''120 percent of the LTC–DRG specific per diem payment amount.'' When we finalized the ''IPPS comparable per diem amount'' option to the SSO payment adjustment in the RY 2008 LTCH PPS final rule we stated in the preamble that ''the IPPS comparable per diem amount [was] capped at the full IPPS comparable amount that is used under the blend option of the current SSO policy * * *'' (72 FR 26907). However, we neglected, at that time, to revise the regulation text. Therefore, we are proposing to clarify our regulations at § 412.52(d)(4)(i)(C) to reflect existing policy that the ''IPPS comparable per diem amount'' is calculated as a per diem that is capped at an amount comparable to what would have been a full payment under the inpatient prospective payment system, such that an SSO payment made under the ''IPPS comparable per diem amount'' option may also not exceed the full amount comparable to what would otherwise be paid under the inpatient prospective payment system.

4. Proposed One-Time Prospective Adjustment to the Standard Federal Rate Under § 412.523(d)(3)

In the August 30, 2002 LTCH PPS final rule (67 FR 55954), we set forth regulations implementing the LTCH PPS, based upon the broad authority granted to the Secretary, under section 123 of the BBRA (as amended by section 307(b) of the BIPA). Section 123(a)(1) of the BBRA required that the system ''maintain budget neutrality.'' The statute requires the LTCH PPS to be budget neutral in FY 2003, so that estimated aggregate payments under the LTCH PPS for FY 2003 would be equal to the estimated aggregate payments that would have been made if the LTCH PPS were not implemented for FY 2003. The methodology for determining the LTCH PPS standard Federal rate for FY 2003 that would ''maintain budget neutrality'' is described in considerable detail in the August 30, 2002 final rule (67 FR 56027 through 56037). Our methodology for estimating payments for the purposes of budget neutrality calculations used the best available data, and necessarily reflected several assumptions (for example, costs, inflation factors and intensity of services provided) in estimating aggregate payments that would be made if the LTCH PPS was not implemented. In performing our budget neutrality calculations, we took into account the statute's requirement that certain statutory provisions that affect the level of payments to LTCHs in years prior to the implementation of the LTCH PPS shall not be taken into account in the development and implementation of the LTCH PPS. Specifically, section 307(a)(2) of the BIPA requires that the increases to the target amounts and the increases to the cap on the target amounts for LTCHs provided for by section 307(a)(1) of the BIPA (as set forth in section 1886(b)(3)(J) of the Act) and the enhanced continuous improvement bonus (CIB) payments for LTCHs provided for by section 122 of the BBRA (as set forth in section 1886(b)(2)(E) of the Act) are not to be taken into account in the development and implementation of the LTCH PPS.

In the August 30, 2002 final rule, we also stated our intentions to monitor LTCH PPS payment data to evaluate whether later data varied significantly from the data available at the time of the original budget neutrality calculations (for example, data related to inflation factors, intensity of services provided, or behavioral response to the implementation of the LTCH PPS). To the extent the later data significantly differ from the data employed in the original calculations, the aggregate amount of payments during FY 2003 based on later data may be higher or lower than the estimates upon which the budget neutrality calculations were based. Therefore, in that same final rule, under the broad authority conferred upon the Secretary in developing the LTCH PPS, including the authority for establishing appropriate adjustments, provided by section 123(a)(1) of the BBRA, as amended by section 307(b) of BIPA, we provided in § 412.523(d)(3) of the regulations for the possibility of making a one-time prospective adjustment to the LTCH PPS rates by a deadline of October 1, 2006, so that the effect of any significant difference between actual payments and estimated payments for the first year of the LTCH PPS would not be perpetuated in the LTCH PPS rates for future years. This deadline was revised to July 1, 2008, in the RY 2007 LTCH PPS final rule

because sufficient time had not elapsed since the start of the LTCH PPS for new data to be generated that would have enabled us to conduct a comprehensive reevaluation of our budget neutrality calculations (71 FR 27842 through 27844). Therefore, we did not implement the one-time prospective adjustment provided under § 412.523(d)(3) at that time; however, we stated that we would continue to collect and interpret new data as it became available in order to determine whether we should propose such an adjustment in the future. Furthermore, we revised § 412.523(d)(3) by changing the original October 1, 2006 deadline to July 1, 2008, to postpone the prospective one-time adjustment due to the time lag in the availability of Medicare data upon which a proposed adjustment would be based, noting that there is a lag time between the submission of claims data and cost report data, and the availability of that data in the MedPAR files and HCRIS, respectively. We also explained that we believed that postponing the deadline of the prospective one-time prospective adjustment to the LTCH PPS rates provided for in § 412.523(d)(3) to July 1, 2008, would allow our decisions regarding a possible adjustment to be based on more complete and up-to-date data (71 FR 27842 through 27845).

Section 114(c)(4) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173) (MMSEA) provides that the ''Secretary shall not, for the 3-year period beginning on the date of the enactment of this Act, make the one-time prospective adjustment to long-term care hospital prospective payment rates provided for in section 412.523(d)(3) of title 42, Code of Federal Regulations, or any similar provision.'' That provision delayed the effective date of any one-time prospective adjustment until no earlier than December 29, 2010. Accordingly, we revised § 412.523(d)(3) of the regulations to conform with this requirement (73 FR 26801 through 26804 and 26839). Then, section 3106 of the Affordable Care Act amended section 114(c) of the MMSEA by specifying an additional 2-year delay in the one-time prospective adjustment to the standard Federal rate at § 412.523(d)(3). Thus, under current law the Secretary is precluded from making the one-time adjustment to standard Federal rate until December 29, 2012. Therefore, we revised § 412.523(d)(3) to conform with this requirement (75 FR 50399 and 50416).

Prior to the statutory delay in the application of any one-time prospective adjustment required when the MMSEA was enacted on December 29, 2007, we had developed a methodology for evaluating whether to propose a one-time prospective adjustment under § 412.523(d)(3) of the regulations. In order to inform the public of our thinking, and to stimulate comments for our consideration during the statutory delay in implementing any one-time prospective adjustment, we discussed our analysis and its results in the RY 2009 LTCH PPS proposed and final rules (73 FR 5353 through 5360 and 26800 through 26804, respectively).

Evaluating the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3) requires a thorough review of the relevant LTCH data (as described below). As we discussed in the RY 2009 LTCH PPS proposed and final rules, we conducted a thorough review of the relevant data, that is, cost data from FY 2002, representing the final year LTCHs were paid under the TEFRA payment system. The cost report data for FY 2002 is comprised of a high proportion of settled and audited cost reports submitted by LTCHs. We also have payment data on the first year of the LTCH PPS (that is, FY 2003). On the basis of our review of these data sources, we discussed a potential methodology for determining whether the one-time prospective adjustment provided for under § 412.523(d)(3) of the regulations should be proposed and the computation an adjustment, if appropriate, based on that potential methodology. We also discussed that under that potential methodology, our analysis indicated that a permanent adjustment factor of 0.9625 to the LTCH PPS standard Federal rate could be warranted. Consistent with the requirements of section 114(c)(4) of the MMSEA, which delayed the implementation of such an adjustment, we did not propose any one-time prospective adjustment to the standard Federal rate. However, we presented our analysis and welcomed public comment to inform the public of our analysis if and when we decide to propose (and ultimately finalize) such an adjustment under § 412.523(d)(3).

As we discussed in the RY 2009 LTCH PPS final rule (73 FR 26803), our policy objective in providing for this one-time prospective adjustment has always been to ensure that computations based on the earlier, necessarily limited (but at that time best available) data available at the inception of the LTCH PPS would not be built permanently into the rates if data available at a later date could provide more accurate results. When we established the FY 2003 standard Federal rate in a budget neutral manner, we used the most recent LTCH cost data available at that time (that is, FY 1999 data), and trended that data forward to estimate what Medicare would have paid to LTCHs in FY 2003 under the TEFRA payment system if the PPS were not implemented for FY 2003. As we discussed in the RY 2009 LTCH PPS final rule (73 FR 26803), after a thorough evaluation of the currently available data in light of this stated policy objective, we believe that the most appropriate methodology for evaluating an adjustment to the original budget neutrality adjustment would be to compare estimated payments in the first year under the LTCH PPS to what estimated payments would have been under the prior TEFRA payment system for that year based on the best available data. Accordingly, in that same final rule, we revised § 412.523(d)(3) to provide for the possibility of making a one-time prospective adjustment to LTCH PPS rates so that ''the effect of any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years.''

The regulations at § 412.523(d)(3) provide that the Secretary may make a one-time prospective adjustment to the LTCH PPS rates in order to ensure that any ''significant'' difference is not perpetuated in the LTCH PPS rates for future years. The regulation does not specifically define what constitutes a significant difference for this purpose. In this proposed rule, in evaluating whether a one-time prospective adjustment under § 412.523(d)(3) is warranted, we are proposing to consider as ''significant'' any difference greater than or equal to a 0.25 percentage point difference between the original budget neutrality calculations and budget neutrality calculations based on the more recent data now available. As we discussed in the RY 2009 LTCH PPS final rule (73 FR 26804), we believe this proposed threshold would avoid making an adjustment to account for very minor deviations between earlier and later estimates of budget neutrality. It would also be consistent with thresholds that we employ for similar purposes in other prospective payment systems. For example, under the capital IPPS, we make a forecast error correction in the framework used to update the capital Federal rate if a previous forecast of input prices varies by at least a 0.25 percentage point from actual input price changes (72 FR 47425). We do not

believe that we should treat differences greater than or equal to 0.25 percent as not ''significant,'' since the effect of any difference would be magnified as the rates are updated each year.

In order to determine whether a one-time prospective adjustment would be warranted, as we discussed in the RY 2009 LTCH PPS proposed and final rules, we evaluated several issues regarding the data to use for this purpose. These issues and our proposals related to these issues are discussed below.

As noted previously, as we considered the appropriateness of a one-time prospective adjustment to the standard Federal rate, it is necessary to estimate both aggregate payments under the LTCH PPS for FY 2003 and the estimated aggregate payments that would have been made under the TEFRA system in FY 2003 if the LTCH PPS were not implemented. While it is possible to determine actual TEFRA payments to LTCHs for FY 2002, the last year of payment under that methodology, it is necessary to estimate what TEFRA payments would have been in FY 2003 if the new LTCH PPS had not been implemented. In developing our proposed methodology for evaluating a one-time prospective adjustment, we considered whether we should use actual FY 2003 costs to calculate estimated TEFRA payments for FY 2003 or use costs for FY 2002 trended forward to FY 2003 as the basis for the calculation. As we discussed in the RY 2009 LTCH PPS final rule (73 FR 26802), basing the estimate on actual FY 2003 costs would have the considerable advantage of avoiding the need to inflate FY 2002 costs to FY 2003 costs. However, there is also a potentially serious disadvantage to using actual FY 2003 costs. Because FY 2003 was the first year of payment under the LTCH PPS, the cost experience of LTCHs in that year would reflect their response to the incentives provided by the new payment system, instead of reflecting behavior under the reasonable cost payment system. Indeed, implementation of an LTCH PPS should directly affect the behavior of LTCHs, and, therefore, the level of costs in LTCHs. One of the incentives of a PPS is to improve efficiency in the delivery of care, which generally results in decreased cost per discharge. For this reason, using FY 2003 costs directly could be a poor basis for estimating payments that ''would have been made if the LTCH PPS were not implemented.'' On balance, however, we believe that trending forward for 1 year the costs incurred under the last year of the TEFRA payment system poses a smaller prospect for distortion than using costs incurred during the subsequent year, when the incentives faced by LTCHs to reduce costs could have had a significant effect. We also note that some LTCH stakeholders have expressed concern that using FY 2003 costs directly would provide a poor basis upon which to estimate payments that ''would have been made if the LTCH PPS were not implemented'' for precisely the reasons discussed above. Therefore, we believe that basing the estimate of FY 2003 TEFRA payments on FY 2002 costs trended forward should satisfy these concerns.

In this proposed rule, under the broad authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of BIPA, in evaluating the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3) of the regulations, we are proposing to base our calculation of the estimated aggregate payments that would have been made if the LTCH PPS were not implemented (that is, estimated FY 2003 TEFRA payments) on FY 2002 costs trended forward for the reasons discussed above. Specifically, under our proposed methodology, we trended forward the most recent available LTCH FY 2002 costs to FY 2003 using the excluded hospital market basket, because we believe these data best reflect the price changes in hospital inpatient costs realized by LTCHs from FY 2002 to FY 2003. We believe using the excluded hospital market basket to update FY 2002 reasonable cost-based (TEFRA) payments in order to estimate FY 2003 TEFRA payments is appropriate because the TEFRA payment system under which LTCHs were paid prior to the implementation of the LTCH PPS utilized the excluded hospital market basket to update the hospital-specific limits on payment for operating costs of LTCHs. In addition, we used the excluded hospital market basket to update the inpatient hospital operating and capital costs of LTCHs when we developed the initial LTCH PPS standard Federal rate for FY 2003 (67 FR 56029 through 56031). We believe that the LTCH cost report data for FY 2002 currently available is appropriate to use for this purpose because, as noted above, it is comprised of settled and audited cost reports submitted by LTCHs. (We note that this is the same methodology for evaluating the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3) that we presented in the RY 2009 LTCH PPS proposed and final rules (73 FR 5356 and 26802, respectively).)

As discussed above, to determine whether a one-time prospective adjustment under § 412.523(d)(3) may be warranted, we believe that an estimate of the payments that would have been made in FY 2003 under the TEFRA methodology should be compared to estimated payments under the new LTCH PPS in FY 2003. We explained in the RY 2009 LTCH PPS final rule (73 FR 26802) that the most direct way to determine payments under the new LTCH PPS is simply to aggregate the actual payments calculated under the LTCH PPS methodology for the discharges that occurred during the first year of the LTCH PPS (FY 2003). However, that approach raises an issue of consistency since the discharges for which Medicare payments were made under the LTCH PPS during FY 2003 are not the same as the discharges for which costs were incurred during the last year of payment under the TEFRA methodology, FY 2002. For these reasons discussed above, we believe that the best way to estimate the TEFRA payments that would have been made to LTCHs during FY 2003 is to use inflated FY 2002 costs as a proxy for FY 2003 costs. Comparing actual FY 2003 LTCH PPS payments to FY 2003 TEFRA payments estimated on the basis of FY 2002 discharges would amount to a comparison between payments related to two different sets of discharges, potentially skewing the results. Therefore, for the purpose of consistency, rather than comparing TEFRA payments based on FY 2002 costs updated to FY 2003, to aggregate LTCH PPS payments for discharges that actually occurred in FY 2003, it would be preferable to compare estimated TEFRA payments based on updated FY 2002 costs to the estimated payments that would have been made under LTCH PPS methodology in FY 2003 for those same FY 2002 discharges.

In this proposed rule, under the broad authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of BIPA, in evaluating the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3) of the regulations, we are proposing to base our estimate of FY 2003 LTCH PPS payments on the same set of discharges (from FY 2002) which are the basis for the estimate of what would have been paid in FY 2003 under the reasonable cost-based (TEFRA) payment system. Specifically we are proposing to compare—

- Estimated aggregate FY 2003 TEFRA payments calculated on the basis of FY 2002 costs updated to FY 2003; to

• Estimated aggregate payments that would have been made in FY 2003 under the LTCH PPS methodology, by applying the FY 2003 LTCH payment rules to the discharges that occurred in FY 2002.

We believe that this approach would ensure that we are comparing the estimated FY 2003 TEFRA payments, which are based on updated costs incurred for FY 2002 discharges, to the estimated PPS payments that would have been made for those same FY 2002 discharges under the new LTCH PPS payment methodology. (We note that this is the same methodology for evaluating the appropriateness of the possible one-time prospective adjustment under § 412.523(d)(3) of the regulations that we presented in the RY 2009 LTCH PPS proposed and final rules (73 FR 5356 and 73 FR 26802, respectively).)

Under our proposal to use FY 2002 LTCH costs as a basis for estimating FY 2003 LTCH TEFRA payments in evaluating whether to propose a one-time prospective adjustment under § 412.523(d)(3), we are proposing to update LTCHs' FY 2002 costs for inflation to FY 2003 by our Office of the Actuary's current estimate of the actual increase in the excluded hospital market basket from FY 2002 to FY 2003 of 4.2 percent. This updated amount would serve as the proxy for actual FY 2003 costs under the TEFRA payment system in the proposed budget neutrality computation for purposes of the one-time prospective adjustment at § 412.523(d)(3). We note that when estimating reasonable cost-based payments under the TEFRA payment system, under our proposed methodology we updated LTCHs' TEFRA target amounts from FY 2002 to FY 2003 using the forecasted market basket percentage increase of 3.5 percent, as discussed in greater detail below. This approach maintains consistency with the approach taken in the FY 2003 IPPS final rule in which we established an applicable rate-of-increase percentage to update TEFRA target amounts from FY 2002 to FY 2003 of 3.5 percent (67 FR 50289). This increase was based on our Office of the Actuary's forecasted increase in the excluded hospital market basket for FY 2003, using the best available data at that time. Based on more recent data, our Office of the Actuary now estimates the actual increase in the excluded hospital market based from FY 2002 to FY 2003 is 4.2 percent (as stated above). We believe it is appropriate to propose to use the current estimate of the actual increase in the excluded hospital market basket based from FY 2002 to FY 2003 (4.2 percent) to update LTCHs' FY 2002 costs for inflation to FY 2003 because this reflects the most recent estimate of increases in the prices of goods and services realized by LTCHs when providing inpatient hospital services.

Our proposed methodology to estimate FY 2003 LTCH payments under the TEFRA payment system is similar in concept to the methodology we used to estimate FY 2003 LTCH total payments under the TEFRA payment system when we determined the initial standard Federal rate in the August 30, 2002 final rule (67 FR 56030 through 56033). We note that our proposed methodology for estimating FY 2003 LTCH total payments under the TEFRA payment system using FY 2002 cost data for the purposes of the one-time prospective adjustment at § 412.523(d)(3), includes modifications to the methodology we used to estimate FY 2003 LTCH total payments under the TEFRA system when we implemented the LTCH PPS because we are using data from a later period (FY 2002 as compared to FYs 1998 and 1999), as discussed in greater detail below. In general, we are proposing to estimate total LTCH payments under the TEFRA payment system in FY 2003 using the following steps:

• Estimate each LTCH's payment per discharge for inpatient operating costs under the TEFRA payment system for FY 2003, including continuous bonus improvement payments (proposed step 1);

• Estimate each LTCH's payment per discharge for capital-related costs for FY 2003 (proposed step 2); and

• Sum each LTCH's estimated operating and capital payment per case to determine its estimated total FY 2003 TEFRA payment system payment per discharge (proposed step 3).

We discuss each of these proposed steps in greater detail below.

Proposed Step 1.—Estimate each LTCH's payment per discharge for inpatient operating costs under the TEFRA payment system for FY 2003.

Under our proposed methodology, the first step in the process of estimating total FY 2003 payments under the TEFRA payment system would be to estimate each LTCH's payment per discharge for inpatient operating costs under the TEFRA payment system. Until FY 1998, the payment methodology for inpatient operating costs under the TEFRA payment system was a relatively straightforward process. First, we calculated a target amount by dividing the Medicare total allowable inpatient operating costs in a base year by the number of Medicare discharges. The provider's target amount under the TEFRA payment system (referred to as the TEFRA target amount) was then updated by a rate-of-increase percentage (§ 413.40(c)(3) of the regulations to determine the TEFRA target amount for the subsequent cost reporting period (§ 413.40(c)(4)(i) and(ii)). Generally, for any particular cost reporting period, the Medicare payment for inpatient operating costs would be the lesser of the hospital's allowable net inpatient operating costs, or the updated TEFRA target amount multiplied by the number of Medicare discharges during the cost reporting period, that is, the TEFRA ceiling (§ 413.40(a)(3)).

The TEFRA payment system methodology described above, broadly speaking, is the general approach that we are proposing to use to arrive at an estimate of what Medicare payments for hospital inpatient operating costs would have been in FY 2003 under the TEFRA payment system. That is, under our proposed methodology, each LTCH's FY 2003 TEFRA target amount would be calculated by updating its estimated FY 2002 target amount per discharge by the full market basket percentage increase. The sum of all LTCH payments for operating costs (TEFRA target amount multiplied by Medicare discharges), bonus or relief payments, continuous improvement bonus payments, and payments for capital-related costs yields, in general, the estimate of what total Medicare payments to LTCHs would have been in FY 2003 under the TEFRA payment system if the LTCH PPS had not been implemented.

However, because sections 4413 through 4419 of the BBA of 1997, section 122 of the BBRA of 1999, and section 307(a)(1) of the BIPA made numerous changes to the TEFRA payment system, our proposed methodology reflects variations in the method described above to arrive at the estimate of FY 2003 payments for the inpatient operating costs of each LTCH under the TEFRA payment system, depending on the participation date of the hospital. Specifically, we are proposing to make the requisite computations differently for two classes of hospitals, ''existing'' hospitals and ''new'' hospitals. (A detailed explanation of the provisions affecting LTCHs, established by each of the amendments, is found in the August 30, 2002 final rule that implemented the LTCH PPS (67 FR 55959).) We discuss below these specific BBA, BBRA, and BIPA changes, and their impact on the calculations of estimated FY 2003 TEFRA payments for ''existing'' and ''new'' hospitals under our proposed methodology for estimating total LTCH payments under the TEFRA payment

system in FY 2003 for purposes of the one-time prospective adjustment under § 412.523(d)(3). As discussed in greater detail below, we are proposing to employ two approaches to estimate Medicare payments under the TEFRA payment system to LTCHs in FY 2003, depending on how these changes in calculating TEFRA payments, as established by the amendments, applied to each LTCH. (We note, the discussion below of the specific BBA, BBRA, and BIPA changes and their impact on the calculations of estimated FY 2003 TEFRA payments for ''existing'' and ''new'' hospitals under our proposed methodology for estimating total LTCH payments under the TEFRA payment system in FY 2003 for purposes of the one-time prospective adjustment under § 412.523(d)(3) is the same as the discussion presented in the RY 2009 LTCH PPS proposed rule (73 FR 5356 through 5359).)

The first set of changes that we would take into account was included in the BBA. The BBA made significant changes to the TEFRA payment methodology starting with cost reporting periods beginning on or after October 1, 1997. While the changes were applicable to three types of PPS-excluded providers (rehabilitation hospitals and units, psychiatric hospitals and units, and LTCHs), the following discussion will address the provisions of the amendments as they relate to LTCHs.

The first change to consider under the BBA is section 4414 that established caps on the TEFRA target amounts for cost reporting periods beginning on or after October 1, 1997, for LTCHs that were paid as IPPS-excluded providers prior to that date. The cap was determined by taking the 75th percentile of target amounts for cost reporting periods ending in FY 1996 for each class of provider (rehabilitation hospitals and units, psychiatric hospitals and units, and LTCHs), updating that amount by the market basket percentage increases to FY 1998, and applying it to the cost reporting period beginning on or after October 1, 1997 (62 FR 46018). The cap calculated for FY 1998 was updated by the applicable market basket percentages for cost reporting periods beginning during FY 1999 through 2002. Providers subject to the 75th percentile cap were paid the lesser of their inpatient operating costs or the TEFRA target amount, which was limited by the 75th percentile cap amount (67 FR 55959). In addition, section 4411 of the BBA established a formula for calculating the update factor for FY 1999 through FY 2002 that was dependent on the relationship of a provider's inpatient operating costs to its ceiling amount based on data from the most recently available cost report. Section 121 of the BBRA provided that the 75th percentile cap amount should be wage adjusted, starting with cost reporting periods beginning on or after October 1, 1999, and before October 1, 2002.

The second change that we would take into account was section 4415 of the BBA. This provision revised the percentage factors used to determine the amount of bonus and relief payments for LTCHs meeting specific criteria. If a provider's net inpatient operating costs did not exceed the hospital's ceiling, a bonus payment was made to the LTCH (§ 413.40(d)(2) of the regulations). The bonus payment was the lower of 15 percent of the difference between the hospital's inpatient operating costs and the ceiling, or 2 percent of the ceiling. In addition, relief payments were made to providers whose net inpatient operating costs were greater than 110 percent of the ceiling (or adjusted ceiling, if applicable). These relief payments were the lower of 50 percent of the allowable inpatient operating costs in excess of 110 percent of the ceiling (or the adjusted ceiling, if applicable) or 10 percent of the ceiling (or adjusted ceiling, if applicable) (§ 413.40(d)(3)(ii) of the regulations).

The third change that should be considered would be the additional incentive established by section 4415 of the BBA, the CIB payment for providers meeting certain conditions and that kept their costs below the target amount. Eligibility for the CIB payment required that a provider had three full cost reporting periods as an IPPS-excluded provider prior to the applicable fiscal year (62 FR 46019). To qualify for a CIB payment, a provider's operating costs per discharge in the current cost reporting period had to be lower than the least of any of the following: its target amount; its expected costs, that is, the lower of its target amount or allowable inpatient operating costs per discharge from the previous cost reporting period, updated by the market basket percent increase for the fiscal year; or, its trended costs, that is, the inpatient operating costs per discharge from its third full cost reporting period, updated by the market basket percentage increase to the applicable fiscal year (62 FR 46019; § 413.40(d)(5)(ii)(B) of the regulations). For providers with their third or subsequent full cost reporting period ending in FY 1996, trended costs are the lower of their allowable inpatient operating costs per discharge or target amount updated forward to the current year (§ 413.40(d)(5)(ii)(A) of the regulations). The CIB payment equals the lesser of 50 percent of the amount by which the operating costs were less than expected costs, or 1 percent of the ceiling (§ 413.40(d)(4) of the regulations). Section 122 of the BBRA increased this percentage for LTCHs for FY 2001 to 1.5 percent of the ceiling, and beginning in FY 2002, to 2 percent of the ceiling (§ 413.40(d)(4)(ii) and (iii) of the regulations). The increase in the CIB payment percentage is not to be accounted for in the development and implementation of the LTCH PPS in accordance with section 307(a)(2) of BIPA.

The fourth change that we would take into account was section 4416 of the BBA, which significantly revised the payment methodology for ''new'' IPPS-excluded providers. This provision applies to three classes of providers—psychiatric hospitals and units, rehabilitation hospitals and units, and LTCHs—that were not paid as excluded hospitals prior to October 1, 1997. The payment amount for a new provider for the first 12-month cost reporting period is the lower of its Medicare inpatient operating cost per discharge or a limit based on 110 percent of the national median of target amounts for the same class of hospital for cost reporting periods ending in FY 1996, updated by the market basket percentage increases to the applicable period, and wage-adjusted. The payment limit in the second 12-month cost reporting period is the same 110 percent limit as for the first year (§ 413.40(f)(2)(ii)). A new provider's target amount would be established in its third cost reporting period by updating the amount paid in its second cost reporting period by the market basket percentage increase for hospitals and hospital units excluded from the IPPS, applicable to the specific year, as published annually in the **Federal Register**, which then becomes the target amount for its third cost reporting period. The target amount for the fourth and subsequent cost reporting periods is determined by updating the target amount from the previous cost reporting period by the applicable market basket percentage increase.

Finally, two provisions under BIPA specifically related to LTCHs. Section 307(a) of BIPA provided a 2 percent increase to the wage-adjusted 75th percentile cap for existing LTCHs for cost reporting periods beginning in FY 2001, and a 25 percent increase to the target amount for LTCHs, subject to the increased 75th percentile cap. However, it is important to note that in accordance with section 307(a)(2) of BIPA, the 2 percent increase to the 75th percentile cap and the 25 percent

increase to the target amount were not to be taken into account in the development and implementation of the LTCH PPS.

In this proposed rule, under our proposed methodology, in order to determine what a LTCH's estimated payments would be under the TEFRA payment system in FY 2003, we are proposing to use cost report data for LTCHs from the Hospital Cost Reporting Information System (HCRIS) for FYs 1999 through 2002. In addition, to determine whether a LTCH is ''new,'' the certification date for each LTCH was obtained from the On-line Survey & Certification Automated Reporting (OSCAR) file. Based on the certification date, a LTCH would either be a ''new'' LTCH, meaning a LTCH that was not paid as an excluded hospital prior to October 1, 1997, or, an ''existing'' LTCH, meaning a LTCH that was paid as an excluded hospital prior to October 1, 1997. This could include a LTCH that was certified as an LTCH on or after October 1, 1997, but was previously paid as another type of IPPS-excluded provider prior to October 1, 1997. Our proposed approach to estimating Medicare payments in FY 2003 under the TEFRA payment system would vary somewhat, depending on whether an LTCH was ''existing'' or ''new'' is discussed in greater detail below. Below we discuss our proposed methodology for estimating FY 2003 inpatient operating payments under the TEFRA payment system for ''existing'' hospitals (proposed Step 1.a.) and ''new'' hospitals (proposed Step 1.b.), and our proposed methodology for estimating CIB payments under the TEFRA payment system in FY 2003 (under proposed Step 1.c.).

Proposed Step 1.a.—Estimate FY 2003 inpatient operating payments under the TEFRA payment system for ''existing'' LTCHs.

Based on the applicable statutory changes mentioned above, under our proposed methodology, the first step would be to estimate FY 2003 inpatient operating payments under the TEFRA payment system for ''existing'' LTCHs. ''Existing'' LTCHs are those receiving payment as IPPS-excluded providers in cost reporting periods prior to FY 1998. These LTCHs were subject to the 75th percentile cap on their hospital-specific target amounts. While section 307(a)(1) of BIPA provided for a 2-percent increase to the 75th percentile cap amount for LTCH's for cost reporting periods beginning in FY 2001 and a 25-percent increase to the target amount for cost reporting periods beginning in FY 2001 (subject to the limiting or cap amount determined under section 1886(b)(3)(H) of the Act), section 307(a)(2) of BIPA precluded accounting for these increases in developing the LTCH PPS. In addition, section 122 of the BBRA increased the CIB payment percentage to 1.5 percent for FY 2001 and 2.0 percent for FY 2002 (§ 413.40(d)(4)(ii) and (iii)). But these increases, also, are not to be accounted for the development and implementation of the LTCH PPS in accordance with section 307(a)(2) of BIPA. Therefore, to ensure that these increases would be excluded from the computations, as required by the statute, we are proposing to estimate an existing LTCH's FY 2003 target amount by starting with the hospital's target amount from the FY 2000 cost report, the year prior to when these increases were effective. Target amounts and payments for FY 2003 would be simulated using the FY 2000 target amount in the hospital's cost report and updating the target amount for each subsequent cost reporting period by the applicable rate-of-increase percentage as described in § 413.40(c)(3)(vii) through FY 2002. The target amount from FY 2002 would be updated by the forecasted market basket percentage increase of 3.5 percent to arrive at the FY 2003 target amount (§ 413.40(c)(3)(viii)). (We note that the forecasted increase in the excluded hospital market basket for FY 2003 of 3.5 percent would be used to establish the applicable rate-of-increase percentage used to update TEFRA target amounts in accordance with § 413.40(c)(3)(viii) in the FY 2003 IPPS final rule (67 FR 50289)). Based on more recent data, our Office of the Actuary currently estimates an increase of 4.2 percent in the excluded hospital market basket for FY 2003, which we are proposing to use to update LTCHs' FY 2002 costs to FY 2003, as described below.) In a small number of cases where FY 2002 operating cost data were not available, we would use operating cost data from the most recent year available and trend it forward to FY 2003. In addition, we would estimate FY 2003 bonus or relief payments without the inclusion of the 2-percent and 25-percent increases to the cap amount and target amount, respectively, and without the 1.5 percent and 2.0 percent increases to the CIB payments, consistent with section 307(a)(2) of BIPA as discussed above.

In addition, because comparisons are made between the target amount and Medicare inpatient operating costs to determine bonus or relief payments, under our proposed methodology, we would estimate FY 2003 operating costs for each LTCH by updating its FY 2002 operating costs by the actual percentage increase in operating costs for PPS-excluded hospitals from FY 2002 to FY 2003 (4.2 percent, as determined by our Office of the Actuary) because this is currently our best estimate of actual cost increase from FY 2002 to FY 2003 realized by excluded hospitals, including LTCHs. As discussed earlier, we are proposing to estimate the FY 2003 operating costs using FY 2002 costs rather than using the costs reported on the FY 2003 cost report.

The 75th percentile cap for LTCHs for FY 2002, without the 2-percent and 25-percent increases to the cap and target amount, respectively, was $30,783 for the wage-index adjusted labor-related share, and $12,238 for the nonlabor-related share. If a LTCH's costs and hospital-specific target amount were above the 75th percentile cap, Medicare's payment under the TEFRA system would be the wage-index adjusted cap amount. If under our proposed payment model a LTCH's estimated FY 2002 TEFRA payment would have been limited by the wage-adjusted 75th percentile cap in FY 2002, that amount would be updated by the forecasted market basket percentage increase (of 3.5 percent) to FY 2003 to determine the LTCH's FY 2003 target amount that was used to estimate its TEFRA payment system amount for FY 2003 under our proposed methodology.

Proposed Step 1.b.—Estimate FY 2003 inpatient operating payments under the TEFRA payment system for ''new'' LTCHs.

Next, under our proposed methodology, we would estimate FY 2003 hospital operating payments under the TEFRA payment system applied to ''new'' LTCHs based on the applicable statutory changes discussed above. A ''new'' LTCH is one that was first paid as an IPPS-excluded hospital on or after October 1, 1997. For a ''new'' LTCH, payment in the hospital's first 12-month cost reporting period is the lower of its Medicare net inpatient operating costs per discharge or the wage-adjusted 110 percent median amount determined for that particular year (§ 413.40(f)(2)(ii) of the regulations). For the hospital's second 12-month cost reporting period, payment is the lower of their costs, or the same 110 percent median amount that was used in the first cost reporting period, that is, it is not updated. The hospital's ''target amount'' is established in the third cost reporting period by updating the per discharge amount that was paid in the prior cost reporting period by the estimated market basket percentage increase for hospitals and hospital units excluded from the IPPS,

applicable to the specific year, as published annually in the **Federal Register**. Therefore, if the LTCH was paid its costs in the previous cost reporting period because costs were lower than the 110 percent median amount, the hospital's cost per discharge for the second cost reporting period is updated and becomes the target amount for the hospital's third cost reporting period. Target amounts for subsequent cost reporting periods are determined by updating the previous year's target amount by the applicable market basket percentage increase.

New LTCHs with their first 12-month cost reporting period beginning in FY 1998 would have had a target amount calculated under section 1886(b)(7)(A)(ii) of the Act in FY 2000. Therefore, consistent with our proposals concerning ''existing'' LTCHs (described in proposed Step 1.a. above), in estimating the FY 2003 target amount for ''new'' LTCHs we are proposing to use the target amount from the FY 2000 cost report and update that target amount by the applicable estimated market basket percentage increases as published annually in the **Federal Register** for the IPPS final rule, without the 25-percent increase, to FY 2003. That is, we used 3.4 percent to update from FY 2000 to FY 2001, 3.3 percent to update from FY 2001 to FY 2002, and 3.5 percent to update from FY 2002 to FY 2003. For LTCHs with their first 12-month cost reporting period beginning in FY 1999, we would use the lower of their costs or target amount from their FY 2000 cost report, and updated that amount by the applicable estimated market basket percentage increase to establish the target amount in FY 2001, without the 25-percent increase. Next, we would continue to update that target amount by the estimated market basket percentage increases to FY 2003. We believe that it is necessary to propose to compute an estimated target amount for LTCHs that are ''new'' in FY 1999 under our proposed methodology in order to eliminate the potential inclusion of the increase to the target amounts provided for by section 307(a)(1) of BIPA (consistent with the statute).

The 25-percent increase (under section 307(a) of the BIPA) to the target amount would not be an issue for LTCH's with their first 12-month cost reporting period beginning in FYs 2000, 2001, and 2002 because they would not have a ''target amount'' based on sections 1886(b)(7)(A)(ii) of the Act, in FY 2001. Rather, for these LTCHs, under our proposed methodology we would determine the estimated payment amount for their first 12-month cost reporting period by looking at their certification date from the OSCAR file, the applicable 110 percent median amount (adjusted by their wage-index) and their costs from the applicable cost report, and then proceed in accordance with the policy in § 413.40(f)(2)(ii) of the regulations, to arrive at estimated FY 2003 TEFRA payments.

Proposed Step 1c.—Estimate CIB payments that would have been made in FY 2003 under the TEFRA payment system (for both ''existing'' and ''new'' LTCHs).

In addition to the TEFRA system payments for operating costs, and any bonus or relief payments made, we also are proposing to add an amount to account for the estimate of the CIB payments that would have been made in FY 2003 under the TEFRA payment system under § 413.40(d)(4). We are proposing to estimate what CIB payments would have been in FY 2003 by using actual CIB payments from the cost reports for FYs 1999 and 2000, as they would not include the statutory increases to the target amount discussed above, and recalculated CIB payments for FYs 2001 and 2002 based on cost report data. Based on these historical CIB payments, we estimated that CIB payments in FY 2003 would have been approximately $10 million. Just as the TEFRA payments and bonus and relief payments had to be recalculated in particular years to eliminate percentage increases that are not to be included in our budget neutrality calculations (as required by the statute), we believe that it is necessary to propose to recalculate the CIB payments in FYs 2001 and 2002 to eliminate the percentage increases to these payments as provided for under section 122 of BBRA, such that they would not be accounted for in the development of the LTCH in accordance with section 307(a)(2) of BIPA. Therefore, under our proposed methodology, we are proposing to add $10 million as an estimate of the CIB payments that would have been made in FY 2003 under the TEFRA payment system to our estimated FY 2003 TEFRA system payments for operating costs, including any bonus or relief payments.

Step 2.—Estimate each LTCH's payment per discharge for inpatient capital costs under the TEFRA payment system for FY 2003.

As we discussed above, under our proposed methodology, the second step in estimating total payments under the TEFRA payment system is to estimate each LTCH's payment per discharge for capital-related costs for FY 2003. Under the TEFRA payment system, in accordance with the regulations at 42 CFR Part 413, Medicare allowable capital costs are paid on a reasonable cost basis. Therefore, we are proposing to update each LTCH's payment for capital-related costs directly from the FY 2002 cost report for inflation using the FY 2003 capital excluded hospital market basket estimate of 0.7 percent, consistent with the methodology used to establish the initial standard Federal rate (67 FR 56031). Thus, we are proposing to determine capital-related costs per case using capital cost data from Worksheets D, Parts I and II, and total Medicare discharges for the cost reporting period from Worksheet S–3. (We note that since payments for capital-related costs are on a reasonable-cost basis, capital payments were the same for ''existing'' and ''new'' LTCHs.)

Proposed Step 3.—Sum each LTCH's estimated operating and capital payment per case to determine its estimated total FY 2003 TEFRA payment system payment per discharge.

Under our proposed methodology for estimating FY 2003 LTCH total payments under the TEFRA payment system using FY 2002 cost data for the purposes of the one-time prospective adjustment at § 412.523(d)(3), after estimating payments for inpatient operating costs under the TEFRA payment system for FY 2003 and payments for capital-related costs under the TEFRA payment system for FY 2003, we would sum each LTCH's estimated operating and capital payment per case to determine its estimated total FY 2003 TEFRA payment system payment per discharge. Therefore, we are proposing to add the estimate of each LTCH's payment per discharge for inpatient operating costs under the TEFRA payment system for FY 2003, including continuous improvement bonus payments (determined under proposed Steps 1.a. through 1.c. above) and the estimate of each LTCH's payment per discharge for capital-related costs for FY 2003 (determined under proposed Step 2 above).

Once we estimate total TEFRA payments as the sum of each LTCH's estimated operating and capital payment per case, under our proposed methodology for evaluating the one-time prospective adjustment at § 412.523(d)(3), the next step is to estimate FY 2003 payments under the LTCH PPS. As we discussed above, we believe that the best approach is to propose to use FY 2002 LTCH claims data as a proxy for estimating FY 2003 LTCH PPS payments in evaluating the one-time prospective adjustment at § 412.523(d)(3). We note that we are proposed to use the same FY 2002 LTCH MedPAR data that was used to

develop the FY 2004 LTC–DRG relative weights in the FY 2004 IPPS final rule (68 FR 45376), as explained below. As we discussed in that final rule, there is a data problem with the FY 2002 claims data for LTCHs where multiple bills for the stay were submitted. Specifically, given the long stays at LTCHs, some providers had submitted multiple bills for payment under the reasonable cost-based reimbursement system for the same stay. In certain LTCHs, hospital personnel apparently reported a different principal diagnosis on each bill because, under the reasonable cost-based (TEFRA) reimbursement system, payment was not dependent upon principal diagnosis, as it is under a DRG-based PPS system. As a result of this billing practice, we discovered that only data from the final bills were being extracted for the MedPAR file. Therefore, it was possible that the original MedPAR file was not receiving the correct principal diagnosis. In that same IPPS final rule, we discussed how we addressed this problem in the LTCH FY 2002 MedPAR data when we used that data to determine the FY 2004 LTC–DRG relative weights. Therefore, for the evaluation of the one-time prospective adjustment at § 412.523(d)(3) in this proposed rule, we are proposing to use the same ''corrected'' FY 2002 LTCH MedPAR data that was used to develop the FY 2004 LTC–DRG relative weights. For the reader's benefit, we are providing a summary of how we addressed the multiple bill problem in the FY 2002 LTCH MedPAR data below. As we explained in the FY 2004 IPPS final rule (68 FR 45376), we addressed this problem by identifying all LTCH cases in the FY 2002 MedPAR file for which multiple bills were submitted. For each of these cases, beginning with the first bill and moving forward consecutively through subsequent bills for that stay, we recorded the first unique diagnosis codes up to 10 and the first unique procedure codes up to 10. We then used these codes to appropriately group each LTCH case to a LTC–DRG for FY 2004. (We note that this is the same data we used to estimate FY 2003 payments under the LTCH PPS for purposes of evaluating the one-time prospective adjustment at § 412.523(d)(3) that we presented in the RY 2009 LTCH PPS proposed rule (73 FR 5359).)

In this proposed rule, we are proposing to estimate FY 2003 LTCH PPS payments using the same general methodology that we used to estimate FY 2003 payments under the LTCH PPS (without a budget neutrality adjustment) when we determined the initial standard Federal rate in the August 30, 2002 final rule (67 FR 56032). Specifically, we are proposing to estimate FY 2003 LTCH PPS payments for each LTCH by simulating payments on a case-by-case basis by applying the final FY 2003 payment policies established in the August 30, 2002 final rule that implemented the LTCH PPS (67 FR 55954) based on the LTCH case-specific discharge information from the FY 2002 MedPAR files (as explained above), and we also are proposing to use LTCH provider-specific data from the FY 2003 Provider-Specific File (PSF), as these were the data used by fiscal intermediaries to make LTCH payments during the first year of the LTCH PPS (FY 2003). Under our proposed methodology, we are proposing to use the FY 2003 LTC–DRG Grouper (Version 22.0), relative weights, and average length of stay (67 FR 55979 through 55995); we are proposing to make adjustments for differences in area wage levels established for FY 2003 as set forth at § 412.525(c) using the appropriate phase-in wage index values for FY 2003 (67 FR 56015 through 56020); we are proposing to make a cost-of-living adjustment for LTCHs located in Alaska and Hawaii as set forth at § 412.525(b) (67 FR 56022); we are proposing to make adjustments for SSO cases based on the method for determining payment applicable for discharges occurring during FY 2003 in accordance with § 412.529(c)(1) (67 FR 55975 and 55995 through 56002); and we are proposing to include additional payments for HCO cases in accordance with former § 412.525(a) for determining payments for discharges occurring in FY 2003 and the FY 2003 fixed-loss amount of $24,450 (67 FR 56023). (We note that correctly billed interrupted stay cases under § 412.531 are single LTCH cases in the MedPAR files; therefore, we estimated a single LTCH PPS payment for those cases.) Under this proposed methodology, for purposes of this calculation we are proposing to simulate case-by-case payments for each LTCH as if it were paid based on 100 percent of the standard Federal rate in FY 2003 rather than the transition blend methodology set forth at § 412.533. To determine total estimated PPS payments for all LTCHs, we are proposing to sum the individual estimated LTCH PPS payments for each LTCH. (We note that this is the same methodology we used to estimate FY 2003 payments under the LTCH PPS for purposes of evaluating the one-time prospective adjustment at § 412.523(d)(3) that we presented in the RY 2009 LTCH PPS proposed rule (73 FR 5359 through 5360).)

In order to determine if there is any difference between estimated total TEFRA payments and estimated LTCH PPS payments in FY 2003 under our proposed methodology for evaluating a possible one-time prospective adjustment under § 412.523(d)(3), we are proposing to determine a case-weighted average estimated TEFRA payment, consistent with the methodology used when we determined the initial standard Federal rate in the FY 2003 LTCH PPS final rule (68 FR 56032). Under this proposed methodology, each LTCH's estimated total FY 2003 TEFRA payment per discharge would be determined by summing its estimated FY 2003 operating and capital payments under the TEFRA payment system based on FY 2002 cost report data (as described in proposed Step 3 above), and dividing that amount by the number of discharges from the FY 2002 cost report data. Next, we would determine each LTCH's average estimated TEFRA payment weighted for its number of discharges in the FY 2002 MedPAR file (for the purpose of estimating FY 2003 LTCH PPS payments, as discussed above) by multiplying its average estimated total TEFRA payment per discharge by its number of discharges in the FY 2002 MedPAR file. We would then estimate total case-weighted TEFRA payments by summing each LTCH's (MedPAR) case-weighted estimated FY 2003 TEFRA payments. Under our proposed methodology, we are proposing to compare these estimated FY 2003 total TEFRA payments to estimated FY 2003 total LTCH PPS payments in order to determine whether a one-time prospective adjustment would be appropriate. (As discussed in greater detail above, we are proposing to determine both estimated total FY 2003 TEFRA payments and estimated total FY 2003 LTCH PPS payments based on FY 2002 cost report and claims data, respectively.) Our proposal to adjust our proposed estimate of FY 2003 TEFRA payments for the number of discharges that we are proposing to use to estimate FY 2003 LTCH PPS payments would ensure that the comparison of estimated aggregate FY 2003 TEFRA payments to estimated aggregate FY 2003 LTCH PPS payments would be based on the same number of LTCH discharges. (We note that this is the same methodology we used to compare estimated FY 2003 total TEFRA payments to estimated FY 2003 total LTCH PPS payments for purposes of evaluating the one-time prospective adjustment at § 412.523(d)(3) that we presented in the

RY 2009 LTCH PPS proposed rule (73 FR 5360).)

For this proposed rule, using the proposed methodology and data described above, we have calculated that estimated FY 2003 LTCH PPS payments are approximately 2.5 percent higher than estimated payments to the same LTCHs in FY 2003 if the LTCH PPS had not been implemented (that is, estimated total FY 2003 TEFRA payment system payments). This analysis was based on approximately 91,300 LTCH discharges for 250 LTCHs. As discussed above, we are proposing that any difference greater than or equal to 0.25 percentage points that is ''significant'' for purposes of determining whether the one-time prospective adjustment provided under § 412.523(d)(3) would be warranted. Although we project that estimated FY 2003 LTCH PPS payments are approximately 2.5 percent higher than estimated FY 2003 TEFRA payments, proposing to reduce the standard Federal rate by 2.5 percent would not ''maintain budget neutrality'' for FY 2003 (that is, estimated FY 2003 LTCH PPS payments would not be equal to estimated FY 2003 TEFRA payments) because a considerable number of LTCH discharges are projected to have received a LTCH PPS payment in FY 2003 based on the estimated cost of the case (rather than a payment based on the standard Federal rate) under the payment adjustment for SSO cases at § 412.529. Specifically, under our proposed methodology our payment analysis indicates that nearly 20 percent of estimated FY 2003 LTCH PPS payments are SSO payments that were paid based on estimated cost and not based on the LTCH PPS standard Federal rate. These SSO cases that receive a payment based on the estimated cost of the case are generally unaffected by any changes to the standard Federal rate because the estimated cost of the case is determined by multiplying the Medicare allowable charges by the LTCH's cost-to-charge ratio (§ 412.529(d)(2)). In other words, if we were to propose to reduce the standard Federal rate by 2.5 percent, estimated total FY 2003 LTCH PPS payments would still be greater than estimated total FY 2003 TEFRA payments (that is, would not be budget neutral), and this difference would be perpetuated in the LTCH PPS payment rates for future years. This is because the estimated LTCH PPS payments for those SSO cases that in FY 2003 were estimated to have been paid 120 percent of the estimated cost of the case generally are not affected (that is, in this case, not lowered) by any one-time prospective adjustment budget neutrality factor that would be applied to the standard Federal rate because those payments are not derived from the standard Federal rate (as explained above). Therefore, it is necessary to propose to offset the standard Federal rate by a factor that is larger than 2.5 percent in order to ensure that estimated total FY 2003 LTCH PPS payments would be equal to estimated total FY 2003 TEFRA payments in order to ''maintain budget neutrality.'' To determine the necessary adjustment factor that would need to be applied to the standard Federal rate in order to ''maintain budget neutrality,'' we are proposing to simulate FY 2003 LTCH PPS payments using the same payment simulation model discussed above (that we proposed to use to estimate FY 2003 LTCH PPS payments without a budget neutrality factor). Using iterative payment simulations using the data from the 250 LTCHs in our database, we determined that we would need to apply a factor of 0.9625 (that is, a reduction of approximately 3.75 percent rather than 2.5 percent) to the standard Federal rate in order to make estimated total FY 2003 LTCH PPS payments equal to estimated total FY 2003 TEFRA payments consistent with our stated policy goal of the one-time prospective adjustment at § 412.523(d)(3) (that is, to ensure that the difference between estimated total FY 2003 LTCH PPS payments and estimated total FY 2003 TEFRA payments is not perpetuated in the LTCH PPS payment rates in future years). (We note that this proposed adjustment of approximately −3.75 percent is the same result of the evaluation of the one-time prospective adjustment at § 412.523(d)(3) that we presented in the RY 2009 LTCH PPS proposed and final rules (73 FR 5360 and 26804, respectively).) As we note in the RY 2009 LTCH PPS proposed and final rules, in the years following the initial implementation of the LTCH PPS, we have adopted some revised policies and adjustments to LTCH PPS payment levels. However, none of these revised policies and payment adjustments have addressed the intended purpose of the one-time prospective adjustment allowed under § 412.523(d)(3) of the regulations, to ensure that any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 are not perpetuated in the LTCH PPS rates for future years. For example, the adjustments that we have made to account for coding changes in excess of real severity increases in RYs 2007 through 2010 were made to account for changes in coding behavior in the years following the implementation of the LTCH PPS, and not to address any issue regarding the budget neutrality calculations that were used to establish the base rate for the LTCH PPS.

In this proposed rule, based on the proposed methodology described above, under the broad authority granted to the Secretary under section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to revise § 412.523(d)(3) to specify that the standard Federal rate would be permanently reduced by 3.75 percent so that the estimated difference between projected aggregate LTCH PPS payments in FY 2003 and the projected aggregate payments that would have been made in FY 2003 under the TEFRA payment system if the LTCH PPS had not been implemented. Consistent with current law, we also are proposing that this adjustment would not apply to payments for discharges occurring on or after October 1, 2012, and on or before December 28, 2012. Furthermore, given the magnitude of this adjustment and in acknowledgement of hopeful research outcomes (discussed above in section VII.E.2. of this preamble), we are proposing to phase-in this approximate 3.75 percent reduction to the standard Federal rate over a 3-year period. Although the adjustment to the standard Federal rate provided for at § 412.523(d)(3) is called a ''one-time'' prospective adjustment, as stated above, this proposed adjustment would be permanently applied to the standard Federal rate so that the effect of the estimated difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years. During this proposed 3-year period, we intend to further explore potential revisions to certain LTCH PPS payment policies as discussed above in section VII.E.2. of this preamble. Under this proposal, we would make a one-time prospective adjustment by applying a factor of 0.98734 to the standard Federal rate in FY 2013 (which would not be applicable to payments for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, consistent with current law), FY 2014 and FY 2015 to completely account for our estimate (determined using the proposed methodology described above) that a factor of 0.9625 (that is 0.98734

× 0.98734 × 0.98734 = 0.9625) needs to be applied to the standard Federal rate in order to ensure that the difference between estimated total FY 2003 LTCH PPS payments and estimated total FY 2003 TEFRA payments is not perpetuated in the LTCH PPS payment rates in future years consistent with our stated policy goal of the one-time prospective adjustment at § 412.523(d)(3). In other words, we are proposing that in determining the standard Federal rate in each year for FYs 2013 through 2014, we would multiply the standard Federal rate otherwise determined in absence of the one-time prospective adjustment at § 412.523(d)(3) by 0.98734 in order to ensure that the estimated difference between estimated total FY 2003 LTCH PPS payments and estimated total FY 2003 TEFRA payments is not perpetuated in the LTCH PPS payment rates in future years.

VIII. Proposed Quality Data Reporting Requirements for Specific Providers and Suppliers

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 for most settings and to measure various aspects of care for most 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 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 Reporting (OQR) Program (formerly referred to as 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 inpatient rehabilitation hospitals, hospices, and ambulatory surgical centers, and an end-stage renal disease quality improvement program (76 FR 628 through 646) 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 Medicare and Medicaid 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. As appropriate, we will consider the adoption of measures with electronic specifications, so that the electronic collection of performance information is part of care delivery. Establishing such a system will require interoperability between EHRs and CMS data collection systems, additional infrastructural 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 many 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 elements for many measures 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 primarily to EHR-based reporting of data for many measures that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

We have also implemented a Hospital Value-Based Purchasing (VBP) Program under section 1886(o) of the Act. In 2011, we issued the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547). We adopted additional policies for the Hospital VBP Program in section IV.B. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51653 through 51660) and in section XVI. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74527 through 74547). Under the Hospital VBP Program, hospitals will 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 (other than readmission measures) specified under the Hospital IQR Program as required by section 1886(o)(2)(A) of the Act.

In selecting measures for the Hospital IQR Program, we are mindful of the conceptual framework of the Hospital VBP Program. Section 1886(o)(2)(B)(i)(I) of the Act states that for FY 2013, the selected measures for the Hospital VBP Program must cover at least the following five specified conditions or procedures: Acute myocardial infarction (AMI), Heart failure (HF), Pneumonia (PN), surgical care, 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 HAIs (or any successor HHS plan). Section 1886(o)(2)(B)(i)(II) of the Act provides that, for FY 2013, measures selected for the Hospital VBP Program must also be related to the Hospital Consumer Assessment of Healthcare Providers and Systems survey (HCAHPS).

The Hospital IQR Program is linked with the Hospital VBP Program because the measures and reporting infrastructure for both programs 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 healthcare for its beneficiaries. Value-based purchasing is 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. As we stated in the Hospital Inpatient VBP Program proposed rule (76 FR 2455), we applied the following principles for the development and use of measures and scoring methodologies:

- 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 this effort, we will continuously seek to align our measures with the adoption of e-specified measures, so the electronic collection of performance information is part of care delivery.
- To the extent practicable, measures used by CMS should be nationally endorsed by a multistakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

We also view the Hospital-Acquired Condition (HAC) payment adjustment program authorized by section 3008 of the Affordable Care Act and the Hospital VBP Program as being related but separate efforts to reduce HACs. The Hospital VBP Program is an incentive program that awards payments to hospitals based on quality performance, while the program established by section 3008 of the Affordable Care Act creates a payment adjustment resulting in payment reductions for the lowest performing hospitals based on their rates of HACs.

Although we intend to monitor the various interactions of programs authorized by the Affordable Care Act and their overall impact on providers and suppliers, we also view programs that could potentially affect a hospital's Medicaid payment as separate from programs that could potentially affect a hospital's Medicare payment.

In this section VIII. of this proposed rule, we are proposing changes to, or implementing, the following Medicare quality reporting systems:

- In section VIII.A., the Hospital IQR Program.
- In section VIII.B., the Hospital VBP Program.
- In section VIII.C., the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program.
- In section VIII.D., the Long-Term Care Hospital Quality Reporting (LTCHQR) Program.
- In section VIII.E., the Ambulatory Surgical Center Quality Reporting (ASCQR) Program.
- In section VIII.F., the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program.

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background

a. 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 through 43861) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181) for detailed discussions of the history of the Hospital IQR Program, including the statutory history and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51636 through 51637) for the measures we have adopted for the Hospital IQR measure set through FY 2015.

b. 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 (TJC) Specifications Manual for National Hospital Quality Measures (Specifications Manual). This Specifications Manual is posted on the CMS QualityNet Web site at *https://www.QualityNet.org.* We generally update the Specifications Manual on a semiannual basis and include in the updates 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.

Many of the quality measures used in different Medicare and Medicaid reporting programs are endorsed by the National Quality Forum (NQF). The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other healthcare stakeholder organizations. The NQF was established to standardize healthcare quality measurement and reporting through its consensus development process. As part of its regular maintenance process for endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes to NQF on an annual basis. NQF solicits information from measure stewards for annual reviews and in order to review measures for continued endorsement in a specific 3-year cycle.

Through NQF's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, changes to exclusions to the patient population, definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

In this proposed rule, we are proposing that if the NQF updates an endorsed measure that we have adopted for the Hospital IQR Program in a manner that we consider to not substantially change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we would revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We would also post the updates on the QualityNet Web site at *https://www.QualityNet.org.* We would provide sufficient lead time for hospitals to implement the changes where changes to the data collection systems would be necessary.

We would continue to use the rulemaking process to adopt changes to a measure that we consider to substantially change the nature of the measure. We believe that this proposal adequately balances our need to

incorporate NQF updates to NQF-endorsed Hospital IQR Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We invite public comment on this proposal.

c. 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. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51608 through 51609), we adopted a policy 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. 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, structural measures, Emergency Department Throughput timing measures, hospital acquired condition measures, immunization measures, and hospital acquired infection 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, although 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 and memorandums, Hospital Open Door Forums, 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. Removal and Suspension of Hospital IQR Program Measures

a. Considerations in Removing 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 except when they are removed or replaced as indicated. In previous rulemakings, we have referred to the removal of measures from the Hospital IQR Program as ''retirement.'' We have used this term to indicate that Hospital IQR Program measures are no longer included in the Hospital IQR Program measure set for one or more indicated reasons. However, we note that this term may imply that other payers/purchasers/programs should cease using these measures that are no longer required for the Hospital IQR Program. In order to clarify that this is not our intent, beginning with this rulemaking cycle, we will use the term ''remove'' rather than ''retire'' to refer to the action of no longer including a measure in the Hospital IQR Program.

As we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185), the criteria that we consider when determining whether to remove 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 (''topped out'' measures); (2) availability of alternative measures with a stronger relationship to patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) the availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic; (5) the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic; (6) the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and, (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm. These criteria were suggested by commenters during rulemaking, and we agreed that these criteria should be among those considered in evaluating Hospital IQR Program quality measures for removal.

Additionally, we take into account the views of the Measure Application Partnership (MAP). The MAP is a public-private partnership convened by the NQF for the primary purpose of providing input to HHS on selecting performance measures for quality reporting programs and pay for reporting programs. The MAP views patient safety as a high priority area and it strongly supports the use of NQF-endorsed safety measures. Furthermore, for efficiency and streamlining purposes, we strive to eliminate redundancy of similar measures.

b. Hospital IQR Program Measures Removed in Previous Rulemakings

In previous rulemakings, we have removed several Hospital IQR Program quality measures, including:

- PN–1: Oxygenation Assessment for Pneumonia, a ''topped out'' measure, because measures with very high performance among hospitals present little opportunity for improvement and do not provide meaningful distinctions in performance for consumers (73 FR 48604).
- AMI–6: Beta Blocker at Arrival 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, 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 remove such a measure, confirm the removal in the next IPPS rulemaking cycle, and notify hospitals and the public of the decision to promptly remove measures through the usual hospital and QIO communication channels used for the Hospital IQR Program. These channels include memos, email notification, and QualityNet Web site postings.
- Mortality for Selected Procedures Composite measure because the measure is not considered suitable for

purposes of comparative reporting by the measure developer (75 FR 50186).

- Three adult smoking cessation measures: AMI–4: Adult Smoking Cessation Advice/Counselling; HF–4: Adult Smoking Cessation Advice/Counselling; and PN–4: Adult Smoking Cessation Advice/Counselling, because these measures are ''topped-out'' and no longer NQF-endorsed (76 FR 51611).
- PN–5c: Timing of Receipt of Initial Antibiotic Following Hospital Arrival measure out of concerns that the continued collection of this measure might lead to the unintended consequence of antibiotic overuse (76 FR 51611).

c. Proposed Removal of Hospital IQR Program Measures for FY 2015 Payment Determination and Subsequent Years

To accommodate the expansion of the measure set, we have considered the removal of additional Hospital IQR measures using our stated measure removal criteria. Based on some of these criteria, we are proposing to remove 17 measures from the Hospital IQR Program. One of these 17 measures is chart-abstracted, and the other 16 are claims-based.

(1) Proposed Removal of One Chart-Abstracted Measure

We are proposing to remove the SCIP–Venous Thromboembolism (VTE) measure: ''SCIP–VTE–1: Surgery patients with recommended VTE prophylaxis ordered'' measure because we believe that the ''SCIP–VTE–2: Surgery patients who received appropriate VTE prophylaxis within 24 hours of pre/post surgery'' measure currently used in the Hospital IQR Program assesses practices that are more proximal in time to better surgical outcomes resulting from the use of VTE prophylaxis. We also note that during a recent NQF maintenance review of SCIP–VTE–1, the measure was not recommended for continued endorsement.

(2) Proposed Removal of 16 Claims-Based Measures

We are proposing to remove eight HAC measures, three AHRQ Inpatient Quality Indicator (IQI) measures, and five AHRQ Patient Safety Indicator (PSI) measures from the Hospital IQR Program measure set.

(A) Proposed Removal of Eight Hospital-Acquired Condition (HAC) Measures

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50194 through 50196), for the FY 2012 payment determination, we adopted 8 claims-based HAC measures based on 8 of the 10 conditions applicable under the HAC payment provisions specified in section 1886(d)(4)(D) of the Act apply. These eight HAC measures are: Air Embolism; Blood Incompatibility; Catheter-Associated Urinary Tract Infection (UTI); Falls and Trauma: (Includes Fracture Dislocation, Intracranial Injury, Crushing Injury, Burn, Electric Shock); Foreign Object Retained After During Surgery; Manifestations of Poor Glycemic Control; Pressure Ulcer Stages III or IV; and Vascular Catheter Associated Infections. Six of these HACS were identified by NQF as serious reportable events.

We are proposing to remove these eight HAC measures based on several considerations. First, the MAP recommended that we replace the HAC measures in the Hospital IQR Program with NQF-endorsed measures. Second, we seek to reduce redundancy among the measures in the program. Two of the eight HAC measures address HAIs which are addressed by other measures currently in the Hospital IQR Program. These two HAI measures are the NQF-endorsed CAUTI and CLABSI measures collected via the CDC's NHSN system. An additional three of the eight HAC measures address similar topics (pressure ulcers, air embolism, and manifestations of poor glycemic control) to patient safety indicators that are included in the NQF-endorsed AHRQ PSI composite that is also included in the Hospital IQR Program. Accordingly, because more broadly applicable NQF-endorsed measures are available that address the same HAIs and HACs, we believe it is appropriate to remove these measures from the program. We note that section 3008 of the Affordable Care Act will require public reporting of HAC measures, including measures for conditions adopted under section 1886(d)(4)(D) of the Act. HACs remain an important aspect of our strong commitment to measure patient harm and safety. ''Safer care'' is one of the six priorities identified to address the three aims established under the National Quality Strategy. We intend to pursue development of an all-cause harm composite measure for potential use in our quality reporting programs.

(B) Proposed Removal of Three AHRQ IQI Measures

In the FY 2009 IPPS final rule (73 FR 48607), we adopted three claims-based AHRQ IQI outcome measures for the FY 2010 payment determination: (1) IQI–11: Abdominal aortic aneurysm (AAA) repair mortality rate (with or without volume); (2) IQI–19: Hip fracture mortality rate; and (3) IQI–91: Mortality for selected medical conditions (composite).

We are proposing to remove these three AHRQ IQI measures from the Hospital IQR Program. In removing measures from the Hospital IQR Program, we seek to eliminate measures that would not be used under the Hospital VBP Program, and to reduce redundancy among the measures in the Hospital IQR Program. Three of the six conditions in the IQI composite measure overlap with 30-day mortality measures that we have in the Hospital IQR Program, and which were recommended by the MAP for use in the Hospital VBP Program. The proposed removal of these AHRQ IQI measures would eliminate unnecessary redundancy in the Hospital IQR measure set. We also believe that inclusion of a large number of in-hospital mortality measures, the performance on which is highly dependent upon hospital discharge patterns, may lead to unintended consequences of patients being discharged sooner than advisable. We invite public comment on this proposal.

(C) Proposed Removal of Five AHRQ PSI Measures

In the FY 2009 IPPS final rule (73 FR 48607), we adopted three claims-based PSI outcome measures for the FY 2010 payment determination: (1) PSI–06: Iatrogenic pneumothorax; (2) PSI–14: Postoperative wound dehiscence; and (3) PSI–15: Accidental puncture or laceration. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50194), we adopted two more claims-based PSI outcome measures for the FY 2012 payment determination: PSI–11: Post Operative Respiratory Failure; and PSI 12: Post Operative PE or DVT.

We are proposing to remove these five AHRQ PSI measures from the Hospital IQR Program because four of these five individual measures (all but PSI 11) are included in the NQF-endorsed AHRQ PSI Composite measure that is already included in the Hospital IQR Program. Also, the post-operative ventilator associated events assessed in PSI–11 could be captured more robustly using non-administrative data collected via the NHSN in the near future. Therefore, we are proposing to remove these five individual PSIs from the Hospital IQR Program measure set in order to eliminate unnecessary redundancy. We invite public comment on this proposal.

In summary, for the FY 2015 payment determination and subsequent years, we are proposing to remove the SCIP–VTE–1 measure, eight HAC measures, three AHRQ IQI measures, and five AHRQ PSI measures from the Hospital IQR measure set. The list of measures we are

proposing to remove is set out in the table below. We invite public comment on these proposals.

Topic	17 Measures proposed for removal from hospital IQR program measure set for FY 2015 and subsequent payment determinations
Surgical Care Improvement Project (SCIP) Measures.	• SCIP INF VTE–1 Surgery patients with recommended Venous Thromboembolism (VTE) prophylaxis ordered.
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. • IQI 91 Mortality for selected medical conditions (composite).
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.

d. Suspension of Data Collection for the FY 2014 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51611), we suspended data collection for four measures beginning with January 1, 2012 discharges, affecting the FY 2014 payment determination and subsequent years.

Topic	Hospital IQR program measures suspended for FY 2015 payment determination and subsequent years
Acute Myocardial Infarction (AMI) ..	• AMI–1 Aspirin at arrival. • AMI–3 ACEI/ARB for left ventricular systolic dysfunction. • AMI–5 Beta-blocker prescribed at discharge.
Surgical Care Improvement Project (SCIP).	• SCIP INF–6 Appropriate Hair Removal.

We suspended, rather than removed, these measures because although our analysis indicated that these measures are topped-out measures (that is, their performance is uniformly high nationwide, with little variability among hospitals), some commenters still believed that the processes assessed by the measures were tied to better patient outcomes, and that removal of the measures from the program may result in declines in performance and hence worse outcomes.

The suspension of data collection for these four measures will be continued unless we have evidence that performance on the measures is in danger of declining. Should we determine that hospital adherence to these practices has unacceptably declined, we would resume data collection using the same form and manner and on the same quarterly schedule that we finalize for these and other chart abstracted measures, providing at least 3 months of notice prior to resuming data collection. Hospitals would be notified of this via CMS listservs, CMS e-mail blasts, national provider calls, and QualityNet announcements. In addition, we would comply with any requirements imposed by the Paperwork Reduction Act before resuming data collection of these four measures.

3. Proposed Measures for the FY 2015 and FY 2016 Hospital IQR Program Payment Determinations

a. Additional 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 would promote better, safer, more efficient care. We believe it is important to expand the pool of measures to include measures that aim toward improving patient safety. This goal is supported by many reports documenting that tens of thousands of patients do not receive safe care in the nation's hospitals.[48,49]

In addition to our goals to align measures and support the Hospital VBP Program, we also take into account other considerations in implementing and expanding the Hospital IQR Program:

• Our overarching purpose is to support the National Quality Strategy's three-part aim of better health care for individuals, better health for populations, and lower costs for health care. The Hospital IQR Program will help achieve the three-part aim by creating transparency around the quality of care at inpatient hospitals to support patient decision-making and quality improvement. Given the availability of well-validated measures and the need to balance breadth with minimizing burden, measures should take into account and address, as fully as possible, the six domains of measurement that arise from the six priorities of the National Quality Strategy: Clinical care; Person- and caregiver-centered experience and outcomes; Safety; Efficiency and cost

[48] 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.

[49] 2009 National Healthcare Quality Report, pp. 107–122. ''Patient Safety,'' Agency for Healthcare Research and Quality.

reduction; Care coordination; and Community/population health. More information regarding the National Quality Strategy can be found at: *http://www.hhs.gov/secretary/about/priorities/priorities.html* and *http://www.ahrq.gov/workingforquality/*. HHS engaged a wide range of stakeholders to develop the National Quality Strategy, as required by the Affordable Care Act.

• We seek to collect data in a manner that balances the need for information related to the full spectrum of quality performance and the need to minimize the burden of data collection and reporting. Within the framework of our statutory authority and taking into account programmatic considerations, measures used in the Hospital IQR Program should be harmonized with other Medicare/Medicaid quality reporting programs and incentive programs to promote coordinated efforts to improve quality.

• As part of our burden reduction efforts, we will continuously weigh the relevance and utility of the measures compared to the burden on hospitals in submitting data under the Hospital IQR Program. We seek 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. 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.

• To the extent practicable, measures we use should be nationally endorsed by a multistakeholder organization. Section 3001(a)(2) of the Affordable Care Act 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 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.'' Accordingly, we attempt to utilize endorsed measures whenever possible.

• Measures should be developed with the input of providers, purchasers/payers, and other stakeholders. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. We take into account widely accepted criteria established in medical literature.

• Section 1890A(a)(4) of the Act, as added by section 3014(b) of the Affordable Care Act, requires the Secretary to take into consideration input from multistakeholder groups in selecting quality and efficiency measures that have been endorsed by the entity with a contract under section 1890 of the Act, currently NQF, and measures that have not been endorsed. The MAP is a partnership comprised of multi-stakeholder groups that was convened by NQF to provide input on measures. Accordingly, we consider the MAP's recommendations in selecting quality and efficiency measures (*http://www.qualityforum.org.map/*).

• HHS Strategic Plan and Initiatives. HHS is the U.S. government's principal agency for protecting the health of all Americans. HHS accomplishes its mission through programs and initiatives. Every 4 years HHS updates its Strategic Plan and measures its progress in addressing specific national problems, needs, or mission-related challenges. The goals of the HHS Strategic Plan for Fiscal Years 2010 through 2015 are: Strengthen Health Care; Advance Scientific Knowledge and Innovation; Advance the Health, Safety, and Well-Being of the American People; Increase Efficiency, Transparency, and Accountability of HHS Programs; and Strengthen the Nation's Health and Human Services Infrastructure and Workforce (*http://www.hhs.gov/about/FY2012budget/strategicplandetail.pdf*). HHS prioritizes policy and program interventions to address the leading causes of death and disability in the United States, including heart disease, cancer, stroke, chronic lower respiratory diseases, unintentional injuries, and preventable behaviors. Initiatives such as the HHS Action Plan to Reduce HAIs in clinical settings and the Partnership for Patients exemplify these programs.

• CMS Strategic Plan. We strive to ensure that measures for different Medicare and Medicaid programs are aligned with priority quality goals, that measure specifications are aligned across settings, that outcome measures are used whenever possible, and that quality measures are collected from EHRs as appropriate.

• 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 in the Medicare population have been reported, despite established clinical guidelines, across populations or geographic areas.

• 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 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. In addition to giving hospitals more advance notice in planning quality reporting, this multiyear 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. However, we indicated that these finalized measure sets for multiple years 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 began using 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.

b. Proposed Hospital IQR Program Measures for the FY 2015 Payment Determination and Subsequent Years

(1) Process for Retention of Hospital IQR Program Measures Adopted in Previous Payment Determinations

We previously finalized 76 measures for the FY 2015 Hospital IQR Program measure set (76 FR 51636 through 51637). We note that this number includes the four measures for which we have suspended data collection.

In past rulemakings, we have proposed to retain previously adopted measures for each payment determination on a year-by-year basis and invited public comment on the proposal to retain such measures for all future payment determinations unless otherwise specified. Specifically, for the purpose of streamlining the rulemaking process, we are proposing that when we adopt measures for the Hospital IQR Program beginning with a payment determination and subsequent years, these measures are automatically adopted for all subsequent payment determinations unless we propose to remove, suspend, or replace the measures. We invite public comment on this approach.

(2) Proposed Additional Hospital IQR Program Measures for the FY 2015 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51636 through 51637), we finalized 17 new measures for the Hospital IQR measure set for FY 2015 payment determination: 3 HAI measures collected through the NHSN, (MRSA Bacteremia, C. difficile SIR, and the Healthcare Personnel Influenza Vaccination), the Stroke measure set (8 measures) and the VTE measure set (6 measures).

(A) Proposed New Survey-Based Measure Items for Inclusion in the HCAHPS Survey Measure for the FY 2015 Payment Determination and Subsequent Years

For the FY 2015 payment determination and subsequent years, we are proposing to add the NQF-endorsed 3-Item Care Transition Measure (CTM–3) (NQF #0228) to the existing HCAHPS survey. This measure is NQF-endorsed; therefore, the measure meets the selection criteria under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. The 3-Item Care Transition was developed by the University of Colorado Health Sciences Center for the NQF Endorsement Project entitled ''National Voluntary Consensus Standards for Quality of Cancer Care.'' The MAP supports the immediate inclusion of the CTM–3 measure within the Hospital IQR Program. The three care transitions items that comprise the CTM–3, which we are proposing to add to the HCAHPS survey beginning with January 2013 discharges, are listed below. Detailed information on scoring methodology can be found on the Care Transition Measure Web site: *http://www.caretransitions.org/documents/CTM3Specs0807.pdf.*

The HCAHPS Survey was designed to accommodate the addition of supplemental items, provided such items adhere to the relevant HCAHPS survey protocols, see HCAHPS Quality Assurance Guidelines V7.0, p. 72: *http://www.hcahpsonline.org/files/HCAHPS%20Quality%20Assurance%20Guidelines%20V7.0%20March%202012.pdf.* The survey items that comprise the CTM–3 that we propose to add to HCAHPS meet these protocols. The addition of select items to HCAHPS is consistent with the survey's original design, development and NQF endorsement. Further, the CTM–3 was designed by its developers to be consistent and compatible with extant HCAHPS items and HCAHPS sampling and survey administration protocols. The original, NQF-endorsed CTM–3 items and response options are as follows:

- The hospital staff took my preferences and those of my family or caregiver into account in deciding what my health care needs would be when I left the hospital.
  - ☐ Strongly Disagree
  - ☐ Disagree
  - ☐ Agree
  - ☐ Strongly Agree
  - ☐ Don't Know/Don't Remember/Not Applicable
- When I left the hospital, I had a good understanding of the things I was responsible for in managing my health.
  - ☐ Strongly Disagree
  - ☐ Disagree
  - ☐ Agree
  - ☐ Strongly Agree
  - ☐ Don't Know/Don't Remember/Not Applicable
- When I left the hospital, I clearly understood the purpose for taking each of my medications.
  - ☐ Strongly Disagree
  - ☐ Disagree
  - ☐ Agree
  - ☐ Strongly Agree
  - ☐ Don't Know/Don't Remember/Not Applicable

In order to make the CTM–3 items more fully consistent and compatible with the original HCAHPS Survey items, we have made a few small modifications. Specifically, we are proposing: (1) To slightly reword the first care transition item by adding the phrase, ''During this hospital stay;'' (2) to delete the ''Don't Know/Don't Remember/Not Applicable'' response option from each item; and (3) to add a new response option, ''I was not given any medication when I left the hospital,'' to the third care transition item. These small modifications preserve the integrity and utility of the HCAHPS Survey as it is expanded to encompass a new dimension of patients' experience of hospital care. The developer of the CTM–3 has agreed to these modifications, which we believe are consistent with the NQF endorsements of the original 27-item HCAHPS Survey and of the CTM–3.

After incorporating these modifications, the CTM–3 items that we are proposing to add to the HCAHPS Survey are as follows:

- During this hospital stay, staff took my preferences and those of my family or caregiver into account in deciding what my health care needs would be when I left.
  - ☐ Strongly disagree
  - ☐ Disagree
  - ☐ Agree
  - ☐ Strongly agree
- When I left the hospital, I had a good understanding of the things I was responsible for in managing my health.
  - ☐ Strongly disagree
  - ☐ Disagree
  - ☐ Agree
  - ☐ Strongly agree
- When I left the hospital, I clearly understood the purpose for taking each of my medications.
  - ☐ Strongly disagree
  - ☐ Disagree
  - ☐ Agree
  - ☐ Strongly agree
  - ☐ I was not given any medication when I left the hospital

We also are proposing to add two items to the ''About You'' section of the HCAHPS survey beginning with January 2013 discharges. These two items would not be included in public reporting of the HCAHPS survey but may be employed in the patient-mix adjustment of survey responses.

The two proposed ''About You'' items are as follows:

- During this hospital stay, were you admitted to this hospital through the Emergency Room?
  - ☐ Yes
  - ☐ No
- In general, how would you rate your overall mental or emotional health?
  - ☐ Excellent
  - ☐ Very good
  - ☐ Good
  - ☐ Fair
  - ☐ Poor

The two new ''About You'' items were developed and tested in the Three-State Pilot Study of HCAHPS in 2003. Neither item was adopted in the national implementation of HCAHPS in 2006; however, current circumstances, as explained below, warrant the addition of these items to the HCAHPS survey at this time. We invite public comment on the two proposed ''About You'' items.

Until 2010, ''emergency room admission'' as a point of origin for hospital patients was an administrative code provided by hospitals and was used as a patient-mix adjustment for HCAHPS scores. However, since July 2010, the ''Point of Origin for Admission or Visit'' code for Emergency Room has been discontinued for use by Medicare payment systems and, thus became unavailable for HCAHPS patient-mix adjustment. In the original HCAHPS mode experiment, we determined empirically that emergency room admission status both vary across hospitals and have an important bearing on patient experience of care: *http://www.hcahpsonline.org/files/Final%20Draft%20Description%20of%20HCAHPS%20Mode%20and%20PMA%20with%20bottom%20box%20modedoc%20April%2030,%202008.pdf.* The inclusion of a new patient-reported survey item will allow us to again use emergency room admission as a patient-mix adjustment variable.

We have received numerous inquiries and requests from hospitals and researchers to add a survey item concerning the patient's overall mental health. The survey item we are proposing to add, which is very similar in structure to the existing ''overall health'' item, will allow us to introduce a patient-mix adjustment for this characteristic in the future. Although we chose not to add a survey item about patient's overall mental health status in the national implementation of HCAHPS in 2006, we continue to receive inquiries and requests from hospitals and researchers on this topic. Some researchers claim that mental health status is an important factor in how patients respond to HCAHPS survey items. The continuing interest in this topic, coupled with the direct impact of HCAHPS performance on hospital payments beginning in October 2012, led to the decision to add an overall mental health item to the HCAHPS survey. The overall mental health survey item we have chosen very closely resembles the Overall General Health item in the HCAHPS Survey, has been extensively tested, and is currently included in several other CAHPS surveys.

We are proposing to add these two ''About You'' items to the existing HCAHPS survey, with required collection beginning January 1, 2013. More detail regarding HCAHPS requirements is included in the Form, Manner and Timing section of this preamble for this program. We invite public comment on the proposed addition of these items for the FY 2015 payment determination.

(B) Proposed New Claims-Based Measures for the FY 2015 Payment Determination and Subsequent Years

(i) Hip/Knee Complication: Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) (NQF #1550)

The THA and TKA are commonly performed procedures for the Medicare population that improve quality of life. In 2003, there were 202,500 THAs and 402,100 TKAs performed,[50] and the number of procedures performed annually has increased steadily over the past decades. Annual hospital charges are projected to increase by 340 percent to $17.4 billion for THA and by 450 percent to $40.8 billion for TKA by 2015. Annual hospital charges are projected to increase by 340 percent to $17.4 billion for THA and by 450 percent to $40.8 billion for TKA by 2015.[51] The post-operation complications of these procedures are high considering these are selective procedures and usually the complications are devastating to patients. For example, rates for periprosthetic joint infection, a rare but devastating complication, have been reported at 2.3 percent for THA/TKA patients with rheumatoid arthritis,[52] and 1.6 percent in primary elective TKA patients after 1 and 2 years of follow up, respectively.[53] Two studies reported 90-day death rates following THA at 0.7 percent[54] and 2.7 percent.[55] Reported rates for pulmonary embolism following TKA range from 0.5 percent to 0.9 percent.[56,57,58,59] Reported rates for septicemia range from 0.1 percent, during the index admission[60] to 0.3 percent, 90 days following discharge for primary TKA.[61] Rates for bleeding and hematoma following TKA have been reported at 0.94 percent[62] to 1.7 percent.[63] In 2005, annual hospital charges totaled $3.95 billion and $7.42 billion for primary THA and TKA, respectively.[64] Combined, THA and TKA procedures account for the largest payments for procedures under Medicare.[65]

Both hip and knee arthroplasty procedures improve the function and quality of life of patients with disabling arthritis, and the volume and cost associated with these procedures are very high. We believe it is important to assess the quality of care provided to Medicare beneficiaries who undergo one or both of these procedures.

The Hip/Knee Complication: Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) measure (NQF # 1550) is an outcome measure. We are proposing this measure for the Hospital IQR Program because outcome measures are priority areas for the Hospital IQR Program. We believe it is important to assess the quality of care provided to Medicare beneficiaries who undergo one or both of these procedures and publicly report

[50] Kurtz S, Ong K, Lau E, Mowat F, Halpern M., Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am. Apr 2007;89(4):780–785.

[51] Kurtz SM, Ong KL, Schmier J, et al., Future clinical and economic impact of revision total hip and knee arthroplasty. J Bone Joint Surg Am. Oct 2007;89 Suppl 3:144–151.

[52] Bongartz, T, Halligan CS, Osmon D, et al. Incidence and risk factors of prosthetic joint infection after total hip or knee replacement in patients with rheumatoid arthritis. Arthritis Rheum. 2008; 59(12): 1713–1720.

[53] Kurtz S, Ong K, Lau E, Bozic K, Berry D, Parvizi J. Prosthetic joint infection risk after TKA in the Medicare population. Clin Orthop Relat Res. 2010;468:5.

[54] Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684.

[55] Soohoo NF, Farng E, Lieberman JR, Chambers L, Zingmond, DS. Factors That Predict Short-term Complication Rates After Total Hip Arthroplasty. Clin Orthop Relat Res. Sep 2010;468(9):2363–2371.

[56] Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684.

[57] Mahomed NN, Barrett JA, Katz JN, *et al.* Rates and outcomes of primary and revision total hip replacement in the United States medicare population. *J Bone Joint Surg Am.* Jan 2003;85–A(1):27–32.

[58] Khatod M, Inacio M, Paxton EW, *et al.* Knee replacement: epidemiology, outcomes, and trends in Southern California: 17,080 replacements from 1995 through 2004. Acta Orthop. Dec 2008;79(6):812–819.

[59] Solomon DH, Chibnik LB, Losina E, *et al.* Development of a preliminary index that predicts adverse events after total knee replacement. Arthritis & Rheumatism. 2006;54(5):1536–1542.

[60] Browne, JA, Cook C, Hofmann A, Bolognesi MP. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. 2010;17(2): 152–156.

[61] Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684.

[62] Browne, JA, Cook C, Hofmann A, Bolognesi MP. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. 2010;17(2): 152–156.

[63] Huddleston JI, Maloney WJ, Wang Y, Verzier N, Hunt DR, Herndon JH. Adverse Events After Total Knee Arthroplasty: A National Medicare Study. The Journal of Arthroplasty. 2009;24(6, Supplement 1):95–100.

[64] Kurtz S, Ong K, Lau E, Mowat F, Halpern M., Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am. Apr 2007;89(4):780–785.

[65] Bozic KJ, Rubash HE, Sculco TP, Berry DJ., An analysis of medicare payment policy for total joint arthroplasty. J Arthroplasty. Sep 2008;23(6 Suppl 1):133–138.

the hospital rates for consumer choice of care.

The proposed measure assesses complications occurring after THA and TKA surgery from the date of the index admission to 90 days post date of the index admission. The outcome is one or more of the following complications: acute myocardial infarction, pneumonia, or sepsis/septicemia within 7 days of admission; surgical site bleeding, pulmonary embolism or death within 30 days of admission; or mechanical complications, periprosthetic joint infection or wound infection within 90 days of admission. The data indicated that the median hospital-level risk-standardized complication rate for 2008 was 4.2 percent, with a range from 2.2 percent to 8.9 percent in hospitals. The variation in complication rates suggest that there are important differences in the quality of care delivered across hospitals, and that there is room for quality improvement.

In 2010, we developed a hospital-level risk-standardized complication rate (RSCR) following elective primary THA and TKA surgery. NQF endorsed this THA and TKA complication measure in February 2012 (NQF #1550). In its Pre-Rulemaking Report for 2012, the MAP also recommended the inclusion of this measure in the Hospital IQR Program. We are proposing to adopt the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) measure for the Hospital IQR Program for the FY 2015 payment determination and subsequent years. This measure is NQF-endorsed (NQF #1550); therefore, the measure meets the selection criteria under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. The measure specifications can be found at: *http://www.qualityforum.org/Projects/Surgery_Maintenance.aspx#t=2&s=&p=.*

The proposed measure uses the same hierarchical logistic modeling (HLM) methodology that is specified for other NQF-endorsed CMS inpatient outcome measures previously adopted for this program, including AMI, HF, and PN readmission and mortality measures because this modeling has already been subjected to NQF review, and has been determined to appropriately account for the types of patients a hospital treats, the number of patients it treats, and the quality of care it provides. The HLM model estimates risk-standardized complications rates. Medicare Part A and Part B (FFS) claims are the data source we used to develop the measure and that we are proposing to use to calculate the measure if finalized. Index admission diagnoses and in-hospital comorbidities would be assessed using Medicare Part A claims. Additional comorbidities prior to the index admission would be assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to index (initial) admission. Enrollment and post-discharge mortality status would be obtained from Medicare's enrollment database which contains beneficiary demographic, benefit/coverage, and vital status information.

The proposed Total Hip and Total Knee Arthroplasty Complication measure includes Medicare FFS beneficiaries, aged 65 years or older, admitted to non-Federal acute care hospitals for THA or TKA. The measure methodology identifies eligible index admissions, using the following ICD–9–CM procedure codes: 81.51 Total Hip Arthroplasty; and 81.54 Total Knee Arthroplasty in Medicare Part A inpatient claims data. The measure specifications will be updated yearly and will be specified using ICD–10.

In addition, the proposed measure includes patients who have had continuous enrollment in Medicare FFS for one year prior to the date of index admission to ensure full data availability for risk adjustment. We restrict the sample to admissions of patients enrolled in Medicare FFS coverage in the 12 months prior to and including the time of their index admission to a non-Federal acute care hospital because of the availability of complete administrative data for most Medicare FFS patients.

The proposed measure does not include beneficiaries enrolled in Medicare Managed Care (''Medicare Advantage'') plans because only partial administrative data are reported to CMS. We would not have complete data on these Medicare Advantage enrollees. Patients under age 65 (the qualifying age for Medicare coverage for those not considered disabled or with end-stage renal disease) or for whom we otherwise have incomplete information—for example, those enrolled in a Medicare Advantage plan during any part of the relevant time period— will also be excluded to ensure data comparability. Additionally, these restrictions on the data allow for an appropriately comprehensive risk-adjustment for patient case-mix and comorbidity that would not be possible without access to data available to this population.

The proposed measure excludes patients with hip fractures (patients with hip fractures have higher mortality, complication rates and the procedure (THA) is not elective); patients undergoing revision procedures (may be performed at a disproportionately small number of hospitals and are associated with higher mortality, complication and readmission rates); patients undergoing partial hip arthroplasty (primarily done for hip fractures and are typically performed on patients who are older, more frail, and with more comorbid conditions) ; patients undergoing resurfacing procedures (different type of procedure which is typically performed on younger, healthier patients); patients who are transferred to the index hospital (it is likely that the procedure is not elective); patients who leave the hospital against medical advice (it is likely that the procedure is not elective); patients with more than two THA/TKA procedure codes during the index hospitalization (unlikely that patients would receive more than two THA/TKA procedures in one hospitalization, and this pattern may reflect coding errors); and patients with multiple admissions for THA/TKA in the 12 months studies.

Consistent with the requirements in section 1886(b)(3)(B)(viii)(VIII) of the Act, the proposed measure is risk-adjusted. It takes into account the patient case-mix to assess hospital performance. The patient risk factors are defined using the Hierarchical Condition Categories (CC), which are clinically relevant diagnostic groups of ICD–9–CM codes.[66] The CCs used in the risk adjustment model for this measure, are provided at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1182785083979*. The proposed measure meets the statutory requirement because it adjusted for hospital patient mix including age and comorbidities to ensure that hospitals that care for a less healthy patient population are not penalized unfairly. The measure methodology defines ''complications'' as Acute myocardial infarction; Pneumonia; Sepsis/septicemia; Pulmonary embolism; Surgical site bleeding; Death; Wound infection; Periprosthetic joint infection; and Mechanical complication within 30 to 90 days post the index date of admission, depending on the complication. The decision on the appropriate follow-up period was based on our analysis of 90-day trends in complication rates using the 2008 Medicare FFS Part A Inpatient Data. We found that rates for mechanical complications are elevated until 90 days

[66] Pope G, Ellis R, Ash A, *et al.,* Principal Inpatient Diagnostic Cost Group Models for Medicare Risk Adjustment. Health Care Financing Review. 2000;21(3):26.

post the date of index admission. We found that the rates for four other complications—death, surgical site bleeding, wound infection, and pulmonary embolism—are elevated for 30 days, and that AMI, pneumonia, and sepsis/septicemia level off 7 days post date of index admission. The following table presents the follow-up period for each complication.

COMPLICATION FOLLOW-UP PERIODS

Complication	Follow-up period (days)
Death	30
Mechanical complications	90
Periprosthetic joint infection (PJI)	90
Surgical site bleeding	30
Wound infection	30
Pulmonary embolism	30
AMI	7
Pneumonia	7
Sepsis/septicemia	7

We are proposing to calculate the hospital risk-standardized complication rate by producing a ratio of the number of ''predicted'' complications (that is, the adjusted number of complications at a specific hospital based on its patient population) to the number of ''expected'' complications (that is, the number of complications if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw complication rate.

We invite public comment on the proposed inclusion of the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty measure in the Hospital IQR Program for the FY 2015 payment determination and future years. (ii) Hip/Knee Readmission: Hospital-Level 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) (NQF #1551)

As previously stated, outcome measures such as complications and readmissions are the priority areas for the Hospital IQR Program. The THA and TKA are commonly performed procedures that improve quality of life. The complications are usually devastating to the patient and costly to the Medicare program. Furthermore we believe that there is an opportunity for quality improvement by hospitals to improve quality of life for the patient. The 2008 Medicare FFS claims data indicate that 30-day hospital-level risk-standardized readmission rates ranged from 3.06 percent to 50.94 percent among hospitals with a median rate of 6.06 percent. The mean risk-standardized readmission rate was 6.3 percent. This variation suggests there are important differences in the quality of care received across hospitals, and that there is room for improvement.

Given the high volume and high cost associated with these hip and knee procedures (relative to other elective procedures performed in the Medicare population), we believe that it is imperative to assess the quality of care provided to Medicare beneficiaries who undergo one or both of these procedures. A measure that addresses readmission rates following THA and TKA provides an opportunity to provide targets for efforts to improve the quality of care and reduce costs for patients undergoing these elective procedures. The measure also increases transparency for consumers and provides patients with information that could guide their choices. Finally, it has the potential to lower health care costs associated with readmissions. The development of risk-adjusted measures of patient readmission outcomes can provide a critical perspective on the provision of care, and support improvements in care for the Medicare patient population following THA/TKA hospitalization.

We are proposing to adopt the Hip/Knee Readmission: Hospital 30-Day All-Cause Readmission Following Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) measure for the Hospital IQR Program for the FY 2015 payment determination and subsequent years. This measure is NQF-endorsed; therefore, the measure meets the selection criteria under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. The measure specification for this measure can be found on the Web site at: *http://www.qualityforum.org/Projects/Surgery_Maintenance.aspx#t=2&s=&p=*. In its Pre-Rulemaking Report, the MAP recommended the inclusion of this measure in the Hospital IQR Program. The objective of this proposed measure is to assess readmission from any cause within 30 days of the initial total hip arthroplasty and total knee arthroplasty admissions for patients discharged from the hospital following elective primary THA and TKA.

The proposed measure uses the same HLM methodology that is specified for the NQF-endorsed AMI, HF, and PN 30-day risk-adjusted all-cause readmission measures in the Hospital IQR Program because it has already been subjected to NQF review and has been determined to appropriately account for the types of patients the hospital treats, the number of patients it treats, and the quality of care it provides. The HLM model estimates risk-standardized readmission rates. The data source we used to develop the measure and that we would use to calculate the measure if finalized is Medicare Part A (FFS) claims. Index admission diagnoses and in-hospital comorbidity data would be assessed using Medicare Part A claims. Additional comorbidities prior to the index admission would be assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to index (initial) admission. Enrollment status would be obtained from Medicare's enrollment database which contains beneficiary demographic, benefit/coverage, and vital status information.

The proposed measure includes admissions for patients who were Medicare FFS beneficiaries, aged 65 years or older, admitted to non-Federal acute care hospitals with an ICD–9–CM code for THA or TKA. Eligible index admissions would be identified using the following ICD–9–CM procedure codes: 81.51 (Total hip arthroplasty); and 81.54 (Total knee arthroplasty) in Medicare Part A inpatient claims data.

In addition, patients must have had continuous enrollment in Medicare FFS for one year prior to the date of index admission to ensure full data availability for risk adjustment. We restrict the included cases to admissions of patients enrolled in Medicare FFS coverage in the 12 months prior to and including the time of their index admission to a non-Federal acute care hospital because of the availability of complete administrative data for most Medicare FFS patients.

We are proposing not to include beneficiaries enrolled in Medicare Managed Care (''Medicare Advantage'') plans because only partial administrative data are reported to CMS. We would not have complete data on these Medicare Advantage enrollees. Patients under age 65 (the qualifying age for Medicare coverage for those not considered disabled or with end-stage renal disease) or for whom we otherwise have incomplete information—for example, those enrolled in a Medicare Managed Care plan during any part of the relevant time period—will also be excluded to ensure data comparability.

We are proposing to exclude patients with hip fractures (patients with hip fractures have higher mortality, complication and readmission rates and the procedure (THA) is generally not elective); patients undergoing revision procedures (may be performed at a disproportionately small number of hospitals and are associated with higher readmission rates); patients undergoing

partial hip arthroplasty (partial arthroplasties are primarily done for hip fractures and are typically performed on patients who are older, more frail, and with more comorbid conditions); patients undergoing resurfacing procedures (resurfacing procedures are a different type of procedure which are typically performed on younger, healthier patients); patients who are transferred into the index hospital (it is likely that the procedure is not elective); patients who are admitted for the index procedure and subsequently transferred to another acute care facility (attribution of readmission to the index hospital would not be possible in these cases); patients who leave the hospital against medical advice (providers do not have the opportunity to provide the highest quality care for these patients); patients with more than two THA/TKA procedure codes during the index hospitalization (unlikely that patients would receive more than two THA/TKA procedures in one hospitalization and this may reflect a coding error); patients without at least 30-days post-discharge enrollment in Medicare FFS (the 30-day readmission outcome cannot be assessed for the standardized time period); and patients who die during the index admission (patients who die during the initial hospitalization are not eligible for readmission).

The proposed measure methodology does not count readmissions that are associated with a subsequent ''planned'' THA/TKA procedure within 30-days of discharge from index hospitalization. Some patients may elect to stage their orthopedic replacement procedures across hospitalizations (for example, a patient may have the left and right knees replaced within one or two weeks of each other, potentially across multiple hospitalizations). The planned readmissions are defined as a second admission with a procedure code for THA or TKA AND a primary discharge diagnosis of osteoarthritis, rheumatoid arthritis, osteonecrosis, or arthropathy (excluding septic arthropathy).

Consistent with the requirements in section 1886(b)(3)(B)(viii)(VIII) of the Act, the proposed measure is risk-adjusted. It takes into account patient age and comorbidities to allow a fair assessment of hospital performance. The measure defines the patient risk factors for readmission using diagnosis codes collected from all patient claims one year prior to patient index hospitalization for THA and TKA. The patient diagnosis codes are grouped using Hierarchical Condition Categories (CCs), which are clinically relevant diagnostic groups of ICD–9–CM codes.[67]

The CCs used in the risk adjustment model for this measure, are provided at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069856694*. Patient risk factors are used to determine how sick the patients are on admission (that is, patient comorbidities). The hospital measure rates are calculated taking into account how sick their patients are. In summary, age and comorbidities present at the time of admission would be adjusted for differences in hospital case mix (patient risk factors).

The proposed measure uses the HLM methodology for risk adjustment. As we do for all the other 30-day readmission measures adopted for the Hospital IQR Program, we would calculate (using the HLM) the hospital risk-standardized readmission rate by producing a ratio of the number of ''predicted'' readmissions (that is, the adjusted number of readmissions at a specific hospital) to the number of ''expected'' readmissions (that is, the number of readmissions if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw readmission rate.

While the hip and knee complications measure will inform quality improvement efforts targeted toward minimizing medical and surgical complications during surgery and in the recovery phase, the hip and knee readmission measure portrays a broader range of medical and surgical outcomes affected by in-hospital care and the transition to post-acute care. This measure was endorsed by the NQF (#1551) and recommended by the MAP for the Hospital IQR Program in its Pre-Rulemaking report for 2012.

We are proposing to include the Hospital-Level 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) measure in the Hospital IQR Program for the FY 2015 payment determination and future years. We invite public comment on this proposal.

(iii) Hospital-Wide Readmission (Tentative NQF #1789)

During 2003 and 2004, over 2.3 million Medicare patients (almost one fifth of all Medicare beneficiaries) were rehospitalized within 30 days of discharge from an acute care hospital, and it was estimated that readmissions within 30 days of discharge cost Medicare more than $17 billion annually.[68] In its 2007 Report to the Congress, MedPAC estimated that in 2005, 17.6 percent of hospital patients were readmitted within 30 days of discharge.[69] MedPAC estimated that the average payment for a ''potentially preventable'' readmission was approximately $7,200. A 2006 Commonwealth Fund Report estimated that if national readmission rates were lowered to the levels achieved by the top performing regions, Medicare would save $1.9 billion annually.[70] We believe that reducing preventable readmissions will bring down healthcare costs.

Since 2009, we have publicly reported risk-standardized readmission rates (RSRRs) for three conditions: heart failure (HF), pneumonia (PN) and acute myocardial infarction (AMI) on *Hospital Compare (http://www.hospitalcompare.hhs.gov/),* as part of the efforts to improve quality of care and lower healthcare costs. However, these three conditions account for only a relatively small proportion of total hospital readmissions. High RSRRs and substantial variations in hospital RSRRs were found. The median 30-day RSRRs across hospitals is 19.9 percent for AMI (range from 15.3 percent to 26.8 percent); 24.8 percent for HF (range from 17.0 percent to 33.0 percent); and 18.4 percent for PN (range from 13.8 percent to 26.4 percent).[71]

A hospital's readmission rate is affected by complex and critical aspects of care such as communication between providers or between providers and patients; prevention of, and response to, complications; patient safety; and coordinated transitions to the outpatient environment. While disease-specific measures of readmission are useful in identifying deficiencies in care for specific groups of patients, they account for only a small minority of total readmissions.[72] By contrast, a hospital-

[67] Pope G, Ellis R, Ash A, *et al.,* Principal Inpatient Diagnostic Cost Group Models for Medicare Risk Adjustment. Health Care Financing Review. 2000;21(3):26.

[68] Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. N Engl J Med. Apr 2 2009;360(14):1418–1428.

[69] Medicare Payment Advisory Commission (MedPAC), Report to the Congress: Promoting Greater Efficiency in Medicare. 2007.

[70] The Commonwealth Fund, Why Not the Best? Results from a National Scorecard on U.S. Health System Performance. 2006: Harrisburg, PA.

[71] Bernheim S, Wang Y, Grady J, *et al.* Measures Maintenance Technical Report: Acute Myocardial Infarction. Heart Failure, and Pneumonia 30-day Risk Standardized Mortality Measures. 2011; Available at: *http://www.qualitynet.org/.*

[72] Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. N Engl J Med. Apr 2 2009;360(14):1418–1428.

wide, all-condition readmission measure could portray a broader sense of the quality of care in hospitals. Consequently, hospital-wide, all-condition readmission measures can promote hospital quality improvement and better inform consumers about care quality.

Studies have estimated the rate of preventable readmissions to be as low as 12 percent and as high as 76 percent.[73,74] Some readmissions are unavoidable, for example, those that result from inevitable progression of disease or worsening of chronic conditions. However, readmissions may also result from poor quality of care or inadequate transitional care. Randomized controlled trials have shown that improvement in the following areas can directly reduce hospital readmission rates: Quality of care during the initial admission; improvement in communication with patients, their caregivers and their clinicians; patient education; pre-discharge assessment; and coordination of care after discharge. Successful randomized trials have reduced 30-day readmission rates by 20–40 percent.[75,76,77,78,79,80,81] Evidence that hospitals have been able to reduce readmission rates through these quality-of-care initiatives illustrates the degree to which hospital best practices can affect readmission rates.

Our Quality Improvement Organizations (QIOs) began projects to improve care transitions during the 9th Statement of Work in fourteen communities by applying successful interventions learned from clinical trials, such as medication reconciliation, increased patient education, follow up after discharge, and post-discharge instructions for patients.[82] Important interventions to integrate care for populations and communities now continue among all 53 QIOs on a national scale in the QIO 10th Statement of Work which began August 2011.

Because many studies have shown readmissions to be related to quality of care, and that interventions have been able to reduce 30-day readmission rates, we believe that it is appropriate to include an all-condition readmission rate as a quality measure in the Hospital IQR Program. Promoting quality improvements leading to successful transition of care for patients from acute care to outpatient setting, and reducing short term, preventable hospital-wide readmission rates are CMS's priority objectives.

To provide a broader assessment of the quality of care at hospitals, especially for hospitals with too few AMI/HF/PN readmissions to count separately, we have developed a Hospital-Wide Readmission (HWR) measure using 2008 Medicare FFS data. Detailed information and specifications for this measure can be found on the NQF Web site at: *http://www.qualityforum.org/Projects/Readmissions_Endorsement_Maintenance.aspx#t=2&s=&p=7%7C6%7C5%7C4%7C.* The objective of the proposed HWR measure is to assess the hospital-level, risk-standardized rate of unplanned, all-cause readmissions after admissions for any eligible condition within 30 days of hospital discharge. The proposed measure comprises a single summary score, derived from the results of five different models, one for each of the following specialty cohorts (groups of discharge condition categories or procedure categories): Medicine, surgery/gynecology; cardiorespiratory; cardiovascular; and neurology.

We are proposing to use one year of data to calculate the measure rate for the HWR measure, which we believe is sufficient to calculate this measure in a statistically reliable manner. The reliability of a hospital's measure rate is related to its sample size. For its rate to be calculated reliably statistically, a hospital needs to have a sufficient number of patient cases to which the measure applies. Because the proposed HWR measure addresses over 90 percent of Medicare FFS hospitalizations for patients aged 65 and older, we believe one year of data would yield a sufficient number of cases to assess hospital performance in a statistically reliable manner. In contrast, for the condition-specific readmission measures for AMI, Heart Failure and Pneumonia, each of which address a smaller proportion of Medicare FFS Hospitalizations than the HWR measure, we must use three years of data for to have a enough patient cases to calculate the rates for these measures. We also believe that use of one year of data for the HWR measure is appropriate because it allows us to calculate up-to-date hospital performance for the most recent year, rather than calculating hospital performance over the course of three years, as we must do for the AMI, HF, and PN readmission measures. The proposed measure methodology is described in greater detail below.

The proposed measure uses 30 days following the index admission as the timeframe for assessing hospital performance because within this timeframe, readmissions are more likely attributable to care received during the index hospitalization and during the transition to the outpatient setting. For example, hospitals, in collaboration with their medical communities take actions to reduce readmission, such as ensuring patients are clinically ready at discharge, reducing risk of infection, reconciling medications, improving communications among providers involved in management principles, and educating patients about symptoms to monitor, whom to contact with questions, and where and when to seek follow-up care. Furthermore our ''time-to-event curve'' analyses showed a readmission curve with rapid early accrual of readmissions with a stable and consistent readmission rate thereafter; the curve typically stabilized within 30-days of discharge. Finally, the proposed 30-day timeframe is consistent with the other publicly reported CMS readmission measures endorsed by the NQF.

The proposed HWR measure defines the outcome as ''all-cause'' unplanned readmissions. Unplanned readmissions

[73] Benbassat J, Taragin M. Hospital readmissions as a measure of quality of health care: advantages and limitations. Arch Inter Med 2000;160(8):1074–81.

[74] Medicare Payment Advisory Commission (U.S.). Report to the Congress promoting greater efficiency in Medicare. Washington, DC: Medicare Payment Advisory Commission, 2007.

[75] Jack BW, Chetty VK, Anthony D, Greenwald JL, Sanchez GM, Johnson AE, *et al.* A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. Ann Intern Med 2009;150(3):178–87.

[76] Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing patients and caregivers to participate in care delivered across settings: the Care Transitions Intervention. J Am Geriatr Soc 2004;52(11):1817–25

[77] Courtney M, Edwards H, Chang A, Parker A, Finlayson K, Hamilton K. Fewer emergency readmissions and better quality of life for older adults at risk of hospital readmission: a randomized controlled trial to determine the effectiveness of a 24-week exercise and telephone follow-up program. J Am Geriatr Soc 2009;57(3):395–402.

[78] Garasen H, Windspoll R, Johnsen R. Intermediate care at a community hospital as an alternative to prolonged general hospital care for elderly patients: a randomised controlled trial. BMC Public Health 2007;7:68.

[79] Koehler BE, Richter KM, Youngblood L, Cohen BA, Prengler ID, Cheng D, *et al.* Reduction of 30-day postdischarge hospital readmission or emergency department (ED) visit rates in high-risk elderly medical patients through delivery of a targeted care bundle. J Hosp Med 2009;4(4):211–218.

[80] Naylor M, Brooten D, Jones R, Lavizzo-Mourey R, Mezey M, Pauly M. Comprehensive discharge planning for the hospitalized elderly. A randomized clinical trial. Ann Intern Med 1994;120(12):999–1006.

[81] Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, *et al.* Comprehensive discharge planning and home follow-up of hospitalized elders: a randomized clinical trial. Jama 1999;281(7):613–20.

[82] Jack BW, Chetty VK, Anthony D, Greenwald JL, Sanchez GM, Johnson AE, *et al.* A reengineered hospital discharge program to decrease rehospitalization: A randomized trial. Ann Intern Med 2009;150(3):178–87.

are acute clinical events experienced by a patient that require urgent hospital admission. Higher than expected unplanned readmission rates suggest lower quality of care and are the focus of quality measurement as part of quality improvement efforts. Because planned readmissions are not a signal of quality of care, we chose to exclude planned readmissions from being considered as an outcome for this measure. The proposed measure includes hospitalizations of patient who was age 65 or older (at the time of admission) who were in Medicare Fee-for-Service (FFS) for 12 months prior to the index admission, and who remained in Medicare FFS for at least 30-days post-discharge. The measure excludes patients who died during the index admission; patients who were transferred to another acute care hospital; patients who were discharged against medical advice; and patients who died within the 30-day post-discharge period. The measure also excludes admissions for medical treatment of cancer; for primary psychiatric disease (patients admitted for psychiatric treatment are typically cared for in separate psychiatric or rehabilitation centers which are not comparable to acute care hospitals); or for physical rehabilitation and prosthetic services.

The proposed measure excludes patients undergoing medical treatment for their cancer as their primary procedure because we concluded that readmission may not be a good quality indicator for this cohort of patients compared to other cohorts. For example, the cancer cohort had more than twice the post-discharge mortality of any other cohort. It also has a planned readmission rate six times that of any other cohort—41 percent of readmissions in this cohort were considered planned. This indicates that readmission in this population is a different phenomenon than for other cohorts. Most importantly, this cohort's risk standardized readmission ratio (SRR) was poorly correlated with the composite hospital-wide SRR of all other cohorts. Statistically this implies that readmission for the cancer cohort is likely measuring an aspect of quality very different from that for other cohorts. Consequently, we elected to exclude this subset of cancer patients from the measure.

For this measure, a patient is considered to have been readmitted if they experience one or more inpatient admissions within the 30 days after being discharged from an initial inpatient admission, whether the patient was readmitted to the same hospital or another. The proposed measure identifies ''planned readmissions'' in claims data that will not count as readmissions in the measure using an algorithm that identifies readmissions that are likely to be planned as opposed to readmissions due to probable complications. The algorithm was based on two main principles:

- The ''planned'' readmissions are those in which one of a pre-specified list of procedures took place (we refer readers to the measure methodology documentation on the NQF Web site at: *http://www.qualityforum.org/Projects/Readmissions_Endorsement_Maintenance.aspx#t=2&p=2√3√&s* for the list), or those for maintenance chemotherapy or rehabilitation. Maintenance chemotherapy and rehabilitation are common planned readmissions that are reliably distinguishable in the data even though they are not accompanied by procedures.
- Admissions for acute illness or for complications of care are likely not ''planned.'' Clinically, any procedure completed during an admission for an acute illness is not likely to have been planned, even if that procedure is usually planned in other non-acute cases.

Therefore, the proposed measure uses procedure codes and discharge diagnosis categories for each readmission to identify planned readmissions. Readmissions that occur for planned procedures (we refer readers to the measure methodology report on the NQF Web site at: *http://www.qualityforum.org/Projects/Readmissions_Endorsement_Maintenance.aspx#t=2&p=2√3√&s* for the list) and which are not for acute diagnoses or complications of care (listed below) are identified as planned.

For example, some patients have their gallbladders removed after having been identified as having symptomatic gallstones. Usually this is a surgery that is planned in advance and scheduled. However, occasionally a patient becomes acutely ill or has sudden inflammation or infection that requires a gallbladder surgery that was not planned in advance. The measure uses the patients' principal discharge diagnosis to differentiate between patients coming in for gallbladder removal with chronic gallstones (biliary disease) and patients acutely ill with inflamed gallbladders (cholecystitis) who are having an unplanned gallbladder removal.

Therefore, the proposed HWR measure defines planned readmissions which are excluded from the measure as any readmission:

- In which any of these procedures set out in the table below are performed if the discharge condition category is not acute or a complication of care, as discussed below; or
- For maintenance chemotherapy.

All other readmissions are considered unplanned and are counted as readmissions in the measure.

The following is the list of planned procedures based on the full AHRQ Clinical Classification Software (CCS) procedure category list.

PROCEDURE CATEGORIES CONSIDERED PLANNED DEPENDING ON THE DISCHARGE CONDITION

	Description
45	Percutaneous transluminal coronary angioplasty (PTCA).
	Rehabilitation (condition CCS 254).
84	Cholecystectomy and common duct exploration.
157	Amputation of lower extremity.
44	Coronary artery bypass graft (CABG).
78	Colorectal resection.
51	Endarterectomy; vessel of head and neck.
113	Transurethral resection of prostate (TURP).
99	Other OR gastrointestinal therapeutic procedures.
48	Insertion; revision; replacement; removal of cardiac pacemaker or cardioverter/defibrillator.
	Maintenance Chemotherapy (condition CCS 45).
211	Therapeutic radiology for cancer treatment.
3	Laminectomy; excision intervertebral disc.
43	Heart valve procedures.
152	Arthroplasty knee.
158	Spinal fusion.
55	Peripheral vascular bypass.
52	Aortic resection; replacement or anastomosis.
36	Lobectomy or pneumonectomy.
153	Hip replacement; total and partial.
60	Embolectomy and endarterectomy of lower limbs.
85	Inguinal and femoral hernia repair.
104	Nephrectomy; partial or complete.
1	Incision and excision of CNS.
124	Hysterectomy; abdominal and vaginal.
167	Mastectomy.
10	Thyroidectomy; partial or complete.
114	Open prostatectomy.
74	Gastrectomy; partial and total.
119	Oophorectomy; unilateral and bilateral.
154	Arthroplasty other than hip or knee.
	Radical laryngectomy, revision of tracheostomy, scarification of pleura (ICD–9 codes 30.4, 31.74, 34.6).
166	Lumpectomy; quadrantectomy of breast.

PROCEDURE CATEGORIES CONSIDERED PLANNED DEPENDING ON THE DISCHARGE CONDITION—Continued

	Description
64	Bone marrow transplant.
105	Kidney transplant.
176	Other organ transplantation.

PROCEDURE CATEGORIES CONSIDERED PLANNED DEPENDING ON THE DISCHARGE CONDITION—Continued

	Description
	Electroshock therapy (ICD–9 codes 94.26, 94.27).

The algorithm is designed to identify admissions for acute illness or complication of care as ''unplanned'' readmissions. The acute and complication discharge condition categories for unplanned readmissions are listed below.

DISCHARGE CONDITION CATEGORIES CONSIDERED ACUTE OR COMPLICATIONS OF CARE

AHRQ CCS	Description
237	Complication of device; implant or graft.
106	Cardiac dysrhythmias.
	Fracture (condition CCS 207, 225, 226, 227, 229, 230, 231, 232).
100	Acute myocardial infarction.
238	Complications of surgical procedures or medical care.
108	Congestive heart failure; nonhypertensive.
2	Septicemia (except in labor).
146	Diverticulosis and diverticulitis.
105	Conduction disorders.
109	Acute cerebrovascular disease.
145	Intestinal obstruction without hernia.
233	Intracranial injury.
116	Aortic and peripheral arterial embolism or thrombosis.
122	Pneumonia (except that caused by TB or sexually transmitted disease).
131	Respiratory failure; insufficiency; arrest (adult).
157	Acute and unspecified renal failure.
201	Infective arthritis and osteomyelitis (except that caused by TB or sexually transmitted disease).
153	Gastrointestinal hemorrhage.
130	Pleurisy; pneumothorax; pulmonary collapse.
97	Peri-; endo-; and myocarditis; cardiomyopathy.
127	Chronic obstructive pulmonary disease and bronchiectasis.
55	Fluid and electrolyte disorders.
159	Urinary tract infections.
245	Syncope.
139	Gastroduodenal ulcer (except hemorrhage).
160	Calculus of urinary tract.
112	Transient cerebral ischemia.
	All condition categories.

To compare readmission performance across hospitals, the proposed measure accounts for differences in patient characteristics (patient case mix) as well as differences in mixes of services and procedures offered by hospitals (hospital service-mix). The proposed measure includes 93.4 percent of Medicare FFS hospitalizations occurring in 2008, and includes 92.1 percent of readmissions following those hospitalizations.

The proposed measure uses the conditions and procedures defined by the AHRQ CCS, which is a widely used and accepted method of grouping patients into diagnostic categories. The AHRQ CCS collapsed the more than 17,000 different ICD–9–CM diagnosis and procedure codes into 285 clinically-coherent, mutually-exclusive condition categories and 231 mutually-exclusive procedure categories. We created five major specialty cohorts based on organization of care (medical, surgery/gynecology, cardiorespiratory, cardiovascular, and neurology), and assigned each condition category to a cohort. Admissions that included major surgical procedures (regardless of condition category) were assigned to the surgery/gynecology cohort. We estimated separate adjustment coefficients for each cohort using a single set of risk factors. We used hierarchical logistic regression to adjust for differences in hospital case mix and to account for the clustering of patients within a hospital. We adjusted for case mix differences among hospitals by risk-adjusting for patients' comorbid conditions identified in inpatient episodes of care for the 12 months prior to the index admission as well as those present at admission. We did not risk adjust for diagnoses that may have been a complication of care during the index admission. We used CMS Condition Category groups (CMS–CCs) to define the comorbid risk adjusters and used a fixed set of comorbid risk variables across models. We risk adjusted for service mix differences among hospitals within each major cohort by including indicator variables for discharge condition categories (as defined by AHRQ CCS) in each model.

Finally, we used each of the five cohort models to calculate predicted and expected numbers of readmissions for each hospital in each cohort. We then derived a single summary score from the results of the five models by calculating the volume-weighted log average of the predicted over expected ratios from each model and multiplying the resulting ratio by the average national readmission rate. This approach allowed us to take into account the variation in hospital specialty cohort mix.

The proposed HWR measure was recommended to the NQF board of directors for endorsement in March 2012 by the NQF Consensus Standards Approval Committee (CSAC). The MAP supported selection of the HWR measure for the Hospital IQR Program contingent on NQF endorsement. This measure is in the final stages of the NQF measure endorsement process, and we

expect its endorsement to be finalized in the coming months.

We are proposing to adopt this measure in the Hospital IQR Program for the FY 2015 payment determination and subsequent years under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act. This section 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), 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-endorsed measures, and we were unable to identify any other NQF-endorsed measures that assess hospital-wide readmissions. We also are not aware of any other hospital-wide readmission measures that have been endorsed or adopted by a consensus organization other than NQF. The one other hospital-wide readmissions measure of which we are aware is the Risk-Adjusted 30-Day All-Cause Readmission Rate measure (formerly NQF #0329). This measure was endorsed by NQF, but NQF removed the measure's endorsement during a recent consensus development project that recommended endorsement of the HWR measure. Accordingly, we propose to adopt the HWR measure under the Secretary's authority set forth at section 1886(b)(3)(B)(IX)(bb) of the Act. We invite public comment on this proposal.

(C) Proposed New Chart-Abstracted Measure: Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation (NQF #0469)

For the FY 2015 payment determination and subsequent years, we are proposing to add a chart-abstracted measure, Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation. In launching the Strong Start Initiative (*http://www.innovation.cms.gov/initiatives/strong-start/*) to help reduce preterm births, the HHS Secretary indicated in a press release that more than half a million infants are born prematurely in America each year, and that this trend has increased 36 percent over the last 20 years. Preterm births may require additional medical attention and early intervention services. Some recent research indicates that elective deliveries before 39 weeks increase the risk of significant complications for mother and baby, as well as long-term health problems.[83,84,85,86] Preterm births are a growing public health problem that has significant consequences for families well into a child's life.

As a public campaign to reduce preterm births, the Strong Start Initiative's objective is to test ways to reverse this trend by helping provide expectant mothers with the care they need for a healthy delivery and a healthy baby, and by focusing on reducing early elective deliveries, which can lead to a variety of health problems for mothers and infants.

The Strong Start Initiative cuts across many agencies within HHS and involves external organizations including the March of Dimes, and the American College of Obstetricians and Gynecologists (ACOG). We believe that a reduction in the number of nonmedically indicated elective deliveries at >=37 to <39 weeks gestation will result in a substantial decrease in neonatal morbidity and mortality, as well as a significant savings in healthcare costs. In addition, the rate of cesarean sections should decrease with fewer elective inductions resulting in decreased length of stay and healthcare costs. The proposed measure would assist hospitals in tracking nonmedically indicated early term elective deliveries and reduce the occurrence of such deliveries. This measure would assess patients with elective vaginal deliveries or elective cesarean sections at >=37 and <39 weeks of gestation completed. The numerator for this measure is the number of patients with elective deliveries with principal or other procedure codes for one or more of the following: Medical induction of labor, and cesarean section while not in active labor or experiencing spontaneous rupture of membranes. Exclusions are: Less than 8 years of age; Greater than or equal to 65 years of age; Length of Stay >120 days; and enrolled in clinical trials.

We are proposing to adopt this measure for the Hospital IQR Program because we believe this measure furthers the National Quality Strategy's three-part aim of better health care for individuals, better health for populations, and low costs for health care. Additionally, we have determined that the measure is relevant to the nearly 2 million Medicare beneficiaries who are aged 44 and under, most of whom are dual eligible beneficiaries, who have the potential to be impacted by pre-term births. This is evidenced by the fact that, in 2011, Medicare paid for roughly 14,000 births. The measure is NQF-endorsed; therefore, the measure meets the selection criteria under section 1886(b)(3)(B)(viii)(IX)(aa) of the Act. The measure is currently under NQF maintenance review. In its Pre-Rulemaking report for 2012, the MAP also recommended the inclusion of this measure in the Hospital IQR Program. TJC is the measure steward of this measure and the detailed measure specification can be found on the TJC Web site at: *http://manual.jointcommission.org/releases/TJC2012A/MIF0166.html*.

We are proposing to add this measure to the Hospital IQR Program for the FY 2015 payment determination, with collection beginning with January 1, 2013 discharges. Although this measure is chart-abstracted, we are proposing that this measure would be collected in aggregated numerator, denominator, and exclusion counts per hospital via a Web-based tool (as opposed to collecting patient-level data from hospitals). Specific details regarding this proposed approach to data collection are included in section VIII.A.5. of this preamble on the form, manner, and timing of quality data submission for the Hospital IQR Program. We anticipate that the e-specifications of this measure will be completed in the summer of 2012. We intend to move to EHR-based collection of this and other measures once the necessary infrastructure to do so is in place. We invite public comment on our proposal to adopt this measure.

(D) Clarification Regarding Existing Hospital IQR Program Measures That Have Undergone Changes During NQF Measure Maintenance Processes

As discussed previously, once adopted, we retain measures in the Hospital IQR Program unless specifically stated otherwise. Recently the CLABSI and CAUTI measures were expanded to pertain to non-ICU locations in hospitals and to other types of care settings as part of NQF

[83] Glantz, J. (Apr. 2005). Elective induction vs. spontaneous labor associations and outcomes. *J Reprod Med*. 50(4):235–40.

[84] Vardo, J., Thornburg, L., Glantz, J., (2011). Maternal and neonatal morbidity among nulliparous women undergoing elective induction of labor. J. Reprod Med. 56(1–2): 25–30.

[85] Tita, A., Landon, M., Spong, C., Lai, Y., Leveno, K., Varner, M, *et al*. (2009). Timing of elective repeat cesarean delivery at term and neonatal outcomes. [Electronic Version]. *NEJM*. 360:2, 111–120.

[86] Clark, S., Miller, D., Belfort, M., Dildy, G., Frye, D., & Meyers, J. (2009). Neonatal and maternal outcomes associated with elective delivery. [Electronic Version]. *Am J Obstet Gynecol*. 200:156.e1–156.e4.

maintenance review. These measures retained their original NQF numbers as these changes were not considered substantive. However, we will continue to require hospitals to submit data for these two measures on ICU locations only for the Hospital IQR Program. We seek comment from hospitals on the feasibility and timing of expanding collection of these measures to include non-ICU locations in hospitals.

NQF, in addition to expanding the care settings to which the CLABSI and CAUTI measures could apply, also changed how these measures are calculated. The original endorsed version of the measures calculated an infection rate per 1,000 central line days for CLABSI and for 1,000 urinary catheter days for CAUTI. In the course of its maintenance review, NQF changed the way the measures are calculated from an infection rate per 1,000 days to a standardized infection ratio (''SIR''), which is comprised of the actual rate of infection over the expected rate of infection. We note that although the previously endorsed versions of the CAUTI and CLABSI measures did not include the SIR calculation, we have reported the CDC-calculated SIR for both measures on the *Hospital Compare* Web site. While use of this calculation is different from the original NQF-endorsed measure output, we believe the SIR is a more accurate way to calculate the CLABSI and CAUTI measures for comparative purposes rather than the rate per 1,000 infection days because it takes into account hospitals' case mix. We will continue to report SIRs for both measures because this calculation is now consistent with NQF's endorsement of the measures. We also note that use of the SIR calculation does not change the type of data that hospitals submit on the CLABSI and CAUTI measures.

In summary, we are proposing the removal of 17 measures (1 chart-abstracted measure and 16 claims-based measures) from the measure set for the FY 2015 payment determination and subsequent years. We are proposing to add survey items to the existing HCAHPS survey. We also are proposing to add 3 claims-based measures and 1 chart-abstracted measure to the measure set for the FY 2015 payment determination and subsequent years, for a total of 59 measures. These 59 measures are listed below.

Topic	Proposed hospital IQR program measures for FY 2015 payment determination and subsequent years
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 (STK) 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 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–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 Measures.	• HCAHPS survey (expanded to include one 3-item care transition set* and two new ''About You'' items).
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. • 30-day Risk Standardized Readmission following Total Hip/Total Knee Arthroplasty.* • Hospital-Wide All-Cause Unplanned Readmission (HWR).*
AHRQ Patient Safety Indicators (PSIs) Composite Measures.	• Complication/patient safety for selected indicators (composite).

Topic	Proposed hospital IQR program measures for FY 2015 payment determination and subsequent years
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. • 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. • Catheter-Associated Urinary Tract Infection. • MRSA Bacteremia. • Clostridium Difficile (C.Diff). • Healthcare Personnel Influenza Vaccination.
Surgical Complications	• Hip/Knee Complication: Hospital-level Risk-Standardized Complication Rate (RSCR) following Elective Primary Total Hip Arthroplasty.*
Emergency Department (ED) 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 (IMM) Measures.	• Immunization for Influenza. • Immunization for Pneumonia.
Cost Efficiency	• Medicare Spending per Beneficiary.
Perinatal Care	• Elective delivery prior to 39 completed weeks of gestation.*

* New measures/items proposed for the FY 2015 payment determination and subsequent years.

c. Proposed Hospital IQR Program Quality Measures for the FY 2016 Payment Determination and Subsequent Years

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74466), we adopted the Safe Surgery Checklist Use measure for the Hospital OQR Program for CY 2014 payment determination. In the same rule, we adopted this measure for the ASCQR Program for CY 2015 payment determination (76 FR 74507). This structural measure assesses whether a hospital outpatient department utilizes a Safe Surgery checklist that assesses whether effective communication and safe practices are performed during three distinct perioperative periods: (1) The period prior to the administration of anesthesia; (2) the period prior to skin incision; and (3) the period of closure of incision and prior to the patient leaving the operating room. The use of such checklists has been credited with dramatic decreases in preventable harm, complications, and post-surgical mortality.[87] Like hospital outpatient settings and ambulatory surgical centers, acute care hospitals also perform many surgical procedures. Therefore, we believe this measure is also applicable for hospital inpatient settings in strengthening patient safety precautions in hospitals and we are proposing to adopt this measure for the Hospital IQR Program for FY 2016 payment determination and subsequent years.

For this proposed structural measure, a hospital inpatient department would indicate whether or not it uses a safe surgery checklist for its surgical procedures that includes safe surgery practices during each of the three critical perioperative periods discussed above. The measure would not require a hospital to report whether it uses a checklist in connection with any individual inpatient procedures. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74505 through 74506) for the detailed discussion of the Safe Surgery Checklist Use measure.

We are proposing to adopt this Safe Surgery Checklist structural measure, which is not NQF-endorsed, under the exception authority provided in section 1886(b)(3)(B)(IX)(bb) of the Act. This section 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), 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-endorsed measures, and we were unable to identify any NQF-endorsed measures that assess use of safe surgery checklists. We also are not aware of any other safe surgery checklist use measures that have been endorsed or adopted by a consensus organization other than NQF. Accordingly, we propose to adopt the Safe Surgery Checklist measure under the Secretary's authority set forth at section 1886(b)(3)(B)(IX)(bb) of the Act.

This measure was included on the pre-rulemaking list for consideration by the MAP, and this multistakeholder organization comprised of affected parties supported the direction of this measure pending availability of specifications. These specifications will be made available in an upcoming manual release for the ASC Quality Reporting Program which will be available on Quality Net Web site at *http://www.qualitynet.gov*. The proposed safe surgery checklist measure assesses the adoption of a best practice for surgical care that is broadly accepted and in widespread use among affected parties. In addition to being adopted by The World Federation of Societies of Anesthesiologists, the use of a safe surgery checklist is one of the safe surgery principles endorsed by the Council on Surgical and Perioperative Safety, which is comprised of the American Association of Nurse Anesthetists, the American College of Surgeons, the American Association of Surgical Physician Assistants, the American Society of Anesthesiologists, the American Society of PeriAnesthesia Nurses, the AORN, and the Association of Surgical Technologists. Two State agencies (Oregon and South Carolina), the Veterans Health Administration,[88] numerous hospital systems, State hospital associations (such as California

[87] Haynes, A.B.; Weiser, T.G.; Berry, W.G. *et al.* (2009). ''A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population.'' New England Journal of Medicine. 360: 491–499.

[88] Neily, J; Mills, PD, Young-Xu, Y. (2010). ''Association between implementation of a Medical Team Training Program and Surgical Mortality.'' JAMA. 304 (15): 1693–1700.

and South Carolina), national accrediting organizations, and large private insurers have endorsed the use of a safe surgery checklist as a best practice for reducing morbidity, mortality, and medical errors.[89,90] Although there is not currently an NQF endorsed measure for safe surgery checklist use, because the use of a safe surgery checklist is a widely accepted best practice for surgical care, we believe that the proposed structural measure of Safe Surgery Checklist use reflects consensus among affected parties. We also note that TJC included safe surgery checklist practices among those to be used to achieve National Patient Safety Goals (NPSGs) adopted for 2011 for surgeries performed in ambulatory settings and hospitals.

Given that this measure is pivotal in preventing human errors in surgical operations which are commonly performed by acute care hospitals, we are proposing to adopt this measure for the Hospital IQR Program for the FY 2016 payment determination and subsequent years. This proposal would achieve our goal to align measures across settings.

In summary, we are proposing to add one new structural measure to the Hospital IQR measure set for the FY 2016 payment determination. The 60 measures for the FY 2016 payment determination and subsequent years are listed below.

Topic	Proposed hospital IQR program measures for FY 2016 payment determination and subsequent years
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 (STK) 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 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–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 Measures.	• HCAHPS survey (expanded to include one 3-item care transition set * and two new ''About You'' items).
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. • 30-day Risk Standardized Readmission following Total Hip/Total Knee Arthroplasty.* • Hospital-Wide All-Cause Unplanned Readmission (HWR).*
AHRQ Patient Safety Indicators (PSIs) Composite Measures.	• Complication/patient safety for selected indicators (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. • Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care. • Participation in a Systematic Clinical Database Registry for General Surgery.

[89] Haynes, AB; Weiser, TG; Berry, WR *et al.* (2009) ''A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population.'' NEJM. 360: 491–499.

[90] Birkmeyer, JD (2010) ''Strategies for Improving Surgical Quality—Checklists and Beyond.'' NEJM. 363: 1963–1965.

Topic	Proposed hospital IQR program measures for FY 2016 payment determination and subsequent years
Healthcare-Associated Infections Measures.	• Safe Surgery Checklist Use.** • Central Line Associated Bloodstream Infection. • Surgical Site Infection. • Catheter-Associated Urinary Tract Infection. • MRSA Bacteremia. • Clostridium Difficile (C.Diff). • Healthcare Personnel Influenza Vaccination.
Surgical Complications	• Hip/Knee Complication: Hospital-level Risk-Standardized Complication Rate (RSCR) following Elective Primary Total Hip Arthroplasty.*
Emergency Department (ED) 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 (IMM) Measures.	• Immunization for Influenza. • Immunization for Pneumonia.
Cost Efficiency	• Medicare Spending per Beneficiary.
Perinatal Care	• Elective delivery prior to 39 completed weeks of gestation.*

* New measures/items proposed for FY 2015 payment determination and subsequent years.
** New measures proposed for FY 2016 payment determination and subsequent years.

4. Possible New Quality Measures and Measure Topics for Future Years

We anticipate that, as EHR technology evolves and more infrastructure is put in place, we will have the capacity to accept electronic reporting of many of the clinical chart-abstracted measures that are currently part of 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 use EHR-based reporting for many chart-abstracted measures 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 to report chart-abstracted measures.

Once the e-specifications and the EHR-based collection mechanism are available for the smoking and alcohol cessations measures developed by TJC, we intend to propose two TJC smoking and alcohol cessation measure sets for inclusion in the Hospital IQR Program. Each of these TJC sets consists of four measures:

• Smoking Cessation Set—(1) TAM–1 Tobacco Use Screening; (2) TAM–2 Tobacco Use Treatment Provided or Offered; (3) TAM–3 Tobacco Use Treatment Management at Discharge; and (4) TAM–4 Assessing Status after Discharge, and

• Alcohol Cessation Set—(1) TAM–5 Alcohol Use Screening; (2) TAM–6 Alcohol Use Brief Intervention Provided or Offered; (3) TAM–7 Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge; and (4) TAM–8 Substance Use: Assessing Status after Discharge.

These measure sets were recommended by the MAP for inclusion in the Hospital IQR Program, provided they complete the NQF endorsement process prior to inclusion. We invite public comment on our intention to propose these measure sets.

We also note that consistent with the updated NQF endorsements of the CLABSI (NQF #139) and CAUTI (NQF #138) measures, we intend to propose to collect data for non-ICU patients as well for these two measures at a future time, and we seek public comment on the feasibility and timing of expanding data collection for acute care hospitals.

We intend to support the following measure domains in the Hospital IQR measure set in future measurement proposals for the Hospital IQR Program: Clinical quality (for example, the AMI, HF, PN, STK, and VTE measures), care coordination (for example, the mortality measures), patient safety (for example, the SCIP and HAI measures), patient and caregiver experience of care (for example, the HCAHPS measure), population/community health (for example, the global immunization measures), and efficiency (for example, the Medicare Spending per Beneficiary measure). This approach will enhance better patient care while bringing the Hospital IQR Program in line with our other established quality reporting and pay-for-performance programs.

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. CMS requires that hospitals submit data in accordance with the specifications for the appropriate discharge periods. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/*. Hospitals submit quality data through the secure portion of the QualityNet (formerly known as QualityNet Exchange) Web site (*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. Proposed Procedural Requirements for the FY 2015 Payment Determination and Subsequent Years

The Hospital IQR Program procedural requirements are now codified in

regulation at 42 CFR 412.140. Hospitals should refer to the regulation for participation requirements. For the FY 2015 payment determination and future years, we are proposing to modify the following procedural requirements and the corresponding regulation text.

• In order to ensure that hospitals that participate in the Hospital IQR Program are submitting data for a full year, we are proposing 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 by December 31 of the calendar year preceding the first quarter of the calendar year in which the chart-abstracted IQR data submission is required for any given fiscal year. For example, if a hospital wishes to participate in FY 2015, it must submit a pledge by December 31, 2012, and submit data beginning with January 1, 2013 discharges. We also are proposing to modify our regulations at § 412.140(a)(3)(i) to reflect this proposed requirement.

• Currently, 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. In order to decrease the time between final submission of IQR data and IQR payment determination notification for the hospitals, we are proposing that a subsection (d) hospital may withdraw from the Hospital IQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet Web site. The hospital must submit the withdrawal form by May 15 prior to the start of the payment year affected. For example, if a hospital seeks to withdraw from the FY 2015 payment determination, the hospital must submit the withdrawal form to CMS by May 15, 2014. If a hospital withdraws from the program, it will receive a reduction until such time as it meets the participation requirements. This proposal will also align with the final abstraction data submission deadline which will eliminate the burden of one extra deadline for providers and vendors. We also are proposing to modify our regulations at § 412.140(b) to reflect this proposed requirement.

c. Proposed Data Submission Requirements for Chart-Abstracted Measures

For FY 2015 andsubsequent years, we are proposing to retain the 4½ months quarterly submission deadline for chart-abstracted quality measures. We also are proposing to retain the aggregate population and sampling deadline of 4 months. Hospitals would continue to be required 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 (76 FR 51640 through 51641). We are proposing the same 14-day period after the aggregate population and sample size count deadline to submit the required patient-level records. For the FY 2015 payment determination and subsequent years, hospitals must submit data for four consecutive calendar year discharge quarters. For example for FY 2015, the submission quarters are as follows: 1Q CY 2013, 2Q CY 2013, 3Q CY 2013 and 4Q CY 2013.

We are proposing to collect a new chart-abstracted measure for FY 2015, Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation. Although this is a chart-abstracted measure, we are proposing that this measure would be collected in aggregated numerator, denominator, and exclusion counts per hospital via a Web-based tool. The complete data submission requirements, submission deadlines, and data submission mechanism, known as the Web-Based Measure Tool, will be posted on the QualityNet Web site at: *http://www.qualitynet.org/*. The Web-Based Measure Tool will be an Internet database for hospitals to submit their aggregate data. We are proposing that hospitals submit data in accordance with the specifications for the appropriate proposed reporting periods to the Web-Based Measures Tool that will be found in the hospital section on the QualityNet Web site (*http://www.qualitynet.org/*).

d. Proposed Sampling and Case Thresholds Beginning With the FY 2015 Payment Determination

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), we continued, for the FY 2015 payment determination and subsequent years, the approach we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230) regarding hospital submission of population and sampling data. We are not proposing any changes to these requirements.

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.

e. Proposed HCAHPS Requirements for the FY 2014, FY 2015, and FY 2016 Payment Determinations

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), beginning with discharges occurring in third quarter CY 2011, we established that 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 change, we did not make 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 the FY 2016 Hospital IQR payment determinations, we are proposing to continue these HCAHPS requirements. 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 2016 Hospital IQR Program, we are proposing that the HCAHPS data would be based on discharges from January 1, 2014 through December 31, 2014.

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 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, and 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 obtain and 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 obtaining and 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 an appropriate 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) and the HCAHPS Review and Correction Report that are available. These reports enable a hospital to ensure that its survey vendor has submitted the data on time, the data has been accepted into the QIO Clinical Warehouse, and the data accepted into the QIO Clinical Warehouse are complete and accurate.

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 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 invite public comment on our proposal to continue using these HCAHPS requirements for the FY 2016 payment determination.

f. Proposed Data Submission Requirements for Structural Measures

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 through 51644), beginning with FY 2013, we finalized the period of data collection for which hospitals will submit the required registry participation information once annually for the structural measures via a Web-based collection tool. We finalized our proposal for FY 2014 for submission of structural measures between April 1, 2013 and May 15, 2013 with respect to the time period of January 1, 2012 through December 31, 2012. We are proposing to continue this policy for FY 2015 and subsequent years. For the FY 2015 payment determination, the period of data collection for which hospitals will submit the required registry participation information for the structural measures via a Web-based collection tool will be between April 1, 2014 and May 15, 2014, with respect to the time period of January 1, 2013 through December 31, 2013. We invite public comment on this proposal.

g. Proposed Data Submission and Reporting Requirements for Healthcare-Associated Infection (HAI) Measures Reported via NHSN

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51644 through 51645), we adopted the data submission and reporting standard procedures that have been set forth by CDC for NHSN participation in general and for submission of the HAI measures to NHSN. The existing data collection and submission timeframes for the HAI measures for the FY 2014 payment determination align with the submission timeframes for chart abstracted measures. The data submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/* . Hospitals will 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 calendar quarter of CY 2013, for FY 2015 quarters, CMS will obtain the hospital-specific calculations that have been generated by the NHSN for the Hospital IQR Program.

We are proposing to continue this policy, with the two exceptions discussed below, for the FY 2015 payment determination and subsequent years.

Topic	FY 2015 Payment determination: Hospital associated infection measures (CDC/NHSN)
	Central Line Associated Blood Stream Infection. Surgical Site Infection. Catheter Associated Urinary Tract Infection. MRSA Bacteremia. Clostridium difficile. Healthcare Provider Influenza Vaccination.

We realize that some hospitals may not have locations that meet the NHSN criteria for CLABSI or CAUTI reporting, for example, when a hospital has no ICUs. We are proposing to provide an exception for the CLABSI and CAUTI measures for hospitals that do not have an ICU, reducing the burden associated with reporting to NHSN. In addition, we recognize that some facilities may perform so few procedures requiring surveillance under the Surgical Site Infection (SSI) measure that the data may not be meaningful for *Hospital Compare* or sufficiently reliable to be utilized for payment determination. We are proposing to provide an exception for these hospitals from the reporting requirement in any given year if the hospital performed fewer than a combined total of 10 colon and abdominal hysterectomy procedures in the calendar year prior to the reporting year. For example, a hospital that performed only 2 colon surgeries and 4 abdominal hysterectomies in 2012 would not be required to report the SSI measure in 2014. We are proposing to provide hospitals with a single HAI exception form, to be used for seeking an exception for any of the CLABSI, CAUTI and SSI measures, which will be available on QualityNet. We invite public comment on this proposal.

6. Proposed Supplements to the Chart Validation Process for the Hospital IQR Program for the FY 2015 Payment Determination and Subsequent Years

For the FY 2015 payment determination and subsequent years, we are proposing to continue using, with some modifications, the validation requirements and methods we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50227 through 50229) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51648). The modifications we are proposing, explained in detail below, are as follows: (a) Using separate validation approaches for chart-abstracted clinical process of care and HAI measures; (b) changing the number of hospitals included in the base annual validation random sample; and (c) using targeted selection of supplemental hospitals to be added to the base sample. As described below, these proposals are intended to strengthen the Hospital IQR Program by validating a larger set of measures, increasing opportunities to detect poor reporting through different approaches to targeting and scoring, and increasing the rigor associated with our validation process, all while ensuring that the wider scope and greater rigor only modestly increases the burden of validation activities on hospitals relative to prior years. We invite public comment on each of these proposals.

a. Separate Validation Approaches for Chart-Abstracted Clinical Process of Care and HAI Measures

(1) Background and Rationale

We finalized reporting to the Hospital IQR Program of 25 chart-abstracted measures in 7 topic areas: acute myocardial infarction (AMI); heart failure (HF); pneumonia (PN); surgical care improvement project (SCIP); emergency department throughput (ED); immunization (IMM); and HAIs for the FY 2014 payment determination and subsequent years in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51628 through 51629). For the FY 2015 payment determination and subsequent years, we are proposing to continue validating the chart-abstracted clinical process of care measures with the exception of the SCP–VTE–1 measure, which we are proposing for removal from the Hospital IQR program starting with the FY 2015 payment determination. We are also proposing to continue validating the one HAI measure—CLABSI—that we finalized for validation in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51646). We also are proposing to validate two additional HAI measures, catheter-associated urinary tract infection (CAUTI) and surgical site infection (SSI), which were finalized for inclusion in the Hospital IQR Program for the FY 2014 payment determination and subsequent years in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51628 through 61629). We are proposing to add these two measures to those we validate so that we can ensure data reliability on all chart-abstracted measures on which hospitals will have been reporting data under the Hospital IQR Program for at least one year prior to the FY 2015 payment determination.

The inclusion of the three chart-abstracted HAI measures—CLABSI, CAUTI, and SSI—in the Hospital IQR Program reflects HHS' priority to increase patient safety by preventing HAIs. As finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51645), the mechanism for reporting HAI measures is different from the mechanism for reporting on the chart-abstracted clinical process of care measure sets (AMI, ED, IMM, HF, PN, SCIP). In addition, the infection events for which hospitals would report on the HAI measures occur rarely relative to the events for which hospitals would report on the clinical process of care measure sets. We cannot report a single number describing the national incidence for these three HAIs collectively or individually because infection rates vary by the type of hospital, their patient populations, device utilization rates, and performance of different types of surgeries.[91] However, we know that these events are sufficiently rare that if we did not find a way to target records with a higher probability of including an HAI, many hospitals would have to submit virtually all records per quarter to effectively validate the HAI measure set. For these reasons, we are proposing, and we describe below in section VIII.A.6.a.(3) of this preamble, to separate the approaches for targeting and sampling of records for HAI validation from the approaches finalized for validation of the chart-abstracted clinical process of care measure sets in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51647 through 51648), and summarized in VIII.A.6.a.(2) of this preamble, and we are proposing to calculate separate scores for the group of clinical process of care measure sets and the HAI measure set as described in VIII.A.6.a.(4) of this preamble.

[91] Dudeck MA, Horan TC, Peterson KD, *et al.* National Healthcare Safety Network (NHSN) Report, data summary for 2010, device-associated module. Am J Infect Control. 2011 Dec;39(10):798–816. Edwards JR, Peterson KD, Mu Y, *et al.* National Healthcare Safety Network (NHSN) report: Data summary for 2006 through 2008, issued December 2009. Am J Infect Control 2009 Dec; 37:783–805.

(2) Selection and Sampling of Clinical Process of Care Measures for Validation

The approach to selection and sampling of clinical process of care measure sets for validation was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51648) for the 2014 payment determination and subsequent years. These measures and measure sets are shown in the table below.

HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM CHART-ABSTRACTED CLINICAL PROCESS OF CARE MEASURES TO BE VALIDATED FOR THE FY 2014 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Topic	Measures
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.
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 postoperative serum glucose. • SCIP INF–9 Postoperative urinary catheter removal on postoperative 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.
Emergency Department Throughput (ED) 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 (IMM) Measures.	• Immunization for Influenza. • Immunization for Pneumonia.

* We are proposing to remove this measure from the Hospital IQR Program starting with the FY 2015 payment determination.

We describe the validation approach for these measures, which was finalized in FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51648), for informational purposes only. A total of 15 records will be selected per quarter for the chart-abstracted clinical process of care measures. Three records per quarter will be sampled from among all records submitted to the Warehouse in each of four groups defined as part of the AMI, HF, PN, and SCIP measure sets. In addition, three records per quarter will be sampled from among the remaining submissions to the Warehouse and will be validated for the ED and IMM measure sets. CMS will also abstract data regarding the ED and IMM measure sets from records submitted for the AMI, HF, PN, and SCIP measure sets.

We finalized our proposal in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51648) to abstract ED and IMM data from all cases selected from other measure sets (AMI, HF, PN, SCIP, and CLABSI). For the FY 2015 payment determination and subsequent years, we are proposing to discontinue abstracting ED and IMM data from cases selected for the CLABSI measure. We are proposing this change in order to be consistent with the policy proposed in section VIII.A.6.a.(1) of this preamble to calculate separate scores for HAI and chart-abstracted clinical process of care measure sets.

Accordingly, for the FY 2015 payment determination and future years, we are proposing to continue our current validation approach for chart-abstracted clinical process of care measures as finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51648) with the exception of discontinuing our policy of abstracting ED and IMM cases from CLABSI records. The chart-abstracted clinical process of care measures we have previously finalized for validation for the FY 2015 and subsequent years' payment determinations are set out above.

(3) Selection and Sampling of HAI Measures for Validation

As explained in section VIII.A.6.a.(1) of this preamble, we are proposing separate selection, sampling, and validation scoring for HAI measures. The HAI measures we are proposing to validate for the FY 2015 payment determination and subsequent years are CLABSI, CAUTI, and SSI.

HAI MEASURES IN THE HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM TO BE VALIDATED FOR THE FY 2015 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Measures Continued for Validation for the FY 2014 Payment Determination

HAI MEASURES IN THE HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM TO BE VALIDATED FOR THE FY 2015 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

- Central line-associated blood stream infection (CLABSI) among intensive care unit (ICU) patients.

Additional Measures Proposed for Validation for the 2015 Payment Determination

- Surgical Site Infection (SSI) among patients with procedures for colon surgery or abdominal hysterectomy.
- Catheter-associated urinary tract infection (CAUTI) among ICU patients.

Because the events reported in the HAI measure set occur rarely, they require a targeted approach to validation. For the FY 2015 payment determination and subsequent years, we are proposing to validate these measures by identifying records that are ''candidate HAI events,'' which we define below. We would construct three separate lists of candidate events, one for each HAI measure. The proposed process to construct these lists is detailed further below. Each listing of candidate events will include both actual HAI events as well as many non-events. The purpose in creating these listings would be to identify records that are more likely to contain HAI events than CMS could obtain through a simple random sample of hospital discharges each quarter. In each case, this proposed process would minimize burden to hospitals while enriching the validation sample by targeting candidate events. As described later in this section, a combined list of candidate HAI events would be created from the three separate candidate HAI lists (for CLABSI, CAUTI, and SSI). The final list would be used to generate a random sample of medical records to be reviewed and evaluated for the presence or absence of one or more of the HAI events. We describe the proposed sample size later in this section and describe the scoring process in section VIII.A.6.a.(4) of this preamble.

We are also proposing to discontinue the practice finalized in FY 2012 IPPS/LTCH final rule (76 FR 5148) of abstracting CLABSI data from the records selected for the chart-abstracted clinical process of care measure sets (AMI, ED/IMM, HF, PN, SCIP). We are proposing this change in order to be consistent with the policy proposed in section VIII.A.6.a.(1) of this preamble to calculate separate scores for HAI and chart-abstracted clinical process of care measure sets. We invite public comment on this proposal.

We finalized a two-phase process for identifying and constructing lists of candidate CLABSI events in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51648). This process is summarized for the readers' information. In the first phase, each sampled hospital quarterly provides CMS with listings of positive blood cultures drawn from ICU patients. The listings include ''all blood cultures positive for infection status taken from ICU patients conducting CLABSI surveillance [92] during the discharge quarter'' (76 FR 51646). These listings are annotated to identify each ICU patient on this list who had a central venous catheter (CVC). The listings are then reviewed by a CMS contractor who produces a list of unique episodes of care for ICU patients with a CVC and that include either at least one positive blood culture for a known pathogen, or at least two positive blood cultures for the same common commensal. A blood culture which is positive for a common commensal may reflect a contaminated sample. Therefore, when the only positive blood culture result is for a common commensal, the second culture bearing the same result must be drawn from the patient within 48 hours of the first; this would confirm that the first positive common commensal result is not a consequence of contamination. A list of common commensals is provided by CDC.[93]

We are proposing to modify this process for FY 2015 and subsequent years by requiring the Medicare health insurance claim (HIC) number to be added to the positive blood culture list if a patient has one. As explained further below, we are proposing this addition specifically so that we may identify candidate CLABSIs that we also identify as candidate SSIs. Because the candidate SSIs would be identified through claims, the HIC number is needed to match patients from the candidate CLABSI list with those from the candidate SSI list. To protect this sensitive information, we are proposing that positive blood culture lists be submitted through the Secure Data Exchange on the QualityNet Web site. We invite public comment on each of these proposed modifications to the identification of candidate CLABSI events.

For the FY 2015 payment determination and subsequent years, we are proposing to adapt the process finalized to identify candidate CLABSI events in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51648) to identify candidate CAUTI events. In the first stage of this process, a CMS contractor would request a listing of positive urine cultures among ICU patients from the hospitals targeted for validation. The culture list would indicate the name of each pathogen detected and the number of colony forming units per ml. For the same reasons and following the same processes as those explained for CLABSI above, we are proposing to require the hospital to report the Medicare HIC number for Medicare patients included on this list.

In the second stage of this process, the CMS contractor would apply NHSN criteria to eliminate those urine cultures that are not consistent with the definition of an ICU-associated CAUTI. The contractor would then remove duplicates from the same patient to produce a list which would include only one entry per ICU patient. Our intent is to target a set of patient discharges with a higher probability of having a CAUTI event than one could obtain from a simple random sample of patient discharges. We invite public comment on this proposal.

The final HAI measure we are proposing for targeted validation is SSI. Consistent with Hospital IQR Program reporting requirements for this measure, we are proposing that validation will target SSIs among patients with colon surgeries and abdominal hysterectomy procedures.[94] We are proposing a process for identifying candidate SSIs that is different from that which we are proposing for candidate CLABSI and CAUTI both because post-discharge follow-up is so critical to proper ascertainment and because SSIs are reported more consistently in claims data than CLABSI and CAUTI. Thus, claims data provide a resource for selecting candidate events for SSI using a methodology which limits burden to hospitals. Accordingly, we are proposing to select candidate events from among Medicare FFS claims for patients who have had colon surgeries or abdominal hysterectomies as defined by NHSN.[5] For each Medicare FFS

[92] *http://www.cdc.gov/nhsn/PDFs/FINAL-ACH-CLABSI-Guidance.pdf.*

[93] *http://www.cdc.gov/nhsn/XLS/Common-Skin-Contaminant-List-June-2011.xlsx.*

[94] *http://www.cdc.gov/nhsn/PDFs/FINAL-ACH-SSI-Guidance.pdf.*

patient who had a relevant surgery in the period under validation, a CMS contractor would review the index claim (that is, the one denoting the surgery) and all subsequent readmissions to the index hospital within a 30 day post-discharge period. To identify ''candidate SSI events,'' we would look specifically for discharge diagnoses on the index claim and all inpatient claims in the 30 days post-discharge that might indicate infection. Examples of such diagnoses include ''post-operative shock'' (ICD–9–CM: 998.0), ''post-operative wound disruption (ICD–9–CM: 998.3), and postoperative infection (ICD–9–CM: 998.5). A description of our general approach, and a list of ICD–9–CM codes which we are proposing to use to identify applicable candidate SSIs is included in Appendix 1 of ''Platt R, Kleinman K, Thompson K, et al. Using automated health plan data to assess infection risk from coronary artery bypass surgery. Emerg Infect Dis. 2002 Dec;8(12):1433–41,'' which may be accessed online at *http://www.cdc.gov/eid/content/8/12/pdfs/v8-n12.pdf*.[95]

Although diagnoses which identify candidate SSIs may also be identified during readmission to hospitals other than the index hospital, for validation of SSI for the FY 2015 payment determination, we are proposing to exclude these candidate events. We are proposing this approach because we will be unable to distinguish between a candidate SSI that the index hospital determined was not an actual SSI because it did not meet properly applied NHSN case definitions, and an actual SSI that the index hospital failed to properly identify and document. Although records from the readmitting hospital may provide evidence as to the likelihood that a candidate SSI was an actual SSI, the index hospital may not have had access to this information. Therefore, if the index hospital does not report a candidate SSI event associated with a readmission to another hospital, and also does not document this event, we do not know what information, if any, the index hospital used to assess the candidate event.

This situation arises because although our regulation at 42 CFR 482.24 requires hospitals to maintain medical records that document HAI, it does not require hospitals to document that follow-up was performed. We understand that this represents a gap in our validation program for SSI, and solicit public comments on how we might fill this gap in the future.

After identifying the three separate sets of candidate events for CLABSI, CAUTI, and SSI, we will combine the lists and remove any duplicates for a given episode of care. Removing duplicates is a standard statistical practice which is important for the accuracy of the estimates.[96] Next, we are proposing to draw a random sample of 12 candidate events per quarter from which to assess reliability of HAI reporting. Over four quarters, this would yield a sample size of 48 candidate events per year. Whenever a sample is used to estimate a statistic such as reliability for the entire population of events, that estimate is said to be made with error, commonly referred to as the margin of error. For hospitals with 480 or more candidate HAI events each year, and assuming a relatively constant number of candidates per quarter, the annual sample size will be sufficient to estimate a score of 75 percent with a margin of error plus or minus 10 points with 90 percent confidence. We believe this is the smallest sample size that would be sufficient to identify hospitals that are reporting HAI data poorly and have 480 or more candidate events.

However, if there are fewer than 480 candidate events per year, the finite population correction applies, such that the margin of error will decrease as the total number of candidate events per year gets smaller.[97] Based on our analysis of CLABSI data previously reported under the Hospital IQR Program, estimating the relative occurrence of CLABSI, CAUTI, and SSI, and allowing for the fact that there may be many candidates for every confirmed HAI, we expect that most hospitals will have fewer than 480 candidate HAI events per year (or 120 per quarter), which will allow us to estimate a score of 75 percent for these hospitals with a margin of error even less than plus or minus 10 points with 90 percent confidence.

In the event that a hospital has 12 or fewer candidate HAIs in a given quarter, it is still possible to produce accurate estimates of reliability. In quarters in which a hospital has 12 or fewer candidate HAI events, we are proposing to select all candidates, which will allow us to measure reliability without any margin of error. These quarterly estimates will have no sampling error because we will not be drawing a sample, but rather will be using the entire population for that quarter. If a hospital has 12 or fewer cases in every quarter, we may estimate reliability of HAI reporting for the year without any margin of error. If a hospital has no candidate events in the year, we would not be able to estimate a reliability rate. Therefore, as discussed in section VIII.A.6.a.(4) of this preamble, we would not attempt to estimate an HAI score for hospitals with 0 cases. We invite public comment on these proposed sample sizes.

(4) Validation Scoring for Chart-Abstracted Clinical Process of Care Measures and HAI Measures

As noted in section VIII.A.6.a.(1) of this preamble, HAIs occur rarely relative to the clinical process of care measures. The rarity of HAIs creates problems for validation scoring of this measure set. To produce an overall score that combines the scores for the individual measure sets, CMS computes a weighted average of each measure set score for each quarter.[98] The weight applied to each measure set is proportionate to the occurrence of records that were submitted to the Warehouse for that measure set. Because CLABSI, CAUTI, and SSI occur rarely, we anticipate that the total number of records targeted for validation of these measures will account for much less than 25 percent of the combined total of all records submitted to the Warehouse. Consequently, if the scores for HAI were combined with the other measure sets, a hospital could potentially report incorrectly for all HAI targeted records, and still meet our established reliability criterion of 75 percent, thus passing validation. This would mean that our process would fail to offer proper quality control for the HAI measure set. Although HAIs are rare, we believe that validation of HAI reporting is critical because it supports HHS' priority to reduce these infections.

For all of these reasons, we are proposing separate scoring processes for the HAI and chart-abstracted clinical process of care measure sets, and to require hospitals to receive passing scores on both processes to pass validation for the FY 2015 payment determination and subsequent years. We are proposing changes to our regulations at § 412.140(d)(2) to address this proposed requirement. In particular, our regulation currently states that ''A hospital meets the validation

[95] Platt R, Kleinman K, Thompson K, *et al.* Using automated health plan data to assess infection risk from coronary artery bypass surgery. Emerg Infect Dis. 2002 Dec;8(12):1433–41.

[96] ''Duplicate listings'' in Kish L. *Survey Sampling,* John Wiley & Sons, New York: 1995, pp.58–59.

[97] ''2.6 The finite population correction.'' Cochran WG. *Sampling Techniques,* third edition. John Wiley & Sons, New York, 1977, pp. 24–25.

[98] ''Confidence Interval Calculation'', *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1138115987129*, last accessed March 19, 2012.

requirement with respect to a fiscal year if it achieves a 75-percent score as determined by CMS.'' We are proposing to change this language to state: ''A hospital meets the validation requirement with respect to a fiscal year if it achieves a passing score, as determined by CMS, on applicable measure sets.'' We propose to define ''passing score'' to mean a score of 75-percent on both of the chart-abstracted clinical process of care and HAI measure set groupings that apply to the hospital. The proposed computation and evaluation of passing for these separate scores are described further below.

For the chart-abstracted clinical process of care measures, we are not proposing any changes to the methodology for reviewing charts, computing the score for each measure set, computing a summary score across all measure sets, or computing the variance around these summary scores. This process was described in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50226).

For the FY 2015 payment determination and subsequent years, we are proposing to use the same basic approach to CLABSI scoring that we finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51647), but to modify this scoring process to include consideration of all three HAI measures simultaneously. For example, if a sampled record is determined to include a CLABSI event and no CAUTI or SSI events, and one CLABSI event, was reported to NHSN, we are proposing to assign the record a score of 1/1. If a sampled record had two independent episodes of CLABSI, CAUTI, or SSI or a combination of infections, both events would have to be reported to NHSN to receive a score of 1/1. Similarly, if no events were reported to NHSN and the medical record indicated there were no events, we are proposing that the record would receive a score of 1/1. We are proposing to assign a score of 0/1 to a record if no event was reported to NHSN and at least one CLABSI, CAUTI, or SSI was detected, or if an event was reported but for the wrong infection. For example, if an SSI was reported to NHSN as a CLABSI, the record would receive a 0/1. We are also proposing to assign a score of 0/1 to a record if an event was reported to NHSN for CLABSI, CAUTI, or SSI, and the CMS contractor determined that there was no such event.

For the FY 2015 payment determination and subsequent years, we are proposing a slightly different process for requesting medical records for SSI. Specifically, we are proposing that when a candidate SSI is identified based on a readmission diagnosis, CDAC would request two records per candidate SSI event. This proposal is necessary because many SSIs are not diagnosed until after patient discharge. In these circumstances, the hospital might first become aware of the SSI upon readmission. Therefore, the information needed to evaluate the presence or absence of an SSI for these candidate events would be divided across two records: (1) The medical record for the hospitalization during which surgery was performed; and (2) the medical record for the readmission to treat the candidate infection. Therefore, we are further proposing for the FY 2015 payment determination and subsequent years that when a candidate SSI is identified based on a readmission diagnosis, we evaluate the occurrence of an SSI event related to the index hospitalization using data in both records. In contrast, we are proposing to limit evaluation of CLABSI and CAUTI to the record for the index hospitalization. We are proposing these changes to incorporate CAUTI and SSI into HAI scoring, which were not part of previous validation efforts. We invite comments on these proposals.

This proposed process will be used to create a mean HAI score for each hospital. The mean will equal the number of HAI records correctly classified divided by the total number of HAI records scored. As described in section VIII.A.6.a.(3) of this preamble, a sample of up to 12 records is to be drawn quarterly, for annual sample of up to 48. The approach of dividing the year into 4 quarters and drawing an independent random sample from each is known as stratified random sampling. When the validation sample includes all of the candidate HAI events that a hospital generates in a year, reliability is measured without error. In this case, the upper bound of the confidence interval will be exactly the same as the estimate of reliability. However, when this score is based on only a sample of records containing candidate HAIs, we must compute a variance around this mean. We are proposing to compute the confidence interval by applying the appropriate formula for the variance of a proportion in a stratified random sample.[99]

[99] ''Section 5.10 Stratified sampling for proportions'' in Cochran WG. Sampling Techniques, third edition. John Wiley and Sons, New York,1977, pp. 107–108.

(5) Criteria to Evaluate Whether a Score Passes or Fails

Historically, we have used two criteria for passing validation in the Hospital IQR Program, which were described in FY 2011 IPPS/LTCH PPS final rule (75 FR 50226):

- Require all Hospital IQR Program participating hospitals selected for validation to attain at least a 75-percent validation score per quarter to pass the validation requirement.
- Use the upper bound of a one-tailed 95 percent confidence interval to estimate the validation score.

For the FY 2015 payment determination and subsequent years, we are proposing to modify both of these criteria. We are proposing that hospitals achieve scores of 75 percent or higher for both the chart-abstracted clinical process of care measure grouping and the HAI score to pass validation. We are proposing to compute each score by combining the data across all four quarters, instead of by considering the quarters separately. We are proposing to make this change because 4 quarters combined can provide a more accurate estimate of reliability than could be attained from a single quarter.

We also are proposing that if hospital has no candidate CLABSI, CAUTI, or SSI in the year to be validated or a hospital has been excepted from NHSN reporting for all three HAIs, it will only be required to achieve a 75 percent score for the chart-abstracted clinical process of care measures to pass validation. We are making this proposal because, in these instances, no HAI score can be computed.

For the FY 2015 payment determination and subsequent years, we are proposing to replace the use of a one-tailed 95 percent confidence interval with a two-tailed 90 percent confidence interval. The reason for this proposal is so that we may identify hospitals passing our annual 75 percent threshold that also have scores within the statistical margin of error for not passing this annual requirement. The upper bound of a two-tailed 90 percent confidence interval is exactly the same number as the upper bound of a one-tailed 95 percent confidence interval. Therefore, this proposal will have no impact on the number of hospitals in the base annual sample that pass or fail validation. The Government Accountability Office (GAO) has noted that CMS does not have a methodology to address hospitals, for which ''the statistical margin of error for their accuracy included both passing and

failing levels.'' [100] For data included in the GAO report, one-quarter to one-third of hospitals fell into this category. CMS has subsequently taken steps to address other GAO concerns, which has reduced the percentage of hospitals that neither passed nor failed validation to 7 percent in the FY 2012 payment determination.

Nonetheless, we believe that there is value in looking more closely at the remainder of these hospitals. For the FY 2015 payment determination and subsequent years, we propose to identify those hospitals which have neither passed nor failed, using a two-tailed confidence interval. In addition, for the purpose of payment determination in FY 2015 and subsequent years, we are proposing to continue to pass these hospitals, while also targeting these hospitals for validation next year, which we are proposing in section VIII.C.6.c. of this preamble.

If, as in previous years, our only concern was in hospitals with an upper bound for the reliability rate below 75 percent, we would have 95 percent confidence in the upper bound. However, because we are proposing to identify hospitals for which ''the statistical margin of error for their accuracy included both passing and failing levels,'' we must consider both an upper and lower confidence bound. Therefore, the same interval provides only 90 percent confidence (5 percent of samples will have lower interval bounds based on the sample that are higher than the actual reliability for the population and 5 percent will have upper interval bounds that are lower than the actual reliability rate for the population). Computing a two-tailed interval and adjusting its confidence level from 95 to 90 percent is the only way to maintain the computation for the upper bound using the same formula as that used in previous years and also calculate the lower bound,[100,101] which will allow us to identify hospitals that would otherwise neither pass nor fail validation. We invite public comment on this proposal.

b. Number and Manner of Selection for Hospitals Included in the Base Annual Validation Random Sample

As finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50225–50227), validation of chart-abstracted measures in the Hospital IQR Program uses a base annual random sample of 800 hospitals. For the FY 2015 payment determination and subsequent years, we are proposing to reduce the total base sample size of hospitals included in the annual validation random sample from 800 to 400. One of our goals in targeting a certain number of hospitals for our base annual random sample is to estimate the total percentage of hospitals that have been reporting unreliable data for the Hospital IQR Program. The minimum sample size required to assess the percentage of hospitals in the Hospital IQR Program have been reporting unreliable data depends on the expected percentage of hospitals that fail validation. Because a very high percentage of Hospital IQR Program hospitals pass validation (more than 99 percent of the hospitals in the FY 2012 payment determination), we believe that we can reduce burden on hospitals by selecting fewer hospitals for the base annual random sample without adversely affecting our estimate of this percentage. We are not proposing to change the criteria for selecting the annual validation random sample because we believe that these criteria are appropriate for sample selection.

For informational purposes, we are summarizing the finalized definition of a hospital eligible for validation, as provided in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50227). Those eligible for validation are the subset of subsection (d) hospitals who successfully submitted ''at least one [IQR] case for the third calendar quarter of the year two years prior to the year to which the validation applies would be eligible to be selected for validation.'' For example, for the FY 2015 payment determination, we would select the sample in early 2013, and all Hospital IQR Program-eligible hospitals that submitted at least one IQR case for third quarter 2012 discharges would be eligible to be selected for validation.

c. Targeting Criteria for Selection of Supplemental Hospitals for Validation

We have established policies for supplementation to the base annual random sample of hospitals. In particular, our supplemental validation sample includes all hospitals that fail validation in the previous year (75 FR 50227 through 50229), a policy that we do not intend to change. We also finalized a policy in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51645 through 51646), that the validation sample drawn for the FY 2015 payment determination and subsequent years will include in the fourth year all hospitals not randomly occurring in the sample in the previous three years to the sample. We have reassessed this policy.

We believe that we have identified an approach with comparable benefits to reliability which would have a smaller total burden to hospitals, and at less cost to CMS. Based on chance alone, we would expect that about 1,500 (slightly less than half of all IPPS-eligible) hospitals would not have been sampled in the previous three years. Of these, less than 200 would be expected to be randomly selected as part of the base validation sample of 400 hospitals for the FY 2015 payment determination. Accordingly, this means that for the FY 2015 payment determination, the supplemental sample size would be about 1,300 hospitals. To increase the sample size by 1,300 hospitals in a single year is unnecessarily burdensome; we believe we can have the same influence on hospitals that have not been recently validated simply by increasing their probability of selection through targeting in subsequent years. Therefore, for the FY 2015 payment determination and subsequent years, we are proposing to discontinue our policy of including hospitals in the supplemental validation sample in the fourth year that have not been validated in the previous three years. We are proposing, however to use the lack of recent validation as one of several targeting criteria for a supplemental random sample described further below. For the FY 2015 payment determination and subsequent years, we are proposing to add targeting criteria as a supplement to the base random sample of up to 200 additional hospitals. We believe that this proposal would improve data quality by increased targeting of hospitals with possible or confirmed past data quality issues. As finalized in the FY 2011 IPPS/LTCH PPS final rule the supplement will include all hospitals that fail validation in the previous year. In addition, we are proposing to draw a random sample of hospitals meeting one or more of the following criteria to reach a total supplemental sample size of up to 200 hospitals (including those failing). We invite public comment on the proposal to include a targeted sample, and to use the following as criteria for targeting the additional hospitals:

- Any hospital with abnormal or conflicting data patterns. An example of abnormal data pattern would be if a hospital has extremely high or extremely low values for a particular measure. Consistent with the Hospital OQR program, we propose to define an extremely high or low value as one that falls more than 3 standard deviations

[100] Government Accountability Office. ''Hospital Quality Data. CMS needs more rigorous methods to ensure reliability of publicly released data''. GAO–06–54, January 2006.

[101] ''Chapter 8 Interval estimation'' in Wonnacott TH, Wonnacott RJ. Introductory statistics for business and economics, 2nd edition, 1977, John Wiley & Sons, New York, pp.199–201, 231–232.

from the mean (76 FR 74485). An example of a conflicting data pattern would be if two records were identified for the same patient episode of care but the data elements were mismatched for primary diagnosis. Primary diagnosis is just one of many fields that should remain constant across measure sets for an episode of care. Other examples of fields that should remain constant across measure sets are patient age and sex. Frequent occurrence of these types of data conflicts may indicate larger data quality problems. Any hospital not included in the base validation annual sample and with statistically significantly more abnormal or conflicting data patterns per record than would be expected based on chance alone ($p < .05$), would be included in the population of hospitals targeted in the supplemental sample.

- Any hospital with rapidly changing data patterns. For this targeting criterion, we propose to define a rapidly changing data pattern as a hospital which improves its quality for one or more measure sets (that is, AMI, HF, PN, SCIP, ED, IMM, or HAI) by more than 2 standard deviations from one year to the next, and also has a statistically significant difference in improvement (one-tailed $p < .05$). This pattern might indicate rapid quality improvement. It may also indicate a potential change in the accuracy of the data reported, and would be worthy of targeted validation.
- Any hospital that submits data to NHSN after the Hospital IQR Program data submission deadline has passed, which could suggest that the hospital had data for relevant time periods that was not used in calculating Hospital IQR measure rates.
- Any hospital that joined the Hospital IQR Program within the previous 3 years, and which has not been previously validated. When a hospital first enters the program, its staff may need additional support/education to ensure their understanding of reporting requirements. Moreover, receiving this feedback early in a hospital's participation may ensure that good data reporting habits are established when a hospital's process may not yet be entrenched.
- Any hospital that has not been randomly selected for validation in any of the previous 3 years.
- For the FY 2016 payment determination and subsequent years, we are proposing to add to the targeting criteria proposed for the 2015 payment determination by identifying hospitals that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent. Relative to hospitals whose confidence interval lies entirely above the target reliability rate of 75 percent, a confidence interval that includes 75 percent would indicate a higher level of uncertainty as to the reliability of data for that particular hospital. This proposal is related to the proposal to produce a two-sided confidence interval (discussed in section VIII.A.6.b of this preamble). It is intended to respond to concerns that CMS does not have a methodology to address hospitals, for which ''the statistical margin of error for their accuracy included both passing and failing levels.'' The reason that we are proposing implementation of this criterion beginning with the 2016 payment determination is that it is not feasible to implement this change until after we implement changes to the confidence interval, as proposed in section VIII.A.6.b. of this preamble.

As noted above, the established procedure for drawing the base random sample involves selection of hospitals ''early'' in the calendar year two years prior to the payment determination FY 2011 IPPS/LTCH PPS final rule (75 FR 50227). For example, the base sample for the FY 2015 payment determination will be drawn early in 2013. We are proposing that the selection of hospitals targeted in the supplemental sample for the FY 2015 payment determination occur after the FY 2014 payment determination; this will separate the timing of selection of base and supplemental samples. We are proposing to do so because CMS may need extra time to review hospital data before identifying the hospitals to include in the supplemental sample. Moreover, information regarding a hospital's status as failing or passing is not known at the time the base sample is drawn.

As finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50219), the quarters included in the validation effort for each year's payment determination will be the 4th calendar quarter of the year that occurs 2 years before the payment determination and the first 3 calendar quarters of the following calendar year. For example, for the FY 2015 payment determination, the quarters included in validation would be the fourth quarter of calendar year 2012 through the third quarter of calendar year 2013.

7. Proposed Data Accuracy and Completeness Acknowledgement Requirements for the FY 2015 Payment Determination and Subsequent Years

We are proposing to require hospitals to continue to electronically acknowledge their data accuracy and completeness once annually. For the FY 2014 payment determination, the submission deadline for the Data Accuracy and Completeness Acknowledgement was aligned with the final submission quarter for each fiscal year. We are proposing to continue this approach for FY 2015 and subsequent years. For example, we are proposing that the submission deadline for the Data Accuracy and Completeness Acknowledgement would be May 15, 2014, with respect to the time period of January 1, 2013, through December 31, 2013. We invite public comment on this proposal.

8. Public Display Requirements for the FY 2015 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), we continued, 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. We are not proposing any changes to these requirements.

The Hospital IQR Program quality measures are typically reported on the *Hospital Compare* Web site at: *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.

9. Reconsideration and Appeal Procedures for the FY 2015 Payment Determination

The Hospital IQR Program reconsideration and appeals requirements were adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651) and are found at 42 CFR 412.140(e) of our regulations. The form for reconsiderations and a detailed description of the reconsideration process are available on the QualityNet Web site at: *http://www.qualitynet.org/* > Hospitals-

Inpatient > Hospital Inpatient Quality Reporting Program > APU Reconsiderations.

10. Hospital IQR Program Disaster Extensions or Waivers

The Hospital IQR Program disaster extensions or waiver requirements were adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51652) and can be found at 42 CFR 412.140(e) and (c)(2), respectively. The forms and a detailed description of the extension or waiver process are available on the QualityNet Web site at: *http://www.qualitynet.org/* > Hospitals-Inpatient > Hospital Inpatient Quality Reporting Program.

11. 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.

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 anticipated future reporting of clinical quality measures under the Hospital IQR Program. Through the EHR Incentive Programs we expect that the anticipated future 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 certain 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 the 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 where it is possible to report the data via certified EHR technology. 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, when available, 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.

Ultimately, we do not anticipate having two different sets of clinical quality measures for the EHR Incentive Programs 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 reporting infrastructure for electronic submission as an additional reporting mechanism 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 data rather than clinical data. Thus, not all Hospital IQR 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 note that the provisions in this proposed rule do not implicate or implement any HITECH statutory provisions. Those provisions are the subject of separate rulemaking and public comment.

B. Proposed PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Statutory Authority

Section 3005 of the Affordable Care Act added a new subsection (a)(1)(W) and new subsection (k) to section 1866 of the Act. Section 1866(k) of the Act establishes a Quality Reporting Program for a hospital described in section 1886(d)(1)(B)(v) of the Act (hereafter referred to as a ''PPS-Exempt Cancer Hospital'' or ''PCH''). Section 1866(k)(1) of the Act provides that, for FY 2014 and each subsequent fiscal year, a PCH shall submit data to the Secretary in accordance with section 1866(k)(2) of the Act with respect to such a fiscal year. Section 1866(k)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, each hospital described in section 1886(d)(1)(B)(v) of the Act shall submit data to the Secretary on quality measures specified under section 1866(k)(3) of the Act in a form and manner, and at a time, specified by the Secretary.

Section 1866(k)(3)(A) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act, unless an exception under section 1866(k)(3)(B) of the Act applies. The National Quality Forum (NQF) currently holds this contract. The NQF is a voluntary, consensus-based, 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 healthcare quality measurement and reporting through its consensus development processes. We have generally adopted NQF-endorsed measures in our reporting programs. However, section 1866(k)(3)(B) of the Act provides an exception. Specifically, it provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Under section 1866(k)(3)(C) of the Act, the Secretary must publish the measure selection for PCHs no later than October 1, 2012, with respect to FY 2014.

Section 1866(k)(4) of the Act requires the Secretary to establish procedures for making public the data submitted by PCHs under the PCHQR Program. Such procedures must ensure that a PCH has the opportunity to review the data that is to be made public with respect to the hospital prior to such data being made public. The Secretary must report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished by PCHs on the CMS Internet Web site.

2. Covered Entities

Section 1886(d)(1)(B)(v) of the Act excludes particular cancer hospitals from payment under the IPPS. This proposed regulation covers only those PPS-excluded cancer hospitals meeting eligibility criteria specified in 42 CFR 412.23(f).

3. Proposed Quality Measures for PCHs for FY 2014 Program and Subsequent Program Years

a. Considerations in the Selection of the Quality Measures

Section 1866(k)(3)(A) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act, unless an exception under section 1866(k)(3)(B) applies. The statutory requirement under section 1866(k)(3)(B) of the Act provides an exception that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

As appropriate, we have developed the principles we are using for the development and use of measures for the PCHQR Program on those we are using for the Hospital IQR Program:

- Public reporting should rely on a mix of standards, outcomes, process of care measures, and patient experience of care measures, including measures of care transitions and changes in patient functional status.
- The measure set should evolve so that it includes a focused core set of measures appropriate to the cancer hospital category that reflects the level of care and the most important areas of service and measures for cancer hospitals. Measures will address gaps in quality of cancer care.
- We also consider input solicited from the public. For instance, CMS held a Listening Session on September 8, 2011, to receive input from consumers, advocacy groups, and providers on the measures under consideration for and implementation of the PCHQR Program.
- We considered suggestions and input from a PCH Technical Expert Panel (TEP), convened by a CMS measure development contractor, which rates potential PCH quality measures for importance, scientific soundness, usability, and feasibility. The TEP membership includes health-care providers specializing in treatment of cancer, cancer researchers, consumer and patient advocates, disparities experts, and representatives from payer organizations.

Like the Hospital IQR Program, the PCHQR Program also supports the National Quality Strategy, national priorities, HHS Strategic Plans and Initiatives, CMS Strategic Plans, takes into consideration the recommendations of the Measure Application Partnership (MAP), and strives for burden reduction whenever possible. We refer readers to the discussion of these topics in section VIII.A.3.a. of this proposed rule on ''Additional Considerations in Expanding and Updating Quality Measures'' under the Hospital IQR Program.

b. Proposed PCHQR Program Quality Measures for FY 2014 Program and Subsequent Program Years

We are proposing to adopt five quality measures for the FY 2014 program and subsequent program years. Specifically, we are proposing to adopt two CDC/NHSN-based HAI quality measures (outcome measures): (1) Central Line-Associated Bloodstream Infection (CLABSI); and (2) Catheter-Associated Urinary Tract Infection (CAUTI); and three cancer process of care measures: (1) Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer; (2) Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer; and (3) Adjuvant hormonal therapy.

All five of these proposed measures were reviewed by the MAP, and were recommended for inclusion in the PCHQR Program. For details regarding MAP input, please refer to the MAP Pre-Rulemaking reports located at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*.

(1) Proposed CDC/NHSN–Based Healthcare-Associated Infection (HAI) Measures

HAIs are among the leading causes of death in the United States. CDC estimates that as many as 2 million infections are acquired each year in hospitals and result in approximately 90,000 deaths per year.[102] 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 number of days of hospitalization required for patients and add considerable health care costs.

The reduction of HAIs is a priority for HHS, as evidenced by HHS's 2009 publication of an Action Plan to Reduce HAIs.[103] 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 HAIs. In 2009, a Steering Committee, which included scientists and program officials across the Government, developed the HHS Action Plan to Prevent HAIs, 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

[102] 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.

[103] Available at: *http://www.hhs.gov/ash/initiatives/hai/actionplan/*.

morbidity and mortality were most severe in that setting and the scientific information on prevention and the capacity for 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.

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. We note that the House Committee on Appropriations asked in a 2009 Report that CMS include in its ''pay for reporting'' system for subsection (d) hospitals two infection control measures, one of which was a central line-associated bloodstream infections measure (H. Rep. No. 111–220, at 159 (2009)). In the Report, the Committee stated that ''[i]f 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 this proposed rule, we are proposing to adopt two NQF-endorsed HAI measures as stated in the above for the FY 2014 program and subsequent program years for the PCHQR Program: (1) National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure; and (2) National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure. These proposed measures were developed by the CDC and are currently collected by the CDC via the NHSN. We are proposing to adopt these two measures for several reasons. First, we believe that these measures support the National Quality Strategy priority of patient safety as these measures focus on serious infections that can prolong patient hospital stays and increase the risk of mortality.[104] Second, the Technical Expert Panel (TEP) convened by our measure development contractor identified CLABSI and CAUTI as high priority quality issues for PCHs as an important area of quality measurement and promoting potential for improved outcomes. Third, MAP reviewed these HAI measures and supported inclusion of these measures in the PCHQR Program as they address the National Quality Strategy's priority of safer care (see MAP Pre-Rulemaking Final Report at: *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*).

Fourth, these two HAI measures foster alignment with other our quality reporting programs. In the FY 2011 IPPS/LTCH PPS final rule, we adopted the CLABSI measure for the Hospital IQR Program. The CLABSI measure is currently being collected as part of the FY 2013 Hospital IQR measure set, and data submission on the measure began with January 2011 events.[105] In the Hospital IQR Program, collection of this measure is limited to ICU locations. This measure also has been adopted for the FY 2014 payment determination under the LTCHQR Program; for the LTCHQR Program, data collection for this measure extends to all inpatient locations in the LTCH.

In the FY 2012 IPPS/LTCH PPS final rule, we adopted the Catheter Associated Urinary Tract Infection (CAUTI) rate per 1,000 urinary catheter days for Intensive Care Unit Patients measure for both the FY 2014 Hospital IQR and LTCHQR measure sets. In the Hospital IQR Program, collection of this measure is limited to ICU locations; for the LTCHQR Program, collection of this measure extends to all inpatient locations except neonatal ICUs. This measure is a high priority HAI measure that is 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.

We are proposing to collect data for these two HAI measures via the NHSN, which is a secure, Internet-based surveillance system maintained and managed by CDC, and can be used by all types of health care facilities in the United States, including acute care hospitals, cancer hospitals, long term care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, and ambulatory surgery centers. The NHSN enables health care 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 health care facilities to submit patient-level data on measures mandated through their specific State legislation. Currently, 28 States require hospitals to report HAIs using NHSN, and CDC provides support to more than 5,000 hospitals that are using NHSN.

NHSN data collection occurs via manual data entry into a Web-based tool hosted by CDC provided without charge to providers and via electronic reporting by providers directly to NHSN. The NHSN Agreement to Participate and Consent Form specifies the purposes to which NHSN data are put, including enabling providers, such as cancer hospitals, to report data via NHSN to CMS in fulfillment of CMS's quality measurement reporting requirements for those data.

In addition, data submission for HAI measures through electronic health record technology (EHRs) may be possible in the near future and this would further reduce reporting burden on hospitals.

(A) Proposed Central Line-Associated Blood Stream Infections Measure ((CLABSI), NQF #0139)

The proposed CLABSI measure was originally developed by CDC to assess the percentage of ICU and high-risk nursery patients who, over a certain amount of days, acquired central line catheter-associated bloodstream infections. CDC recently updated this measure to expand the care setting to all inpatient settings (not just ICUs). As indicated previously, the measure has been renamed as National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure and we are proposing to adopt this measure for use for the FY 2014 program and subsequent program years. This measure is considered an outcome measure by NQF as it relates to the results of the quality of care provided to patients; it is risk adjusted by which the observed infection rate for a particular location in a hospital is compared to an expected infection rate calculated based on the specific location within other facilities that report to the NHSN. Measure specifications may be accessed at: *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf*.

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 patients are discharged from short-term acute care hospital intensive care units (ICUs) or ICU stepdown units with these central lines in place.

[104] CDC/NHSN Manual. Device-Associated Module, CLABSI Event. Available at *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf*, accessed on January 20, 2011.

[105] The CDC captures HAI data based on the onset of an event, rather than based on the discharge date.

Bloodstream infections are usually serious infections typically causing a prolongation of hospital stay and increased cost and risk of mortality.[106] An estimated 248,000 bloodstream infections occur in U.S. hospitals each year.[107] Furthermore, despite the preventability of these infections, CLABSIs result in thousands of deaths each year and billions of dollars in added costs to the U.S. health care system, CDC is providing guidelines and tools to the health care community to help reduce central line catheter-associated bloodstream infections. CLABSIs can be prevented through proper management of the central line. 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.[108] 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 U.S. hospitals.

This measure is NQF-endorsed and, therefore, meets the requirement of section 1866(k)(3)(A) of the Act, which states that quality measures selected for the PCHQR Program must be endorsed by the entity with a contract under section 1890(a) of the Act, unless an exception under section 1866(k)(3)(B) of the Act applies.

We invite public comment on our proposal to adopt the NHSN Central Line-Associated Bloodstream Infection (CLABSI) outcome measure for the PCHQR Program for collection in both ICU and non-ICU locations within a PCH to align with the recently-expanded NQF-endorsed measure specifications for the FY 2014 program and subsequent program years.

(B) Proposed Catheter Associated Urinary Tract Infection Measure ((CAUTI), NQF #0138)

The catheter-associated urinary tract infection (CAUTI) measure was developed by CDC to measure the percentage of patients with CAUTIs in the ICU context. CDC has recently updated the specifications of this measure to include all inpatient settings (not just ICUs). This measure has been renamed as National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure and we are proposing to adopt this measure for use for the FY 2014 program and subsequent program years. This measure is considered an outcome measure as it relates to the results of the quality of care provided to patients; it is risk adjusted by which the observed infection rate for a particular location in a hospital is compared to an expected infection rate calculated based on the specific location within other facilities that report to the NHSN. Measure specifications may be accessed at: *http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf*.

The urinary tract is the most common site of HAI, accounting for more than 30 percent of infections reported by acute care hospitals.[109] 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.[110] Prevention of CAUTIs is discussed in the CDC/HICPAC document, *Guideline for Prevention of Catheter-associated Urinary Tract Infections,* which includes recommendations for proper insertion techniques, including hand washing, insertion by trained staff, use of sterile gloves, drapes, sponges and antiseptic or sterile solution for cleaning and lubricant jelly for insertion.[111]

UTIs are a major cause of morbidity and mortality. The HHS 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.

This measure is NQF-endorsed and, therefore, meets the requirement of section 1866(k)(3)(A) of the Act, which states that quality measures selected for the PCHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, unless an exception under section 1866(k)(3)(B) of the Act applies.

We invite public comment on our proposal to adopt the NHSN Catheter-Associated Urinary Tract Infection (CAUTI) outcome measure for the PCHQR Program for collection in both ICU and non-ICU locations within a facility to align with the recently expanded NQF-endorsed measure specifications for the FY 2014 program and subsequent program years.

(2) Proposed Cancer-Specific Measures

We are proposing to adopt three measures related to the treatment of colon cancer and two types of breast cancer (hormone receptor-negative and hormone receptor-positive). Specifically, these proposed measures are: (i) Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer (NQF #0223); (ii) Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer (NQF #0559); and (iii) Adjuvant hormonal therapy (NQF # 0220). The proposed measures were developed by the American College of Surgeons/Commission on Cancer.

We are proposing to adopt these three cancer treatment-related quality measures for several reasons. First, national cancer incidence rates suggest that breast and colon cancer will become two of the more common diagnoses (in 2012, 29 percent of cancer diagnosis in females will be breast cancer, and 6 percent of cancer diagnosis in both genders will be colon cancer [112]); these cancers are also highly prevalent among Medicare beneficiaries.

[106] CDC/NHSN Manual. Device-Associated Module, CLABSI Event. Available at *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf*, accessed on January 20, 2011.

[107] 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.

[108] 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).

[109] 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.

[110] Wong ES., Guideline for prevention of catheter-associated urinary tract infections. Infect Control 1981; 2:126–30.

[111] Gould CV, Umscheid CA, Agarwal RK, Kuntz G, Pegues DA, *et al.,* Guideline for prevention of catheter-associated urinary tract infections. Infect Control 2009; 31:319–326.

[112] Siegel R, Naishadham D, Jemal A. Cancer statistics, 2012. CA Cancer J Clin 2012; 62:10–29.

We believe the high incidence of these types of cancer creates an opportunity for measurements to make an impact on the quality of cancer care. Second, these measures support the National Quality Strategy's priority to promote the most effective prevention and treatment practices for the leading causes of mortality due to cancer. Third, the TEP convened by our measure development contractor identified the treatment of breast and colon cancer as high priority quality issues for PCHs due to the high incidence of these types of cancers and rated these measures highest compared to other potential program measures based on an assessment of the importance, scientific acceptability, usability, and feasibility of these measures. Also, participants in a CMS-convened Listening Session on September 8, 2011 expressed support for the proposed measures. The transcript for this Listening Session can be found at *http://www.cms.gov/HospitalQualityInits/05_HospitalHighlights.asp#TopOfPage*. Fourth, the MAP reviewed these cancer-specific measures and supported inclusion of these measures in the PCHQR Program. All of the three proposed cancer-specific measures are NQF-endorsed; therefore they satisfy the requirement of section 1866(k)(3)(A) of the Act relating to the selection of endorsed measures for the PCHQR Program. Furthermore, section 1866(k)(4) of the Act provides that quality measures reported in the PCHQR Program should assess process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to PCHs. We believe these three proposed cancer-specific measures meet the above statutory criteria, as they track important processes in the treatment of colon and breast cancer.

Although these measures are not currently reported in other HHS programs, they are reported by over 1,500 cancer programs as part of their accreditation by the Commission on Cancer, a program of the American College of Surgeons (see *http://www.facs.org/cancer/ncdb/index.html*), further indicating their importance as the Commission on Cancer has taken a leading role in establishing national standards to ensure quality in the provision of cancer care.

We are proposing that PCHs would submit the data needed to calculate these measures to a CMS contractor. We believe that a CMS contractor-based data collection mechanism would reduce the potential reporting burden because currently the majority of PCHs are submitting HAI and cancer-specific measures to the appropriate entities.

(A) Proposed Adjuvant Chemotherapy Is Considered or Administered Within 4 Months (120 days) of Surgery to Patient Under the Age of 80 With AJCC III (Lymph Node Positive Colon Cancer) (NQF #0223)

This proposed measure examines whether adjuvant chemotherapy is delivered within a specified period of time after a diagnosis of colon cancer. Specifically, it looks at the proportion of patients 18–79 with AJCC Stage III (lymph node positive) colon cancer for whom adjuvant chemotherapy is considered or administered within 4 months of diagnosis. Stage III colon cancer is colon cancer that has spread outside the colon to one or more lymph nodes. The adjuvant chemotherapy measure is a process measure as it addresses whether a defined treatment was delivered to a patient; the measure is not risk adjusted by which the measure does not attempt to account for hospital patient populations or other differences between hospitals. Detailed specifications for this proposed measure can be accessed on the Web site of the measure steward, the American College of Surgeons at: *http://www.facs.org/cancer/ncdb/colonmeasures.pdf*. Additionally, CMS will provide a link to the specification manual on the QualityNet Web site.

Colorectal cancer plays a sizeable role in affecting both health and health care costs in the United States. The American Cancer Society estimates that 51,690 Americans will die of colorectal cancer in 2012.[113] According to the National Cancer Institute, more than $14.1 billion was spent on colorectal cancer in 2010.[114]

Appropriate treatment may improve survival rates and reduce the likelihood of costly recurrence. Strong evidence suggests that treating Stage III colon cancer patients with adjuvant chemotherapy improves overall survival and disease-free survival.[115] In addition to being supported by evidence, this measure is consistent with the National Comprehensive Cancer Network's (NCCN) guidelines for the treatment of colon cancer (COL–4: T3–4, N1–2, MO), which recommend that colon cancer patients should receive adjuvant chemotherapy.

Section 1866(k)(3)(A) of the Act requires quality measures selected for the PCHQR Program to be endorsed by the entity with a contract under section 1890(a) of the Act, unless an exception under 1866(k)(3)(B) applies. This measure is NQF-endorsed and therefore, it meets the statutory endorsement requirements.

We invite public comment on our proposal to adopt the Adjuvant Chemotherapy Is Considered or Administered Within 4 Months (120 days) of Surgery to Patient Under the Age of 80 With AJCC III (lymph node positive colon cancer) measure for the PCHQR Program for the FY 2014 program and subsequent program years.

(B) Proposed Combination Chemotherapy Is Considered or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 With AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (NQF #0559)

This proposed measure assesses the proportion of women ages 18–69 who have their first diagnosis of breast cancer at AJCC Stage IC, II or III and whose primary tumor is hormone (estrogen and progesterone) receptor negative for whom combination chemotherapy is considered or administered within 4 months of diagnosis. Hormone receptor negative means that hormones, such as estrogen, do not drive tumor growth. This measure is a process measure as it addresses whether a defined treatment was delivered to a patient; the measure is not risk adjusted in that the measure does not attempt to account for differences in hospital patient populations or other differences between hospitals. Detailed specifications for this proposed measure can be accessed on the Web site of the measure steward, the American College of Surgeons, at: *http://www.facs.org/cancer/ncdb/breastmeasures.pdf*. Additionally, CMS will provide a link to the specification manual on the QualityNet Web site.

The number of deaths from breast cancer has declined while spending has increased. The American Cancer Society estimates that 39,510 Americans will die of breast cancer in 2012.[116] Spending on breast cancer care is higher than for any other type of cancer: according to the National Cancer Institute, more than $16.5 billion was

[113] Siegel R, Naishadham D, Jemal A. Cancer statistics, 2012. CA Cancer J Clin 2012; 62:10–29.

[114] Mariotto AB, Yabroff KR, Shao Y, Feuer EJ, and Brown ML. Projections of the Cost of Cancer Care in the United States: 2010–2020. JNCI 2011; 103:117–128.

[115] André T, Boni C, Navarro M, *et al.* Improved Overall Survival With Oxaliplatin, Fluorouracil, and Leucovorin As Adjuvant Treatment in Stage II or III Colon Cancer in the MOSIAC Trial. J Clin Onc 2009; 27:3109–3116.

[116] Siegel R, Naishadham D, Jemal A. Cancer statistics, 2012. CA Cancer J Clin 2012; 62:10–29.

spent on breast cancer care in 2010.[117] Evidence shows that treating hormone receptor negative breast cancer patients with combination chemotherapy is associated with a reduced risk of relapse or death.[118] This measure is also consistent with NCCN's guidelines for the treatment of invasive breast cancer (BINV–4, 7–8), which recommend adjuvant chemotherapy for patients with hormone receptor negative tumors, and therefore the measure aligns with recognized standards of treatment.

This measure is NQF-endorsed and therefore, it meets the requirements under section 1866(k)(3)(A) of the Act which states that quality measures selected for the PCHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, unless an exception under section 1866(k)(3)(B) of the Act applies.

We invite public comment on our proposal to adopt the Combination Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 With AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (NQF #0559) quality measure for the PCHQR Program for the FY 2014 program and subsequent program years.

(C) Proposed Adjuvant Hormonal Therapy (NQF #0220)

This proposed measure assesses whether recommended treatment is delivered within a specified period of time from a patient's breast cancer diagnosis. Specifically, it tracks the proportion of eligible women 18 years or older who have their first diagnosis of breast cancer at AJCC T1c or Stage II or III and whose primary tumor is hormone (estrogen or progesterone) receptor positive breast cancer for whom tamoxifen or a third generation aromatase inhibitor is considered or administered within 1 year of diagnosis. Hormone receptor positive means that estrogen or progesterone promotes the growth of cancer cells. This measure is a process measure as it relates to whether a defined treatment was delivered to a patient; it is not risk adjusted. Detailed specifications for this proposed measure can be accessed on the Web site of the measure steward, the American College of Surgeons, at: *http://www.facs.org/cancer/ncdb/breastmeasures.pdf*. Additionally, we will provide a link to the specification manual on the QualityNet Web site.

The American Cancer Society estimates that two-thirds of breast cancer cases are hormone receptor positive.[119] As stated previously, appropriate and effective treatment is important to both the health and cost outcomes of breast cancer care. The measure is consistent with NCCN's guidelines (BINV–5, 6 and 9 and BINV–E) for the treatment of invasive breast cancer, which recommend hormone therapy for patients with hormone receptor positive breast cancer, and with the American Society of Clinical Oncology's (ASCO) Update on adjuvant endocrine therapy for women with hormone receptor positive breast cancer. The ASCO guideline cites a wide body of supporting evidence for this method of treatment.

This measure is NQF-endorsed and therefore, it meets the requirement under section 1866(k)(3)(A) of the Act, which states that quality measures selected for the PCHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, unless an exception under section 1866(k)(3)(B) of the Act applies.

We invite public comment on our proposal to adopt the Adjuvant hormonal therapy measure for the PCHQR Program for the FY 2014 program and subsequent program years.

In summary, we are proposing to adopt five quality measures for the PCHQR Program for the FY 2014 program and subsequent program years (listed in the table below): (1) NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (data submission for ICU and non-ICU locations via CDC/NHSN); (2) NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (data submission for ICU and non-ICU locations via CDC/NHSN); (3) Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer (data submission to CMS contractor); (4) Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer (data submission to CMS contractor); and (5) Adjuvant hormonal therapy (data submission to CMS contractor). We invite public comment on these proposed measures for the FY 2014 program and subsequent program years. The proposed details regarding data submission for these measures are covered in section VIII.B. of this preamble.

Topic	Proposed measures for PCHQR program beginning with FY 2014 program and subsequent program years
Safety and Healthcare Acquired Infections—HAI.	• NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure. • NHSN Catheter-Associated Urinary Tract Infections (CAUTI) Outcome Measure.
Cancer-Specific Treatments	• Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer. • Combination Chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative Breast Cancer. • Adjuvant Hormonal Therapy.

4. Possible New Quality Measures Topics for Future Years

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the cancer hospital setting. Therefore, through future rulemaking, we intend to propose new measures that help us further our goal of achieving better health care and improved health for Medicare beneficiaries who obtain cancer services through the widespread dissemination and use of performance information. Additionally, we are considering initiating a call for input to assess the following measure domains: Clinical quality of care, care coordination, patient safety, patient and caregiver experience of care, population/

[117] Mariotto AB, Yabroff KR, Shao Y, Feuer EJ, and Brown ML. Projections of the Cost of Cancer Care in the United States: 2010–2020. J Natl Cancer Inst 2011; 103:117–128.

[118] Fisher B, Jeong JH, Anderson S, *et al.:* Treatment of axillary lymph node-negative, estrogen receptor-negative breast cancer: updated findings from National Surgical Adjuvant Breast and Bowel Project clinical trials. J Natl Cancer Inst 96 (24): 1823–31, 2004.

[119] American Cancer Society. Breast Cancer Hormone Therapy. *http://www.cancer.org/Cancer/BreastCancer/DetailedGuide/breast-cancer-treating-hormone-therapy* Last revised 01/06/2012.

community health and efficiency. We believe this approach will promote better cancer care while bringing the PCHQR Program in line with other established quality reporting and performance improvement programs such as the Hospital IQR, the Hospital OQR, the ESRD QIP, and others within CMS' purview.

We welcome public comment and suggestions for these, or other, measurement areas.

5. Maintenance of Technical Specifications for Quality Measures

Many of the quality measures used in different Medicare and Medicaid reporting programs are NQF-endorsed. As part of its regular maintenance process for endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes to NQF on an annual basis. NQF solicits information from measure stewards for annual reviews and in order to review measures for continued endorsement in a specific 3-year cycle.

Through NQF's measure maintenance process, NQF endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, changes to exclusions to the patient population, definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act. In this proposed rule, we are proposing that if the NQF updates an endorsed measure that we have adopted for the PCHQR Program in a manner that we consider to not substantially change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we would revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We would also post the updates on the CMS QualityNet Web site at *https://www.QualityNet.org*. We would provide sufficient lead time for PCHs to implement the changes where changes to the data collection systems would be necessary.

We would continue to use the rulemaking process to adopt changes to measures that we consider to substantially change the nature of the measure. We believe that this proposal adequately balances our need to incorporate NQF updates to NQF-endorsed PCH measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We invite public comment on this proposal.

Additionally, we will provide a Specifications Manual that will contain links to measure specifications, data abstraction information, data submission information, and other information necessary for PCHs to participate in the PCHQR Program. This manual would be posted on the QualityNet Web site at: *https://www.QualityNet.org*. We would maintain the technical specifications for the quality measures by updating this manual periodically, which would include detailed instructions for PCHs to use when collecting and submitting data on the required measures. These updates would be accompanied by notifications to PCHQR Program-participating users, providing sufficient time between the change and effective dates in order to allow users to incorporate changes and updates to the measure specifications into data collection systems. We would revise the Specification Manual and provide links to reflect such endorsement changes which also would be posted on the QualityNet Web site at: *https://www.QualityNet.org*. We invite public comment on the previously described proposed policy on maintenance of technical specifications for quality measures.

6. Proposed Public Display Requirements for the FY 2014 Program and Subsequent Program Years

Section 1866(k)(4) of the Act requires the Secretary to establish procedures for making the data submitted under the PCHQR Program available to the public. Such procedures shall ensure that a PCH has the opportunity to review the data that is to be made public with respect to the hospital prior to such data being made public. Section 1866(k)(4) of the Act also provides that the Secretary shall report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospital on the CMS Internet Website. In order to meet these requirements, we are proposing to publicly display the submitted data on the Hospital Compare Web site (*http://www.hospitalcompare.hhs.gov/*). Before the data are publicly displayed, we propose that PCHs will have the opportunity to review their data prior to the public reporting of the measure rates consistent with section 1866(k)(4) of the Act. We are proposing that PCHs have the opportunity to review their data 30 days prior to the public reporting of the measure rates because we would continue our current practice of preview reporting data for the PCHQR program in alignment with the HIQR program.

The Hospital Compare Website serves to encourage consumers 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.

However, some information that may not be relevant to or easily understood by beneficiaries and information for which there are unresolved display issues or design considerations that may not make them suitable for inclusion on the Hospital Compare Web site may be made available on other CMS Web sites, such as *http://www.cms.gov* and/or *http://www.qualitynet.org*. In such circumstances, affected parties would be notified via CMS listservs, CMS e-mail blasts, and QualityNet announcements regarding the release of confidential hospital-specific preview reports to individual hospitals followed by the posting of data on a CMS Web site other than Hospital Compare.

We invite public comment on the previously described proposals regarding the public display of quality measures.

7. Proposed Form, Manner, and Timing of Data Submission for FY 2014 Program and Subsequent Program Years

a. Background

Section 1866(k)(2) of the Act requires that, for the FY 2014 program and each subsequent program year, each PCH must submit to the Secretary data on quality measures established under section 1866(k)(3) of the Act in a form and manner, and at a time as specified by the Secretary.

The complete data submission requirements and submission deadlines will be posted on the QualityNet Web site at: *http://www.QualityNet.org/*. In general, we are proposing that PCHs

submit data to the CDC for the HAI measures (CLABSI and CAUTI), and the CMS contractor for the three Cancer-Specific measures (Adjuvant Chemotherapy for Stage III Colon Cancer; Combination Chemotherapy for AJCC T1c or Stage II or III Hormone Receptor-Negative Breast Cancer; and Hormone Therapy for AJCC T1c or Stage II or III Hormone Receptor-Positive Breast Cancer). As set forth below, 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 the proposed HAI measures to NHSN. We refer readers to the CDC's website for detailed data submission and reporting procedures. We are also proposing procedures for PCHs to follow when submitting data on the three proposed cancer-specific measures.

b. Proposed Procedural Requirements for FY 2014 Program and Subsequent Program Years

In order to participate in the PCHQR Program for the FY 2014 program and subsequent program years, we are proposing that PCHs must comply with the procedural requirements outlined in this section. We have aligned these proposed procedural requirements with the Hospital IQR Program to the extent possible to streamline the procedural requirements across different types of providers. We are proposing that PCHs must do the following:

- Register with QualityNet before participating PCHs begin reporting and regardless of the method used for submitting the data.
- Identify QualityNet Administrator(s) who follows the registration process located on the QualityNet Website (*http://www.QualityNet.org*).
- PCHs participating in the PCHQR Program must complete an online Data Accuracy and Completeness Acknowledgement (DACA) via QualityNet, which states that the quality measure results and any and all data including numerator and denominator data provided, are accurate and complete. We are proposing that the time period for submitting the DACA would be August 31 of the preceding fiscal year. For more information on DACA, please refer to the section below entitled, ''Proposed Data Accuracy and Completeness Acknowledgement (DACA) Requirements for the FY 2014 Program and Subsequent Program Years.''
- Enroll in CDC/NHSN and register with the CMS contractor collecting the Cancer-Specific measures before participating PCHs begin reporting.

We strongly encourage PCHs to complete an online Notice of Participation (NOP) via QualityNet. This form would grant CMS written authorization from the PCH to publicly report the PCH's measure rate on a CMS Web site.

PROPOSED CMS NOTICE OF PARTICIPATION TIMEFRAME

Program year (fiscal year)	Notice of participation (NOP) deadline
FY 2014	August 15, 2013.
FY 2015	August 15, 2014.
Subsequent Fiscal Years.	August 15 of the preceding fiscal year.

c. Proposed Reporting Mechanisms for FY 2014 Program and Subsequent Program Years

For the purpose of reporting quality measures under the PCHQR Program, we are proposing to adopt the following data submission mechanisms. With respect to the proposed HAI measures (CLABSI and CAUTI), we are proposing that PCHs submit the data to the CDC through the NHSN database. 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 the proposed HAI measures to NHSN. We refer readers to the CDC's website (*http://www.cdc.gov/nhsn/*) for detailed data submission and reporting procedures. After the final submission deadline has passed, CMS will obtain the PCH-specific calculations that have been generated by the NHSN for the PCHQR Program.

With respect to the three proposed (3) cancer-specific measures, we are proposing that PCHs submit the data to the CMS contractor. The CMS Contractor would then calculate the quality measures rates and submit those rates to CMS on a quarterly basis.

We invite public comment on our proposed reporting mechanisms.

(1) Proposed Reporting Mechanism for the Proposed HAI Measures

We are proposing to adopt a quarterly submission process for the proposed HAI measures –CLABIS AND CAUTI, that use similar reporting mechanism to the one finalized for the Hospital IQR program (75 FR 50223) starting with October 1, 2012 infection events. We have successfully implemented this reporting mechanism in the Hospital IQR program and intend to use similar reporting mechanism to collect data for the PCHQR program. We welcome comment on this proposal.

(2) Proposed Reporting Mechanism for the Proposed Cancer-Specific Measures

We are proposing to collect the three cancer-specific measures data using a CMS contractor starting with the FY2014 program. Similar to the reporting mechanism we are proposing to adopt for the proposed HAI measures, we anticipate that PCHs would report their measure data to the contractor, which would then calculate the measure rates and submit those rates to CMS. Should these proposed measures be finalized, we will publish the technical specifications and file layouts necessary for reporting in enough time to enable PCHs to incorporate any necessary changes to their information systems. We invite public comment on our proposed reporting requirements.

d. Proposed Data Submission Timelines for FY 2014 Program and Subsequent Program Years

We are proposing that PCHs must adhere to the following timelines in reporting their measure data:

Time line (calendar year)	Quality measures *	CMS submission deadline
Q4 (October–December 2012)	NHSN CLABSI Outcome Measure **	May 15, 2013.
	NHSN CAUTI Outcome Measure **	May 15, 2013.
	Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer +.	August 15, 2013.
	Combination Chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative Breast Cancer +.	August 15, 2013.
	Adjuvant Hormonal Therapy +	May 15, 2014.
Q1 (January–March 2013)	NHSN CLABSI Outcome Measure **	August 15, 2013.
	NHSN CAUTI Outcome Measure **	August 15, 2013.

Time line (calendar year)	Quality measures *	CMS submission deadline
	Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer +.	November 15, 2013.
	Combination Chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative Breast Cancer +.	November 15, 2013.
	Adjuvant Hormonal Therapy +	August 15, 2014.
Subsequent calendar quarters	NHSN CLABSI Outcome Measure **	November 15 of each respective year.
	NHSN CAUTI Outcome Measure **	November 15 of each respective year.
	Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer +.	February 15 of each respective year.
	Combination Chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative Breast Cancer +.	February 15 of each respective year.
	Adjuvant Hormonal Therapy +	November 15 of each respective year.

* Referred to as the HAI and Cancer-Specific Treatment Quality Measures.
** HAI event occurred in applicable quarter.
+ Initial diagnosis in applicable quarter.

Our principal rationale for these proposed timeframes is to align the HAI measure submission deadlines with existing CMS deadlines to collect the same quality measure information. We also seek to align our timeframes with those of the ACoS, which separately collects the same type of cancer-specific measure data from many PCHs. By aligning these deadlines by measure, we strive to reduce burden by using information already collected by many PCHs in their own quality measurement and improvement efforts. The proposed quarterly CDC/NHSN submission timeframes and deadlines also match the existing Hospital IQR quarterly submission timeframes for the same HAI measure. In the case of the three cancer-specific quality measures, we also believe that these proposed submission timeframes will give PCHs enough time to measure follow-up chemotherapy (4 months following the cancer diagnosis) and hormone therapy visits (12 months following the cancer surgery), as well as identify and correct discordant submitted data (2 months for the two proposed chemotherapy measures, and 3 months for the proposed adjuvant hormone therapy measure).

We invite public comment on the proposed data submission methods and timelines.

e. Proposed Data Accuracy and Completeness Acknowledgement (DACA) Requirements for FY 2014 Program and Subsequent Program Years

We are proposing to require PCHs to electronically acknowledge their data accuracy and completeness once annually. PCHs would submit an electronic acknowledgement that the data provided to meet the applicable annual PCHQR Program data submission requirement is accurate and complete to the best of the facility's knowledge at the time of data submission. We are proposing to begin annual DACA submission starting with the FY 2015 program, and such submission deadline would be due to CMS no later than August 31, 2014. We are proposing to begin the DACA with the FY 2015 program in an effort to provide ample opportunity for the PCHs to become familiar with the reporting processes. Therefore, we are not proposing submission of a DACA for the FY 2014 PCHQR Program. We are proposing that the DACA submission deadline for each program year be August 31 preceding the respective PCHQR Program year. We are proposing August 31 as the DACA deadline for several reasons. First, requiring PCHs to acknowledge their data's accuracy and completeness by August 31 preceding the respective PCHQR Program year provides us with sufficient time to ensure compliance with the program by October 1, the start of the fiscal year. Second, we believe it is appropriate to make the deadline for DACA the same as the deadline for data submission. Lastly, we are proposing to align our DACA deadline with other quality reporting programs, such as the Hospital IQR Program.

PROPOSED CMS DATA ACCURACY AND COMPLETENESS ACKNOWLEDGEMENT (DACA) TIMEFRAME

Program year (fiscal year)	Data accuracy and completeness acknowledgement (DACA) deadline
FY 2014	Not required.
FY 2015	August 31, 2014.
Subsequent Fiscal Years.	August 31 of the preceding fiscal year.

We invite public comments on our proposed data accuracy and completeness acknowledgement requirements.

C. Hospital Value-Based Purchasing (VBP) Program

1. Statutory Background

Section 1886(o) of the Act, as added by section 3001(a)(1) of the Affordable Care Act, requires the Secretary to establish a hospital value-based purchasing program (the Hospital Value-Based Purchasing (VBP) Program) under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

Section 1886(o)(1)(B) of the Act states that the Hospital VBP Program applies to payments for hospital discharges occurring on or after October 1, 2012. In accordance with section 1886(o)(6)(A) of the Act, we are required to make value-based incentive payments under the Hospital VBP Program to hospitals that meet or exceed performance standards

for a performance period for a fiscal year. As further required by section 1886(o)(6)(C)(ii)(I) of the Act, we will base each hospital's value-based payment percentage on the hospital's Total Performance Score (TPS) for a specified performance period. In accordance with section 1886(o)(7) of the Act, the total amount available for value-based incentive payments for a fiscal year will be equal to the total amount of the payment reductions for all participating hospitals for such fiscal year, as estimated by the Secretary. For FY 2013, the available funding pool will be equal to 1.00 percent of the base-operating DRG payments to all participating hospitals, as estimated by the Secretary, and the size of the applicable percentage will increase to 1.25 percent for FY 2014, 1.50 percent for FY 2015, 1.75 percent for FY 2016, and 2.0 percent for FY 2017 and successive fiscal years.

Section 1886(o)(1)(C) of the Act generally defines the term ''hospital'' for purposes of the Hospital VBP Program as a subsection (d) hospital (as that term is 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 has 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 that apply to the hospital 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 FY 2013 Hospital VBP Program

In April 2011, we issued the Hospital Inpatient VBP Program final rule to implement section 1886(o) of the Act (76 FR 26490 through 26547). As described more fully in that final rule, for the FY 2013 Hospital VBP Program, we adopted 13 measures, including 12 clinical process of care measures and 8 dimensions from the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS), that we categorized into two domains (76 FR 26495 through 26511). We grouped the 12 clinical process of care measures into a clinical process of care domain, and placed the HCAHPS survey measure into a patient experience of care domain. We adopted a 3-quarter performance period from July 1, 2011 through March 31, 2012 for these measures (76 FR 26494 through 26495), and performance standards on which hospital performance will be evaluated. To determine whether a hospital meets or exceeds the performance standards for these measures, we will assess each hospital's achievement during this specified performance period, as well as its improvement during this period as compared with its performance during a 3-quarter baseline period from July 1, 2009 through March 31, 2010 (76 FR 26493 through 26495).

We will then calculate a TPS 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, weighting each domain score (for the FY 2013 Hospital VBP Program, the weights will be clinical process of care = 70 percent, patient experience of care = 30 percent), and adding together the weighted domain scores. We will convert each hospital's TPS into a value-based incentive payment percentage using a linear exchange function and will then convert the value-based incentive payment percentage into a per discharge value-based incentive payment amount. We will incorporate the reduction to each hospital's base operating DRG payment amount for each discharge, as well as the value-based incentive payment amounts that the hospital earned as a result of its performance (if applicable) into our claims processing systems in January 2013, and these adjustments will apply to FY 2013 discharges. We refer readers to the Hospital Inpatient VBP Program final rule for further explanation of the details of the FY 2013 Hospital VBP Program (76 FR 26490 through 26547).

3. FY 2014 Hospital VBP Program Measures

For FY 2014, we have adopted 17 measures for the Hospital VBP Program, including the 12 clinical process of care measures and the HCAHPS measure that we adopted for the FY 2013 program, 1 new clinical process of care measure (SCIP–Inf–9: Postoperative Urinary Catheter Removal on Postoperative Day 1 or 2), and 3 mortality outcome measures (Acute Myocardial Infarction (AMI) 30-Day Mortality Rate, Heart Failure (HF) 30-Day Mortality Rate, Pneumonia (PN) 30-Day Mortality Rate). The clinical process of care, HCAHPS, and mortality measures are discussed in more detail in the Hospital Inpatient VBP Program final rule (76 FR 26510 through 26511) and SCIP–Inf–9 is discussed in more detail in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74530). We are proposing to codify this for quality measures selection in our regulations at 42 CFR 412.164.

Although we also previously adopted 8 HAC measures, 2 AHRQ composite measures, and a Medicare Spending Per Beneficiary Measure for the FY 2014 program, we have suspended the effective date of these measures, with the result that these measures will not be included in the FY 2014 Hospital VBP Program (76 FR 74528 through 74530).

Set out below is a complete list of the measures adopted for the FY 2014 Hospital VBP Program:

CLINICAL PROCESS OF CARE, PATIENT EXPERIENCE OF CARE AND OUTCOME MEASURES FOR THE FY 2014 HOSPITAL VBP PROGRAM

IV. Measure ID	Measure description
Clinical Process of Care Measures	
Acute myocardial infarction:	
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival.
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival.
Heart Failure:	
HF–1	Discharge Instructions.
Pneumonia:	
PN–3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.
PN–6	Initial Antibiotic Selection for CAP in Immunocompetent Patient.

CLINICAL PROCESS OF CARE, PATIENT EXPERIENCE OF CARE AND OUTCOME MEASURES FOR THE FY 2014 HOSPITAL VBP PROGRAM—Continued

IV. Measure ID	Measure description
Healthcare-associated infections:	
SCIP–Inf–1	Prophylactic Antibiotic Received Within One 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.
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.
Surgeries:	
SCIP–Card–2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period.
SCIP–VTE–1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered.
SCIP–VTE–2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery.
Patient Experience of Care Measures	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey.*
Outcome Measures	
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate.
MORT–30–HF	Heart Failure (HF) 30-Day Mortality Rate.
MORT–30 PN	Pneumonia (PN) 30-Day Mortality Rate.

*The finalized dimensions of the HCAHPS survey for use in the FY 2014 Hospital VBP Program are: Communication with Nurses, Communication with Doctors, Responsiveness of Hospital Staff, Pain Management, Communication about Medicines, Cleanliness and Quietness of Hospital Environment, Discharge Information and Overall Rating of Hospital. These are the same dimensions that we adopted for the FY 2013 program.

4. Other Previously Finalized Requirements for the Hospital VBP Program

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74532 through 74547), we finalized a number of other policies for the FY 2014 Hospital VBP Program including: The minimum number of cases that a hospital must report to receive a score on a mortality measure; the minimum number of measures that a hospital must report in order to receive a score on the outcome domain; the baseline and performance periods; the performance standards for the clinical process of care and patient experience of care measures (we previously finalized the performance standards for the 3 mortality outcome measures in the Hospital Inpatient VBP Program final rule (76 FR 26513)); the scoring methodology; and the domain weighting methodology. We also finalized for all years of the program a process that will allow hospitals to review and correct the data that they submit to the QIO Clinical Warehouse on clinical process of care measures, their clinical process of care measure rates, their HCAHPS data, and their patient-mix and mode adjusted HCAHPS scores.

5. Proposed Hospital VBP Program Payment Adjustment Calculation Methodology

a. Proposed Definitions of the Term ''Base Operating DRG Payment Amount'' for Purposes of the Hospital VBP Program

Section 1886(o)(7)(D) of the Act generally defines the base operating DRG payment amount, with respect to a hospital for a fiscal year, as ''the payment amount that would otherwise be made under section 1886(d) (determined without regard to subsection (q) [the Hospital Readmissions Reduction Program]) for a discharge if [the Hospital VBP Program] 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); and * * * such other payments under subsection (d) determined appropriate by the Secretary.'' Paragraphs (5)(A), (5)(B), (5)(F), and (12) of section 1886(d) of the Act refer to outlier payments, indirect medical education (IME) payments, disproportionate share (DSH) payments, and low-volume hospital payments, respectively.

The payment that would otherwise be made with respect to a discharge is the applicable average standardized amount adjusted for resource utilization by the applicable MS–DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index (and by the applicable COLA for hospitals located in Alaska and Hawaii), which is often referred to as the ''the wage-adjusted DRG operating payment.'' The payment amount that would otherwise be made with respect to a discharge also includes any adjustments to the wage-adjusted DRG operating payment that the hospital qualifies for, including an outlier adjustment (under section 1886(d)(5)(A) of the Act) an IME adjustment (under section 1886(d)(5)(B) of the Act), a disproportionate share payment adjustment (under section 1886(d)(5)(F) of the Act); a low-volume payment adjustment (under section 1886(d)(12) of the Act), an adjustment for new medical services or technologies under section 1886(d)(5)(K) of the Act (often referred to as ''new technology add-on payments''), and/or any other adjustment determined appropriate by the Secretary.

Consistent with section 1886(o)(7)(D) of the Act, we are proposing to generally define the term ''base operating DRG payment amount'' for purposes of the Hospital VBP Program as the wage-adjusted DRG operating payment plus any applicable new technology add-on payment. We are proposing to include the new technology add-on payment amount in the definition of base operating DRG payment amount for the Hospital VBP Program because the provision of a new technology to a Medicare beneficiary is a treatment

decision, unlike the other add-on payments which are excluded by statute (for example, IME and DSH add-ons). We believe that it represents a cost to the Medicare program that should be subject to the applicable percent reduction to the base operating DRG payment amount which creates the funding pool for value-based incentive payments. We also note that this proposed definition is consistent with the definition of ''base operating DRG payment amount'' that we are proposing to adopt for the Hospital Readmissions Reduction Program, and we believe that maintaining consistency to the extent possible with other Medicare incentive payment programs is an important goal for the Hospital VBP Program. There are no other subsection (d) payment adjustments that would otherwise apply to the discharge on a per-claim basis. As required by the statute, the ''base operating DRG payment amount'' would not include an outlier, IME, DSH, or low-volume payment adjustment that would otherwise apply to the discharge.

We are proposing to codify the definition of wage-adjusted DRG payment amount and the general definition of base-operating DRG payment amount in our regulations at § 412.160. We welcome public comment on these proposed definitions.

Section 1886(o)(7)(D)(ii)(I) of the Act states that in the case of a Medicare-dependent, small rural hospital (MDH) (with respect to discharges occurring during FY 2012 or FY 2013) or a sole community hospital (SCH), the base operating DRG payment amount is defined as the payment amount that would otherwise be made under section 1886(d) without regard to certain factors that affect payments to these categories of hospitals (sections 1886(b)(3)(I) and (L) of the Act, and section 1886(d)(5)(D) of the Act for SCHs, and section 1886(d)(5)(G) of the Act for MDHs). Consistent with the definition we are proposing to adopt for other subsection (d) hospitals, we are proposing to define the term ''base operating DRG payment amount'' for MDHs and SCHs as the wage-adjusted DRG operating payment amount plus any applicable new technology add-on payment. The proposed base operating DRG payment amount for SCHs and MDHs would not include an outlier, IME, DSH, and/or low-volume payment adjustment that would otherwise apply to the discharge. The base operating DRG payment amount for SCHs and MDHs would not include an outlier, IME, DSH, and/or low-volume payment adjustment that would otherwise apply to the discharge. Consistent with section 1886(o)(7)(D)(ii)(I) of the Act, we are also proposing to exclude from this definition of base operating DRG payment amount the difference between the hospital-specific payment rate and the Federal rate payment. This proposed definition is consistent with that being proposed under the Hospital Readmissions Reduction Program (discussed in section IV.A. of this preamble). We are proposing to codify this definition in our regulations at 42 CFR 412.160.

We welcome public comment on this proposed definition of the base operating DRG payment amount for MDHs and SCHs under the Hospital VBP Program. We note that, under current law, the MDH program is set to expire at the end of FY 2012, after which all MDH hospitals would be paid in the same manner as other subsection (d) hospitals, unless they qualify for SCH status, as discussed in section VIII.C.5.b. of this preamble.

Section 1886(o)(7)(D)(ii)(II) of the Act states that in the case of a hospital that is paid under section 1814(b)(3) of the Act, ''the term 'base operating DRG payment amount' means the payment amount under that section.'' Acute care hospitals located in the State of Maryland are not paid under the IPPS but are, instead, paid under a special waiver provided by section 1814(b)(3) of the Act. For these hospitals, we are proposing that the term ''base operating DRG payment amount'' means the payment amount under section 1814(b)(3) of the Act. This proposed definition is consistent with the definition we are proposing under the Hospital Readmissions Reduction Program (discussed in section IV.A.. of this preamble). We are proposing to codify this definition in our regulations at 42 CFR 412.160. We welcome public comment on the proposed definition of base-operating DRG payment amount for Maryland hospitals under the Hospital VBP Program.

b. Proposals for Calculating the Funding Amount for Value-Based Incentive Payments Each Year

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum total of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. To implement these sections, and create the funding pool for value-based incentive payments for each fiscal year, we are proposing that beginning with FY 2013 discharges, every hospital that meets the definition of a hospital in section 1886(o)(1)(C) of the Act (referred to here as an eligible hospital) would receive a reduction to its base operating DRG payment amount for each discharge in a fiscal year, regardless of whether we have determined that the hospital has earned a value-based incentive payment for that fiscal year. The total amount of the reductions across all eligible hospitals for a fiscal year would constitute the total amount available from which we could make value-based incentive payments for that fiscal year. We are proposing to estimate the total amount of the reductions across all eligible hospitals and the size of the funding pool prior to the start of each fiscal year because that is the only way, operationally, that we can calculate each hospital's value-based incentive payment percentage in a manner such that the estimated sum total of the value-based incentive payments for hospitals for the fiscal year would be equal to the estimated total amount available for value based incentive payments to all eligible hospitals.

The data we are proposing to use to estimate these amounts is inpatient claims data from the Medicare Provider Analysis and Review (MedPAR) file. We believe that the use of MedPAR data is appropriate because we also use this data to calculate other IPPS payment adjustment amounts, including the DRG relative weights, budget neutrality factors, outlier thresholds, and standardized amounts. The proposed use of claims data from the MedPAR file is also consistent with our proposal in this proposed rule to determine applicable hospitals' base operating DRG payment amounts, for purposes of calculating their aggregate payments for excess readmissions and aggregate payments for all discharges for determining the readmissions payment adjustment factor under the Hospital Readmissions Reduction Program (section IV.A. of this preamble).

We are proposing to run the MedPAR data for purposes of estimating the base operating DRG payment reduction amounts, as well as the size of the funding pool that will apply to a fiscal year, in December of the previous fiscal year so that we can provide preliminary estimates in the IPPS/LTCH PPS proposed rule. We are also proposing to provide the final estimates in the IPPS/LTCH PPS final rule using the March update. The data will contain inpatient claims information related to discharges from the fiscal year that ended the previous September. For example, with respect to the FY 2014 Hospital VBP Program, we would run the MedPAR

data in December, 2012 and that data would contain claims related to FY 2012 discharges. We would use that data to provide preliminary estimates in the FY 2014 IPPS/LTCH PPS proposed rule. The March 2013 update of this MedPAR data would then be used to provide final estimates in the FY 2014 IPPS/LTCH PPS final rule.

We believe that this proposed approach will enable us to gather the most recent Medicare utilization data available in order to estimate the total amount of the base operating DRG payment amount reductions and the size of the value based incentive payment funding pool for the applicable fiscal year. We also believe that this approach will enable us to calculate each hospital's payment adjustment factor that will apply to its discharges in the applicable fiscal year, and to notify each hospital of such at the same time that we are proposing to notify each hospital regarding its performance, for purposes of making this information publicly available under section 1886(o)(10)(A) of the Act. In this way, hospitals will be able to consider this information during the review and correction period (the details of which are proposed below). We believe that it is important to notify a hospital of its value-based incentive payment adjustment factor at the start of review and corrections, so that hospitals can consider the payment impact of the TPS in their determination of whether or not to request review and corrections.

In order to estimate the total base operating DRG payment reductions across all hospitals for a fiscal year, we are proposing to sum the estimated total base operating DRG payment amount per discharge for each hospital in that fiscal year. We would then multiply that estimated total annual base operating DRG payment amount by the applicable percent, which we are proposing to define in our regulations at § 412.160 as the percentage specified in section 1886(o)(7)(C) of the Act. The product of the estimated total annual base operating DRG amount for a hospital and the applicable percent would be equal to taking the applicable percent reduction from each individual base operating DRG payment amount per hospital and then summing those reductions. We welcome public comment on this proposed approach to calculating the available pool of funds for value-based incentive payments.

For the purpose of estimating the total amount available for value-based incentive payments for a fiscal year, we are proposing to apply an inflation factor so that our estimate of the available pool of funds will more accurately reflect estimated total base operating DRG payments in the fiscal year in which the value-based incentive payments will actually be made. For example, in estimating the size of the FY 2013 funding pool, we inflated the FY 2011 MedPAR data to FY 2013 dollars because the value-based incentive payment amounts will actually be paid in FY 2013.

Our actuaries provided us with this inflation factor, which included assumptions on changes in Medicare fee-for-service case mix and discharge levels. According to this proposed methodology, we estimate the available amount for FY 2013 value-based incentive payments to be $956 million. As noted above, under our proposed methodology, we would update this estimate using the March 2012 update of the FY 2011 MedPAR data for purposes of finalizing it in the FY 2013 IPPS/LTCH PPS final rule.

We note that, for the purposes of calculating the value-based incentive payment adjustment factors under the Hospital VBP Program, we would be able to use FY 2011 claims to accurately calculate the value-based incentive payment percentage, without application of this inflation factor. This is because a constant inflation factor applied across all hospitals' total annual base-operating DRG payment amounts would not change the slope of the payment exchange function which we previously adopted for use in determining each hospital's value-based incentive payment amount. Application of an inflation factor would, therefore, not impact the amount of a hospital's value-based incentive payment amount under the Hospital VBP program for the fiscal year.

We considered adopting a different approach that would apply only to the FY 2013 Hospital VBP Program because we do not anticipate beginning to make value-based incentive payments to hospitals for that program year until January 2013. Under this approach, we would estimate the total amount of funding available to make the value-based incentive payments using the latest available FY 2011 claims data from MedPAR, with payment amounts modeled using the rates, factors and policies finalized in the FY 2013 IPPS/LTCH PPS final rule. This data would include claims information that was not available at the time we ran the March update. However we are not proposing to adopt this approach because we believe that is important to establish a consistent process for annually estimating the total amount available to make value-based incentive payments to hospitals, as well as the payment adjustments that will be made to hospitals as a result of their performance under the Hospital VBP Program. Beginning with the FY 2014 Hospital VBP Program, we intend to make the value-based incentive payments to hospitals as part of the claims payment process, beginning at the start of the fiscal year, so it would not be possible to use the modeled base-operating DRG payment amount estimates based on the finalized rates, factors and policies established in the IPPS/LTCH PPS final rule applicable to the fiscal year, as they will typically not be finalized in time to notify hospitals of their value-based incentive payment adjustments at the start of the review and corrections process.

Further, these factors, rates, and policies would not typically be finalized in time for us to notify hospitals of the net result of the base operating DRG payment amount reduction and the value-based incentive payment adjustment no later than 60 days prior to the start of the fiscal year, as required by section 1866(o)(8) of the Act. We also believe that our proposal to use the March update of the MedPAR file represents an accurate estimate of annual base operating DRG amounts because it reflects the most recently available utilization data, while preserving the interest in notifying hospitals of the payment impact in time for them to request review and correction.

We are proposing to use a different methodology for purposes of estimating the reduced annual base operating DRG payment amounts for SCHs and MDHs. In general, eligible hospitals in the Hospital VBP Program include SCHs and current MDHs (we note that MDH status is set to expire under current law after FY 2012 and would, therefore, no longer exist in FY 2013), because they meet the definition of a ''subsection (d)'' hospital. SCHs are paid in the interim (prior to cost report settlement) on a claim by claim basis at the amount that is the higher of the payment based on the hospital-specific rate or the IPPS Federal rate based on the standardized amount. At cost report settlement, the fiscal intermediary or A/B MAC determines if the hospital would receive higher aggregate operating IPPS payments using the hospital-specific rate (for all claims) or the Federal rate (for all claims). MDHs are paid the sum of the Federal payment amount plus 75 percent of any amount by which the hospital-specific rate payment exceeds the Federal rate payment amount.

Although MDH status is to expire at the end of FY 2012, the payments reflected on FY 2011 claims for current

MDHs may be based on the hospital-specific rate. As discussed above, we are generally proposing to use historical MedPAR data to determine the base operating DRG payment amounts that would be used to estimate the amount of funding available for value-based incentive payments for the FY 2013 Hospital VBP Program. Consistent with that proposal, for SCHs and hospitals that have MDH status in FY 2012, we are proposing to use MedPAR data to model the reduced base operating DRG payment amount for each claim as if it were paid based on the Federal standardized amount, rather than using the payments information on the claim (that is, regardless of whether a claim was paid under the hospital-specific rate or the Federal rate, the reduced base operating DRG payment amounts for SCHs and current MDHs would be estimated using the Federal rate).

We welcome public comment on these proposals. We also welcome comment on other suggested approaches to most accurately estimate these amounts.

c. Proposed Methodology To Calculate the Value-Based Incentive Payment Adjustment Factor

In accordance with section 1886(o)(6)(C)(i) of the Act, for each eligible hospital that receives a TPS greater than zero with respect to a fiscal year, we are proposing to calculate a value-based incentive payment percentage for that hospital for that fiscal year. In accordance with section 1886(o)(6)(C)(ii) of the Act, the value-based incentive payment percentage that we calculate for the hospital will be based on that hospital's individual TPS, and the total amount of value-based incentive payments to all hospitals in the fiscal year will be equal to the total amount available for value-based incentive payments for the fiscal year, as estimated by the Secretary. We are proposing to define the term ''value-based incentive payment percentage'' in § 412.160 as the percentage of the total base operating DRG payment amount that a hospital has earned back, based on its TPS to that fiscal year. The hospital may earn a value-based incentive payment percentage that is less than, equal to, or more than the applicable percent. The applicable percent that we will use to reduce the base operating DRG payment amount for each FY 2013 discharge is 1.0 percent.

A hospital may earn a value-based incentive payment percentage that is greater than the applicable percent, which would result in that hospital receiving a value-based incentive payment adjustment factor that is greater than one and a higher base operating DRG payment amount for each discharge than it would have received in the absence of the Hospital VBP Program. The proposed calculation of the value-based incentive payment adjustment factor is discussed in further detail below. A hospital may earn a value-based incentive payment percentage that is equal to the applicable percent, which would result in the hospital receiving a value based incentive payment adjustment factor of 1 and the same base operating DRG payment amount that it would have received for each discharge in the absence of the Hospital VBP Program. Alternatively, a hospital may earn a value-based incentive payment percentage that is less than the applicable percent, which would result in the hospital receiving a value-based incentive payment adjustment factor that is less than one and a lower base operating DRG payment amount for each discharge than it would have received in the absence of the Hospital VBP Program.

In order to convert a hospital's TPS into a value-based incentive payment factor that would be applied to each discharge in the applicable fiscal year, we are proposing to use the linear exchange function that we finalized in the Hospital Inpatient VBP Program final rule (76 FR 26534). Under this proposed methodology, we would utilize the following computed amounts:

- The hospital's estimated total annual base-operating DRG amount for all discharges for the applicable fiscal year;
- The applicable percent for the fiscal year (1.0 percent in FY 2013);
- The (linear) exchange function slope; and
- The hospital's TPS.

The following six (6) steps illustrate our proposed methodology:

Step 1: Estimate the hospital's total annual base-operating DRG amount. First, we would estimate each hospital's total annual base operating DRG amount for all discharges in the applicable fiscal year. As we discussed above, we are proposing to estimate this amount using Medicare inpatient claims data taken directly from the most recently available MedPAR files.

Step 2: Calculate the total annual estimated base operating DRG payment reduction amount across all eligible hospitals. Second, we are proposing to estimate the total base operating DRG reduction amount across all eligible hospitals (which is the total amount available for value-based incentive payments) according to the following two steps:

Step 2a: Repeat Step 1 for all eligible hospitals, and multiply the *estimated total amount for each hospital* by the applicable percent. For FY 2013, the applicable percent is 1.0 percent; then

Step 2b: Add together the amount for each hospital calculated under Step 2a. This sum is the total amount available for value-based incentive payments, and the numerator of the linear exchange function slope that is calculated in Step 3 below.

Step 3: Calculate the linear exchange function slope. Third, we would calculate the linear exchange function slope. As noted above, we finalized the use of a linear exchange function for the purpose of converting a hospital's TPS into a value-based incentive payment percentage. We would calculate the linear exchange function slope using the following steps:

Step 3a: Convert the TPS for each hospital into a decimal by dividing it by 100. The TPS may range from zero to 100. In this step, we express it as a number between zero and 1.

Step 3b: Multiply each hospital's estimated total base-operating DRG payment reduction amount for the applicable fiscal year (from Step 2a above) by the hospital's TPS (decimal between zero and one from Step 3a above).

Step 3c: Add together the numbers computed in Step 3b above. This sum represents the denominator of the linear exchange function slope that is calculated in Step 3d below.

Step 3d: The exchange function slope equals the sum computed in Step 2b above divided by the sum computed in Step 3c above.

Step 4: For each hospital, calculate the hospital's value-based incentive payment percentage for the fiscal year. We are proposing to use the exchange function slope (from Step 3) and the hospital's TPS to calculate the hospital's value-based incentive payment percentage that it earned as a result of its performance under the Hospital Inpatient VBP Program for the fiscal year. We could calculate the value-based incentive payment percentage by multiplying the applicable percent by the amount computed for the hospital in Step 3a and the exchange function slope as computed in Step 3d above. This is the mathematical approach to locating the place along the linear exchange function where a given hospital's TPS score would be located and identifying the corresponding value-based incentive payment percentage. As we note above, the value-based payment percentage could be greater than, equal to, or less

than the applicable percent that is applied to reduce the base operating DRG payment amount for each discharge.

Step 5: Compute the net percentage change in the hospital's base-operating DRG payment amount for each discharge. Fifth, we are proposing to calculate the net percentage change to the hospital's base operating DRG payment amount for each discharge in the applicable fiscal year. We would calculate the net change as an intermediate step, in order to determine the value-based incentive payment adjustment factor described in Step 6, below. The net percentage change in the hospital's base operating DRG payment amount for each discharge would be the difference between the applicable percent and the value-based incentive payment percentage. We would calculate this net change for each hospital by subtracting the applicable percent used in Step 2a (1 percent for FY 2013) from the value based incentive payment percentage computed for the hospital in Step 4. This net change in the base-operating DRG payment amount would be expressed as a percentage and could be positive, zero, or negative, depending on the hospital's TPS and the exchange function slope.

Step 6: To calculate this factor, we would convert the hospital's individual net percentage change in its base-operating DRG payment amount, from Step 5, from a percentage into a number (by removing the percent sign and dividing it by 100) and add it to 1. The 1 would reflect the base operating DRG payment amount that the hospital would have received for a discharge in the absence of the Hospital VBP Program. The result is that a hospital with a positive net percentage change to its total base operating DRG payment amount would have a value-based incentive payment adjustment factor that is greater than one. This means that we would multiply the hospital's base operating DRG payment amount for each discharge occurring in the applicable fiscal year by a number greater than one.

A hospital with no net percentage change to its total base operating DRG payment amount percentage would have a value-based incentive payment adjustment factor of one. This means that we would multiply its base operating DRG payment amount for each discharge occurring in the applicable fiscal year by 1, and its base-operating DRG payment amount would be equal to what it would have been in the absence of the Hospital VBP Program.

A hospital with a negative net percentage change to its total base-operating DRG payment amount percentage would have a value-based incentive payment adjustment factor that is less than one. This means that we would multiply the hospital's base operating DRG payment amount for each discharge occurring in the applicable fiscal year by a number less than one.

Example Calculation of the Value-Based Incentive Payment Amount Adjustment: As an example, assume the following information:

- The hospital's estimated total annual base operating DRG payment amount for all discharges in the applicable fiscal year = $1,000,000;
- The applicable percent that is applied to all discharges of eligible hospitals in FY 2013 = 1.0 percent;
- The exchange function slope = 2.0;
- The hospital's TPS = 80.

Under our proposal, we would replicate the six steps to convert a hospital's TPS into a value-based incentive payment adjustment factor as follows:

Step 1: Estimate the hospital's total annual base operating DRG payment amount. We would add together the estimated base-operating DRG payment amount for each FY 2013 discharge. In this example, we assume this total amount would be $1,000,000.

Step 2: Calculate the *total annual estimated* base operating DRG payment reduction amount across all eligible hospitals. Second, we would:

Step 2a: Repeat Step 1 for all eligible hospitals, and multiply the total amount for each hospital by the applicable percent, which is 1.0 percent in this example: $1,000,000 * .01 = $10,000; and

Step 2b: Add together the amount for each hospital calculated in Step 2a above. In this example, we assume this amount is a given. We note that computing this amount requires knowledge of all eligible hospitals' estimated total base operating DRG payment reduction amount.

Step 3: Calculate the linear exchange function slope, which we assume in this example to be 2.0. We note that computing the slope requires knowledge of all eligible hospitals' estimated total base operating DRG payment reduction amount and their TPS to compute the relevant sums that are used in the numerator and denominator of the slope.

Step 4: Calculate the hospital's value-based incentive payment percentage. The hospital's value-based payment percentage would be computed as follows: 0.01 (The applicable percent would be multiplied by 0.80 (the hospital's TPS divided by 100) and 2.0 (the exchange function slope). Mathematically, 0.01 * 0.80 * 2.0 = 0.016, which can be written as 1.60 percent. Therefore, the hospital's value-based incentive payment percentage for the FY 2013 Hospital VBP program would be 1.60 percent ($16,000 in this example).

Step 5: Compute the net percentage change in the hospital's base-operating DRG payment amount for each discharge by subtracting 1.0 percent (the applicable percent) from the value-based incentive payment percentage that the hospital earned based on its TPS.

In this example, the net percentage change would equal 1.60 percent minus 1.00 percent, or 0.60 percent. In this example, the net percentage change is positive and corresponds to a dollar amount of 0.60 percent of the estimated total annual base operating DRG payment amount for the hospital of $1,000,000(0.60 percent * $1,000,000 = $6,000).

Step 6: Compute the value-based payment adjustment factor as equal to the net percentage change calculated in Step 5), expressed as a number, plus one. In this example, the hospital's value-based payment adjustment factor would equal the sum of 0.006 (0.60 percent expressed as a number) plus one.

Therefore, this hospital's value-based payment adjustment factor would equal 1.006, and this factor would be multiplied by the based operating DRG payment amount for each discharge occurring in FY 2013. This hospital had a positive net percentage change to its total base operating DRG payment amount and would have a value-based incentive payment adjustment factor that is greater than one, so we would multiply the hospital's base operating DRG payment amount for each discharge occurring in the applicable fiscal year by a number greater than one. In this example, the hospital would earn a total value-based incentive payment estimated at $16,000 for all discharges in the fiscal year) that is greater than the 1.0 percent base operating DRG payment reduction amount applied to each discharge in the fiscal year (estimated $10,000 total reduction), which would result in the hospital receiving a higher payment amount for each discharge occurring in FY 2013 than it otherwise would have received, in the absence of the Hospital VBP Program (an estimated $6000 total increase in base operating DRG payments for the fiscal year).

We welcome comments on this proposal.

d. Proposed Timing of the Base Operating DRG Payment Amount Reduction and Value-Based Incentive Payment Amount Adjustment for FY 2013 and Future Hospital VBP Program Years

The applicable percent reduction and the value-based incentive payment adjustments are distinct adjustments which we are required to make to base operating DRG payment amounts for eligible hospitals under the Hospital VBP Program. In this section, we outline our proposals for applying these adjustments to the base-operating DRG payment amounts.

In the Hospital Inpatient VBP Program final rule, for the FY 2013 program, we established that we would incorporate the value-based incentive payment adjustment into our claims processing system in January 2013, and that the adjustment would apply to all FY 2013 discharges, including those that occurred beginning on October 1, 2012 (76 FR 26536). Because of this January 2013 application of the value-based incentive payment adjustment, we are proposing that we would not apply the 1.00 percent applicable reduction to the base operating DRG payment amount for each discharge until we apply the value-based incentive payment adjustment factor. In other words, we would add the value-based incentive payment amount to the hospital's reduced base-operating DRG payment amount for each FY 2013 discharge at the same time that we apply the 1.00 percent reduction to the base operating DRG payment amount. The simultaneous application of the 1.00 percent reduction to the base-operating DRG payment amounts and the value-based incentive payment amount (if applicable, based on the hospital's TPS) would prevent hospitals from receiving a 1.00 percent reduction to their base operating DRG payment amounts before they receive their value-based incentive payment amount adjustment. Accordingly, under our proposal, beginning in January 2013, a hospital would receive a base operating DRG payment amount for each discharge occurring in FY 2013 that is the net result of the application of the 1.00 percent reduction and the application of the hospital's individual value-based incentive payment amount adjustment.

In FY 2014 and future years of the Hospital VBP Program, we are proposing to apply both the applicable percent reduction and the value-based incentive payment amount adjustment to the base operating DRG payment amount for a discharge during the regular claim payment process, beginning in October of each fiscal year. These adjustments would be made simultaneously with respect to each discharge.

We invite public comment on this proposal.

e. Proposed Process for Reducing the Base Operating DRG Payment Amount and Applying the Value-Based Incentive Payment Amount Adjustment for FY 2013

In developing our proposal for FY 2013, we have considered two different methodologies for applying the 1.00 percent reduction to the base operating DRG payment amount for each discharge, and for applying the value-based incentive payment adjustment to the reduced base operating DRG payment amount: (1) Reprocessing the claims submitted prior to January 2013, which is when we expect to incorporate the value-based incentive payment adjustments into our claims processing system; and (2) modifying the exchange function slope, in such a way as to redistribute the value-based incentive payment adjustments for discharges occurring prior to incorporating the adjustments into our claims processing system. Neither approach would require hospitals to resubmit claims.

We are proposing to reprocess the claims submitted by hospitals for discharges occurring between October 1, 2012 and such time as the value-based incentive payment adjustments are incorporated into the claims processing system. We believe that this approach is the most straightforward way to address the January implementation of FY 2013 value-based incentive payment adjustments. For the second methodology we considered, we would need to modify the exchange function slope, because adjustments would not have been made beginning on October 1, 2012, the start of FY 2013. As described in section VIII.C.5.c. of this preamble, calculation of the exchange function slope is based on the hospital TPS and the amount available for value-based incentive payments. The total amount available to make value based incentive payments to eligible hospitals is equal to the total of their base-operating DRG payment reduction amounts, as estimated by the Secretary, according to section 1886(o)(6)(C)(ii)(I) of the Act.

Under this approach, we would account for this delay in implementation of applicable percent reductions and value-based incentive payment adjustments by modifying the computed exchange function slope so that we could use it to calculate a value-based incentive payment adjustment for each hospital that would distribute the total amount available for value based incentive payments between January and September 30, 2013. We would modify the exchange function to accomplish this by multiplying its slope by the following fraction: The total number of days in the fiscal year/(divided by) the number of days between the date we incorporate adjustments and the end of the fiscal year. For example, if the date the value-based adjustment is incorporated into the system is January 15, then the number of days between January 15, 2013 and September 30, 2013 is 258. Therefore, we would multiply the exchange function slope by 365/258, in order to redistribute the value-based incentive payment adjustments that occur on or after January 15, 2013 in such a manner that they also account for discharges occurring between October 1, 2012 and January 15, 2013. For purpose of calculating the exchange function slope modification, we would assume that hospitals' base operating DRG payments are constant throughout the fiscal year (that is, DRG payments are not concentrated in the beginning or the end of the year, for example).

We believe that this alternative approach could cause confusion regarding payment amounts for discharges that occur between the beginning of the fiscal year and the implementation of the value-based incentive payment adjustments but are not billed until after the implementation of the value-based incentive payment adjustments. Those claims would be paid as though the applicable percent reduction and the value-based incentive payment adjustments were not in effect, because they would be based on date of discharge.

We invite public comment on our proposed approach to reprocess hospital inpatient claims that are billed between October 1, 2012 and such time as we are able to incorporate the value-based incentive payment adjustments into our claims processing system in January 2013. We recognize that hospitals would be responsible for maintaining their own internal accounting systems in order to accommodate the reprocessing of these claims in January 2013; therefore, we are also inviting public comment on the alternative approach described above of modifying the exchange function slope to redistribute the value-based incentive payment adjustments, or any other approaches which might minimize the administrative burden imposed upon hospitals.

6. Proposed Review and Corrections Processes

a. Background

Section 1886(o)(10)(A)(i) of the Act requires that the Secretary make information available to the public regarding individual hospital performance in the Hospital VBP Program, including: (1) The performance of the hospital on each measure that applies to the hospital; (2) the performance of the hospital with respect to each condition or procedure; and (3) the hospital's TPS. To comply with this requirement, we stated in the Hospital Inpatient VBP Program final rule that we intended to publish hospital scores with respect to each measure, each hospital's condition-specific score (that is, the performance score with respect to each condition or procedure, for example, AMI, HF, PN, and SCIP), each hospital's domain-specific score, and each hospital's TPS on the *Hospital Compare* Web site (76 FR 26534 through 26536).

Section 1886(o)(10)(A)(ii) of the Act requires the Secretary to ensure that each hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to each hospital under section 1886(o)(10)(A)(i) of the Act prior to such information being made public. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74545), we finalized procedures that will enable hospitals to review and correct both the underlying data and measure rates for the clinical process of care measures and HCAHPS dimensions under the Hospital VBP Program (76 FR 74545 through 74547).

In this proposed rule, we are making additional proposals that will enable hospitals to review and correct their claims-based measure rates, as well as their condition-specific scores, domain-specific scores, and TPSs.

b. Proposed Review and Corrections Process for Claims-Based Measure Rates

We use claims/administrative data to calculate measure rates for measures that we have adopted for a number of pay for reporting and pay for performance programs, such as the Hospital VBP Program. For claims-based measures used in the Hospital IQR Program, we currently provide hospitals with confidential reports containing the measure rate calculations and accompanying confidential detailed discharge-level information prior to making the rates available to the public. With respect to the claims-based measures we adopt for the Hospital VBP Program, we are proposing to deliver the same type of confidential reports and accompanying confidential detailed discharge-level information for purposes of providing hospitals an opportunity to review and submit corrections for their claims-based measure rates under section 1886(o)(10)(A)(ii) of the Act.

The confidential reports would contain the claims-based measure rate calculations and would be accompanied by additional confidential discharge-level information based on the most recent administrative data available at the time we run the data for purposes of calculating the rates. As we discuss below, we are proposing to create extracts of the data to be used for measure rate calculation purposes approximately 90 days after the last discharge date in the performance period for the measure. Our intent in providing the confidential reports and accompanying discharge-level data to hospitals is twofold: (1) To provide hospitals with an opportunity to review and submit corrections for the measure rates that we will make available to the public; and (2) to facilitate hospitals' quality improvement efforts with respect to the measures. The discharge-level information would contain data derived from claims and administrative data that were used in the calculation of the measure rates. Depending on the measure, this discharge level information might include data elements such as dates of admission, dates of discharge, patient risk factors, primary and secondary diagnoses, procedures, dates of death, dates of service after discharge by the same or other providers/suppliers, and provider/supplier numbers. The confidential reports and accompanying discharge level data would be delivered to each hospital via its secure QualityNet account.

We are proposing to provide hospitals a period of 30-days to review and submit corrections for the claims-based measure rates contained in their confidential reports. This 30-day period would begin the day hospitals' confidential reports and accompanying discharge-level data are posted to QualityNet. These measure rates will be used for performance scoring, value-based incentive payment amount calculations, and public reporting for the Hospital VBP Program. Based on our previous experience with public reporting of measures under the Hospital IQR Program, including the 30-day risk standardized mortality rates and the AHRQ Patient Safety Indicators, we believe this 30-day period will allow enough time for hospitals to review their data and notify us of suspected errors in the measure rate calculations, and for us to incorporate appropriate corrections to the calculations. During the review and correction period, hospitals should notify us of suspected errors using the technical assistance contact information provided in their confidential reports.

The review and correction process we are proposing to adopt for the claims-based measure rates would not allow hospitals to submit corrections related to the underlying claims data we used to calculate the measure rates, or allow hospitals to add new claims to the performance period data set that we ran to calculate the rates. This is because it is necessary to take a static ''snapshot'' of the claims in order to perform the calculations. For purposes of this program, we would calculate the claims-based measures using claims and corrections to claims submitted by hospitals that were incorporated into our claims database during the approximately 90 day period following the last date of discharge to be included in the measure calculation.

We recognize that under our current timely claims filing policy, hospitals have up to one year from the date of discharge to submit a claim. However, in using claims and other administrative data to calculate measure rates for the Hospital VBP Program, we are proposing to create data extracts using claims information as it exists in our Common Working File (CWF) approximately 90 days after the last discharge date in the performance period for the measures. For example, if the last discharge date in the performance period for a measure is June 30, 2011, we would create the data extraction on or about September 30, 2011 and use that data to calculate the measure rate for that performance period. Hospitals would then receive the measure rate in their confidential reports and accompanying data, and they would have an opportunity to review and submit corrections to that rate. As we stated above, hospitals would not be able to submit corrections to the underlying data that we extracted on or about September 30, 2011, and would also not be able to add claims to the data set. We would consider the underlying claims and administrative data to be complete for purposes of the Hospital VBP Program claims-based measure calculations at the conclusion of the approximately 90 day period following the last date of discharge used in the performance period.

We considered a number of factors in determining that an approximately 90 day ''run-out'' period is appropriate for purposes of calculating the claims-based measure rates. First, we seek to provide

timely quality data to hospitals for the purpose of quality improvement, and to the public for the purpose of transparency. Next, we seek to make payment adjustments to hospitals as close in time to the applicable performance period as possible. Finally, we seek to have as complete a data set as possible, recognizing that hospitals have up to one year from the date of discharge to submit a claim under our timely claims filing policy.

After we run the data and create the data extract for purposes of calculating the measure rate for a claims-based measure, it takes several months to incorporate other data needed to complete the rate calculation (particularly in the case of a risk-adjusted and/or episode based measure). We then need to generate and check the rate calculations, as well as program, populate, and deliver the confidential reports and accompanying data to hospitals. We are also aware that hospitals would like to receive performance information under the Hospital VBP Program as close in time to the performance period as possible. If we were to wait to run the data for purposes of calculating the claims-based measure rates until at least 12 months after the last discharge date in the performance period, we would not, for operational reasons, be able to provide the measure rates to hospitals 18 to 24 months after the performance period ended. We believe that this would create an unacceptably long delay both for hospitals that are interested in receiving timely measure rate calculations for their own quality improvement efforts, and for us to (1) calculate TPSs for a program year and (2) publicly report hospital performance on the *Hospital Compare* Web site. Therefore, we are proposing to extract the data needed to calculate a claims-based measure approximately 90 days after the last discharge date for the measure's performance period so that we can best balance our need to provide timely program information to hospitals against the need to calculate the claims-based measures using as complete as a data set as possible.

During the 30-day review and correction period, hospitals should notify us of suspected errors in our calculation of the measure rates using the technical support contacts provided in the hospital's confidential report. We would investigate the validity of each submitted correction and notify hospitals of the results. Should we confirm that we made an error in calculating one or more claims-based measure rates included in a hospital's confidential report, we would correct the calculation(s) and issue a new confidential report to the hospital. We are proposing that once the 30-day review and corrections period has concluded, we would not accept any additional corrections submitted by a hospital.

We invite public comment on the proposed review and correction process for claims-based measure rates to be used in the Hospital VBP Program.

c. Proposed Review and Correction Process for Condition-Specific Scores, Domain-Specific Scores and TPSs

We are proposing to adopt a review and corrections process that will enable hospitals to review and submit corrections with respect to their performance on each condition (the condition-specific score), their performance on each domain (the domain-specific score) and their TPSs. Under this proposed process, we would provide each hospital with a TPS Report (this would be a different report than the hospital confidential report and accompanying data described above, and the reports described in previous rules that will enable hospitals to review and correct their chart-abstracted and HCAHPS measure data). A hospital would have 30 days from the date we post the report on its QualityNet account to review the TPS Report and submit any necessary corrections to us via QualityNet. This proposed requirement will enable us to evaluate corrections requests and provide decisions on those requests in a timely manner. As discussed further below, we are also proposing that the submission of a correction through this process be a prerequisite to a hospital being able to submit an appeal of the calculation of its performance assessment with respect to the performance standards and/or its TPS under section 1886(o)(11)(A) of the Act.

Hospitals would not be able to use this proposed review and correction process to ask us to reconsider a hospital's eligibility under section 1886(o)(1)(C) of the Act to participate in the Hospital VBP Program for a fiscal year. However, we seek public comment on whether our determination regarding a hospital's eligibility should be subject to correction.

We believe that this proposed review and corrections process will ensure that hospitals are able to fully and fairly review their condition-specific scores, domain-specific scores, and TPS. We are inviting public comment on this proposal. We note that we anticipate posting FY 2013 hospital performance information on *Hospital Compare* in April 2013. We are proposing to codify this for posting hospital-specific information in our regulations at § 412.163.

We view the review and corrections process as separate and distinct from the appeals process. Each process is aimed at allowing hospitals to seek certain reconsiderations from CMS. The review and corrections process is aimed at correcting data that will be made public on the *Hospital Compare* Web site, while the appeals process allows hospitals to seek reconsideration for errors that may have been introduced during the TPS calculation that may affect hospitals' payments.

7. Proposed Appeal Process Under the Hospital VBP Program

a. Background

Section 1886(o)(11)(A) of the Act requires the Secretary to establish a process by which hospitals may appeal the calculation of a hospital's performance assessment with respect to the performance standards (section 1886(o)(3)(A) of the Act) and the hospital performance score (section 1886(o)(5) of the Act).

Under section 1886(o)(11)(B) of the Act, there is no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following: (1) The methodology used to determine the amount of the value-based incentive payment under section 1886(o)(6) of the Act and the determination of such amount; (2) the determination of the amount of funding available for the value-based incentive payments under section 1886(o)(7)(A) of the Act and the payment reduction under section 1886(o)(7)(B)(i) of the Act; (3) the establishment of the performance standards under section 1886(o)(3) of the Act and the performance period under section 1886(o)(4) of the Act; (4) the measures specified under section 1886(b)(3)(B)(viii) of the Act and the measures selected under section 1886(o)(2) of the Act; (5) the methodology developed under section 1886(o)(5) of the Act that is used to calculate hospital performance scores and the calculation of such scores; or, (6) the validation methodology specified in section 1886(b)(3)(B)(viii)(XI) of the Act.

b. Proposed Appeal Process

We solicited public comments on the general structure and procedures we should consider when developing an appeals process for the Hospital VBP Program in the Hospital Inpatient VBP Program proposed rule (76 FR 2484). We took these comments into consideration

when we developed the proposed appeals process that appears below. We are proposing to implement an administrative appeals process that provides hospitals with the opportunity to appeal the calculation of their performance assessment with respect to the performance standards, as well as their TPS.

We are proposing to codify this proposed appeals process in our regulations at § 412.167.

Under our proposed appeals process, if a hospital is seeking to appeal a calculation of the TPS, measure/dimension score, condition-specific score, domain specific score, or measure rate/data for which the hospital could have submitted a correction during the review and correction process we have both previously finalized (with respect to chart-abstracted and HCAHPS data) and are proposing to adopt in this proposed rule, we would require that the hospital first submit a correction to that calculation, and receive an adverse determination from us, as part of that process before the hospital could challenge it under the appeals process. We are proposing to adopt this requirement because we believe that we will be able to resolve many hospital claims through the review and corrections process, and thus eliminate the need for an appeal. To the extent that a hospital seeks to appeal a calculation that was the subject of a correction request, we are proposing that the deadline for the hospital to submit an appeal under section 1886(o)(11)(A) of the Act would be 30 days from the date the we informed the hospital through QualityNet of our decision on the correction request. For any other appeals requests, we are proposing that hospitals have up to 30 days after the conclusion of the review and corrections period specified above to submit an appeal. We seek public comment on the appropriateness of this proposed appeals timeline and whether we should consider any other possible deadlines.

We are proposing that all appeals be submitted through QualityNet and that they contain the following information:

- Hospital's CMS Certification Number (CCN)
- Hospital Name
- Hospital's basis for requesting an appeal. This must identify the hospital's specific reason(s) for appealing the hospital's TPS or performance assessment with respect to the performance standards.
- CEO contact information, including name, email address, telephone number, and mailing address (must include the physical address, not just the post office box).
- QualityNet System Administrator contact information, including name, email address, telephone number, and mailing address (must include the physical address, not just the post office box).

Consistent with sections 1886(o)(11)(A) and (B) of the Act, we are proposing that hospitals would be able to submit an appeal on the following issues:

- CMS' decision to deny a hospital's correction request that the hospital submitted under the review and corrections process;
- Whether the achievement/improvement points were calculated correctly;
- Whether CMS properly used the higher of the achievement/improvement points in calculating the hospital's measure/dimension score;
- Whether CMS correctly calculated the domain scores, including the normalization calculation;
- Whether CMS used the proper lowest dimension score in calculating the hospital's HCAHPS consistency points;
- Whether CMS calculated the HCAHPS consistency points correctly;
- Whether the correct domain scores were used to calculate the TPS;
- Whether each domain was weighted properly;
- Whether the weighted domain scores were properly summed to arrive at the TPS; and,
- Whether the hospital's open/closed status (including mergers and acquisitions) is properly specified in CMS' systems.

We invite public comment on this proposed administrative appeal process.

8. Proposed Measures for the FY 2015 Hospital VBP Program

a. Relationship Between the National Strategy and the Hospital VBP Program

Section 399HH of the Public Health Service Act, as added and amended by sections 3011 and 10302 of the Affordable Care Act, requires the Secretary to establish a national strategy to improve the delivery of health care services, patient health outcomes, and population health. The Secretary submitted the ''National Strategy for Quality Improvement in Health Care'' on March 21, 2011. The strategy is available at: *http://www.healthcare.gov/law/resources/reports/nationalqualitystrategy032011.pdf.*

We believe we can incorporate the goals of the National Quality Strategy into our policies under the Hospital VBP Program. We view the strategy as an important driver in revamping how Medicare services are paid for, moving increasingly towards rewarding hospitals that deliver better outcomes in health and health care at lower cost to the beneficiaries and communities they serve. Over time, the strategy is also helping us align the goals for quality measurement and improvement in hospitals with those of other providers and suppliers in the health system, promoting shared accountability across care settings for beneficiary care and quality improvement.

We believe that, given the availability of endorsed measures and the need to balance the number and scope of the measures against the burden on participating hospitals, as well as ensuring that the Hospital VBP Program's measure set reflects our quality improvement priorities, the Hospital VBP Program measures should as fully as possible reflect the six measurement domains that arise from the National Quality Strategy's six priorities: Clinical Care; Person- and Caregiver-Centered Experience and Outcomes; Safety; Efficiency and Cost Reduction; Care Coordination; and Community/Population Health. We believe that measure sets should generally rely on a mix of standards, outcome, process of care measures, and patient-reported measures including measures of care transitions, patient experience, and changes in patient functional status, with an emphasis on measurement as close to the patient-centered outcome of interest as possible. We took all of these factors into consideration when developing our measure proposals for the FY 2015 Hospital VBP Program.

In addition, we believe that measure sets should evolve to include a focused set of measures that reflect the most important areas of service and quality improvement for hospitals as well as a core set of measure concepts that align quality improvement objectives across all provider types and settings.

b. Proposed FY 2015 Measures

In the Hospital Inpatient VBP Program final rule (76 FR 26496 through 26497), we adopted a policy under which we would examine whether any clinical process of care measures that were otherwise eligible for inclusion in a Hospital VBP Program measure set were topped-out, and thus, should be excluded because measuring hospital performance on a topped-out measure would have no meaningful effect on a hospital's TPS. Our methodology for evaluating whether a measure is topped-out focuses on two criteria: (1) National

measure data show statistically indistinguishable performance levels at the 75th and 90th percentiles, and (2) National measure data show a truncated coefficient of variation (TCV) less than 0.10.

We analyzed the clinical process of care measures that we believe are eligible for the FY 2015 Hospital VBP Program based on their prior inclusion in the Hospital IQR Program and posting on *Hospital Compare* for ''topped out'' status, and concluded that one of the candidate measures for the FY 2015 Program—SCIP–Inf-10: Surgery Patients with Perioperative Temperature Management—is now ''topped-out.'' Therefore, we are not proposing to include this measure in the FY 2015 Hospital VBP Program.

We welcome public comments on whether any other existing Hospital VBP measures may be ''topped out'' and should therefore be considered for removal from the proposed measure set. We also note that we do not believe it is appropriate at this time to test or re-test proposed outcome measures for ''topped-out'' status because such measures allow CMS to reward hospitals for high-quality outcomes, which is a central aim of quality improvement efforts in the health care system. We further believe that these measures are critical to providing patients with better care and believe it is important to hold hospitals accountable for the clinical outcomes captured by these measures. We invite public comments on this policy, including whether we should examine the proposed outcomes measure set for ''topped-out'' status at this time.

For the FY 2015 Hospital VBP Program, we are proposing to retain 12 of the 13 clinical process of care measures that we have adopted for the FY 2014 program. We are proposing to remove SCIP–VTE–1 from the FY 2015 measure set because this measure is very similar to another measure we have adopted for the program (SCIP–VTE–2) but, in our view, is not as closely linked to better surgical outcomes because it assesses the ordering of VTE prophylaxis, as opposed to the patient's actual receipt of such prophylaxis within 24 hours of surgery. We also note that, during a recent maintenance review of SCIP–VTE–1, the NQF concluded that it would no longer endorse this measure, and we are proposing in this proposed rule to remove the measure from the Hospital IQR Program beginning with the FY 2015 payment determination. Therefore, we are also proposing to retire SCIP–VTE–1 from the Hospital VBP Program measure set beginning with the FY 2015 program. We note that in the future, we anticipate proposing to adopt surgical outcome measures, including one or more measures that assess complications arising from VTE prophylaxis medications, first into the Hospital IQR Program and then into the Hospital VBP Program.

We are proposing to adopt one additional clinical process of care measure—AMI–10: Statin Prescribed at Discharge. This measure has been specified under the Hospital IQR Program for the FY 2013 payment determination (75 FR 50200). AMI–10 measure data were posted on the *Hospital Compare* Web site on January 26, 2012, so as discussed further below, we are proposing a 9-month performance period for this measure for FY 2015. We intend to align the performance period for AMI–10 with the other clinical process measures' performance period in future years. The measure is NQF-endorsed (#0639) and we did not find it to be ''topped-out'' when we examined the list of candidate measures as described above. We also note that current American College of Cardiology (ACC)/American Heart Association (AHA) guidelines place a strong emphasis on the initiation or maintenance of statin drugs for patients hospitalized with AMI, particularly those with LDL-cholesterol levels at or above 100 mg/dL. We therefore believe that this measure is appropriate for use in the Hospital VBP Program.

For the Patient Experience of Care domain, we are proposing to retain the eight dimensions of the HCAHPS survey that we adopted for the FY 2013 and FY 2014 Hospital VBP Program. We believe that the 8 HCAHPS dimensions finalized for the FY 2013 and FY 2014 Hospital VBP Programs are well-understood by hospitals and the public and capture important aspects of the patient's experience in the acute care environment.

For the Outcome domain, we are proposing to retain the three 30-day mortality measures that we finalized for the FY 2014 Hospital VBP Program. As described above, we continue to believe that these measures are important to quality improvement efforts because outcomes measures allow us to reward hospitals for high-quality outcomes, which is a central aim of quality improvement efforts in the health care system. We further believe that these measures are critical to providing patients with better care and believe it is important to hold hospitals accountable for the clinical outcomes captured by these measures. We also are proposing to adopt two additional outcomes measures—PSI–90, the AHRQ PSI composite measure, and the CLABSI: Central Line-Associated Blood Stream Infection measure—for the Outcome domain.

We initially adopted the CLABSI measure for the FY 2013 Hospital IQR Program in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50200 through 50202) and refer readers to that rule for further discussion of the measure. CLABSI is an HAI measure that assesses the rate of laboratory-confirmed cases of bloodstream infection or clinical sepsis among ICU patients. This measure was first NQF-endorsed in 2004, and adopted by the HQA in 2007. The measure can be stratified by the type of ICU and is aggregated to the hospital level by the NHSN. We first posted hospital performance on this measure on *Hospital Compare* on January 26, 2012.

We believe that adoption of the CLABSI measure for the Hospital VBP Program is consistent with the intention captured in the Hospital VBP Program's statutory requirement that we consider measures of HAIs for the FY 2013 Hospital VBP Program's measure set.

We initially adopted the AHRQ PSI composite measure (PSI–90) for the FY 2010 payment determination in the FY 2009 IPPS/LTCH PPS final rule (73 FR 48602 through 48603) and refer readers to that rule for further discussion of that measure. PSI–90 is a composite measure of patient safety indicators developed and maintained by AHRQ and measure data were posted on *Hospital Compare* on October 14, 2011. We believe that its use in the Hospital VBP Program is appropriate in order to encourage hospitals to take all possible steps to avoid threats to patient safety that may occur in the acute care environment.

For the Efficiency domain, we are proposing to adopt one new measure: the Medicare Spending per Beneficiary measure. The proposed measure is inclusive of all Part A and Part B payments from 3 days prior to a subsection (d) hospital admission through 30 days post discharge with certain exclusions. It is risk adjusted for age and severity of illness, and the included payments are standardized to remove differences attributable to geographic payment adjustments and other payment factors. We anticipate submitting the proposed measure to the NQF for endorsement in the near future.

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618 through 51627) for the measure's specifications. Additional information on the measure, including a detailed specification document can be found at: *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%*

2FPage%2FQnetTier3&cid=1228772053996. This measure has been specified under the Hospital IQR Program, and we anticipate publicly posting hospital performance on the measure on the *Hospital Compare* Web site in mid to late April 2012. As discussed further below, we are proposing that the performance period for this measure for the FY 2015 Hospital VBP Program begin on May 1, 2013, which will be more than one year after the performance data has been publicly posted. Further, section 1886(o)(2)(B)(ii) of the Act requires us to ensure that measures selected for the Hospital VBP Program include measures of efficiency, including measures of Medicare spending per beneficiary, for FY 2014 or a subsequent fiscal year. We believe that this proposed measure fulfills that requirement.

The proposed FY 2015 Hospital VBP Program measures appear below:

PROPOSED QUALITY MEASURES FOR FY 2015 HOSPITAL VBP PROGRAM

Measure ID	Description
Clinical Process of Care Measures	
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival.
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival.
AMI–10	Statin Prescribed at Discharge.
HF–1	Discharge Instructions.
PN–3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.
PN–6	Initial Antibiotic Selection for CAP in Immunocompetent Patient.
SCIP–Inf–1	Prophylactic Antibiotic Received Within One 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.
SCIP–Inf–4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose.
SCIP–Inf–9	Urinary Catheter Removed on Postoperative Day 1 or Postoperative Day 2.
SCIP–Card–2	Surgery Patients on Beta-Blocker Therapy Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period.
SCIP–VTE–2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxes Within 24 Hours Prior to Surgery to 24 Hours After Surgery.
Patient Experience Measures	
HCAHPS *	Hospital Consumer Assessment of Healthcare Providers and Systems Survey.
Outcome Measures	
AHRQ PSI composite	Complication/patient safety for selected indicators (composite).
CLABSI	Central Line-Associated Blood Stream Infection.
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate.
MORT–30–HF	Heart Failure (HF) 30-day mortality rate.
MORT–30–PN	Pneumonia (PN) 30-day mortality rate.
Efficiency Measures	
MSPB–1	Medicare spending per beneficiary.

* Proposed dimensions of the HCAHPS survey for use in the FY 2015 Hospital VBP Program are: Communication with Nurses, Communication with Doctors, Responsiveness of Hospital Staff, Pain Management, Communication about Medicines, Cleanliness and Quietness of Hospital Environment, Discharge Information and Overall Rating of Hospital. These are the same dimensions of the HCAHPS survey that have been finalized for prior Hospital VBP program years.

We invite public comment on the proposed measure set for the FY 2015 Hospital VBP Program.

c. Proposed General Process for Hospital VBP Program Measure Adoption for Future Program Years

In order to facilitate measure adoption for the Hospital VBP Program for future years, as well as further align the Hospital VBP Program with the Hospital IQR Program, we are proposing to re-adopt measures from the prior program year for each successive program year, unless proposed and finalized otherwise (for example, because one or more of the clinical process of care measures is topped-out). We intend to continue monitoring Hospital VBP measures for topped-out status and will propose topped-out measures' removal from the program as appropriate in future rulemaking. We will therefore generally re-adopt the prior Program year's measure set unless we propose to add or remove measures through rulemaking and in response to public comments. However, under this policy, once measures are finalized, we would not separately re-propose them for each program year. We invite public comments on this proposal.

9. Proposed Measures and Domains for the FY 2016 Hospital VBP Program

a. Proposed FY 2016 Measures

We are proposing to retain the three 30-day mortality measures that were finalized for the FY 2014 Hospital VBP Program, and which we are proposing to retain for the FY 2015 Hospital VBP Program, for the FY 2016 Hospital VBP Program. We also are proposing to retain PSI–90, which is the AHRQ PSI composite measure that we are proposing to adopt for the FY 2015 Hospital VBP Program, for the FY 2016 program. By proposing to adopt these measures now, we believe we will be able to adopt a longer performance period and collect more data for performance scoring than would be possible if we waited to make this proposal until the FY 2014 IPPS/LTCH PPS proposed rule. We are also proposing to adopt these measures at this time because we recognize that under section 1886(o)(3)(C) of the Act, we must establish and announce performance standards not later than 60 days prior to the beginning of the

performance period for the fiscal year involved. Accordingly, we are proposing that the performance period for these measures would begin October 1, 2012, for purposes of the FY 2016 Hospital VBP Program. If we finalize our proposal above to automatically re-adopt measures from year to year, then the other proposed FY 2015 measures would become part of the FY 2016 measure set unless we proposed otherwise in future rulemaking. We also anticipate adopting additional measures for the FY 2016 Hospital VBP Program in future rulemaking.

The proposed FY 2016 Hospital VBP Program 30-day mortality measures and AHRQ PSI composite measure are shown below:

PROPOSED OUTCOME MEASURES FOR FY 2016 HOSPITAL VBP PROGRAM

Measure ID	Description
AHRQ PSI composite	Complication/patient safety for selected indicators (composite).
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate.
MORT–30–HF	Heart Failure (HF) 30-day mortality rate.
MORT–30–PN	Pneumonia (PN) 30-day mortality rate.

We are not proposing to adopt the CLABSI measure for the FY 2016 Hospital VBP Program at this time, but may propose it in future rulemaking.

We invite public comment on these proposals.

b. Proposed Quality Measure Domains for the FY 2016 Hospital VBP Program

Currently, measure domains are defined by the measure type rather than by measure function. At the time of the Hospital VBP Program's development, we believed this type of measure classification, which was included in the 2007 Report to Congress, was appropriate for the program based on its clarity and simplicity compared to alternative scoring models. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26513 through 26514) for further discussion of our decision to finalize the Three-Domain Performance Scoring Model for the Hospital VBP Program with appropriate modifications for additional domains as necessary. The FY 2014 program's domains are clinical process of care, outcomes, and patient experience of care. The FY 2015 Hospital VBP Program's proposed domains are clinical process of care, outcomes, patient experience of care, and efficiency.

We strive to align quality measurement and value-based purchasing efforts with the National Quality Strategy and across programs. Value-based purchasing programs in particular allow us to link the National Quality Strategy with Medicare reimbursements to providers and suppliers on a national scale. Given this objective, as well as our objective to focus quality measurement on the patient-centered outcome of interest to the extent possible, we are proposing to reclassify the Hospital VBP measures into domains based on the six priorities of the National Quality Strategy, beginning with the FY 2016 Hospital VBP Program. We are making this proposal in this proposed rule to ensure that we have ample time to consider all public comments and finalize any policies in advance of the FY 2016 program year.

We are proposing that the following six domains serve as a framework for measurement and TPS calculations for the Hospital VBP Program beginning with the FY 2016 program year: Clinical Care; Person- and Caregiver-Centered Experience and Outcomes; Safety; Efficiency and Cost Reduction; Care Coordination; and Community/Population Health.

To illustrate how CMS would classify measures into the proposed new domains, we offer the following example using the proposed FY 2015 Hospital VBP measure set:

Proposed FY 2015 measures	Proposed FY 2016 domain	Proposed FY 2015 domain
HF–1 Discharge Instructions	Care Coordination	Clinical Process of Care.
AMI–10 Statin Prescribed at Discharge	Clinical Care	Clinical Process of Care.
AMI–7a Fibrinolytic Agent Received Within 30 Minutes of Hospital Arrival.	Clinical Care	Clinical Process of Care.
AMI–8a Primary PCI Received Within 90 Minutes of Hospital Arrival	Clinical Care	Clinical Process of Care.
Mortality-30–AMI Acute Myocardial Infarction (AMI) 30-day Mortality Rate.	Clinical Care	Outcomes.
Mortality-30–HF Heart Failure (HF) 30-day Mortality Rate	Clinical Care	Outcomes.
Mortality-30–PN Pneumonia (PN) 30–Day Mortality Rate	Clinical Care	Outcomes.
PN–3b Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.	Clinical Care	Clinical Process of Care.
PN–6 Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients.	Clinical Care	Clinical Process of Care.
SCIP Card-2 Surgery Patients on Beta-Blocker Therapy Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period.	Clinical Care	Clinical Process of Care.
SCIP–Inf-01 Prophylactic antibiotic received within 1 hour prior to surgical incision.	Clinical Care	Clinical Process of Care.
SCIP–Inf-02 Prophylactic antibiotic selection for surgical patients	Clinical Care	Clinical Process of Care.
SCIP–Inf-03 Prophylactic antibiotics discontinued with 24 hours after surgery end time.	Clinical Care	Clinical Process of Care.
SCIP–Inf-04 Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose.	Clinical Care	Clinical Process of Care.
SCIP–VTE–2 Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery.	Clinical Care	Clinical Process of Care.
Medicare spending per beneficiary	Efficiency and Cost Reduction	Efficiency.

Proposed FY 2015 measures	Proposed FY 2016 domain	Proposed FY 2015 domain
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems Survey.	Person- and Caregiver-Centered Experience and Outcomes.	Patient Experience of Care.
Central Line-Associated Blood Stream Infection (CLABSI)	Safety	Outcome.
PSI 90 Complication/Patient Safety for Selected Indicators (Composite).	Safety	Outcome.

We acknowledge that some of the measures noted above could appropriately be placed in more than one domain because the quality improvement characteristics they seek to measure, especially for outcome measures, are multifaceted. We believe that the measure classification by domain should reflect the primary measurement objective and the type of quality improvement goal the measure seeks to capture. For example, although a reduction in CLABSIs may reflect improved clinical care, we believe that it better reflects an improvement in patient safety because such infections often cause harm to patients.

We are proposing that the TPS would continue to be determined by aggregating each hospital's scores across all domains. A hospital's score on each domain would also continue to be calculated based on the hospital's score on each measure within the domain, which is based on the higher of its achievement or improvement during the applicable performance period.

We welcome public comment on our proposal to regroup the Hospital VBP Program's quality measures into six domains that better reflect the National Quality Strategy, beginning with the FY 2016 Hospital VBP Program.

We are also soliciting comments on how to properly weight the domains in FY 2016. We believe that domain weighting should primarily balance two factors. First, it should reflect our concept of quality as it relates to the National Quality Strategy and the most critical needs for quality improvement in caring for beneficiaries. Second, it should reflect the relative depth and maturity of measures in each domain. For example, although improvement in the proposed Care Coordination domain is a priority, we would want to take into consideration whether the care coordination measures available for inclusion in that domain in a particular year capture multiple aspects of care coordination. If we did not believe that the measures within a domain captured enough aspects of care, we would consider proposing a relatively lower weight for the domain. We anticipate that the domain weights will evolve over time as the measure set changes.

We also recognize that the current domain weighting system allows us to place higher value on measures closer to the patient-centered outcome of interest by grouping outcome measures into a single domain. In the proposed domain reclassification, the 30-day mortality measures would be grouped with process measures. Although we anticipate that the measure set will evolve over time to be more focused on outcomes, the current measure set continues to emphasize clinical processes. We seek public comment on whether CMS should continue to group all outcome measures in a single domain. In addition, we seek public comment on the implications of and alternatives to the proposed approach of including both clinical process of care measures and outcome measures in the proposed Clinical Care domain under the proposed domain reclassification.

10. Proposed Performance Periods and Baseline Periods for the FY 2015 Hospital VBP Program

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program for a fiscal year that begins and ends prior to the beginning of such fiscal year.

a. Proposed Clinical Process of Care Domain Performance Period and Baseline Period for FY 2015

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74534), for the FY 2014 Hospital VBP Program, we finalized a 9-month (3-quarter) performance period from April 1, 2012 through December 31, 2012 for the clinical process of care domain measures.

As we stated in that final rule with comment period, adopting a 3-quarter performance period for this domain for the FY 2014 Hospital VBP Program would enable us to consider adopting a 12-month performance period for this domain for FY 2015. Therefore, we are proposing to adopt CY 2013 (January 1, 2013 through December 31, 2013) as the performance period for all but one of the clinical process of care domain measures for the FY 2015 program. This proposed performance period for FY 2015 would begin immediately after the end of the FY 2014 performance period and will enable us to begin to make value-based incentive payments to hospitals beginning October 1, 2014. A 12-month performance period would also give us more data on which to score hospital performance, which is an important goal both for CMS and for stakeholders. We also note that a 12-month performance period is consistent with the periods used for the Hospital IQR Program.

However, as noted above, AMI–10 measure data were posted on *Hospital Compare* on January 26, 2012. Therefore, we do not believe we can begin a performance period for this measure on January 1, 2013, which would align with the proposed performance period for all other clinical process of care measures. We considered the most appropriate way to include this measure in the FY 2015 Hospital VBP Program and concluded that we should propose a 9-month performance period from April 1, 2013 through December 31, 2013. As we have stated for prior program years, we believe that a 9-month performance period provides sufficiently reliable quality measure data for clinical process of care measures. We intend to align the AMI–10 measure's performance period with all other clinical process measures for future program years. We welcome public comment on this proposal.

As we explained in the Hospital Inpatient VBP Program final rule (76 FR 26511), we believe that baseline data should be used from a comparable prior period for purposes of calculating the performance standards. However, we also strive to balance that belief with our desire to use the most recently-available data in order to calculate performance standards, as we believe that more recent data more closely reflects current performance on measures. Therefore, we are proposing to adopt CY 2011 (January 1, 2011 through December 31, 2011) as the baseline period for all but one of the Clinical Process of Care domain measures for the FY 2015 Hospital VBP Program. As noted above, we are proposing to adopt a 9-month performance period for the AMI–10 measure. In accordance with our preference for adopting a comparable prior period for purposes of calculating the performance standards, we are proposing to adopt a 9-month baseline period of April 1, 2011 through

December 31, 2011 for the AMI–10 measure.

We welcome public comment on these proposals.

b. Proposed Patient Experience of Care Domain Performance Period and Baseline Period for FY 2015

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74534), for the FY 2014 Hospital VBP Program, we finalized a 9-month (3-quarter) performance period from April 1, 2012 through December 31, 2012 for the Patient Experience of Care domain measure.

As we stated in that final rule with comment period, adopting a 3-quarter performance period for this domain for the FY 2014 Hospital VBP Program would enable us to consider adopting a 12-month performance period for this domain for FY 2015. Consistent with our goal of adopting a full 12-month period for this domain in order to collect a larger amount of HCAHPS survey data compared to a 9-month period, we are proposing to adopt CY 2013 (January 1, 2013 through December 31, 2013) as the performance period for the Patient Experience of Care domain measure for the FY 2015 program. This proposed performance period for FY 2015 would begin immediately after the end of the FY 2014 performance period and would enable us to begin making value-based incentive payments to hospitals beginning on October 1, 2014. We also note that a 12-month performance period is consistent with the periods used for the Hospital IQR Program.

As we explained in the Hospital Inpatient VBP Program final rule (76 FR 26511), we believe that baseline data should be used from a comparable prior period for purposes of calculating the performance standards. Therefore, we are proposing to adopt CY 2011 (January 1, 2011 through December 31, 2011) as the baseline period for the Patient Experience of Care domain measure for the FY 2015 program.

We welcome public comment on these proposals.

c. Proposed Efficiency Domain Measure Performance Period and Baseline Period for FY 2015

We plan to post performance data for the Medicare spending per beneficiary measure on *Hospital Compare* in April 2012. We have therefore concluded that the earliest we may begin a performance period for FY 2015 is one year from the date on which the data was posted. We are proposing an end date of December 31, 2013 for this measure's performance period. This end date is consistent with the end dates proposed for the Clinical Process of Care domain and for the HCAHPS measure in the Patient Experience of Care domain.

In the interest of maintaining consistency across domains, to the extent possible, and in order to ensure that data have been posted for at least 1 year prior to the beginning of the measure performance period, we are proposing to adopt an 8-month performance period (May 1, 2013 through December 31, 2013) for the Medicare spending per beneficiary measure for the FY 2015 Hospital VBP Program. We believe this proposed performance period enables us to collect as much measure data as possible and the time necessary to process claims and incorporate measure data into Hospital VBP Program scores. We are further proposing to adopt a corresponding prior period (May 1, 2011 through December 31, 2011) as the baseline period for purposes of calculating the performance standards. This proposed baseline period would be consistent with the baseline period proposed for other Hospital VBP Program measures in that it precedes the performance period by two years.

We welcome public comment on the proposed FY 2015 performance and baseline period for the Medicare spending per beneficiary measure.

d. Proposed Outcome Domain Performance Periods for FY 2015

(1) Mortality Measures

In the Hospital Inpatient VBP Program final rule (76 FR 26495), we finalized a 12-month performance period (July 1, 2011–June 30, 2012) for the Outcome domain for the FY 2014 Hospital VBP Program. We also finalized a comparable prior period as the baseline period (July 1, 2009 through June 30, 2010) for purposes of calculating improvement points as well as the performance standards.

Due to the lengthy time needed for us to compile claims-based measure data at the individual hospital level and calculate the measure rates and scores (discussed more fully in section VIII.C.6.b. of this preamble in the context of our review and corrections proposal for claims-based measures), we must conclude the performance period for claims-based measures for FY 2015 by June 30, 2013.

We are concerned about the difficulty that varied performance periods impose on participating hospitals. While we believe the public recognizes the need for different performance periods due to varied measure types and collection methods, we strive to propose performance periods that are as consistent as possible from one program year to the next. We believe this consistency is important for all hospitals that are working to improve the quality of care they provide to Medicare beneficiaries and to the entirety of the patient population. However, we are also aware that the Hospital VBP statute requires that we establish and announce performance standards for Hospital VBP measures at least 60 days in advance of the performance period. Because we are proposing to adopt these measures for FY 2015 in this proposed rule, which will not be effective until 60 days after it is finalized, we do not believe we can propose a performance period for these measures beginning earlier than October 1, 2012.

We note that this proposed performance period is less than 12 months, which may raise seasonality concerns with regard to these measures. We note further that we examined the independent analysis of these measures' reliability provided by Mathematica Policy Research, entitled, ''Reporting Period and Reliability of AHRQ, CMS 30-day and HAC Quality Measures—Revised,'' which is available on our Web site (*http://cms.hhs.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf*), and which concluded that the measures may not achieve total reliability for all hospitals for reporting periods as short as 6 months. However, we believe that holding all hospitals accountable using the same period will fairly alleviate those concerns, particularly because these measures are risk-adjusted using a methodology that does not penalize hospitals for poor performance on the measure without a relatively larger sample size. As described further below, while we are concerned about these measures' reliability when adopting a performance period of less than 12 months, we believe that increasing the required minimum number of cases will assure sufficient reliability for these measures for value-based purchasing. Based on this analysis, as well as our objective to include outcome measures in the Hospital VBP Program, we believe that the proposed 9-month performance period for these measures will produce sufficiently reliable results for hospitals.

Therefore, we are proposing to adopt a 9-month performance period for the three 30-day mortality measures for FY 2015 from October 1, 2012 through June 30, 2013. We further are proposing a comparable baseline period from October 1, 2010 through June 30, 2011.

We welcome public comment on our proposal to adopt a performance period for the proposed FY 2015 mortality measures that runs from October 1, 2012 through June 30, 2013, and a baseline period that runs from October 1, 2010, through June 30, 2011.

(2) Proposed AHRQ PSI Composite Measure

We posted hospital performance data on the AHRQ PSI composite measure on *Hospital Compare* on October 14, 2011. Based on that posting date, we believe the earliest we could begin a performance period for FY 2015 is October 14, 2012. As discussed above, we must conclude the performance period for claims-based measures by June 30, 2013 in order to allow sufficient time to calculate the measure rates and scores.

Therefore, we are proposing to adopt a nearly 9-month performance period (October 15, 2012 through June 30, 2013) for the AHRQ PSI composite measure for FY 2015. We believe that this performance period will provide us with sufficiently reliable data on which to base hospitals' scores. We further are proposing to adopt a comparable prior period from October 15, 2010 through June 30, 2011 as the baseline period for purposes of calculating the performance standards.

While we would prefer to adopt a performance period longer than nearly 9-months in order to provide the most reliable measure data possible, we believe that the proposed period enables us to ensure that this measure, which assesses hospital performance on the critical topic of patient safety, is included in hospitals' FY 2015 TPSs and, therefore, will become a focus of quality improvement efforts. We note further that we examined the independent analysis of this measure's reliability provided by Mathematica Policy Research, entitled, ''Reporting Period and Reliability of AHRQ, CMS 30-day and HAC Quality Measures—Revised,'' which is available on our Web site (*http://cms.hhs.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf*), and which concluded that the measure achieves moderate reliability for the majority of hospitals for reporting periods of 6 months or longer. Based on this analysis, as well as our objective to include patient safety measures in the Hospital VBP Program, we believe that the proposed nearly 9-month performance period for this measure will produce reliable results for hospitals.

We welcome public comment on these proposals.

(3) CLABSI Measure

We posted CLABSI measure data on *Hospital Compare* on January 26, 2012. Pursuant to our commitment to post measure data on *Hospital Compare* at least one year prior to the beginning of a performance period for the Hospital VBP Program, the earliest we can begin a performance period for this measure is January 26, 2013. Because, as described above, we believe this measure captures important patient safety data, in this case related to infections that present the possibility of significant harm to hospitalized patients, we believe it is appropriate to adopt the measure as soon as possible for as lengthy a performance period as possible. Adopting an approximately 11-month performance period for this measure will not, in our view, appreciably harm the measure's statistical reliability for purposes of value-based purchasing scoring, particularly because (as described below) we are also proposing to adopt the measure steward's criteria for minimum number of cases to receive a measure score.

Therefore, we are proposing to adopt an approximately 11-month performance period for the CLABSI measure from January 26, 2013 through December 31, 2013 with a comparable baseline period of January 26, 2011 through December 31, 2011 for purposes of calculating the performance standards.

We welcome public comment on these proposals.

The proposed performance and baseline periods for all proposed FY 2015 measures appear below:

Domain	Baseline period	Performance period
Clinical Process of Care	January 1, 2011–December 31, 2011	January 1, 2013–December 31, 2013.
• AMI–10*	• April 1, 2011–December 31, 2011	• April 1, 2013–December 31, 2013.
Patient Experience of Care	January 1, 2011–December 31, 2011	January 1, 2013–December 31, 2013.
Outcome:		
• Mortality	• October 1, 2010–June 30, 2011	• October 1, 2012–June 30, 2013.
• AHRQ	• October 15, 2010–June 30, 2011	• October 15, 2012–June 30, 2013.
• CLABSI	• January 26, 2011–December 31, 2011	• January 26, 2013–December 31, 2013.
Efficiency:		
• Medicare Spending Per Beneficiary-1	• May 1, 2011–December 31, 2011	• May 1, 2013–December 31, 2013.

*As discussed further above, we are proposing a separate performance period for the AMI–10 measure. The proposed 12-month performance period specified above would apply to all other clinical process of care measures.

e. Proposed Performance Periods for Proposed FY 2016 Measures

In order to provide relatively more reliable data for the three proposed 30-day mortality measures and the AHRQ PSI composite measure, we considered how we could adopt a 24-month performance period for the FY 2016 Hospital VBP Program. We do not believe it is feasible to do so at this time given the statutory requirement that we establish and announce performance standards at least 60 days in advance of the applicable performance period. However, we intend to propose to adopt a 24-month performance period for these measures as soon as is practicable and will consider a 24-month performance period in future rulemaking.

Given the time constraints associated with the annual IPPS/LTCH PPS rulemaking schedule, we believe that the longest performance period we can propose for FY 2016 at this time is 21 months. We believe that this performance period will provide relatively more reliable measure data and will enable us to consider adopting a 24-month performance period in the future.

We therefore are proposing to adopt a 21-month performance period for the three proposed 30-day mortality measures and the AHRQ PSI composite measure for the FY 2016 Hospital VBP Program, from October 1, 2012 through July 30, 2014. We are further proposing a baseline period of October 1, 2010 through July 30, 2011, for purposes of calculating performance standards and measuring improvement. We note that this baseline period is identical to the proposed baseline period for these

measures for FY 2015. We also note that this baseline period is shorter than the proposed performance period. We believe it is appropriate to use the most recently-available data to calculate performance standards and are concerned about the possibility of using data from several years prior to the performance period for performance standards. However, we seek public comment on whether we should adopt a 24-month baseline period.

The table below displays the proposed performance period for the FY 2016 mortality and AHRQ PSI composite measures.

Measure	Baseline period	Performance period
Mortality/AHRQ PSI	October 1, 2010–June 30, 2011	October 1, 2012–June 30, 2014.

We welcome public comment on this proposal. We also seek comments on the possibility of adopting a ''rolling'' 2-year performance period for certain claims-based measures during which we would score hospitals using 24 months of data. As an example, under such a policy for mortality measures, hospitals could be scored for the FY 2018 Hospital VBP Program using data from the performance periods for FY 2017 (while not yet proposed, one possibility for that year could be July 1, 2013 through June 30, 2015). For subsequent fiscal years, we would drop the oldest 12 months of data from that period and add the next 12 months. The performance period for the FY 2019 Hospital VBP Program under that policy could be July 1, 2014 through June 30, 2016.

11. Proposed Performance Standards for the Hospital VBP Program for FY 2015 and FY 2016

a. Background

Section 1886(o)(3)(A) of the Act requires the Secretary to establish performance standards for the measures selected under the Hospital VBP Program for a performance period for the applicable fiscal year. The performance standards must include levels of achievement and improvement, as required by section 1886(o)(3)(B) of the Act, and must be established and announced not later than 60 days before the beginning of the performance period for the fiscal year involved, as required by section 1886(o)(3)(C) of the Act. Achievement and improvement standards are discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513). In addition, when establishing the performance standards, section 1886(o)(3)(D) of the Act requires the Secretary to consider appropriate factors, such as: (1) Practical experience with the measures, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods; (2) historical performance standards; (3) improvement rates; and (4) the opportunity for continued improvement. We are proposing to codify this for performance standards in our regulations at § 412.165.

b. Proposed Performance Standards for the FY 2015 Hospital VBP Program Measures

We are proposing to establish performance standards that apply to the FY 2015 Hospital VBP Program using the same methodologies that we previously adopted for the FY 2013 and FY 2014 programs. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for a detailed discussion of the methodology we adopted for the clinical process of care, patient experience of care, and outcome measures, and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656) for a discussion of the methodology we adopted for the Medicare spending per beneficiary measure.

We continue to believe that the finalized methodology for calculating performance standards is appropriate for the Hospital VBP Program given that the program remains relatively new to hospitals and the public. The proposed performance standards for the clinical process, outcome, and Medicare spending per beneficiary measures appear in the first table below, while the proposed performance standards for the patient experience of care (HCAHPS survey) measure appears in the second table below. We note that the performance standards displayed below represent estimates based on the most recently-available data; we will update the standards in the FY 2013 IPPS/LTCH PPS final rule. We also note that the performance standards for the CLABSI measure and the AHRQ PSI composite measure are calculated with lower values representing better performance, in contrast to other measures, on which higher values indicate better performance.

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2015 HOSPITAL VBP PROGRAM CLINICAL PROCESS OF CARE AND OUTCOME DOMAINS, AND THE MEDICARE SPENDING PER BENEFICIARY MEASURE

Measure ID	Description	Achievement threshold	Benchmark
Clinical Process of Care Measures			
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	0.72727	1.00000
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0.92857	1.00000
AMI–10	Statin Prescribed at Discharge	0.90474	
PN–3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.	0.97129	1.00000
PN–6	Initial Antibiotic Selection for CAP in Immunocompetent Patient	0.93671	0.99832
SCIP–Card–2	Surgery Patients on Beta-Blocker Therapy Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period.	0.95122	1.00000
SCIP–Inf–1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision.	0.97872	1.00000
SCIP–Inf–2	Prophylactic Antibiotic Selection for Surgical Patients	0.97882	1.00000
SCIP–Inf–3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time.	0.96154	0.99905
SCIP–Inf–4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose.	0.94799	0.99824

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2015 HOSPITAL VBP PROGRAM CLINICAL PROCESS OF CARE AND OUTCOME DOMAINS, AND THE MEDICARE SPENDING PER BENEFICIARY MEASURE—Continued

Measure ID	Description	Achievement threshold	Benchmark
SCIP–Inf–9	Urinary Catheter Removed on Postoperative Day 1 or Postoperative Day 2.	0.93333	1.00000
SCIP–VTE–2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxes Within 24 Hours Prior to Surgery to 24 Hours After Surgery.	0.94118	0.99938
Outcome Measures			
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate	0.8477	0.8673
MORT–30–HF	Heart Failure (HF) 30-Day Mortality Rate	0.8861	0.9042
MORT–30–PN	Pneumonia (PN) 30-Day Mortality Rate	0.8818	0.9021
PSI–90	Patient safety for selected indicators (composite)	0.4006	0.2754
CLABSI	Central Line-Associated Blood Stream Infection	0.442	0.000
Efficiency Measures			
MSPB–1	Medicare Spending per Beneficiary	Median Medicare spending per beneficiary ratio across all hospitals during the performance period	Mean of the lowest decile of Medicare spending per beneficiary ratios across all hospitals during the performance period.

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2015 HOSPITAL VBP PROGRAM PATIENT EXPERIENCE OF CARE DOMAIN

HCAHPS survey dimension	Floor (percent)	Achievement threshold (percent)	Benchmark (percent)
Communication with Nurses	49.22	76.28	85.56
Communication with Doctors	57.31	79.61	88.72
Responsiveness of Hospital Staff	34.83	62.75	78.59
Pain Management	43.05	69.24	78.24
Communication about Medicines	28.11	60.46	71.72
Hospital Cleanliness & Quietness	40.35	63.79	78.46
Discharge Information	55.10	83.29	89.60
Overall Rating of Hospital	29.26	67.73	83.13

We welcome public comment on these proposed performance standards.

We are also aware that once the ICD–10–CM/PCS coding transition is completed, we will be faced with comparing hospitals' performance from baseline periods coded using ICD–9–CM with performance periods coded using ICD–10–CM/PCS. We note that constructing performance standards from such baseline periods could produce unforeseen consequences for quality measurement and performance scoring. Therefore, we seek comments on how to fairly compare hospitals' performance on quality measures when captured in different coding sets.

c. Proposed Performance Standards for FY 2016 Hospital VBP Program Measures

As described further above, in this proposed rule, we are proposing to adopt the three 30-day mortality measures and the AHRQ PSI composite measure for the FY 2016 Hospital VBP Program. We therefore must also propose performance standards for these measures based on the proposed baseline periods outlined above. Proposed performance standards for these measures appear in the table below. We note that the performance standards displayed below represent estimates based on the most recently-available data; we will update the standards in the FY 2013 IPPS/LTCH PPS final rule. We also note that the performance standards for the AHRQ PSI composite measure are calculated with lower values representing better performance, in contrast to the mortality measures, on which higher values indicate better performance.

PROPOSED PERFORMANCE STANDARDS FOR FY 2016 HOSPITAL VBP PROGRAMS OUTCOME DOMAIN: MORTALITY/PSI COMPOSITE MEASURES

Measure ID	Description	Achievement threshold	Benchmark
Outcome Measures			
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate	0.8477	0.8673
MORT–30–HF	Heart Failure (HF) 30-day mortality rate	0.8861	0.9042

PROPOSED PERFORMANCE STANDARDS FOR FY 2016 HOSPITAL VBP PROGRAMS OUTCOME DOMAIN: MORTALITY/PSI COMPOSITE MEASURES—Continued

Measure ID	Description	Achievement threshold	Benchmark
MORT–30–PN	Pneumonia (PN) 30-day mortality rate	0.8818	0.9021
PSI–90	Patient safety for selected indicators (composite)	0.4006	0.2754

d. Adopting Performance Periods and Standards for Future Program Years

For prior program years, with the exception of the Hospital Inpatient VBP Program proposed and final rule, we have proposed and finalized policies for the Hospital VBP Program in the IPPS/LTCH PPS and OPPS/ASC regulations. However, we do not believe these two rulemaking vehicles are ideally suited for additional Hospital VBP proposals. While we are aware that it is convenient for the public when additional proposals are made in a relatively limited number of rulemaking vehicles, we are concerned about the limitations that these regulations' schedules place on our ability to propose and finalize quality measures, performance periods, and performance standards in a timely manner.

In order to facilitate quality measure adoption for the Hospital VBP Program and ensure that hospitals are kept fully aware of the performance standards to which we intend to hold them accountable and the performance periods during which their performance will be measured, we are proposing to update performance periods and performance standards for future program years via notice on our Web site or another publicly-available Web site. We would establish future performance standards for the clinical process of care, outcome, and patient experience of care measures using the same methodology that we first finalized in the Hospital Inpatient VBP Program final rule (76 FR 26510 through 26513). We would establish future performance standards for the Medicare spending per beneficiary measure using the same methodology that we finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656). In the case of other types of measures whose scoring would not be appropriately described by the methodologies outlined above, we intend to propose and finalize additional scoring methodologies.

We believe that this proposal will enable us to adopt measures representing the best in medical practice into the Hospital VBP Program more quickly and will allow us to establish and announce performance standards and performance periods when necessary outside the annual IPPS/LTCH PPS and OPPS/ASC rulemaking schedules. We believe this flexibility is especially necessary as the Hospital VBP Program continues to evolve and incorporate new types of quality measures.

We welcome public comment on this proposal.

12. Proposed FY 2015 Hospital VBP Program Scoring Methodology

a. General Hospital VBP Program Scoring Methodology

In the Hospital Inpatient VBP Program final rule, we adopted a methodology for scoring clinical process of care, patient experience of care, and outcome measures. As noted in that rule, this methodology outlines an approach that we believe is well understood by patient advocates, hospitals, and other stakeholders because it was developed during a lengthy process that involved extensive stakeholder input, and was based on a scoring methodology we presented in a report to Congress. We also noted in that final rule that we had conducted extensive additional research on a number of other important methodology issues to ensure a high level of confidence in the scoring methodology (76 FR 26514). In addition, we believe that, for reasons of simplicity, transparency, and consistency, it is important to score hospitals using the same general methodology each year, with appropriate modifications to accommodate new domains and measures. We finalized a scoring methodology for the Medicare spending per beneficiary measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656).

For the FY 2015 Hospital VBP Program, we are proposing to use these same scoring methodologies to score hospital performance. We believe these scoring methodologies continue to appropriately capture hospital quality as reflected by the finalized quality measure sets. We also note that re-adopting the finalized scoring methodology from prior program years represents the simplest and most consistent policy for providers and the public.

b. Proposed Domain Weighting for the FY 2015 Hospital VBP Program for Hospitals That Receive a Score on All Four Proposed Domains

As we stated in the Hospital Inpatient VBP Program final rule (76 FR 26491), we believe that domains need not be given equal weight, and that over time, scoring methodologies should be weighted more towards outcomes, patient experience of care, and functional status measures (for example, measures assessing physical and mental capacity, capability, well-being and improvement). We took these considerations into account when developing the domain weighting proposal outlined below.

As discussed above, we are proposing to add the Efficiency domain to the Hospital VBP Program beginning with the FY 2015 program. Therefore, we are proposing the following domain weights for the FY 2015 program for hospitals that receive a score on all four proposed domains:

PROPOSED DOMAIN WEIGHTS FOR THE FY 2015 HOSPITAL VBP PROGRAM FOR HOSPITALS RECEIVING A SCORE ON ALL PROPOSED DOMAINS

Domain	Weight (percent)
Clinical Process of Care	20
Patient Experience of Care	30
Outcome	30
Efficiency	20

We believe this domain weighting appropriately reflects our priorities for quality improvement in the inpatient hospital setting and aligns with the National Quality Strategy's priorities. We believe that the proposed domain weighting will continue to improve the link between Medicare payments to hospitals and patient outcomes, efficiency and cost, and the patient experience. We note that the proposed domain weighting places the strongest relative emphasis on outcomes and the patient experience, which we view as two critical components of quality improvement in the inpatient hospital

setting. We further note that the proposed domain weighting, for the first time, incorporates a measure of efficiency and continues to provide substantial weight to clinical processes. We welcome public comment on this proposed weighting methodology.

c. Proposed Domain Weighting for Hospitals Receiving Scores on Fewer Than Four Domains

In prior program years, we finalized a policy that hospitals must have received domain scores on all finalized domains in order to receive a TPS. However, since the Hospital VBP Program has evolved from its initial two domains to an expanded measure set with four quality domains, we considered whether it was appropriate to continue this policy.

As described further below, we are proposing a higher minimum number of cases for the three 30-day mortality measures for FY 2015 than was finalized for the FY 2014 program in order to improve these measures' reliability given the relatively shorter proposed performance period described above. However, we are concerned that the relatively higher minimum number of cases could result in a substantially larger number of hospitals being excluded from the Hospital VBP Program. We believe that we should make a concerted effort to include as many hospitals as possible in the Program in order to offer quality incentives to as many hospitals as possible and encourage quality improvement as broadly as possible throughout the health care system while maintaining our focus on measure and scoring reliability.

Therefore, we are proposing that, for the FY 2015 Hospital VBP Program and subsequent fiscal years, hospitals with sufficient data to receive at least two domain scores (that is, sufficient cases and measures to receive a domain score on at least two domains) will receive a TPS. We also are proposing that, for hospitals with at least two domain scores, TPSs will be reweighted proportionately to the scored domains to ensure that the TPS is still scored out of a possible 100 points and that the relative weights for the scored domains remain equivalent to the proposed weighting outlined above. We believe that this proposal allows us to include relatively more hospitals in the Hospital VBP Program while continuing to focus on reliably scoring hospitals on their quality measure performance.

We welcome public comment on this proposal.

13. Applicability of the Hospital VBP Program to Hospitals

a. Background

Section 1886(o)(1)(C) of the Act specifies how the Hospital VBP Program applies to hospitals. Specifically, the term ''hospital'' is defined under section 1886(o)(1)(C)(i) of the Act as a ''subsection (d) hospital (as defined in section 1886(d)(1)(B [of the Act])).'' Section 1886(o)(1)(C)(ii) of the Act sets forth a list of exclusions to the definition of the term ''hospital'' with respect to a fiscal year, including a hospital that is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) of the Act (the Hospital IQR Program), a hospital for which, during the performance period for the fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients, a hospital for which there are not a minimum number of measures that apply to the hospital for the applicable performance period for the fiscal year, and a hospital for which there are not a minimum number of cases for the measures that apply to the hospital for the performance period for the fiscal year.

In addition, section 1886(o)(1)(C)(iv) of the Act states that in the case of a hospital that is paid under section 1814(b)(3) of the Act, the Secretary may exempt the hospital from the Hospital VBP Program if the State submits an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under the Hospital VBP Program. We interpret the reference to section 1814(b)(3) of the Act to mean those Maryland hospitals that are paid under section 1814(b)(3) of the Act and that, absent the ''waiver'' specified by section 1814(b)(3) of the Act, would have been paid under the IPPS.

b. Proposed Exemption Request Process for Maryland Hospitals

Acute care hospitals located in the State of Maryland are not currently paid under the IPPS in accordance with a special waiver provided by section 1814(b)(3) of the Act. In the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26530), we finalized our policy that the Hospital VBP Program would apply to acute care hospitals located in the State of Maryland unless the Secretary exercises discretion pursuant to section 1886(o)(1)(C)(iv) of the Act. We also finalized a procedure for the State to submit a report pursuant to section 1886(o)(1)(C)(iv) of the Act in a timeframe that would allow it to be received no later than October 1, 2011, which is the beginning of the fiscal year prior to FY 2013.

We received an FY 2013 exemption request from the Maryland Health Services Cost Review Commission (MHSCRC) on September 30, 2011 and the Secretary approved the exemption request in December 2011. This report included a discussion on how the state program achieved or surpasses the measured results in terms of patient health outcomes and cost savings established under the Hospital VBP Program. When evaluating the MHSCRC's request, we considered the relevant health outcomes for the State's hospitals as described in the MHSCRC's request and noted that they achieve or surpass the current national results for Hospital VBP FY 2013 clinical process of care and HCAHPS dimensions. We also assessed closely-related clinical outcomes as measured by quality data reported through the Hospital IQR Program. For the FY 2013 Hospital VBP Program, however, we did not assess the criterion ''cost savings'' as required by the statute, as the FY 2013 Hospital VBP Program does not use any efficiency measures and is a budget-neutral program pursuant to section 1886(o)(7)(A) of the Act. Maryland hospitals are therefore exempt from the FY 2013 Hospital VBP Program.

Beginning with the FY 2014 program, we are proposing to adopt a new procedure for submission of the report in order for a hospital within the State to be exempt from the Hospital VBP Program. Under this proposed procedure, if the State seeks an exemption with respect to a particular program year, it would need to submit a report that meets the requirements of section 1886(o)(1)(C)(iv) of the Act in a timeframe that allows it to be received by the Secretary on or before November 15 prior to the effective fiscal year (for example, the report seeking an exemption from the FY 2014 program would have to be received by the Secretary no later than November 15, 2012). We anticipate notifying the State, as well as each hospital for which the State has requested an exemption, of our decision whether to grant the request no later than 90 days following the exemption request deadline.

We will evaluate each exemption request to see if the State has demonstrated that it has implemented a similar program for participating hospitals that achieves or surpasses the measured results in terms of patient health outcomes and cost savings relative to the Hospital VBP Program.

We welcome public comment on our proposals.

14. Proposed Minimum Numbers of Cases and Measures for the FY 2015 Hospital VBP Program

a. Background

Section 1886(o)(1)(C)(ii)(III) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for the fiscal year. Section 1886(o)(1)(C)(ii)(IV) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year.

In the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531), we finalized minimum numbers of 10 cases and 4 measures in the clinical process of care domain and 100 completed HCAHPS surveys for the patient experience of care domain. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74532 through 74534), we finalized a minimum number of 10 cases for the three 30-day mortality measures. We also finalized a minimum number of 2 measures with respect to the Outcome domain. In both rules, we finalized a policy that hospitals must have sufficient cases and measures in all domains in order to receive a TPS.

b. Proposed Minimum Numbers of Cases and Measures for the FY 2015 Outcome Domain

As described further above, we are proposing a 9-month performance period for the three 30-day mortality measures for the FY 2015 Hospital VBP Program. We have reassessed the previously finalized 10 case minimum threshold for the three 30-day mortality measures (76 FR 74533 through 74534), as well as reexamining the independent analyses by Brandeis University and Mathematica Policy Research, when considering these three measures' proposed addition. We recognize that the proposed 9-month performance period for these measures would increase the number of hospitals with insufficient cases on the measure (that is, between 10 and 24) to several hundred hospitals, based on past information. We believe that this proposal fulfills our intent to link patient outcomes with payment, relative to reliability and seasonality concerns from using a 9-month performance period.

In order to ensure that the mortality measure scores remain sufficiently reliable, we are proposing to adopt a 25-case minimum for the three 30-day mortality measures for FY 2015. We believe that this proposal will ensure relatively more reliable measure data than could be obtained with the 10-case minimum as has been finalized for FY 2014 given the relatively shorter proposed performance period. As described above, while this may result in fewer hospitals receiving scores on the mortality measures, we have proposed to reallocate domain weighting for hospitals with fewer domain scores than the total number of finalized domains. By doing so, we believe we are appropriately allowing as many hospitals as possible to participate in the Hospital VBP Program while also ensuring reliable quality measure and quality domain data.

We note that this proposed minimum number of cases is higher than has been finalized for other types of measures such as clinical process of care measures. However, we note that clinical process of care measures are not risk-adjusted and are not outcome-based. Because those measures do not require statistical adjustment to estimate hospital-specific differences in case mix, we believe that the relatively smaller case minimum is acceptable for clinical process of care measures.

For the AHRQ PSI composite measure, we are proposing to adopt AHRQ's methodology, which uses three cases for any of the underlying indicators as a case minimum. For the CLABSI measure, we are proposing to adopt CDC's minimum case criteria, which calculates a standardized infection ratio for a hospital on the CLABSI measure if the hospital has 1 predicted infection during the applicable period. We believe that the measure stewards' methodologies for constructing reliable measure data are most appropriate for use in the Hospital VBP Program. Further information on these measures may be found on the QualityNet Web site.

In the CY 2012 OPPS/ASC final rule with comment period, we concluded based on an independent analysis that the minimum number of measures that a hospital must report in order to receive a score on the outcome domain is two measures. We continue to believe that this minimum number is appropriate for the expanded outcome domain because adding measure scores beyond the minimum number of measures has the effect of enhancing the domain score's reliability. For that reason, we are proposing to adopt it for the FY 2015 Hospital VBP Program.

We welcome public comment on these proposals.

c. Proposed Medicare Spending per Beneficiary Measure Case Minimum

As required by section 1886(o)(1)(C)(iii) of the Act, we obtained an independent analysis to help us determine the appropriate minimum number of cases for the Medicare spending per beneficiary measure. For this measure, we are proposing to interpret the term ''case'' in section 1886(o)(1)(C)(ii)(IV) of the Act as a Medicare spending per beneficiary episode. A Medicare spending per beneficiary episode is inclusive of all Part A and Part B payments from 3 days prior to a subsection (d) hospital admission through 30 days post discharge with certain adjustments and exclusions. The independent analysis examines the tradeoff between: Increasing the minimum number of episodes, which shrinks the confidence interval; and reducing the minimum number of episodes, which widens the confidence interval but enables more hospitals to receive a Medicare spending per beneficiary measure score. Because the distribution of Medicare spending per beneficiary episodes is skewed towards higher cost episodes, creating confidence intervals using statistical techniques that assume spending is normally and symmetrically distributed will not accurately describe the likelihood a hospital's true efficiency level falls within the confidence interval bounds.

To account for these statistical issues, the independent analysis uses a simulation-based (''non-parametric bootstrap'') methodology to measure how the confidence interval of the Medicare spending per beneficiary measure changes when the minimum episode threshold increases. Medicare spending per beneficiary is measured for an ''average'' hospital, where the ''average'' hospital case is considered one with a Medicare spending per beneficiary episode distribution that mimics that of the entire population of Medicare spending per beneficiary episodes. This methodology simulates the process of randomly drawing Medicare spending per beneficiary episodes from the population, and thus approximates the actual shape of the Medicare spending per beneficiary measure distribution from which confidence intervals are determined. By repeatedly calculating (in this case, 10,000 times for each minimum episode threshold) a Medicare spending per beneficiary measure for this simulated hospital under differing assumptions on the number of episodes observed, one

can create a confidence interval for the Medicare spending per beneficiary measure of this ''average'' hospital. The upper and lower bounds of the 95 percent confidence interval indicates that 95 percent of the time, the hospital's Medicare spending per beneficiary measure will fall within this range when the minimum number of cases (the minimum episode threshold) is set at different levels. As the minimum episode threshold increases, the width of the confidence interval becomes narrower, but the number of hospitals receiving a Medicare spending per beneficiary measure score decreases.

In developing our proposal, we considered two options for setting the minimum number of cases for the Medicare spending per beneficiary measure: (1) Setting the minimum number of cases at 25; and, (2) setting the minimum number of cases at 50.

We focused on these minimums because we believe that either of them provides a sufficiently narrow range at the 95 percent confidence interval. The independent analysis concludes that if the minimum number of cases is set at 25, then 95 percent of the time a hospital with an average underlying efficiency level (that is, 1.0) would receive an Medicare spending per beneficiary measure score between 0.81 and 1.23. Further, a minimum number of 25 cases would enable 97.8 percent of hospitals to receive a Medicare spending per beneficiary measure score, based on historical data. The analysis also showed that the alternative minimum of 50 cases would result in a 95 percent confidence interval range of 0.86 to 1.16 and would enable 95.9 percent of hospitals to receive a Medicare spending per beneficiary measure score, based on historical data.

After considering the options outlined above, we are proposing to use 25 as the minimum number of cases required in order to receive a score for the Medicare spending per beneficiary measure. We believe that using a minimum number of 25 cases achieves an appropriate balance of our interest in allowing the maximum possible number of hospitals the opportunity to receive a score on the Medicare spending per beneficiary measure and maintaining a sufficiently narrow range for the 95 percent confidence interval. Additionally, although we are proposing to use a minimum of 25 cases for the Medicare spending per beneficiary measure, we also seek comment on whether using a minimum of 50 cases better reaches our goal of maintaining a meaningful measure of Medicare spending across hospitals.

15. Immediate Jeopardy Citations

Under section 1886(o)(1)(C)(ii)(II) of the Act, a hospital is excluded from the Hospital VBP Program if it has been cited by the Secretary during the performance period for deficiencies that pose immediate jeopardy to the health or safety of patients. In the Hospital Inpatient VBP Program final rule (76 FR 26528 through 26530), we finalized our interpretation of this provision to mean that any hospital that we cite through the Medicare State Survey and Certification process for deficiencies during the performance period that pose immediate jeopardy to patients will be excluded from the Hospital VBP Program for the fiscal year. We also finalized our proposal to use the definition of the term ''immediate jeopardy'' that appears in 42 CFR 489.3.

In proposed § 412.160 we are proposing to define ''immediate jeopardy'' in the same way as that term is defined in 42 CFR Part 489, which governs provider agreements and supplier approval. We believe that the language in section 1886(o)(1)(C)(ii)(II) of the Act referring to a hospital having been ''cited'' for deficiencies posing an immediate jeopardy is a reference to the process by which CMS, through agreements with State survey agencies, surveys or inspects hospitals for compliance with the hospital conditions of participation at 42 CFR Part 482 or Emergency Medical Treatment and Labor Act (EMTALA) regulations at § 489.24, and issues deficiency citations for non-compliance with Federal health, safety and quality standards. The survey process is governed by provisions found in 42 CFR Part 488, Survey, Certification and Enforcement Procedures. Further, provisions at 42 CFR Part 489, Provider Agreements and Supplier Approval, define the term ''immediate jeopardy'' at § 489.3; authorize us at § 489.53(a)(3) to terminate the Medicare provider agreement for the hospital's failure to meet the conditions of participation; authorize us at § 489.53(b) to terminate the Medicare provider agreement of a hospital that fails to meet the EMTALA regulatory requirements; and provide at § 489.53(d)(2)(i) for a shortened advance notice to the public of the termination when a hospital with an emergency department is in violation of EMTALA requirements and the violation poses immediate jeopardy. Therefore, we believe that the term ''immediate jeopardy'' should be defined in our Hospital VBP Program regulations in the same manner as it is defined for the purpose of survey, certification, enforcement, and termination procedures.

In § 412.160, we are proposing to define the phrase ''cited for deficiencies that pose immediate jeopardy.'' We are proposing a definition in order to avoid potential ambiguities about the terms ''cited'' and ''deficiencies.'' There are several ways in which a hospital might be found to have an immediate jeopardy situation. Appendix Q of the State Operations Manual (SOM), Pub. No. 100–07, provides guidance to the State survey agencies on our policies concerning the identification and citation of immediate jeopardy and subsequent enforcement actions. The most common way in which an immediate jeopardy situation is identified is when a surveyor or team of surveyors is in the process of conducting a survey at the hospital and accurately identifies those situations which immediately jeopardize the health and safety of patients. Surveyors may be expected, according to State protocols, to consult immediately with their supervisors before declaring an immediate jeopardy, and in cases involving hospitals deemed to meet the conditions of participation based on their accreditation, the State must first consult with the CMS Regional Office (RO).

Once an immediate jeopardy is declared, the hospital's management is informed and expected to take steps to remove the immediate jeopardy, preferably before the survey team concludes the on-site portion of its survey. If the hospital does not remove the immediate jeopardy while the survey team is on-site, it has 23 days to submit an acceptable plan of correction and have an onsite follow-up survey to confirm removal. If the hospital fails to remove the immediate jeopardy in a timely manner, we may terminate the hospital's Medicare provider agreement. There are also situations where a survey team does not declare an immediate jeopardy while on-site, but a subsequent supervisory or CMS RO review of the survey team's findings identifies an immediate jeopardy situation that should have been declared. In such cases, the hospital is promptly advised of the immediate jeopardy and given 23 days to submit an acceptable plan of correction and have an onsite follow-up survey to confirm removal of the immediate jeopardy. It can also happen that a supervisory or CMS RO review will conclude that the survey documentation does not support a finding of an immediate jeopardy, and in such cases no official immediate jeopardy citation will be issued.

It should be noted that removal of an immediate jeopardy is not necessarily the same as correction of the hospital's

noncompliance deficiencies. Removal may be accomplished by an interim measure while the hospital works to create a systematic and permanent correction of its deficient practices.

The Form CMS–2567, Statement of Deficiencies and Plan of Correction, is issued after each survey of a hospital, even if only to indicate that no deficiencies were found during the survey (SOM Section 2728 and SOM Exhibit 7A, Principles of Documentation, Principle #1). The CMS–2567 form constitutes the official notice to a healthcare facility of the survey findings. Statements made by surveyors to the facility while they are on-site are always preliminary in nature. After surveyors have exited the facility, they prepare the Form CMS–2567 based on their observations and survey documentation. Their draft Form CMS–2567 is then subjected to a supervisory review and, in the case of hospitals that are deemed to meet the conditions of participation via accreditation and are being cited for serious noncompliance (that is, condition-level or immediate jeopardy citation), a CMS RO review. The Form CMS–2567 is not considered final until it is transmitted to the healthcare facility, either by the State survey agency or, in certain cases, the CMS RO.

In the case of a survey where an immediate jeopardy situation was found, the Form CMS–2567 must state that the facility was found to have immediate jeopardy. This is the case regardless of whether the immediate jeopardy was removed while the survey team was still on-site at the facility, although on-site removal will be noted if it occurred. Furthermore, it is standard survey practice to cite on the Form CMS–2567 all noncompliance deficiencies identified during a survey even when the healthcare facility corrects those deficiencies after they have been identified by a surveyor, but before the survey team exits the facility (SOM Exhibit 7A, Principles of Documentation, Principle #4).

We considered whether it would be reasonable to treat only those hospitals that failed to remove immediate jeopardy while a survey team was still on-site as having been ''cited for an immediate jeopardy'' solely for the purposes of the Hospital VBP Program. However, we concluded that this would not be equitable, since there are cases where an immediate jeopardy is identified after the survey team has left the hospital through a supervisory or CMS RO review, as described above. We also concluded this approach would not be consistent with the statutory requirement given that the Form CMS–2567 is the official notice to a healthcare facility of deficiencies found during a survey and in light of the fact that CMS includes references to the identification of an immediate jeopardy on the CMS–2567, regardless of when or if it was removed by the facility. We have, therefore, concluded that ''citation'' of an immediate jeopardy within the context of the Hospital VBP Program means the identification of an immediate jeopardy noted on the CMS–2567 that is issued to the hospital after a survey.

We also note that section 1886(o)(1)(C)(ii)(II) of the Act refers to the citation of plural ''deficiencies'' that pose immediate jeopardy and that this requires interpretation of its application to the Hospital VBP Program. We use an Automated Survey Processing Environment (ASPEN) system to catalog deficient practices identified during a survey and to generate the CMS–2567 that is issued to the hospital after the survey. To facilitate processing in the ASPEN system, we have subdivided the regulations applicable to each type of certified healthcare facility into specific ''tags,'' each one of which has corresponding interpretive guidelines in the applicable appendix of the SOM. Hospital tags are found in Appendix A. The ASPEN system also differentiates between ''condition'' and ''standard'' tags for non-long term care enforcement, since it is essential to know whether or not identified noncompliance is found at the condition-level, that is, whether it is considered substantial noncompliance. Each hospital condition of participation has its own condition tag. There are also a varying number of ''standard'' tags within each condition. The number of standard tags identified in the SOM Appendix does not correspond to the number of individual ''standards'' required in the regulations; usually there are more tags than standards, because standards may involve multiple items or requirements under specific conditions of participation that lend themselves to separate evaluation.

While we understand that each tag identified in a CMS–2567 may be viewed as a separate deficiency, we also recognize that the division of the regulations for each ''condition'' and ''standard'' into individual tags was to facilitate the survey and certification process for surveyors. Moreover, in general a set of documented deficient practices that constitute immediate jeopardy would be cited at least in two tags, since there must be a citation at the condition-level to indicate substantial noncompliance, along with citation of any pertinent standard-level tags, which are subsets of the condition tags. We do not believe it was the intent of the statute to count each of these tags related to the same set of circumstances or practices as separate deficiencies under the Hospital VBP Program.

We have concluded, therefore, that a more reasonable interpretation of the Hospital VBP statute is to view each hospital survey for which the CMS–2567 form cited immediate jeopardy as a deficiency. Thus, a hospital would have to have been cited on a CMS–2567 for immediate jeopardy on at least two surveys during the performance period in order to be considered as having multiple deficiencies that pose immediate jeopardy. Accordingly, we are proposing to define in our regulations the term ''cited for deficiencies that pose immediate jeopardy'' under the Hospital VBP Program as meaning that, during the applicable performance period, the hospital had more than one survey for which it was cited for an immediate jeopardy on the Form CMS–2567, Statement of Deficiencies and Plan of Correction.

As required by the statute, hospitals cited during the performance period for multiple deficiencies that pose immediate jeopardy to the health or safety of patients would be excluded from the Hospital VBP Program for the applicable fiscal year. Because we sometimes adopt different performance periods for different measures for purposes of the same program year, we are proposing to exclude hospitals cited for such deficiencies during any of the finalized performance periods for the applicable program year for purposes of that interpretation.

We welcome public comment on this interpretation of the immediate jeopardy exclusion and on our proposals.

D. Long-Term Care Hospital Quality Reporting (LTCHQR) Program

1. Statutory History

In accordance with section 1886(m)(5) of the Act, as added by section 3004 of the Affordable Care Act, the Secretary established the Long-Term Care Hospital Quality Reporting (LTCHQR) Program. Under the LTCHQR Program, for rate year 2014 and each subsequent rate year, in the case of a long-term care hospital (LTCH) that does not submit data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a rate year, any annual update to a standard Federal rate for discharges for the hospital during the rate year, and after application of section 1886(m)(3) of the Act, shall be reduced by two percentage points.

Section 1886(m)(5)(D)(iii) of the Act requires the Secretary to publish the selected measures for the LTCHQR Program that will be applicable with respect to FY 2014 no later than October 1, 2012.

Under section 1886(m)(5)(D)(i) of the Act, the quality measures for the LTCHQR Program are measures selected by the Secretary that have been endorsed by an entity that holds a contract with the Secretary under section 1890(a) of the Act, unless an exception under section 1886(m)(5)(D)(ii) of the Act applies. This contract is currently held by the National Quality Forum (NQF). Section 1886(m)(5)(D)(ii) of the Act provides that an exception may be made 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 that holds a contract with the Secretary under section 1890(a) of the Act. In such a case, section 1886(m)(5)(D)(ii) of the Act authorizes the Secretary to specify a measure(s) 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. The LTCHQR Program was implemented in section VII.C. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756).

2. LTCH Program Measures for the FY 2014 Payment Determination and Subsequent Fiscal Years Payment Determinations

a. Proposed Process for Retention of LTCHQR Program Measures Adopted in Previous Payment Determinations

For the LTCHQR Program, we are proposing that once a quality measure is adopted, it is retained for use in subsequent fiscal year payment determinations, unless otherwise stated. For the purpose of streamlining the rulemaking process, we are proposing that when we initially adopt a measure for the LTCHQR Program for a payment determination, this measure is automatically adopted for all subsequent payment determinations or until we propose to remove, suspend, or replace the measure. Quality measures may be considered for removal by CMS if: (1) Measure performance among LTCHs is so high and unvarying that meaningful distinctions in improvements in performance can be 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) a more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic is available; (6) if a measure that is more strongly associated with desired patient outcomes for the particular topic is available; or (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm. For any such removal, the public will be given a chance to comment through the annual rulemaking process. However, if there is reason to believe continued collection of a measure raises potential safety concerns, we will take immediate action to remove the measure from LTCHQR Program and not wait for the annual rulemaking cycle. Such measures will be promptly removed with LTCHs and the public being immediately notified of such a decision through the usual LTCHQR Program communication channels, including listening session, memos, email notification, and Web posting and their removal formally announced in the next annual rulemaking cycle.

We are inviting public comment on our proposal that once a quality measure is adopted, it is retained for use in the subsequent fiscal year payment determinations unless otherwise stated.

b. Proposed Process for Adoption of Changes to LTCHQR Program Measures

As mentioned previously, quality measures selected for the LTCHQR Program must be endorsed by the NQF unless they meet the statutory criteria for exception. The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other healthcare stakeholder organizations. The NQF was established to standardize healthcare quality measurement and reporting through its consensus development process (*http://www.qualityforum.org/About_NQF/Mission_and_Vision.aspx*). The NQF undertakes review of: (a) New quality measures and national consensus standards for measuring and publicly reporting on performance, (b) regular maintenance processes for endorsed quality measures, (c) measures with time limited endorsement for consideration of full endorsement, and (d) ad hoc review of endorsed quality measures, practices, consensus standards, or events with adequate justification to substantiate the review (*http://www.qualityforum.org/Measuring_Performance/Ad_Hoc_Reviews/Ad_Hoc_Review.aspx*).

The NQF solicits information from measure stewards for annual reviews and in order to review measures for continued endorsement in a specific 3-year cycle. In this measure maintenance process, the measure steward is responsible for updating and maintaining the currency and relevance of the measure and for confirming existing specifications to NQF on an annual basis. As part of the ad hoc review process, the ad hoc review requester and the measure steward are responsible for submitting evidence for review by a NQF Technical Expert panel which, in turn, provides input to the Consensus Standards Approval Committee which then makes a decision on endorsement status and/or specification changes for the measure, practice, or event.

Through NQF's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, changes to exclusions to the patient population, definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act. In this proposed rule, we are proposing that if the NQF updates an endorsed measure that we have adopted for the LTCHQR Program in a manner that we consider to not substantially change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we would revise the LTCH Quality Reporting Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We would also post the updates on our LTCH Quality Reporting Web site at: *http://www.cms.gov/LTCH–Quality-Reporting/*. We would provide sufficient lead time for LTCH to implement the changes where changes to the data collection systems would be necessary.

We would continue to use the rulemaking process to adopt changes to measures that we consider to substantially change the nature of the measure. We believe that this proposal adequately balances our need to incorporate NQF updates to NQF-endorsed LTHCQR Program measures in

the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We invite public comment on this proposal.

3. Proposals for the FY 2014 LTCHQR Program

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756), we adopted three quality measures for the FY 2014 payment determination as listed in the following table:

PREVIOUSLY FINALIZED QUALITY MEASURES FOR THE FY 2014 PAYMENT DETERMINATION

NQF #0138	Urinary Catheter-Associated Urinary Tract Infection [CAUTI] rate per 1,000 urinary catheter days, for Intensive Care Unit [ICU] Patients.
NQF #0139	Central Line Catheter-Associated Blood Stream Infection (CLABSI) Rate for ICU and High-Risk Nursery (HRN) Patients.
NQF #0678	Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay).

The three measures finalized for FY 2014 payment determination were NQF-endorsed at the time, although not for the LTCH setting. We also stated that we expected the NQF would review some of these measures for applicability to the LTCH setting and we anticipated this review might result in modifications to one or more of the measures.

As part of its endorsement maintenance process, under NQF's Patient Safety Measures Project (*http://www.qualityforum.org/projects/patient_safety_measures.aspx*), the NQF reviewed the CAUTI and CLABSI measures previously adopted and expanded the scope of endorsement to include additional care settings, including LTCHs. The original NQF-endorsed numbers were retained for these two expanded measures, but the measures were retitled to reflect the expansion of the scope of endorsement: #0138 Urinary Catheter-Associated Urinary Tract Infection [CAUTI] Rate Per 1,000 Urinary Catheter Days, for Intensive Care Unit [ICU] Patients is now titled National Health Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure and #0139 (Central Line Catheter-Associated Blood Stream Infection [CLABSI] Rate for ICU and High-Risk Nursery (HRN) Patients is now titled National Health Safety Network (NHSN) Central-Line Associated Blood Stream Infection (CLABSI) Outcome Measure (*http://www.qualityforum.org/News_And_Resources/Press_Releases/2012/NQF_Endorses_Patient_Safety_Measures.aspx*).

These expanded measures allow for the calculation of a standardized infection ratio (SIR).[120,121,122,123] For the remainder of this proposed rule, we refer to these measures as the CAUTI measure and CLABSI measure, respectively. We are proposing to adopt the changes to the NQF-endorsed CAUTI and CLABSI measures that we previously finalized for the FY 2014 payment determination, consistent with our stated intention to update these measures with changes resulting from NQF's review of the measures. Further, we are proposing to adopt the NQF-endorsed CAUTI measure and CLABSI measure for the FY 2015 payment determination and all subsequent fiscal year payment determinations. We also are proposing to incorporate any future changes to the CAUTI measure and CLABSI measure to the extent these changes are consistent with our proposal in section VIII.D.2.b. of this preamble to update measures.

We are proposing to retain the measure Percent of Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678), as finalized in the FY 2012 IPPS/LTCH PPS final rule for the FY 2014 payment determination, for FY 2015 and all subsequent fiscal year payment determinations. We also note that the Percent of Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) measure is undergoing NQF review for expansion in the scope of endorsement to include additional care settings, including LTCHs and, to the extent that the measure is updated in a manner that does not substantially change the nature of the measure, we would incorporate the updates consistent with our previous proposal to update measures. For the remainder of this proposed rule, we refer to this measure as the Pressure Ulcer measure. For more information on the history of this measure in the LTCHQR Program, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51753 through 51756).

We invite public comment on our proposal to adopt the revised CAUTI measure (NQF #0138) and CLABSI measure (NQF #0139) beginning with the FY 2014 payment determination. We also invite public comment to retain the Pressure Ulcer measure (NQF #0678) (which was finalized last year for the FY 2014 payment determination) for the FY 2015 payment determination and subsequent fiscal year payment determinations, as shown in the following table.

PROPOSED QUALITY MEASURES TO BE RETAINED FOR THE FY 2014 AND SUBSEQUENT FISCAL YEAR PAYMENT DETERMINATIONS

NQF #0138	National Health Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.
NQF #0139	National Health Safety Network (NHSN) Central Line Associated Blood Stream Infection (CLABSI) Outcome Measure.
NQF #0678	Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay).

[120] Centers for Disease Control and Prevention. (2012, January). Central Line-Associated Bloodstream Infection (CLABSI) Event. Retrieved from *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf.*

[121] National Quality Forum (2012). National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure. Retrieved from *http://www.qualityforum.org/QPS/0139.*

[122] Centers for Disease Control and Prevention. (2012, January). Catheter Associated Urinary Tract Infection Event. Retrieved from: *http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf.*

[123] National Quality Forum (2012). National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure. Retrieved from *http://www.qualityforum.org/QPS/0138.*

We are proposing to use the same data collection and submission methods finalized for these measures (CAUTI, CLABSI and Pressure Ulcer) in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51752 through 51756). We are proposing that data collection for these measures, if they be adopted in the FY 2013 IPPS/LTCH PPS final rule, remain the same for FY 2014 payment determination and all subsequent fiscal year payment determination.

For the proposed CAUTI measure and CLABSI measure, the measure specifications are available on the NQF Web site at: *http://www.qualityforum.org/QPS/0138* and *http://www.qualityforum.org/QPS/0139*, respectively. The data collection and reporting requirements for CAUTI and CLABSI are available at *http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf* and *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf*, respectively.

For the Pressure Ulcer measure, the data collection instrument is the Long-Term Care Hospital (LTCH) Continuity Assessment Record & Evaluation (CARE) Data Set available for download at *http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA–Listing-Items/CMS1252160.html*.[124] Because there are no mandatory standardized data sets being used in LTCHs, we created a new data set, the LTCH CARE Data Set, for use in LTCHs for data reporting for the Pressure Ulcer measure beginning October 1, 2012. This data set incorporates data items contained in other, standardized and clinically established pressure ulcer data sets, including but not limited to the Minimum Data Set 3.0 (MDS 3.0) and CARE data set (Continuity Assessment Records & Evaluation). Beginning on October 1, 2012, LTCHs will begin to use a data collection document entitled the ''LTCH CARE Data Set'' as the vehicle by which to collect the data for the Pressure Ulcer measure for the LTCHQR Program. This data set consists of the following components: (1) Pressure ulcer documentation; (2) selected covariates related to pressure ulcers; (3) patient demographic information; and; (4) a provider attestation section.

The measure specifications for the LTCH CARE Data Set are available on our Web site for the LTCHQR Program at *http://www.cms.gov/LTCH-Quality-Reporting/*. The LTCH CARE Data Set Technical Specifications Draft Version 1.00.1 for the Pressure Ulcer measure are available at the LTCH Quality Reporting Technical Information Web page *http://www.cms.gov/LTCH-Quality-Reporting/05_LTCHTechnical Information.asp#TopOfPage*.

For detailed discussions of the history of the LTCHQR Program, including the statutory authority and further details on the three measures previously finalized for FY 2014 payment determination, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756). We have reproduced portion of the data collection and submission timeline finalized for FY 2014 payment determination in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756) in the following table.

TIMELINE FOR SUBMISSION OF DATA FOR THE LTCHQR PROGRAM FY 2014 PAYMENT DETERMINATION

Data collection timeframe: calendar year (CY) 2012	Final submission deadline for data related to the LTCH quality reporting program FY 2014 payment determination
Q4 (October 1–December 31, 2012).	May 15, 2013.

We refer readers to section VIII.D.5. of this preamble for the proposed timeline for data submission under the LTCHQR Program for the FY 2015 payment determination.

4. Proposed LTCHQR Program Quality Measures for the FY 2016 Payment Determinations and Subsequent Fiscal Years Payment Determinations

a. Considerations in Updating and Expanding Quality Measures under the LTCHQR Program for FY 2016 and Subsequent Payment Update Determinations

We believe that development of a LTCHQR Program that is successful in promoting the delivery of high quality healthcare services in LTCHs is paramount. We seek to adopt measures for the LTCHQR Program that promote better, safer, and more efficient care. Our measure development and selection activities for the LTCHQR Program take into account national priorities, such as those established by the National Priorities Partnership (*http://www.nationalprioritiespartnership.org/*), HHS Strategic Plan (*http://www.hhs.gov/secretary/about/priorities/priorities.html*), and the National Strategy for Quality Improvement in Healthcare (*http://www.healthcare.gov/center/reports/quality03212011a.html*). To the extent practicable, we have sought to adopt measures that 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.

In addition, we consider input from the multi-stakeholder group, the Measures Application Partnership (MAP) (*http://www.qualityforum.org.map/*), in selecting measures for the LTCHQR program. Section 1890A(a)(1) of the Act, as added by section 3014(a) of the Affordable Care Act, requires the entity with a contract under section 1890(a) of the Act, currently NQF, to convene multi-stakeholder groups to provide input to the Secretary on the selection of quality and efficiency measures. Section 1890A(a)(3) of the Act, as added by section 3014(b) of the Affordable Care Act, further requires the entity with a contract under section 1890(a) of the Act to transmit the input of the multistakeholder groups to the Secretary not later than February 1 of each year, beginning in 2012. Section 1890A(a)(4) of the Act requires the Secretary to take into consideration the input of the multi-stakeholder groups in selecting quality and efficiency measures. The MAP is the public-private partnership comprised of multi-stakeholder groups convened by the NQF for the primary purpose of providing input on measures as required by section 1890A(a)(3) of the Act. The MAP's input on quality and efficiency measures was transmitted to the Secretary and is available at (*http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885*). As required by section 1890A(a)(4) of the Act, we considered the MAP's recommendations in selecting quality and efficiency measures for the LTCHQR Program.

b. Proposed New LTCHQR Program Quality Measures Beginning with the FY 2016 Payment Determination

For the FY 2016 payment determination and subsequent fiscal year payment determinations, in addition to retaining the three previously discussed measures (CAUTI measure, CLABSI measure and Pressure Ulcer measure), we are proposing to adopt five additional quality measures for the LTCHQR Program, see table below. Our proposal to add these five measures is part of our effort to promote overarching health care aims and goals in an effective and meaningful manner.

[124] The LTCH CARE Data Set, the data collection instrument that will be used to submit data on this measure, is currently under Paperwork Reduction Act (PRA) review by the Office of Management and Budget. It is discussed in a PRA notice that appeared in the September 2, 2011 **Federal Register** (76 FR 54776). The file number for the LTCH PRA package is CMS–10409.

We also seek to minimize the burden of data collection for LTCHs.

PROPOSED NEW QUALITY MEASURES FOR THE FY 2016 LTCHQR PROGRAM PAYMENT DETERMINATION AND SUBSEQUENT PAYMENT DETERMINATIONS

NQF measure ID	Measure title
NQF #0680	Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay).
NQF #0682	Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay).
NQF #0431	Influenza Vaccination Coverage among Healthcare Personnel.
NQF #0302	Ventilator Bundle.
Not NQF endorsed	Restraint Rate per 1,000 Patient Days.

(1) Proposed New Quality Measure #1 for the FY 2016 Payment Determination and Subsequent Fiscal Years Payment Determinations: Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)

According to the CDC, as of 2011, there are on average over 200,000 hospitalizations due to influenza every year.[125] The Agency for Healthcare Research and Quality (AHRQ) reports that, in 2004, there were more than 37,000 hospitalizations in which influenza was noted during the stay. For over 21,000 of these hospitalizations, influenza was listed as the primary diagnosis. The aggregate hospital costs for these roughly 21,000 hospitalizations were estimated at $146 million.[126]

Although influenza is prevalent among all population groups, the rates of death and serious complications related to influenza are highest among those age 65 and older and those with medical complications that put them at higher risk. The CDC reports that an average of 36,000 Americans die annually from influenza and its complications, and most of these deaths are among people 65 years of age and over.[127] In 2004, 70,000 deaths were caused by influenza and pneumonia, and more than 85 percent of these were among the elderly.[128] Given that many individuals receiving health care services in LTCHs are elderly and/or have several medical conditions, many LTCH patients are within the target population for the influenza vaccination.[129,130] Healthy People 2010 (Objective 14–29) and Healthy People 2020 (Objective IID–12.8) each set a goal of 90 percent of adults vaccinated against pneumococcal disease in long-term care facilities.[131,132] However, among adults age 65 years and older, only 72.1 percent were vaccinated during the 2006–2007 influenza season and only 69.6 percent of adults age 65 years and older were vaccinated during the 2009–2010 influenza season.[133,134] According to information currently available on the Nursing Home Compare Web site (*http://www.medicare.gov/NHCompare*), the national average for the percentage of short-stay residents given the influenza vaccine is roughly 82 percent.[135] No comparable information is currently available on patients in the LTCH setting.

In light of the evidence outlined previously, particularly that many individuals receiving care in the LTCH setting are within the target population for influenza vaccination, we are proposing NQF #0680, Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay), for application in the LTCHQR Program for the FY 2016 payment determination and subsequent fiscal year payment determinations. We note that this measure is currently endorsed for short-stay nursing home residents, but believe this measure is highly relevant for the LTCH setting because, as stated above, many patients receiving care in the LTCH setting are elderly and within the target population for influenza vaccination. The MAP supports the direction of this measure and believes it is an important aspect of care in LTCHs.[136]

Section 1886(m)(5)(D)(ii) of the Act, the exception authority 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 NQFs consensus endorsed measures and were unable to identify any NQF-endorsed measures for influenza vaccination in the LTCH setting. We are unaware of any other measures for influenza

[125] Centers for Medicare & Medicaid Services (2011, May). Adult immunization: Overview. Retrieved from *https://www.cms.gov/adultImmunizations/*.

[126] Milenkovic M, Russo CA, Elixhauser A. (2006). Hospital stays for influenza, 2004 (Healthcare Cost and Utilization Project statistical brief no. 16). Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from *http://www.hcup-us.ahrq.gov/reports/statbriefs/sb16.pdf*.

[127] Centers for Medicare & Medicaid Services (2011, May). Adult Immunization: Overview. Retrieved from *https://www.cms.gov/Immunizations/*.

[128] Gorina Y, Kelly T, Lubitz J, *et al.* (2008, February).Trends in influenza and pneumonia among older persons in the United States. Aging Trends no. 8. Retrieved from *http://www.cdc.gov/nchs/data/ahcd/agingtrends/08influenza.pdf*.

[129] Centers for Disease Control and Prevention. (2008, September). Influenza e-brief: 2008–2009 flu facts for policymakers. Retrieved from *http://www.cdc.gov/washington/pdf/flu_newsletter.pdf*.

[130] Zorowitz, RD. Stroke Rehabilitation Quality Indicators: Raising the Bar in the Inpatient Rehabilitation Facility. Topics in Stroke Rehabilitation 2010; 17 (4):294–304.

[131] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (n.d.). Healthy People 2010 archive. Retrieved from *http://www.healthypeople.gov/2010/*.

[132] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2011, June). Healthy People 2020: Immunization and Infectious Diseases. Retrieved from *http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=23*.

[133] Centers for Disease Control and Prevention. (2008). State specific influenza vaccination coverage among adults—United States, 2006–2007 influenza season. MMWR, 57(38), 1033–1039. Retrieved from *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5738a1.htm*.

[134] Centers for Disease Control and Prevention (2011, May). Seasonal influenza (flu): final estimates for 2009–10 seasonal influenza and influenza A (H1N1) 2009 monovalent vaccination coverage—United States, August 2009 through May 2010. Retrieved from *http://www.cdc.gov/flu/professionals/vaccination/coverage_0910estimates.htm*.

[135] Centers for Medicare & Medicaid Services. (2011). Nursing Home Compare. Available from *http://www.medicare.gov/NHCompare/*.

[136] National Quality Forum (2012) Input on Measures for Consideration by HHS for 2012 Rulemaking. Available from *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885*. pp. 105.

vaccination in the LTCH setting that have been approved by a voluntary consensus standards body and endorsed by NQF. We are proposing to adopt the NQF-endorsed measure the Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680) for application in the LTCH setting for the LTCHQR Program under the Secretary's authority to select non-NQF measures. This proposal is also consistent with the 2008 NQF steering committee recommendation that ''in the interest of standardization and minimizing the burden for those implementing and using measures, measure harmonization is an important consideration in evaluating and recommending measures for endorsement.'' [137] Data on this measure is currently collected and reported as part of the Nursing Home Quality Initiative.

We are proposing that data for this measure will be collected using the same data collection and submission framework that we finalized for the FY 2014 payment determination.[138] We intend to revise the LTCH CARE data set to include new items which assess patients' influenza vaccination status should this proposed measure be adopted. These items will be based on the items from the Minimum Data Set (MDS) 3.0 items.[139] The specifications and data elements for this proposed measure are available in the MDS 3.0 QM User's Manual available on our Web site at: *https://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf.*[140]

By building on the existing reporting and submission infrastructure for LTCHs, such as the LTCH CARE Data Set, which will be used for data collection beginning October 1, 2012, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program. We are proposing that the data collection would cover the period from October 1 through March 31 of each year, which corresponds with how NQF specifies this measure as well as other endorsed influenza vaccination measures. We refer readers to section VIII.D.6. of this preamble for more information on data collection and submission.

We are inviting public comment on this proposed measure for the FY 2016 payment determination and subsequent FYs payment determinations.

(2) Proposed New LTCH Quality Measure #2 for the FY 2016 Payment Determination and Subsequent Fiscal Years Payment Determinations: Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay) (NQF #0682) According to the CDC, pneumococcal disease kills more people in the United States each year than all other vaccine-preventable diseases combined.[141] In 2006, all possible pneumonia diagnoses (including viral, bacterial, and unspecified organisms) killed 55,477 people in the United States and were responsible for 1,232,999 hospital discharges.[142]

Older people and those with chronic health conditions are at higher risk for pneumococcal disease. In 2011 there were more than 40,000 cases of invasive pneumococcal disease in the United States, and approximately one-third of these occurred among persons ages 65 years and older.[143] A 2011 Medicare Payment Advisory Committee (MedPAC) report found that pneumonia is among the top 20 most common Medicare Severity Long-Term Care Diagnosis-Related Groups (MS–LTC–DRG).[144] In 2005, Medicare paid an average of $6,342 per hospital discharge for pneumonia-related short-stay hospitalizations.[145] Death related to pneumonia also affects the elderly at a higher rate. In 2004, 70,000 deaths were caused by influenza and pneumonia, and more than 85 percent of these were amongst the elderly.[146]

Individuals in the LTCH setting are at especially high risk of contracting pneumonia as a complication of another medical condition, such as stroke, previous or recent surgery, or ventilation—all of which are conditions for which patients may spend some of their recovery time in the LTCH.[147,148,149]

Healthy People 2010 (Objective 14–29f) and Healthy People 2020 (Objective IID–13.3) each set a goal of 90 percent of adults vaccinated against pneumococcal disease in long-term care facilities.[150,151] However, estimated pneumococcal vaccination coverage remains below 50 percent in recommended high-risk groups.[152] No comparable information is currently available on patients in the LTCH setting.

In light of the previously described data which we believe reflects the significant impact pneumonia has on Medicare beneficiaries in the LTCH setting, we are proposing a quality measure on the pneumococcal vaccine. Specifically, we are proposing the measure Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay) (NQF #0682) for application in the

[137] National Quality Forum (2008, December). National Voluntary Consensus Standards for Influenza and Pneumococcal Vaccinations. Available from *http://www.qualityforum.org/Publications/2008/12/National_Voluntary_Consensus_Standards_for_Influenza_and_Pneumococcal_Immunizations.aspx.*

[138] The LTCH CARE Data Set, the proposed data collection instrument that would be used to submit data on this proposed measure, is currently under Paperwork Reduction Act (PRA) review by the Office of Management and Budget. It is discussed in a PRA notice that appeared in the September 2, 2011 **Federal Register** (76 FR 54776). The file number for the LTCH PRA package is CMS–10409.

[139] Centers for Medicare & Medicaid Services. MDS 3.0 Item Subsets V1.10.4 for the April 1, 2012 Release. Retrieved from *https://www.cms.gov/NursingHomeQualityInits/30_NHQIMDS30TechnicalInformation.asp.*

[140] Centers for Medicare and Medicaid Services (2012, March). MDS 3.0 Quality Measures User's Manual. V5.0. pp. 15. Retrieved from: *https://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf.*

[141] Centers for Disease Control and Prevention. (2009, March). Pneumococcal polysaccharide vaccine: What you need to know. Retrieved from *http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-ppv.pdf.*

[142] Centers for Disease Control and Prevention, National Center for Health Statistics. (various years 1988–2006). National Hospital Discharge Survey. Available from *http://www.cdc.gov/nchs/nhds/nhds_publications.htm#nhds.*

[143] Centers for Disease Control and Prevention. (2011). Pneumococcal diseases. In The Pink Book: epidemiology and prevention of vaccine preventable diseases (pp. 233–248). Retrieved from: *http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/pneumo.pdf.*

[144] Medicare Payment Advisory Committee (MedPac). (2011, March) Long-term care hospital services. In Report to the Congress: Medicare payment Policy (pp 231–456). Washington, DC. Available from *http://www.medpac.gov/documents/Mar11_EntireReport.pdf.*

[145] Health Care Financing Review. Statistical supplement no. 293. (2007). Baltimore, MD: Centers for Medicare and Medicaid Services.

[146] Gorina Y, Kelly T, Lubitz J, *et al.* (2008, February). Trends in influenza and pneumonia among older persons in the United States. Aging Trends no. 8. Retrieved from *http://www.cdc.gov/nchs/data/ahcd/agingtrends/08influenza.pdf.*

[147] Fagon JY, Chastre J, Hance AJ, Montravers P, Novara A, Gibert C. Nosocomial pneumonia in ventilated patients: a cohort study evaluating attributable mortality and hospital stay. Am J Med 1993;94:281–8.

[148] Gorina Y, Kelly T, Lubitz J, *et al.* (2008, February). Trends in influenza and pneumonia among older persons in the United States. Aging Trends no. 8. Retrieved from *http://www.cdc.gov/nchs/data/ahcd/agingtrends/08influenza.pdf.*

[149] Centers for Disease Control and Prevention. (2011, June). Post-procedure pneumonia (PPP) event. Retrieved from *http://www.cdc.gov/nhsn/PDFs/pscManual/10pscPPPcurrent.pdf.*

[150] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (n.d.). Healthy People 2010 archive. Retrieved from *http://www.healthypeople.gov/2010/.*

[151] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2011, June). Healthy People 2020: Immunization and infectious diseases. Retrieved from *http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=23.*

[152] Centers for Disease Control and Prevention, National Center for Health Statistics. (various years 1988–2006). National Hospital Discharge Survey.

LTCHQR Program for the FY 2016 payment determination and subsequent fiscal year payment determinations. We recognize that the NQF has endorsed this measure for short stay nursing home residents but believe this measure is highly relevant to LTCHs as described previously. This measure reports the percentage of short-stay nursing home residents who were assessed and appropriately given the pneumococcal vaccine (PPV) during a 12-month reporting period. We are proposing this measure because, as stated previously, patients in LTCHs are at high risk of contracting pneumonia as a complication of another medical condition. The MAP supports the direction of this measure and believes it is an important aspect of care in LTCHs.[153]

As indicated previously, section 1886(m)(5)(D)(ii) of the Act provides the Secretary with authority to adopt non-NQF-endorsed measures. We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed measures for pneumococcal vaccination in the LTCH setting. We are unaware of any other measures for pneumococcal vaccination in the LTCH setting that have been approved by voluntary consensus standards bodies and endorsed by NQF. We are proposing to adopt application of the Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay) (NQF #0682) for application in the LTCHQR Program. This application is also consistent with the 2008 NQF steering committee recommendation that ''in the interest of standardization and minimizing the burden for those implementing and using measures, measure harmonization is an important consideration in evaluating and recommending measures for endorsement.'' [154] Data for this measure are currently collected and reported as part of the Nursing Home Quality Initiative.

The specifications and data elements for this proposed measure are available in the MDS 3.0 QM User's Manual available on our Web site at: *https://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf*.[155]

We are proposing that submission of data for this measure will be incorporated into the existing data collection and submission framework for LTCHs that we adopted for the FY 2014 payment determinations.[156] We intend to revise the LTCH CARE data set to include new items which assess patient's pneumococcal vaccination status should this proposed measure be adopted. These items will be based on the items from the Minimum Data Set (MDS) 3.0 items.[157]

By building on the existing LTCH reporting and submission infrastructure, such as the LTCH CARE data set, which will be used by LTCHs for data collection beginning October 1, 2012, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program. For additional information of data collection and submission, we refer readers to section VIII.D.6. of this preamble. We invite public comment on this proposed measure for the FY 2016 payment determination and subsequent fiscal years.

(3) Proposed New LTCH Quality Measure #3 for the FY 2016 Payment Determination and Subsequent Fiscal Years Payment Determinations: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)

As previously noted, influenza virus infections are a major source of preventable mortality in the Medicare population. Between 1976 and 2007, influenza virus infections resulted in an average of 23,607 influenza-related deaths with a yearly range of 3,349 to 48,615 deaths, with approximately 90 percent of these deaths occurring among persons aged 65 or older.[158] Health care personnel are at risk for both acquiring influenza from patients and exposing it to patients, and health care personnel often come to work when ill.[159] One early report of health care personnel influenza infections during the 2009 H1N1 influenza pandemic estimated 50 percent of infected health care personnel had contracted the influenza virus from patients or coworkers in the healthcare setting.[160]

The Advisory Committee on Immunization Practices (ACIP) recommends that all health care personnel get an influenza vaccine every year to protect themselves and patients.[161] Even though levels of influenza vaccination among health care personnel have slowly increased over the past 10 years, less than 50 percent of health care personnel each year received the influenza vaccination until the 2009–2010 season, when an estimated 62 percent of health care personnel got a seasonal influenza vaccination. In the 2010–2011 season, 63.5 percent of health care personnel reported influenza vaccination. Healthy People 2020 (Objective IID–12.9) set a goal of 90 percent for health care personnel influenza vaccination.[162] It is important to measure influenza vaccination of health care personnel every season to track progress toward this objective and to make sure that health care personnel and their patients are protected from influenza.[163] Increased influenza vaccination coverage among health care personnel is expected to result in reduced morbidity and mortality related to influenza virus infection among patients, aligning with the National Quality Strategy's aims of better care and healthy people/communities.

In light of the previously described data which we believe reflects the significant impact influenza has on Medicare beneficiaries in the LTCH setting, we are proposing to adopt an influenza measure. Specifically, we are

[153] National Quality Forum (2012) Input on Measures for Consideration by HHS for 2012 Rulemaking. Available; *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885*. pp. 105.

[154] National Quality Forum (2008, December) National Voluntary Consensus Standards for influenza and pneumococcal vaccinations rretrieved from *http://www.qualityforum.org/Publications/2008/12/National_Voluntary_Consensus_Standards_for_Influenza_and_Pneumococcal_Immunizations.aspx*.

[155] Centers for Medicare and Medicaid Services (2012, March). MDS 3.0 Quality Measures User's Manual. V5.0. pp. 15. Retrieved from: *https://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf*.

[156] The LTCH CARE Data Set, the proposed data collection instrument that would be used to submit data on this proposed measure, is currently under Paperwork Reduction Act (PRA) review by the Office of Management and Budget. It is discussed in a PRA notice that appeared in the September 2, 2011 **Federal Register** (76 FR 54776). The file number for the LTCH PRA package is CMS–10409.

[157] Centers for Medicare & Medicaid Services. MDS 3.0 Item Subsets V1.10.4 for the April 1, 2012 Release. Retrieved from *https://www.cms.gov/NursingHomeQualityInits/30_NHQIMDS30TechnicalInformation.asp*.

[158] Thompson MG, Shay DK, Zhou H, *et al.* Estimates of deaths associated with seasonal influenza—United States, 1976–2007. MMWR Morb Mortal Wkly Rep. 59(33):1057–1062.

[159] Wilde JA, McMillan JA, Serwint J, *et al.* Effectiveness of influenza vaccine in healthcare professionals: A randomized trial. JAMA. 1999; 281: 908–913.

[160] Harriman K, Rosenberg J, Robinson S, *et al.* Novel influenza A (H1N1) virus infections among health-care personnel—United States, April–May 2009. MMWR Morb Mortal Wkly Rep. 2009; 58(23): 641–645.

[161] Fiore AE, Uyeki TM, Broder K, *et al.* Prevention and control of influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010. MMWR Recomm Rep. 2010. 59(08): 1–62.

[162] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2011, June). Healthy People 2020: Immunization and infectious diseases. Retrieved from *http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=23*.

[163] Lindley MC, Zhang J, Euler G. Health care personnel flu vaccination (2011, November). Retrieved from *http://www.cdc.gov/flu/pdf/professionals/vaccination/1112-healthcare.pdf*.

proposing to adopt the CDC-developed Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure for the FY 2016 payment determination and subsequent fiscal year payment determinations. We also note that this measure is undergoing NQF review as part of measure maintenance (*http://www.qualityforum.org/Projects/n-r/Population_Health_Prevention/Population_Health__Prevention_Endorsement_Maintenance_-_Phase_1.aspx#t=2&s=&p=3%7C*). We are proposing to this measure because, as stated previously, it aligns with national initiatives. It is also already endorsed for the LTCH care setting. This measure has been finalized for reporting in the Hospital IQR Program and the Ambulatory Surgical Centers Quality Reporting Program. The MAP supports the direction of this measure and believes it is an important aspect of care in LTCHs.[164]

This measure reports on the percentage of health care personnel who receive the influenza vaccination. Health care personnel refers to all paid and unpaid persons working in health care settings, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from health care personnel. This measure is applicable to LTCHs (we refer readers to the CDC/NHSN Manual, Healthcare Personnel Safety Component Protocol Module, Influenza Vaccination and Exposure Management Modules, which is available at the CDC Web site at: *http://www.cdc.gov/nhsn/PDFs/HSPmanual/HPS_Manual.pdf for measure specifications and additional details.*

We are proposing that data collection for this measure would be through the CDC/NHSN (*http://www.cdc.gov/nhsn/*). It is a secure Internet based system maintained by CDC, and can be utilized by all types of health care facilities in the United States, including LTCHs. NHSN collects data via a Web-based tool hosted by the CDC and available at: *http://www.cdc.nhsn.* For FY 2106 and subsequent future fiscal year payment determinations, we are proposing that the data collection would cover the period from October 1 through March 31 of each year, which corresponds with how NQF specifies this measure as well as other endorsed influenza vaccination measures.

CDC/NHSN is also the proposed data collection and submission framework for reporting on CAUTI and CLABSI measures for the FY 2015 payment determination.[165] Details related to the procedures for using the NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the proposed Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure can be found at *http://www.cdc.gov/nhsn/hps_fluVaccExpos.html*. By building on the CDC/NHSN reporting and submission infrastructure, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program. For additional information on data collection and submission, we refer readers to section VIII.D.6. of this preamble.

We are inviting public comment on this proposed measure for the FY 2016 payment determination and subsequent fiscal years.

(4) Proposed New LTCH Quality Measure #4 for the FY 2016 Payment Determination and Subsequent Fiscal Years Payment Determinations: Ventilator Bundle (NQF #0302)

In 2009, the most frequently occurring diagnosis in the LTCHs was MS–LTC–DRG 207 (Respiratory Diagnosis with Ventilator Support for 96 or more Hours).[166] Ventilator-Associated Pneumonia (VAP) is a costly, often deadly infection. A systematic review of VAP found: (1) Between 10 percent and 20 percent of patients receiving greater than 48 hours of ventilation will develop VAP; (2) ill patients who develop VAP are twice as likely to die as compared with similar patients without VAP; (3) patients with VAP have significantly longer lengths of stay; and (4) patients who have VAP incur over $10,000 in additional hospital costs.[167]

In light of the previously described data on VAP which we believe reflects the significant impact VAP has on Medicare beneficiaries, our measure development contractor introduced the VAP measure for discussion at a technical expert panel convened by it on January 31, 2011. The TEP identified VAP as important for the LTCH setting due to the high percentage of patients on ventilators. However, the panel noted concerns about measuring the rate of VAP due to lack of a consistent definition, concerns of inter-rater reliability, subjective interpretation of VAP, and variability in diagnosing VAP.

Our measure development contractor reviewed this concept again and introduced the Ventilator Bundle (NQF #0302) developed by Institute of Healthcare Improvement for discussion to address some the concerns noted previously at a July 7, 2011 TEP meeting. This comprehensive ventilator care-bundle process measure is designed to facilitate protocols such as weaning, and mitigate ventilator-related infections, such as VAP. The NQF-endorsed ventilator bundle measure consists of four components: (1) Head of the bed elevation ≥30°; (2) daily sedation interruption and assessment of readiness to wean; (3) peptic ulcer disease (PUD) prophylaxis; and (4) deep vein thrombosis (DVT) prophylaxis, The measure steward, the Institute for Healthcare Improvement, also recommends a fifth element be added to the ventilator bundle-process measure: daily oral care with Chlorhexidine (*http://www.ihi.org/offerings/MembershipsNetworks/MentorHospitalRegistry/Pages/VentilatorBundle.aspx*). A meta-analysis of oral decontamination found a statistically significant reduction in VAP with use of antiseptic oral decontamination, which supports such an addition.[168]

We recognize that the Ventilator Bundle (NQF #0302) measure is currently endorsed for ICU patients in the acute care hospital setting; however, we believe this measure is highly relevant for the LTCH setting because ventilator patients are a large segment of the LTCH patient population and a process measure to reduce VAP is important and relevant for the LTCH setting. In addition, the MAP supports the direction of this measure, and believes it is an important aspect of care in LTCHs, and has identified it as a high

[164] National Quality Forum (2012) Input on Measures for Consideration by HHS for 2012 Rulemaking. Available; *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885*. pp. 105.

[165] Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2012 Rates; Hospitals' FTE Resident Caps for Graduate Medical Education Payment, Final Rule. Federal Register (August 18, 2011; 76 FR 51745–51846). Web. *http://www.gpo.gov/fdsys/pkg/FR-2011-08-18/pdf/2011-19719.pdf.*

[166] Medicare Payment Advisory Commission (MedPAC). (2011, March). Long-term care hospital services. In Report to the Congress: Medicare payment policy (pp. 231–256). Washington, DC: Retrieved from *http://medpac.gov/documents/Mar11_EntireReport.pdf.*

[167] Safdar, N., Dezfulian, C., Collard, H., Saint, S. ''Clinical and Economic Consequences of Ventilator Associated Pneumonia''. *Critical Care Medicine.* 2005: 33(10): 2184–93.

[168] Chan, E., Ruest, A., Meade, M., Cook, D. ''Oral decontamination for prevention of pneumonia in mechanically ventilated adults: systematic review and meta-analysis''. *BMJ.* 2007; 334: 889.

priority.[169] Further, we are proposing this measure because it supports the National Quality Strategy by supporting better and safer care that prevents infection among patients at risk for VAP. Therefore, for the above-described reasons, we are proposing Ventilator Bundle NQF #0302 for application in the LTCH setting.

As indicated previously, section 1886(m)(5)(D)(ii) of the Act provides the Secretary with authority to adopt non-NQF-endorsed measures. We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed measures for the ventilator bundle in the LTCH setting. We are unaware of any other measures for the ventilator bundle in the LTCH setting that have been approved by voluntary consensus standards bodies and endorsed by NQF. We are proposing to adopt the Ventilator bundle for application in the LTCHQR Program. Therefore, under the authority of section 1886(m)(5)(D)(ii) of the Act, we are proposing to use the Ventilator Bundle (NQF #0302) measure for application in the FY 2016 LTCHQR Program payment determination and subsequent fiscal year payment determinations.

We further note that this measure is undergoing endorsement maintenance review at the NQF under the Patient Safety Measures-Complications Project (*http://www.qualityforum.org/Projects/n-r/Patient_Safety_Measures_Complications/Patient_Safety_Measures_Complications.aspx#t=2&s=&p=*).

We are proposing that data collection and submission of this measure will be through the LTCH CARE Data Set. We intend to revise the LTCH CARE Data Set to include new items on LTCHs' compliance with each element of the ventilator bundle measure if the measure is finalized. These items would be based on the data elements of the ventilator bundle in use within hospitals implementing the ventilator bundle process measure (NQF #0302). The specifications and data elements for this proposed measure are available at NQF Web site at: *http://www.qualityforum.org/QPS/302*.

By building on the existing LTCH reporting and submission infrastructure, such as the LTCH CARE data set, which will be used by LTCHs for data collection beginning October 1, 2012, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program. For additional information of data collection and submission, we refer readers to section VIII.D.6. of this preamble.

We are inviting public comment on this proposed measure for the FY 2016 payment determination and subsequent fiscal years.

(5) Proposed New LTCH Quality Measure #5 for the FY 2016 Payment Determination and Subsequent Fiscal Year Payment Determinations: Restraint Rate per 1,000 Patient Days

Restraints are used to control behavior for people who exhibit disruptive, aggressive, or dangerous behavior in health care settings.[170,171,172,173] The negative outcomes of restraints may include strangulation, loss of muscle tone, decreased bone density (with greater susceptibility for fractures), pressure sores, increased infections, decreased mobility, depression, agitation, loss of dignity, social isolation, incontinence, constipation, functional decline, abnormal changes in body chemistry and muscular function, and in some cases, patient death.[174,175,176,177,178,179,180,181,182,183] The use of physical restraints also often constitutes a disproportionate infringement on an individuals' autonomy.[184,185]

Research suggests that other clinical interventions are more effective than restraints in preventing injuries from falls. Interventions involving physiologic care, psychosocial care and environmental manipulation, have been shown to be more effective than restraints, generally without increasing staff time or overall cost of treatment.[186,187,188,189,190,191]

The principle of freedom from physical or pharmacological restraint is generally understood and accepted by professional and academic organizations. Groups such as the National Citizens' Coalition for Nursing Home Reform (NCCNHR), the Alzheimer's Association, and the American Physical Therapy Association, as well as numerous nursing homes and academic medical research institutions are involved in limiting the use of restraints. The Untie the Elderly campaign has been working since 1989 to raise public awareness of restraint abuse,[192] and the Advancing Excellence in America's Nursing Homes has recently embedded reduction of the use of restraints in nursing homes as part of an overall goal to increase resident mobility to help nursing home staff address mobility issues including the use of restraints, walking, range of motion, transfer, and prevention of falls.[193]

[169] National Quality Forum (2012)Input on Measures for Consideration by HHS for 2012 Rulemaking. Available; *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885*. pp. 105.

[170] Sullivan-Marx E, Strumpf N, Evans L, *et al.* Initiation of physical restraint in nursing home residents following restraint reduction efforts. Res Nurs Health. 1999;22:369–79.

[171] Capezuti E, Evans L, Strumpf N, *et al.* Physical restraint use and falls in nursing home residents. J Am Geriatr Soc. 1996;44:627–33.

[172] Castle N, Mor V. Physical restraints in nursing homes: a review of the literature since the Nursing Home Reform Act of 1987. Med Care Res Rev. 1998;55(2):139–70.

[173] Minnick AF, MIon LC, Johnson ME, Catrambone C, Lepzig R. Prevalence and variation of physical restraint in the acute care setting in the US. J Nurs Scholarsh. 2007; 39(1): 30–37.

[174] Castle N, Mor V. Physical restraints in nursing homes: a review of the literature since the Nursing Home Reform Act of 1987. Med Care Res Rev. 1998;55(2):139–70.

[175] Williams C, Finch C. Physical restraints: not fit for woman, man, or beast. J Am Geriatr Soc. 1997;45:773–5.

[176] Sullivan-Marx E. Achieving restraint-free care of acutely confused older adults. J Gerontol Nurs.2001;27(4):56–61.

[177] Evans L, Strumpf N, Allen-Taylor S, *et al.* A clinical trial to reduce restraints in nursing homes. J Am Geriatr Soc. 1997;45(6):675–81.

[178] Capezuti E, Maislin G, Strumpf N, *et al.* Side rail use and bed-related fall outcomes among nursing home residents. J Am Geriatr Soc. 2002;50(1):90–6.

[179] Parker K, Miles S. Deaths caused by bed rails. J Am Geriatr Soc. 1997;45:797–802.

[180] Feinsod FM, Moore M, Levenson S. Eliminating full-length bed rails from long term care facilities. Nurs Home Med. 1997;5:257–63.

[181] Minnick AF, MIon LC, Johnson ME, Catrambone C, Lepzig R. Prevalence and variation of physical restraint in the acute care setting in the US. J Nurs Scholarsh. 2007; 39(1): 30–37.

[182] Mohoney JE. Immobility and falls. Clin Geriatr Med. 1998. 14 (4): 699–726.

[183] Inouye SK, Wagner DR, Acompara D, *et al.* A predictive index for functional decline in hospitalized elderly medical patients. J Gen Intern Med. 1993; 8(12):645–652.

[184] Gastmans C, Milison K. Use of physical restraint in nursing homes: clinical-ethical considerations. J Med Ethics. 2006;32:148–52.

[185] McBrian B. Exercising restraint: clinical, legal and ethical considerations for the patient with Alzheimers's disease. Accide emeg nurs. 2997 Apr 15 (2):94–100.

[186] Capezuti E, Evans L, Strumpf N, *et al.* Physical restraint use and falls in nursing home residents. J Am Geriatr Soc. 1996;44:627–33.

[187] Castle N, Mor V. Physical restraints in nursing homes: a review of the literature since the Nursing Home Reform Act of 1987. Med Care Res Rev. 1998;55(2):139–70.

[188] Minnick AF, MIon LC, Johnson ME, Catrambone C, Lepzig R. Prevalence and variation of physical restraint in the acute care setting in the US. J Nurs Scholarsh. 2007; 39(1): 30–37.

[189] Williams C, Finch C. Physical restraints: not fit for woman, man, or beast. J Am Geriatr Soc. 1997;45:773–5.

[190] Sullivan-Marx E. Achieving restraint-free care of acutely confused older adults. J Gerontol Nurs.2001;27(4):56–61.

[191] Evans L, Strumpf N, Allen-Taylor S, *et al.* A clinical trial to reduce restraints in nursing homes. J Am Geriatr S c. 1997;45(6):675–81.

[192] Untie the Elderly Web site; accessed January 21, 2010, at *http://ute.kendaloutreach.org/Default.aspx*.

[193] Advancing Excellence in America's Nursing Homes Web site; accessed March 24, 2012, at *http://*

Continued

CMS and other Federal agencies have issued several regulations regarding restraint use in healthcare settings. In the 2006 Medicare and Medicaid Programs; Hospital Conditions of Participation: Patients' Rights final rule (71 FR 71378 through 71428), we stated that the use of restraints or seclusion ''may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others'' (71 FR 71382).[194] Additionally, in 2010, the Food and Drug Administration's Hospital Bed Safety workgroup released clinical guidance for limiting the use of bed rails, reflecting concern about the safety of restraints.[195] To better align with our guidelines, The Joint Commission updated its standards to establish guidelines limiting the use of restraints and seclusion, and clarifying the documentation and usage protocols for hospitals in 2009.[196]

Recognizing the importance of a restraint rate measure, our measure development contractor convened a technical expert panel to review restraint measures for potential use in the LTCHQR. The TEP reviewed several NQF-endorsed measures for restraint use, including Restraint Prevalence (vest and limb only) (NQF #0203) endorsed for short-term acute care hospitals, HBIPS–2 Hours of Physical Restraint Use (NQF #0640) endorsed for inpatient psychiatric facilities, HBIPS–3 Hours of Seclusion Use (NQF #0641) endorsed for inpatient psychiatric facilities, and Percent of Residents who were Physically Restrained (Long-Stay) (NQF # 0687) endorsed for residents who have been in the nursing home for over 100 days. We note the measures are NQF endorsed, although not for the LTCH setting. We submitted NQF #0687 mentioned above to the MAP for consideration. While the MAP supported the direction of this measure, it also advised the measure needed to tested in and specified for the LTCH setting. Subsequently, we also determined that all four of the above-referenced NQF measures were limited in their potential to produce a meaningful measurement in the LTCH setting since these measures have look back and monitoring periods that are problematic for the LTCH setting.

Upon further investigation, we identified the ''Restraint Rate per 1,000 Patient Days'' measure which was developed by the National Association of Long Term Hospitals (NALTH) and is a non-core measure for The Joint Commission ORYX Initiative. This measure is not NQF endorsed but it is currently specified for and is in use by some LTCHs who submit data for this measure to the NALTH Health Information System. Thus, this measure is specified for and in use for the LTCH setting, thereby, this measure is a feasible and practical measure for LTCH setting. Therefore we believe it addresses the concerns raised by MAP with respect to NQF #0687 which is the need for specification and use in the LTCH setting

After review of the previously referenced NQF-endorsed restraint measures, we are proposing the Restraint Rate per 1,000 Patient Days measure for the FY 2016 LTCHQR Program payment determination and subsequent fiscal year payment determinations under the authority in section 1886(m)(5)(D)(ii) of the Act. We are proposing to use the exception authority because there are no NQF endorsed measures on restraints for the LTCH setting. Further, as explained previously, we have given due consideration to the existing NQF measures on restraints (although not endorsed for the LTCH setting) and we believe they are not appropriate for the LTCHQR. We are proposing this measure because we believe it is a relevant, scientifically sound, valid, and an important measure which is also feasible for data collection in the LTCH setting compared to the existing NQF-endorsed restraint measures previously discussed. For this proposed measure, the measure specifications will be made available on the LTCHQR Program Web site at *http://www.cms.gov/LTCH-Quality-Reporting/*.

We are proposing that the data collection and submission of this measure will be through the LTCH CARE Data Set. This is the same data collection and submission framework which we would use to support providers for reporting on the Percent of Residents with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678) measure.[197]

By building on existing data reporting and submission infrastructure, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program. For more information on data collection and submission, we refer readers to section VIII.D.6. of this preamble.

We are inviting public comment on this proposed measure for the FY 2016 payment determination and subsequent fiscal year payment determinations.

5. Proposed Timeline for Data Submission Under the LTCHQR Program for the FY 2015 Payment Determination

For the FY 2015 payment determination, we are proposing to require data submission on LTCH discharges occurring from January 1, 2013 through December 31, 2013 (CY 2013). LTCHs would follow the proposed deadlines presented in the table below to complete submission of data for each quarter for each proposed measure for the FY 2015 payment determination. For each quarter outlined in the table below during which LTCHs are required to collect data, we are proposing a final submission deadline occurring approximately 135 days after the end of each quarter by which all data collected during that quarter must be submitted to CMS. We believe that this is a reasonable amount of time to allow providers to submit data and make any necessary corrections.

www.nhqualitycampaign.org/files/NewGoals_030612.pdf and Physical Restraints Tracking Tool v1.1 (December, 2011) accessible through *http://www.nhqualitycampaign.org/files/campaign_updates.htm#cms*.

[194] CMS Medicare and Medicaid Programs; Hospital Conditions of Participation: Patients' Rights final rule. 2006. Available from *https://www.cms.gov/CFCsAndCoPs/downloads/finalpatientrightsrule.pdf*.

[195] FDA Hospital Bed Safety Workgroup; accessed January 25, 2010. Available from: *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/MedicalToolsandSupplies/HospitalBeds/default.htm*.

[196] The Joint Commission. Restraint/Seclusion for hospitals that use the joint commission for deemed status purposes. 2009. Available from: *http://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFaqId=260&ProgramId=1*.

[197] The LTCH CARE Data Set, the data collection instrument that will be used to submit data on this measure, is currently under Paperwork Reduction Act (PRA) review by the Office of Management and Budget. It is discussed in a PRA notice that appeared in the September 2, 2011 **Federal Register** (76 FR 54776). The file number for the LTCH PRA package is CMS–10409.

PROPOSED TIMELINE FOR SUBMISSION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2015 PAYMENT DETERMINATION

Data collection timeframe: CY 2013	Proposed final submission deadline for data related to the LTCH Quality Reporting Program FY 2015 payment determination
Q1 (January–March 2013)	August 15, 2013.
Q2 (April–June 2013)	November 15, 2013.
Q3 (July–September 2013)	February 15, 2014.
Q4 (October–December 2013)	May 15, 2014.

We are inviting public comment on this proposed submission timeline for the FY 2015 payment determination.

6. Proposed Timeline for Data Submission Under the LTCHQR Program for the FY 2016 Payment Determination

For the FY 2016 payment determination, we are proposing to require data submission on LTCH discharges occurring from January 1, 2014 through December 31, 2014 (CY 2014). We are proposing this timeframe because we believe this would provide sufficient time for LTCHs and CMS to put processes and procedures in place to meet the additional quality reporting requirements. LTCHs would follow the proposed deadlines presented in the table below to complete submission of data for each quarter. For each quarter outlined in the table below during which LTCHs are required to collect data, we are proposing a final deadline occurring approximately 45 days after the end of each quarter by which all data collected during that quarter must be submitted to CMS. We believe that this is a reasonable amount of time to allow providers to submit data and make any necessary corrections. We are also proposing that similar calendar year collection and submission deadlines would apply to future years payment determinations.

PROPOSED TIMELINE FOR SUBMISSION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2016 PAYMENT DETERMINATION AND SUBSEQUENT FISCAL YEAR PAYMENT DETERMINATIONS

Data collection timeframe: CY 2014	Final submission deadlines for the LTCHQR Program FY 2016 payment determination
Q1 (January–March 2014)	May 15, 2014.
Q2 (April–June 2014)	August 15, 2014.
Q3 (July–September 2014)	November 15, 2014.
Q4 (October–December 2014)	February 15, 2015.

We are inviting public comment on this proposed submission timeline for FY 2016 Payment Determination and future year payment determinations.

7. Proposed Public Display of Data Quality Measures

Under section 1886(m)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by LTCHs under section 1886(m)(5)(C) of the Act available to the public. In addition, section 1886(m)(5)(E) of the Act requires that such procedures shall ensure that a LTCH has the opportunity to review the data that is to be made public with respect to its facility, prior to such data being made public. In addition, the statute requires that the Secretary shall report quality measures that relate to services furnished in LTCHs on our Internet Web site. Therefore, the Secretary will publicly report quality measure data that is reported under the LTCHQR Program. Currently, we are not proposing procedures or timelines for public reporting of LTCHQR Program data.

E. Proposed Quality Reporting Requirements for Ambulatory Surgical Centers (ASCs)

1. Background

Section 109(b) of the Medicare Improvements and Extension Act of 2006 under Division B, Title I of the Tax Relief and Health Care Act of 2006, Public Law 109–432 (MIEA–TRHCA) amended section 1833(i) of the Act by redesignating clause (iv) as clause (v) and adding new clause (iv) to paragraph (2)(D) and by adding new paragraph (7). Section 1833(i)(2)(D)(iv) of the Act authorizes, but does not require, the Secretary to implement the revised ASC payment system ''in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).'' Paragraph (7) contains subparagraphs (A) and (B). Subparagraph (A) of paragraph (7) states the Secretary may provide that an ASC that does not submit ''data required to be submitted on measures selected under this paragraph with respect to a year'' to the Secretary in accordance with this paragraph will incur a 2.0 percentage point reduction to any annual increase provided under the revised ASC payment system for such year. It also specifies that this reduction applies only with respect to the year involved and will not be taken into account in computing any annual increase factor for a subsequent year.

Subparagraph (B) of paragraph (7) states ''[e]xcept as the Secretary may otherwise provide,'' the provisions of subparagraphs (B) through (E) of paragraph (17) of section 1833(t) of the Act, which contain requirements for quality reporting for hospital outpatient services, ''shall apply with respect to services of [ASCs] under this paragraph in a similar manner to the manner in which they apply under such paragraph'' and any reference to a hospital, outpatient setting, or outpatient hospital services is deemed a reference to an ASC, the setting of an ASC, or services of an ASC, respectively. Pertinent to this proposed rule are subparagraphs (B) and (E) of section 1833(t)(17) of the Act. Subparagraph (B) of section 1833(t)(17)

of the Act requires subsection (d) hospitals to ''submit data on measures selected under this paragraph to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this paragraph.'' Subparagraph (E) of section 1833(t)(17) of the Act requires the Secretary to ''establish procedures for making data submitted under this paragraph available to the public.'' Further, these procedures shall ensure that hospitals have the opportunity to review the data before these data are made public. Additionally, the Secretary must ''report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals'' on CMS' Internet Web site.

Thus, subsections (i)(7)(B) and (t)(17)(B) of section 1833 of the Act, read together, require that ASCs submit quality data in a form and manner, and at a time, that the Secretary specifies. Pertinent to this proposed rule, subsections (i)(7)(B) and (t)(17)(B) of section 1833 of the Act, read together, require the Secretary to establish procedures for making data submitted available to the public and to report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and cost of care that relate to services furnished in ASCs on CMS's Internet Web site. Subsection (i)(7)(B) of section 1833 of the Act also specifies that these provisions apply except as the Secretary may otherwise provide.

In the CY 2012 OPPS/ASC final rule with comment period, we finalized our proposal to implement the ASC Quality Reporting Program beginning with the CY 2014 payment determination (76 FR 74492 through 74517). We adopted claims-based measures for the CY 2014 payment determination for services furnished between October 1, 2012 and December 31, 2012. For the CY 2015 payment determination, we adopted the same claims-based measures as adopted for the CY 2014 payment determination and two structural measures. We did not specify the data collection period for the claims-based measures for the CY 2015 payment determination, but specified that reporting for the structural measures would be between July 1, 2013 and August 15, 2013 for services furnished between January 1, 2012 and December 31, 2012 using an online measure submission Web page available at: *http://www.QualityNet.org*. For the CY 2016 payment determination, we adopted the same claims-based and structural measures as adopted for the CY 2015 payment determination and one process of care measure. We did not specify the data collection period for the claims-based or structural measures, but specified that data collection for the process of care measure would be via the National Healthcare Safety Network beginning on October 1, 2014 and continuing through March 31, 2015.

In the CY 2012 OPPS/ASC final rule with comment period, we indicated our intent to issue proposals for administrative requirements, data validation and completeness requirements, and reconsideration and appeals processes in the FY 2013 IPPS/LTCH PPS proposed rule rather than in the CY 2013 OPPS/ASC proposed rule (76 FR 74515), because the FY 2013 IPPS/LTCH PPS proposed rule is scheduled to be finalized earlier and prior to data collection for the CY 2014 payment determination, which is to begin with services furnished on October 1, 2012.

Below we are issuing proposals for administrative requirements, data completeness requirements, extraordinary circumstance waiver or extension requests, and a reconsideration process. As discussed below, we are not proposing to validate claims-based and structural measures. Further, we intend to address appeals of reconsideration decisions in a future rulemaking. To be eligible to receive the full annual increase, we are proposing that ASCs must comply with the requirements specified below for the respective payment determination year.

We invite public comment on these proposals.

2. Proposed Requirements for Reporting of ASC Quality Data

a. Proposed Administrative Requirements

(1) Proposals Regarding QualityNet Account and Administrator for the CYs 2014 and 2015 Payment Determinations

A QualityNet account is required to submit quality measure data to the QualityNet Web site and, in accordance with CMS policy, a QualityNet administrator is necessary to set-up a user account for the purpose of submitting this information to the QualityNet Web site. The main purpose of a QualityNet administrator is to serve as a point of contact for security purposes for quality reporting programs. We believe from our experience that a QualityNet administrator typically fulfills a variety of tasks related to quality reporting, such as creating, approving, editing, and terminating QualityNet user accounts within an organization, and monitoring QualityNet usage to maintain proper security and confidentiality measures. Thus, we highly recommend that ASCs have and maintain a QualityNet administrator. However, we are not proposing that ASCs be required to do so for the CY 2014 payment determination because ASCs are not required to submit data to the quality data warehouse for the CY 2014 payment determination (76 FR 74504) and we do not want to unduly burden ASCs by requiring ASCs to have a QualityNet administrator. We note that a QualityNet account is not necessary to access information that is posted to the QualityNet Web site, such as specifications manuals and educational materials.

As finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74504 through 74509), for the CY 2015 payment determination, we require ASCs to submit structural measure data to the QualityNet Web page. To enter these data into the CMS data system, we are proposing that ASCs will need to identify and register a QualityNet administrator who follows the registration process located on the QualityNet Web site and submits the information as specified on this site. Because submission of structural measure data is not required until the July 1, 2013 to August 15, 2013 time period, we are proposing that ASCs would be required to have a QualityNet administrator at the time facilities submit structural measure data in 2013 for the CY 2015 payment determination, which is no later than August 15, 2013. ASCs may have a QualityNet administrator prior to this date, but we are not proposing that ASCs be required to do so.

We note that there are necessary mailing and processing procedures for having a QualityNet administrator assigned by CMS separate from completion of the forms by the ASC that can require significant time to complete and we strongly caution ASCs to not wait until the deadline to apply; instead, we recommend allowing a minimum of 2 weeks, while strongly suggesting allowing additional time prior to the deadline to submit required documentation in case of unforeseen issues. Because ASCs will need a QualityNet administrator only to have the ability to set up a user account for the purpose of submitting structural measure data once a year, we are proposing that ASCs would not be required to maintain a QualityNet administrator after the entry of the structural measure data in 2013 for the CY 2015 payment determination. Although we highly recommend that ASCs have and maintain a QualityNet administrator, we believe that requiring

an ASC to maintain a QualityNet administrator throughout the year would increase the burden on ASCs.

As a commenter noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74515), QualityNet accounts are automatically deactivated after a 120-day period of inactivity per CMS security policy. If an account is deactivated due to inactivity, it can be reactivated by contacting the QualityNet Help Desk; contact information for the QualityNet Help Desk is located on the QualityNet Web site.

(2) Proposals Regarding Participation Status for the CY 2014 Payment Determination and Subsequent Payment Determination Years

We finalized in the CY 2012 OPPS/ASC final rule with comment period a policy to consider an ASC as participating in the ASC Quality Reporting Program for the CY 2014 payment determination if the ASC includes Quality Data Codes (QDCs) specified for the program on their CY 2012 claims relating to the finalized measures (76 FR 74516).

We are proposing that once an ASC submits any quality measure data, it would be considered as participating in the ASC Quality Reporting Program. Further, we are proposing that, once an ASC submits any quality measure data and is considered to be participating in the program, an ASC would continue to be considered participating in the program, regardless of whether the ASC continues to submit quality measure data, unless the ASC withdraws from the program by indicating on a participation form that it is withdrawing, as discussed below. For example, if an ASC includes any QDCs on its claims for the CY 2014 payment determination, it would be considered participating in the ASC Quality Reporting Program for the CY 2014 payment determination and for every subsequent payment determination unless the ASC withdraws. Likewise, if an ASC did not submit any QDCs for the CY 2014 payment determination, but submitted quality measure data for the CY 2015 payment determination, the ASC would be considered participating in the ASC Quality Reporting Program starting with the CY 2015 payment determination and continuing for subsequent payment determinations unless the ASC withdraws from the program.

We considered whether to propose that an ASC be required to complete and submit a notice of participation form for the CY 2015 payment determination or subsequent payment determination years to indicate that the ASC is participating in the program as we require for hospitals, but decided against this proposal because we were concerned about the burden on ASCs. We believe these proposals will reduce burden on ASCs while accomplishing the purpose of notifying CMS of an ASC's participation in the ASC Quality Reporting Program.

We are proposing that any and all quality measure data submitted by the ASC while participating in the ASC Quality Reporting Program could be made publicly available. This policy would allow us to provide information on the quality of care provided to Medicare beneficiaries which promotes transparency.

We are proposing that once an ASC submits quality measure data indicating its participation in the ASC Quality Reporting Program an ASC must complete and submit an online participation form indicating withdrawal to withdraw from the program. This form would be located on the QualityNet Web site starting in July 2013. We are proposing that an ASC would indicate on the form the initial payment determination year to which the withdrawal applies. We are proposing a different process for ASCs to withdraw from participation than the process we are proposing for an ASC to participate in the ASC Quality Reporting Program because of the payment implications of withdrawal. We are proposing that, in withdrawing from the program, the ASC would incur a 2.0 percentage point reduction in its annual payment update for that payment determination year and any subsequent payment determination year(s) in which it is withdrawn.

We will not make quality measure data publicly available for that payment determination year and any subsequent payment determination year(s) for which the ASC is withdrawn from the program.

We are proposing that an ASC would continue to be deemed withdrawn unless the ASC starts submitting quality measure data again. Once an ASC starts submitting quality measure data, the ASC would be considered participating unless the ASC withdraws, as discussed above. Again, we believe that these proposals would reduce the burden on ASCs of having to notify CMS as to when they are participating.

We are proposing that an ASC can withdraw from the program at any time up to August 31, 2013 for the CY 2014 payment determination; we anticipate that this will be the latest date possible to allow an ASC to withdraw before payment determinations affecting CY 2014 payment are made. We are proposing that an ASC can withdraw from the program at any time up to August 31, 2014 for the CY 2015 payment determination. We will propose withdrawal dates for later payment determinations in future rulemakings.

We are proposing that these administrative requirements would apply to all ASCs designated as open in the CASPER system before January 1, 2012 for the CY 2014 payment determination. Since ASCs are not required to include QDCs on claims until October 2012 for the CY 2014 payment determination, an ASC designated as open in the CASPER system before January 1, 2012 would be operating for at least 10 months before having to report any data. We believe this would be a sufficient amount of time for ASCs to be established to report quality data for the CY 2014 payment determination.

For the CY 2015 payment determination, we are proposing that these administrative requirements would apply to all ASCs designated as open in the CASPER system for at least four months prior to January 1, 2013. We believe that this date and length of operations experience would provide new ASCs sufficient time before having to meet quality data reporting requirements after the program's initial implementation year.

We invite public comment on these proposals relating to administrative requirements.

b. Proposals Regarding Form, Manner, and Timing for Claims-Based Measures for CYs 2014 and 2015 Payment Determinations

(1) Background

In the CY 2012 OPPS/ASC final rule with comment period, we adopted claims based measures for the CYs 2014 and 2015 payment determinations (76 FR 74504 through 74509). We also finalized that, to be eligible for the full CY 2014 ASC annual payment update, an ASC must submit complete data on individual quality measures through a claims-based reporting mechanism by submitting the appropriate QDCs on the ASC's Medicare claims (76 FR 74515 through 74516). Further, we finalized the data collection period for the CY 2014 payment determination, as the Medicare fee-for-service ASC claims submitted for services furnished between October 1, 2012 and December 31, 2012. We did not finalize a date by which claims would be processed to be considered for CY 2014 payment determinations.

We are now proposing that claims for services furnished between October 1, 2012 and December 31, 2012 would have to be paid by the administrative contractor by April 30, 2013 to be included in the data used for the CY 2014 payment determination. We believe that this claim paid date would allow ASCs sufficient time to submit claims while allowing sufficient time for CMS to complete required data analysis and processing to make payment determinations and to supply this information to administrative contractors.

We did not finalize a data collection and processing period for the CY 2015 payment determination, but intend to do so in the CY 2013 OPPS/ASC proposed rule.

(2) Proposed Minimum Threshold for Claims-Based Measures Using QDCs

In the CY 2012 OPPS/ASC final rule with comment period, we finalized that data completeness for claims-based measures would be determined by comparing the number of claims meeting measure specifications that contain the appropriate QDCs with the number of claims that would meet measure specifications, but did not have the appropriate QDCs on the submitted claim. In other words, the numerator will be the total number of claims meeting measure specifications that have QDCs and the denominator will be the total number of claims meeting measure specifications. We stated our intent to propose how we would assess data completeness for claims-based measures in this proposed rule (76 FR 74516). For the initial reporting years, we believe that a lower threshold for data completeness should be established for data collection because ASCs are not familiar with how to report quality data under the ASC Quality Reporting Program, and because many ASCs are relatively small and they may need more time to set up their reporting systems. For the CYs 2014 and 2015 payment determinations, we are proposing that the minimum threshold for successful reporting be that at least 50 percent of claims meeting measure specifications contain QDCs. We believe 50 percent is a reasonable minimum threshold based upon the considerations discussed above for the initial implementation years of the ASC Quality Reporting Program. We intend to propose to increase this percentage for subsequent payment determination years as ASCs become more familiar with reporting requirements for this quality data reporting program.

As stated in CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), ASCs will add the appropriate QDCs on their Medicare Part B claim forms, the Form CMS–1500s submitted for payment, to submit the applicable quality data. A listing of the codes with long and short descriptors is available in transmittal 2425, Change Request 7754 released March 16, 2012 (*http://www.cms.gov/transmittals/downloads/R2425CP.pdf*). Details on how to use these codes for submitting numerators and denominator information will be available in the ASC Quality Reporting Program Specifications Manual located on our Web site (*http://www.cms.hhs.gov*) beginning in April 2012.

We invite public comment on these proposals relating to form, manner, and timing for claims-based measures.

c. ASC Quality Reporting Program Validation of Claims-Based and Structural Measures

We received comments on the CY 2012 OPPS/ASC proposed rule requesting that rules for data validation be adopted as soon as possible (76 FR 74515). We noted that claims-based and structural measures historically have not been validated through independent medical record review in our quality reporting programs for either hospitals or physicians due to the lack of relevant information in medical record documentation for specific data elements of the measures, such as use of a safe surgery checklist. Thus, consistent with other CMS quality reporting programs, we are not proposing to validate claims-based measures (beyond the usual claims validation activities conducted by our administrative contractors) and structural measures for the ASC Quality Reporting Program.

3. Proposed Extraordinary Circumstances Extension or Waiver for the CY 2014 Payment Determination and Subsequent Payment Determination Years

In our experience, there have been times when facilities have been unable to submit information to meet program requirements due to extraordinary circumstances that are not within their control. It is our goal to not penalize such entities for such circumstances and we do not want to unduly increase their burden during these times. Therefore, we are proposing procedures for extraordinary circumstance extension or waiver requests for the submission of information, including but not limited to, QDCs submitted on claims, required under the ASC Quality Reporting Program.

In the event of extraordinary circumstances, such as a natural disaster, that is not within the control of the ASC, we are proposing to adopt a process for an extension or waiver for submitting information for meeting program requirements that is similar to the one adopted for the Hospital OQR Program because this process has been effective for hospitals, and we believe such a process also would be effective for ASCs. We are proposing that an ASC would complete a request form that would be made available on the QualityNet Web site and submit the request to CMS. We are proposing that the following information must be noted on the form:

- ASC CMS Certification Number (CCN) and related National Provider Identifier(s) [NPI(s)];
- ASC Name;
- Contact information for a person at the ASC with whom CMS can communicate about this request, including name, e-mail address, telephone number, and mailing address (must include a physical address, a post office box address is not acceptable);
- ASC'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 ASC would be able to submit required ASC Quality Reporting Program information, and a reasonable basis for the proposed date.

We are proposing that the request form would be signed by a person who has authority to sign on behalf of the ASC and a request form would be required to be submitted within 45 days of the date that the extraordinary circumstance occurred.

Following receipt of such a request, we are proposing that CMS would—

(a) Provide a written acknowledgement using the contact information provided in the request, notifying the ASC contact that the ASC's request has been received;

(b) Provide a formal response to the ASC contact using the contact information provided in the request notifying the ASC of our decision; and

(c) Complete its review of any request and communicate its response within 90 days following CMS's receipt of such a request.

We are proposing that we would also have discretion to grant waivers or extensions to ASCs that have not been formally requested by them when we determine that an extraordinary circumstance, such as an act of nature (for example, hurricane) affects an entire region or locale. We are proposing that,

if we make the determination to grant a waiver or extension to ASCs in a region or locale, we would communicate this decision to ASCs and vendors through routine communication channels, including, but not limited to, e-mails and notices on the QualityNet Web site.

We invite public comment on this proposed process for granting extraordinary circumstances extensions or waivers for the submission of information for the ASC Quality Reporting Program.

4. Proposed ASC Quality Reporting Program Reconsideration Procedures for the CY 2014 Payment Determination and Subsequent Payment Determination Years

We have established similar processes by which participating hospitals can submit requests for reconsideration of quality reporting program payment determinations for the Hospital IQR Program and the Hospital OQR Program. We believe these reconsideration processes have been effective in the hospital quality reporting programs and such a process would be effective for ASC quality reporting. Therefore, we are proposing to implement a reconsideration process for the ASC Quality Reporting Program modeled after the reconsideration processes we implemented for the Hospital IQR and Hospital OQR Programs.

We are proposing that an ASC seeking reconsideration would be required to submit to CMS a Reconsideration Request form that would be made available on the QualityNet Web site. We are proposing that the request form would be signed by a person who has authority to sign on behalf of the ASC and that this form must be submitted by March 17 of the affected payment year (for example, for the CY 2014 payment determination, the request must be submitted by March 17, 2014).

We are proposing to use a deadline of March 17 to provide sufficient time for an ASC to see the effects of a payment reduction on its January claims. Administrative contractors have 30 days to process (pay or deny) clean claims. Administrative contractors have 45 days to process claims other than clean ones (that is, claims that require the contractor to query for more information, look at medical documentation, among others) (Claims Processing Manual, Chapter 1, Section 80; sections 1869(a)(2), 1816(c)(2) and 1842(c)(2) of the Act). We are proposing March 17 because this date is 45 days after an ASC would have had the opportunity to provide one full month of services (that is, March 17 is 45 days after January 31).

This Reconsideration Request form would contain the following information:

- ASC CCN and related NPI(s);
- ASC Name;
- CMS-identified reason for not meeting the affected payment year's ASC Quality Reporting Program requirements as provided in any CMS notification to the ASC;
- ASC basis for requesting reconsideration. We are proposing that the ASC must identify the ASC's specific reason(s) for believing it met the affected payment year's ASC Quality Reporting Program requirements and should receive the full ASC annual payment update;
- Contact information for a person at the ASC with whom CMS can communicate about this request, including name, e-mail address, telephone number, and mailing address (must include physical address, not just a post office box); and
- A copy of all materials that the ASC submitted to comply with the affected payment year's ASC Quality Reporting Program requirements. With regard to information submitted on claims, we are proposing ASCs would not be required to submit copies of all submitted claims, but instead would focus on the specific claims at issue. Thus, ASCs would submit relevant information, which could include copies of the actual claims at issue.

Following receipt of a request for reconsideration, we are proposing that we would:

- Provide an e-mail acknowledgement, using the contact information provided in the reconsideration request, to the ASC contact notifying the ASC that the ASC's request has been received; and
- Provide a formal response to the ASC contact, using the contact information provided in the reconsideration request, notifying the ASC of the outcome of the reconsideration process.

We intend to complete any reconsideration reviews and communicate the results of these determinations within 90 days following the deadline for submitting requests for reconsideration.

We intend to issue proposals regarding appeals of ASC Quality Reporting Program reconsideration decisions in a future rulemaking.

We invite public comment on our proposed reconsideration procedures.

F. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

1. Statutory Authority

Section 1886(s)(4) of the Act, as added and amended by sections 3401(f) and 10322(a) of the Affordable Care Act, requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units. Section 1886(s)(4)(A)(i) of the Act requires that, for rate year (RY) 2014 and each subsequent rate year, the Secretary shall reduce any annual update to a standard Federal rate for discharges occurring during such rate year by 2.0 percentage points for any inpatient psychiatric hospital or psychiatric unit that does not comply with quality data submission requirements with respect to an applicable rate year.

We note that section 1886(s)(4)(A)(i) of the Act uses the term ''rate year.'' Beginning with the annual update of the inpatient psychiatric facility prospective payment system (IPF PPS) that took effect on July 1, 2011 (RY 2012), we aligned the IPF PPS update with the annual update of the ICD–9–CM codes, which are effective on October 1 of each year. The change allows for annual payment updates and the ICD–9–CM coding update to occur on the same schedule and appear in the same **Federal Register** document, thus making updating rules more administratively efficient. To reflect the change to the annual payment rate update cycle, we revised the regulations at 42 CFR 412.402 to specify that, beginning October 1, 2012, the 12-month period of October 1 through September 30 is referred to as a fiscal year (76 FR 26435). For more information regarding this terminology change, we refer readers to the ''Changing the IPF PPS Payment Rate Update Period from a Rate Year to a Fiscal Year'' section of the final rule (76 FR 26434 through 26435). For purposes of the discussion below, the term ''rate year'' and ''fiscal year'' both refer to the period beginning October 1 and ending September 30. To avoid confusion that may be caused by using the term ''rate year'' with respect to the inpatient psychiatric hospitals and psychiatric units quality reporting program, we will use the term ''fiscal year'' rather than ''rate year'' throughout this proposed rule, even when we are referring to statutory provisions that refer to ''rate year.''

As provided in section 1886(s)(4)(A)(ii) of the Act, the application of the reduction for failure to report under section 1886(s)(4)(A)(i) of the Act may result in an annual update of less than 0.0 for a fiscal year,

and may result in payment rates under section 1886(s)(1) of the Act being less than such payment rates for the preceding year. In addition, section 1886(s)(4)(B) of the Act requires that the application of the reduction to a standard Federal rate update be noncumulative across fiscal years. Thus, any reduction applied under section 1886(s)(4)(A) of the Act will apply only with respect to the fiscal year rate involved and the Secretary shall not take into account such reduction in computing the payment amount under the system described in section 1886(s)(1) of the Act for subsequent years.

Section 1886(s)(4)(C) of the Act requires that, for FY 2014 (October 1, 2013 through September 30, 2014) and each subsequent year, each psychiatric hospital and psychiatric unit shall submit to the Secretary data on quality measures as specified by the Secretary. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary. Under section 1886(s)(4)(D)(i) of the Act, measures selected for the quality reporting program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The National Quality Forum (NQF) currently holds this contract. The NQF is a voluntary, consensus-based, 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 generally prefer to adopt NQF-endorsed measures in our reporting programs with some exceptions as provided by law.

For purposes of the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program, section 1886(s)(4)(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, 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. Finally, pursuant to section 1886(s)(4)(D)(iii) of the Act, the Secretary shall publish the measures applicable to the FY 2014 IPFQR Program no later than October 1, 2012.

Section 1886(s)(4)(E) of the Act requires the Secretary to establish procedures for making public the data submitted by inpatient psychiatric hospitals and psychiatric units under the quality reporting program. Such procedures must ensure that a facility has the opportunity to review its data prior to such data being made public. The Secretary must report quality measures that relate to services furnished by the psychiatric hospitals and units on a CMS Web site.

2. Application of the Payment Update Reduction for Failure to Report for FY 2014 Payment Determination and Subsequent Years

Beginning in FY 2014, section 1886(s)(4)(A)(i) of the Act requires the application of a 2.0 percentage point reduction to the applicable annual update to a Federal standard rate for those psychiatric hospitals and units that fail to comply with the quality reporting requirements implemented in accordance with section 1886(s)(4)(C) of the Act, as detailed below. The application of the reduction may result in an annual update for a fiscal year that is less than 0.0 and in payment rates for a fiscal year being less than the payment rates for the preceding fiscal year. Pursuant to section 1886(s)(4)(B) of the Act, any such reduction is not cumulative and it will apply only to the fiscal year involved. We are proposing to add new regulatory text at 42 CFR 412.424 to codify these requirements.

We invite public comment on the proposed language for the application of the payment reduction to an annual update to a standard Federal rate for failure to report for FY 2014 and subsequent years.

3. Covered Entities

The quality reporting requirements in this proposed rule would cover those psychiatric hospitals and psychiatric units that are reimbursed under Medicare's IPF PPS (42 CFR 412.404(b)). For more information on the application of and exceptions to the IPF PPS reimbursement, we refer readers to the ''Overview of the IPF PPS Payment Methodology'' section of the November 15, 2004 final rule titled ''Medicare Program: Prospective Payment System for Inpatient Psychiatric Facilities'' (69 FR 66922 at 66926). In this proposed rule, we are using the term ''inpatient psychiatric facility'' (IPF) to refer to both inpatient psychiatric hospitals and psychiatric units. This usage follows the terminology we have used in the past in our IPF PPS regulations (42 CFR 412.402).

4. Proposed Quality Measures

a. Considerations in Selecting Quality Measures

For purposes of the IPFQR Program, section 1886(s)(4)(D)(i) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act. The statutory requirements under section 1886(s)(4)(D)(ii) of the Act provide an exception that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

In implementing the IPFQR Program, our overarching objective is to support the HHS National Quality Strategy's three-part aim of better health care for individuals, better health for populations, and lower costs for health care (*http://www.ahrq.gov/workingforquality/nqs/#aims*). Implementation of the IPFQR Program will help achieve the three-part aim by creating transparency around the quality of care at IPFs to support patient decision-making and quality improvement. Over time, the IPFQR Program will help align the goals for quality measurement and improvement at IPFs with those of other providers in the health system.

We seek to collect data in a manner that balances the need for information related to the full spectrum of quality performance and the need to minimize the burden of data collection and reporting. We have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care provided by IPFs. We applied the following considerations for the development and selection of measures:

- Given the availability of well-validated measures and the need to balance breadth with minimizing burden, the measures should address as fully as possible the six domains of measurement that arise from the six priorities of the National Quality Strategy: clinical care; person- and caregiver-centered experience and outcomes; safety; efficiency and cost reduction; care coordination; and community/population health.
- Public reporting should rely on a mix of standards, outcomes, process of care measures, and patient experience of

care measures, including measures of care transitions and changes in patient functional status, with an emphasis on measurement as close to the patient-centered outcome of interest as possible.

• The measure sets should evolve so that they include a focused set of measures appropriate to the IPF provider category that reflects the level of care and the most important areas of service and measures for such providers as well as measures addressing a core set of measure concepts that align quality improvement objectives across all provider types and settings.

• Measures should address gaps in quality of inpatient psychiatric care.

• As part of our burden reduction efforts, we continuously seek to weigh the relevance and utility of the measures compared to the burden on hospitals in submitting data under the IPFQR Program. As appropriate, we will align our measures with other Medicare and Medicaid programs and may consider the adoption of meaningful use standards for health information technology (HIT), so that the collection of performance information is part of care delivery.

• To the extent practicable, measures used by CMS should be nationally endorsed by a multistakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. We take into account widely accepted criteria established in medical literature. We consider suggestions and input from technical expert panels (TEPs), convened by CMS contractors, which evaluate IPFQR quality measures for importance, scientific soundness, usability, and feasibility.

We also take into account national priorities and HHS Strategic Plans and Initiatives:

• HHS engaged a wide range of stakeholders to develop the National Quality Strategy, as required by the Affordable Care Act, which pursues three aims (better care, healthy people, and affordable care) that establish a framework with six identifiable priorities (*http://www.hhs.gov/secretary/about/priorities.html* and *http://www.ahrq.gov/workingforquality/ngs*):

•• Ensuring that each person and family is engaged as partners in their care.

•• Promoting effective communication and coordination of care.

•• Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease.

•• Working with communities to promote wide use of best practices to enable healthy living.

•• Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models.

•• Making care safer by reducing harm caused in the delivery of care.

• We consider recommendations of the Measure Application Partnership (MAP) for the inclusion of clinical quality measures (*http://www.qualityforum.org.map/*). The MAP is a public-private partnership convened by the NQF for the primary purpose of providing input to HHS on selecting performance measures for quality reporting programs and pay-for-reporting programs.

• HHS is the United States Government's principal department for protecting the health of all Americans. HHS accomplishes its mission through programs and initiatives. The goals of the HHS Strategic Plan for FYs 2010 through 2015 are: Strengthen Health Care; Advance Scientific Knowledge and Innovation; Advance the Health, Safety, and Well-Being of the American People; Increase Efficiency, Transparency, and Accountability of HHS Programs; and Strengthen the Nation's Health and Human Services Infrastructure and Workforce (*http://www.hhs.gov/secretary/about/priorities.html*). HHS will update this strategic plan every 4 years and measure its progress in addressing specific national problems, needs, or mission-related challenges.

HHS prioritizes policy and program interventions to address the leading causes of death and disability in the United States, including heart disease, cancer, stroke, chronic lower respiratory diseases, unintentional injuries, and preventable behaviors. Initiatives such as the HHS Action Plan to Reduce Healthcare-Associated Infections in clinical settings and the Partnership for Patients exemplify these programs.

• CMS Strategic Plan—CMS strives: (1) To ensure measures for different Medicare and Medicaid programs are aligned with priority quality goals, measure specifications are aligned across settings, and outcome measures are used whenever possible; and (2) to move towards the collection of quality measures from electronic health records (EHRs) as appropriate.

We invite public comments on the considerations used for the development and selection of the proposed quality measures for the IPFQR Program.

b. Proposed Quality Measures Beginning With FY 2014 Payment Determination and Subsequent Years

We are proposing to adopt six quality measures for FY 2014 and subsequent fiscal years. In selecting the proposed quality measures discussed below, we strive to achieve several objectives. First, we believe the measures we are proposing relate to the general aims of better care, better health, and lower cost and address the six domains of quality measurement as fully as possible. Second, we believe the measures are tailored to the needs of improved quality in IPFs; thus, the measures selected are those most relevant to IPFs. Third, we believe the measures promote alignment of quality improvement objectives across provider settings. Finally, we believe the measures are minimally burdensome to IPFs.

We recognize that any quality reporting program will impose certain data collection and reporting requirements on participating facilities. However, we believe that the proposed measures minimize the collection and reporting burden on IPFs because, under Medicare's IPF conditions of participation (CoPs) (42 CFR 482.61), IPFs must maintain documentary evidence of detailed treatment approaches and aftercare considerations. Further, under 42 CFR 482.21, IPFs are required to develop, implement, and maintain an effective, ongoing, hospital-wide data-driven quality assessment and performance improvement (QAPI) program as well as documentary evidence of such program for purposes of demonstrating their operation to CMS. More importantly, § 482.21 requires that IPFs measure, analyze, and track certain quality indicators, including adverse patient events, and other aspects of performance that enable the hospital to assess processes of care, hospital services, and operations as part of their QAPI Program. Because the proposed IPFQR Program measures cover processes that IPFs are currently recording as Medicare CoPs, we do not believe that reporting on the proposed measures would impose a significant burden on IPFs. We note that over one-quarter of IPFs [198] are also already reporting data needed to calculate the proposed measures to The Joint Commission (TJC) for purposes of TJC accreditation. Thus, the IPFQR Program

[198] Out of the 1,741 existing IPFs, 450 are currently reporting the proposed measures to TJC. This equates to approximately 26 percent of IPFs that already report the measures on a regular basis.

will impose little additional burden for those IPFs.

After considering the recommendations and feedback from content area experts and multiple stakeholders, we are proposing, for the FY 2014 payment determination and subsequent years, six NQF-endorsed, Hospital-Based Inpatient Psychiatric Services (HBIPS) measures, which have been developed by and are maintained by TJC for purposes of assessing the quality of inpatient psychiatric services. These measures are: (1) HBIPS–2: Hours of Physical Restraint Use (NQF #0640); (2) HBIPS–3: Hours of Seclusion Use (NQF #0641); (3) HBIPS–4: Patients Discharged on Multiple Antipsychotic Medications (NQF #0552); (4) HBIPS–5: Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification (NQF #0560); (5) HBIPS–6: Post-Discharge Continuing Care Plan Created (NQF #0557); and (6) HBIPS–7: Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider Upon Discharge (NQF #0558).[199] These six proposed process measures are NQF-endorsed and were recommended by the MAP[200] for inclusion in the IPFQR Program. The six proposed measures align with three of the six priorities of the National Quality Strategy: patient safety, promoting effective prevention and treatment practices (clinical quality of care), and promoting effective communication and coordination of care. Technical specifications for these measures can currently be found on the Web site of TJC, the measure steward, at: *http://www.manual.jointcommission.org/releases/TJC2012B/HospitalBasedInpatientPsychiatricServices.html*.

As noted earlier, these six HBIPS measures are currently in use by an estimated 450 TJC-accredited IPFs, thereby posing minimal collection burden for these facilities. We note that an estimated 1,100 facilities, which do not routinely report to TJC, will incur some data collection burden. In addition, summary analyses of current measure results provided to CMS by TJC demonstrate variation in performance among the facilities currently reporting results for these measures, suggesting continued opportunity for quality improvement.

Section 1886(s)(4)(D)(i) of the Act requires that quality measures selected for the IPFQR Program be endorsed by the entity with a contract under section 1890(a) of the Act. As discussed earlier, the current holder of this contract is NQF. The measures are currently NQF-endorsed for reporting overall performance rates and rates for four age groups (children, adolescents, adults, and older adults). We are proposing to require reporting of data for all four age groups for which the measures are currently endorsed. More details regarding this proposal are included in section VIII.F.7. of this preamble. In addition to aligning with previous collection and reporting of these measures by TJC, our proposal reflects the feedback provided by the subject-matter TEP convened by the CMS measure development contractor for this program and focus groups of hospitals and vendors involved in providing inpatient psychiatric services.

We are proposing to collect aggregate data rather than patient level data for FY 2014 and subsequent years in recognition of the considerable burden to providers not accustomed to reporting patient level data. Hospitals are free to use our paper abstraction tool and utilize commonly available software, like spreadsheets, to enter and compute measure rates. We intend to provide a template using a commonly available spreadsheet format used by many hospitals which will be available on the QualityNet Web site (*http://www.qualitynet.org/*). Further, IPFs are free to procure services from TJC vendors to assist them with data collection. However, we note that we do not require the use of TJC vendors. Proposals for collection requirements and submission timeframes are included in section VIII.F.7. of this preamble. The six proposed measures for FY 2014 and subsequent years are described in more detail below.

(1) HBIPS–2 (Hours of Physical Restraint Use)

The use of physical restraints increases a patient's risk of physical injury as well as psychological harm.[201,202] This intervention is intended for use only if a patient is in imminent danger to him/herself or others and if less restrictive interventions have failed. It is not intended to address staff shortages or to be used as a form of discipline or coercion. The President's New Freedom Commission on Mental Health[203] explicitly recommends the reduction of restraint use to improve quality of care. A measure designed to reduce the use of restraints will also help achieve the National Quality Strategy's goal to improve patient safety and reduce the risk of harm from care.

In addition to initiatives to reduce the use of restraints, the subject-matter TEP convened by our measure development contractor identified patient safety as an important measure concept and recommended the use of HBIPS–2 (Hours of Physical Restraint Use) for use in a national IPF quality reporting program. HBIPS–2 is a process measure that is reported as the total number of hours of physical restraint (HBIPS–2) use for all patients admitted to an inpatient psychiatric facility. We believe that fewer reported hours of physical restraint use suggest higher quality of care because reduced restraint time lowers patient risk for physical injury and psychological harm.

The numerator is defined as the total number of hours that all psychiatric inpatients were maintained in physical restraint. The denominator is defined as the number of psychiatric inpatient hours overall. Total leave days are excluded from the denominator.

In addition to meeting the statutory requirements as provided in section 1886(s)(4)(D) of the Act, we believe HBIPS–2 also meets a number of additional considerations we take into account when proposing quality measures for the IPFQR Program. The measure assesses the quality of care provided for inpatient psychiatric patients at the facility level. Approximately 450 IPFs are already collecting the measure for purposes of TJC accreditation. HBIPS–2 received support from the MAP and is aligned with the National Quality Strategy priority for providing safer care.

We invite public comments on the inclusion of the proposed quality measure HBIPS–2, Hours of Physical Restraint Use, in the IPFQR program beginning with the FY 2014 payment determination. Proposals for collection requirements and submission timeframes are included in section VIII.F.7. of this preamble.

(2) HBIPS–3 (Hours of Seclusion Use)

The use of seclusion increases a patient's risk of physical injury as well

[199] The Joint Commission has developed seven Hospital-Based Inpatient Psychiatric Services (HBIPS) measures. Only six of these seven measures are proposed for the FY 2014 payment determination; HBIPS–1 is not proposed.

[200] Measure Application Partnership, *Pre-Rulemaking Final Report: Input on Measures under Consideration by HHS for 2012 Rulemaking,* pages 95–96, Available at: *http://www.qualityforum.org/map/*.

[201] Evans, D., Wood, J., & Lambert, L. (2003). Patient injury and physical restraint devices: A systematic review. Journal of Advanced Nursing, 41: 274–282.

[202] New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America. Final Report.* DHHS Pub. No. SMA–03–3832. Rockville, MD: 2003.

[203] New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America. Final Report.* DHHS Pub. No. SMA–03–3832. Rockville, MD: 2003.

as psychological harm.[204,205] This intervention is intended for use only if a patient is in imminent danger to him/herself or others and if less restrictive interventions have failed. It is not intended to address staff shortages or to be used as a form of discipline or coercion. The President's New Freedom Commission on Mental Health explicitly recommends the reduction of seclusion use to improve quality of care.[206] Measures designed to reduce the use of seclusion will also help achieve the National Quality Strategy's goal to improve patient safety and reduce the risk of harm from care.

The subject-matter TEP convened by our measure development contractor identified patient safety as an important measure concept and recommended the use of HBIPS–3 (Hours of Seclusion Use) for use in a national IPF quality reporting program. HBIPS–3 is a process measure that is reported as the total number of hours of seclusion use for all patients admitted to an IPF. We believe that fewer reported hours of seclusion use suggest higher quality of care because reducing seclusion time lowers patient risk for physical injury and psychological harm.

The numerator is defined as the total number of hours all psychiatric inpatients were held in seclusion. The denominator is defined as the number of psychiatric inpatient hours overall. Total leave days are excluded from the denominator.

In addition to meeting the statutory requirements as provided in section 1886(s)(4)(D) of the Act, we believe HBIPS–3 also meets a number of additional considerations we take into account when proposing quality measures for the IPFQR Program. The measure assesses the quality of care provided for inpatient psychiatric patients at the facility level. Approximately 450 IPFs are already collecting the measure for purposes of TJC accreditation. HBIPS–3 received support from the MAP and is aligned with the National Quality Strategy priority for providing safer care.

We invite public comment on the inclusion of the proposed quality measure HBIPS–3, Hours of Seclusion Use, in the IPFQR Program beginning with the FY 2014 payment determination. Proposals for collection requirements and submission timeframes are included in section VIII.F.7. of this preamble.

(3) HBIPS–4 (Patients Discharged on Multiple Antipsychotic Medications)

An estimated 30 percent to 50 percent of patients in IPFs are treated with two or more antipsychotic medications, which can lead to serious side effects. Among patients without a history of treatment failure on a single antipsychotic, there is insufficient evidence to conclude that patients experience better outcomes if they are prescribed multiple antipsychotics compared to a single antipsychotic. Given the risk of side effects, stakeholders such as the National Association of State Mental Health Program Directors have called for the reduction of unnecessary use of multiple antipsychotics.[207] The American Psychiatric Association recommends the use of multiple antipsychotics only if a patient has had failed attempts on single antipsychotics. In efforts to promote effective treatment practices, a National Quality Strategy priority, we are proposing to include the process measure HBIPS–4, Patients Discharged on Multiple Antipsychotic Medications, in the FY 2014 IPFQR Program. The MAP and the subject-matter TEP convened by our measure development contractor support the inclusion of this measure in the IPFQR Program.

TJC designed HBIPS–4 as part of a paired set with HBIPS–5 (described below), meaning they were developed to be used together. HBIPS–4 is collected on all patients admitted to an IPF and is reported as the rate of patients discharged on multiple antipsychotics. We believe that lower rates are indicative of higher quality of care because reducing the use of multiple antipsychotics reduces the potential risks of harmful side effects to patients. However, there is no expectation that zero percent is the desired outcome because it is recognized that in some circumstances, use of multiple antipsychotics may be appropriate.

The numerator is defined as psychiatric inpatients discharged on two or more routinely scheduled antipsychotic medications. The denominator is defined as all psychiatric inpatient discharges. The measure excludes patients who died, patients with an unplanned departure resulting in discharge due to elopement, and patients with an unplanned departure resulting in discharge due to failing to return from leave.

Taken together, HBIPS–4 and HBIPS–5 are intended to help reduce unnecessary use of multiple antipsychotics and to promote better clinical outcomes and reduced side effects for patients.

In addition to meeting the statutory requirements as provided in section 1886(s)(4)(D) of the Act, we believe HBIPS–4 also meets a number of additional considerations we take into account when proposing quality measures for the IPFQR Program. The measure assesses the quality of care provided for inpatient psychiatric patients at the facility level. Approximately 450 IPFs already are collecting and reporting the measure for purposes of TJC accreditation. HBIPS–4 received support from the MAP and is aligned with the National Quality Strategy priority for promoting effective prevention and treatment practices.

We invite public comment on the inclusion of the proposed quality measure HBIPS–4, Patients Discharged on Multiple Antipsychotic Medications, in the IPFQR Program beginning with the FY 2014 payment determination. Proposals for collection requirements and submission timeframes are included in section VIII.F.7. of this preamble.

(4) HBIPS–5 (Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification)

In efforts to promote effective treatment practices, a National Quality Strategy priority, we are proposing to include the process measure HBIPS–5, Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification, in the FY 2014 IPFQR Program. The MAP and the subject-matter TEP convened by our measure development contractor support the inclusion of this measure in the IPFQR Program.

TJC designed HBIPS–5 as part of a paired set with HBIPS–4, meaning they were developed to be used together. HBIPS–5 is collected on those patients discharged on multiple antipsychotics and is reported as the rate of patients discharged on multiple antipsychotics with appropriate justification. This measure was designed in recognition that there is a subsample of patients for whom multiple antipsychotic use may be appropriate. TJC has identified the following justifications as appropriate reasons for discharging a patient on

[204] Holmes, D., Kennedy, S.L., & Perron, A. (2004). The mentally ill and social exclusion: a critical examination of the use of seclusion from the patient's perspective. Issues in Mental Health Nursing, 25: 559–578.

[205] New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America. Final Report.* DHHS Pub. No. SMA–03–3832. Rockville, MD: 2003.

[206] New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in America. Final Report.* DHHS Pub. No. SMA–03–3832. Rockville, MD: 2003.

[207] National Association of State Mental Health Program Directors. Technical report on polypharmacy. Alexandria, VA: 2001. Retrieved from *http://www.nasmhpd.org/general_files/publications/med_directors_pubs/Polypharmacy.PDF.*

multiple antipsychotics: (1) The medical record contains documentation of a history of a minimum of three failed trials of monotherapy; (2) the medical record contains documentation of a recommended plan to taper to monotherapy or documentation of a plan to decrease the dosage of one or more antipsychotic medications while increasing the dosage of another antipsychotic medication to a level that manages the patient's symptoms with one antipsychotic medication (that is, cross-taper); and (3) the medical record contains documentation of augmentation of Clozapine. Higher rates on HBIPS–5 indicate higher quality of care because documenting the reasons for assigning two or more antipsychotics suggests that careful consideration of the benefits of this course of treatment were weighed against the potential patient side effects.

The numerator statement is defined as psychiatric inpatients discharged on two or more routinely scheduled antipsychotic medications with appropriate justification. The denominator is defined as psychiatric inpatients discharged on two or more routinely scheduled antipsychotic medications. The measure excludes patients who died, patients with an unplanned departure resulting in discharge due to elopement, patients with an unplanned departure resulting in discharge due to failing to return from leave, and patients with a length of stay less than or equal to 3 days.

Taken together, we believe that HBIPS–4 and HBIPS–5 will help reduce unnecessary use of multiple antipsychotics and will lead to better clinical outcomes and reduced side effects for patients.

In addition to meeting the statutory requirements as provided in section 1886(s)(4)(D) of the Act, we believe HBIPS–5 also meets a number of additional considerations we take into account when proposing quality measures for the IPFQR Program. The measure assesses the quality of care provided for inpatient psychiatric patients at the facility level. Approximately 450 IPFs are already collecting and reporting the measure for purposes of TJC accreditation. HBIPS–5 received support from the MAP and is aligned with the National Quality Strategy priority for promoting effective prevention and treatment practices.

We invite public comment on the inclusion of the proposed quality measure HBIPS–5, Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification, in the IPFQR Program beginning with the FY 2014 payment determination. Proposals for collection requirements and submission timeframes are included in section VIII.F.7. of this preamble.

(5) HBIPS–6 (Post-Discharge Continuing Care Plan Created)

When patients are discharged from the hospital, they may benefit from communication of information regarding the care they received or recommendations for their continued care. For a seamless transition from one treatment setting to another, providers that receive patients from inpatient settings need to know information regarding the patient's treatment during hospitalization, recommendations for post-discharge care, and any medications the patient was discharged on. A discharge plan facilitates this transition of information from one setting to another and has been shown to have positive effects on readmissions.

The promotion of effective care coordination is a National Quality Strategy priority. We are proposing process measure HBIPS–6, Post-Discharge Continuing Care Plan Created, to promote care coordination for patients in inpatient psychiatric settings. TJC designed HBIPS–6 as part of a paired set with HBIPS–7; they were developed to be used together. HBIPS–6 measures whether a post-discharge continuing care plan is created. However, the creation of a care plan does not necessarily mean the plan is communicated to the patient's next provider. Therefore, HBIPS–7 measures whether a post-discharge continuing care plan is created and transmitted to the next level of care provider. Together, these two measures can assist facilities in determining where breakdowns in care processes occur. Quality care under HBIPS–6 is indicated by patients who are discharged with a continuing care plan that includes the reason for the hospitalization, the principal discharge diagnosis, discharge medications, and the next level of care recommendations. HBIPS–6 is collected on all patients admitted to IPFs. We believe that higher rates on this measure suggest better quality of care because greater numbers of post-discharge plans indicate greater opportunities for improved patient-provider and provider-provider communication, thus leading to improved patient care and health.

The numerator is defined as psychiatric inpatients for whom the post-discharge continuing care plan is created and contains all of the following: Reason for hospitalization, principal discharge diagnosis, discharge medications, and next level of care recommendations. The denominator is defined as all psychiatric inpatient discharges. Populations excluded from the denominator include patients who died, patients with an unplanned departure resulting in discharge due to elopement, patients or their guardians who refused aftercare, patients or guardians who refused to sign authorization to release information, and patients with an unplanned departure resulting in discharge due to failing to return from leave.

In addition to meeting the statutory requirements as provided in section 1886(s)(4)(D) of the Act, we believe HBIPS–6 also meets a number of additional considerations we take into account when proposing quality measures for the IPFQR Program. It is appropriate to facility-level assessment of quality of care provided by IPFs. Approximately 450 IPFs are already collecting and reporting the measure for purposes of TJC accreditation. HBIPS–6 received support from the MAP and is aligned with the National Quality Strategy priority for promoting better care coordination.

We invite public comment on the inclusion of the proposed quality measure HBIPS–6, Post-Discharge Continuing Care Plan Created, in the IPFQR Program beginning with the FY 2014 payment determination. Proposals for collection requirements and submission timeframes are included in section VIII.F.7. of this preamble.

(6) HBIPS–7 (Post-Discharge Continuing Care Plan Transmitted to the Next Level of Care Provider Upon Discharge)

The promotion of effective care coordination is a National Quality Strategy priority. We are proposing process measure HBIPS–7, Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider upon Discharge, to promote care coordination for patients in inpatient psychiatric settings. TJC designed HBIPS–7 as part of a paired set with HBIPS–6; they were developed to be used together. While the creation of a discharge care plan (as measured in HBIPS–6) is an important part of providing coordinated care, simply creating the plan does not ensure that the necessary information is transferred to the patient's next provider. HBIPS–7 measures both aspects of coordinated care—the creation of a discharge plan and the transmittal of that plan to the next provider. Together, these two measures can assist facilities in determining where breakdowns in care processes occur. As specified by TJC, the discharge plan should be transmitted by the fifth post-discharge day. This measure is collected on all patients admitted to IPFs. We believe

that higher rates on this measure suggest better quality care because the greater the number of post-discharge plans created and transmitted, the greater opportunities for improved patient-provider and provider-provider communication and understanding of what is necessary to improve patient health.

The numerator is defined as psychiatric inpatients for whom the post-discharge continuing care plan was transmitted to the next level of care. The denominator statement is defined as all psychiatric inpatient discharges. Populations excluded from the denominator include patients who died, patients with an unplanned departure resulting in discharge due to elopement, patients who refused (or whose guardians refused) aftercare, patients who refused to sign (or whose guardians refused to sign) authorization to release information, and patients with an unplanned departure resulting in discharge due to failing to return from leave.

In addition to meeting the statutory requirements as provided in section 1886(s)(4)(D) of the Act, we believe HBIPS–7 also meets a number of additional considerations we take into account when proposing quality measures for the IPFQR Program. The measure assesses the quality of care provided for inpatient psychiatric patients at the facility level. Approximately 450 IPFs are already collecting and reporting the measure for purposes of TJC accreditation. HBIPS–7 received support from the MAP and is aligned with the National Quality Strategy priority for promoting better care coordination.

We invite public comment on the inclusion of the proposed quality measure HBIPS–7, Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider upon Discharge, in the IPFQR Program beginning with the FY 2014 payment determination. Proposals for collection requirements and submission timeframes are included in section VIII.F.7. of this preamble.

In summary, we are proposing to include six quality measures to be reported in aggregate form for FY 2014 and subsequent years. These six measures are shown in the table below. Measures adopted for the IPFQR Program would remain in the quality program for all subsequent years unless specifically stated otherwise (for example, through removal or replacement). Proposals for collection requirements and submission timeframes for these measures are included in section VIII.F.7. of this preamble.

PROPOSED QUALITY MEASURES BEGINNING WITH THE FY 2014 IPFQR PROGRAM

National quality strategy priority	NQF No.	Measure ID	Measure description
Patient Safety	0640	HBIPS–2	Hours of Physical Restraint Use.
	0641	HBIPS–3	Hours of Seclusion Use.
Clinical Quality of Care	0552	HBIPS–4	Patients Discharged on Multiple Antipsychotic Medications.
	0560	HBIPS–5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification.
Care Coordination	0557	HBIPS–6	Post-Discharge Continuing Care Plan Created.
	0558	HBIPS–7	Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider Upon Discharge.

c. Maintenance of Technical Specifications for Quality Measures

We will provide a user manual that will contain links to measure specifications, data abstraction information, data submission information, a data submission mechanism known as the Web-based Measure Tool, and other information necessary for IPFs to participate in the IPFQR Program. This manual will be posted on the QualityNet Web site at: *https://www.QualityNet.org*. We will maintain the technical specifications for the quality measures by updating this manual periodically and including detailed instructions for hospitals to use when collecting and submitting data on the required measures. These updates will be accompanied by notifications to IPFQR Program participants, providing sufficient time between the change and effective dates in order to allow users to incorporate changes and updates to the measure specifications into data collection systems.

Many of the quality measures used in different Medicare and Medicaid reporting programs are NQF-endorsed. As part of its regular maintenance process for NQF-endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes to NQF on an annual basis. NQF solicits information from measure stewards for annual reviews, and it reviews measures for continued endorsement in a specific 3-year cycle.

Through NQF's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, changes to exclusions to the patient population, definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act. In this proposed rule, we are proposing that if the NQF updates an endorsed measure that we have adopted for the IPFQR Program in a manner that we consider to not substantially change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we would revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We also would post the updates on the CMS QualityNet Web site at *https://www.QualityNet.org*. We would provide sufficient lead time for IPFs to implement the changes where changes to the data collection systems would be necessary.

We would continue to use the rulemaking process to adopt changes to measures that we consider to substantially change the nature of the measure. We believe that this proposal

adequately balances our need to incorporate NQF updates to NQF-endorsed IPFQR Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We invite public comment on this proposal.

5. Possible New Quality Measures for Future Years

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the inpatient psychiatric setting. Therefore, through future rulemaking, we intend to propose new measures that will help us further our goal of achieving better health care and improved health for Medicare beneficiaries who obtain inpatient psychiatric services, through the widespread dissemination and use of performance information. Additionally, we are considering initiating a call for future measures to solicit input to assess the following measure domains: Clinical quality of care; care coordination; patient safety; patient and caregiver experience of care; population/community health; and efficiency. This approach will enhance better psychiatric care while bringing the IPFQR Program in line with other established quality reporting and performance improvement programs such as the Hospital IQR Program, the Hospital OQR Program, the ESRD QIP, and other CMS quality programs.

We welcome public comment on considerations of additional measure topics for the IPFQR Program in future rulemaking.

6. Public Display Requirements for the FY 2014 Payment Determination and Subsequent Years

Section 1886(s)(4)(E) of the Act requires the Secretary to establish procedures for making the data submitted under the IPFQR Program available to the public. Such procedures shall ensure that an IPF has the opportunity to review the data that is to be made public with respect to the psychiatric hospital or unit prior to such data being made public. The data collected will be displayed on our Web site. Under these requirements, for each payment determination year, we are proposing to publicly display the submitted data on our Web site beginning in the first quarter of the calendar year following the respective payment determination year. Before the data are publicly displayed, we are proposing that IPFs will have the opportunity to preview their data between September 20 and October 19 of the respective payment determination year (refer to the following table).

PROPOSED PUBLIC DISPLAY FOR FY 2014, FY 2015, AND FY 2016

Payment determination year (fiscal year)	30-day preview period	Public display (calendar year)
FY 2014	September 20, 2013–October 19, 2013	2014
FY 2015	September 20, 2014–October 19, 2014	2015
FY 2016	September 20, 2015–October 19, 2015	2016

We believe this timeframe allows for sufficient time for both IPFs and CMS to correct any potential mistakes and fulfill the preview requirement in section 1886(s)(4)(E) of the Act.

We welcome public comment on the proposed preview and public display procedures for FY 2014 and subsequent years.

7. Form, Manner, and Timing of Quality Data Submission for the FY 2014 Payment Determination and Subsequent Years

a. Background

Section 1886(s)(4)(C) of the Act requires that, for the FY 2014 payment determination and each subsequent year, each IPF submit to the Secretary data on quality measures as specified by the Secretary. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary. As required by section 1886(s)(4)(A) of the Act, for any IPF that fails to submit quality data in accordance with section 1886(s)(4)(C) of the Act, the Secretary will reduce any annual update to a standard Federal rate for discharges occurring during such fiscal year by 2.0 percentage points. The complete data submission requirements, submission deadlines, and data submission mechanism known as the Web-Based Measure Tool will be posted on the QualityNet Web site at: *http://www.qualitynet.org/*. The Web-Based Measure Tool is an Internet database for IPFs to submit their aggregate data. We are proposing that IPFs submit data in accordance with the specifications for the appropriate proposed reporting periods to the Web-Based Measures Tool found in the IPF section on the QualityNet Web site (*http://www.qualitynet.org/*). This Web site meets or exceeds all current Health Insurance Portability and Accountability Act (HIPAA) requirements for security of protected health information.

b. Proposed Procedural Requirements for the FY 2014 Payment Determination and Subsequent Years

In order to participate in the IPFQR Program for the FY 2014 payment determination and subsequent years, we are proposing that IPFs must comply with the procedural requirements outlined below. We have aligned these procedural requirements with the Hospital IQR Program to avoid imposing additional burden on providers and to increase efficiencies by virtue of allowing providers to use similar submission requirements across programs. We are proposing that facilities must do the following:

- Register with QualityNet before the IPF begins reporting, regardless of the method used for submitting the 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 (NOP). IPFs that wish to participate in the IPFQR Program must complete an online NOP. Submission of an NOP is an indication that the IPF agrees to participate in the IPFQR Program and public reporting of their measure rates. The timeframe for completing the NOP is between January 1 and August 15 before each respective payment determination year. Accordingly, for the FY 2014 payment determination year, we are proposing that the timeframe for completing the NOP would be between January 1, 2013 and August 15, 2013.
- Any IPF that receives a new CMS Certification Number (CCN) on or after the beginning of the respective payment

determination year and wishes to participate in the IPFQR Program but has not otherwise submitted a NOP using the new CCN must submit a completed NOP no later than 180 days from the date identified as the open date (that is, the Medicare acceptance date) on the approved CMS Quality Improvement Evaluation System to participate in the IPFQR Program.

- Withdrawals from the IPFQR Program will be accepted no later than August 15 before the beginning of each respective payment determination year. We believe the August 15 deadline will give us sufficient time to update payment determinations for each respective year. Accordingly, we are proposing that the withdrawal period for the FY 2014 payment determination year be between January 1, 2013 and August 15, 2013. If in a given payment determination year, an IPF withdraws from the program, it will receive a reduction of 2.0 percentage points to that year's applicable percentage increase. Once an IPF has submitted a NOP, it is considered to be an active IPFQR participant until such time as the IPF submits a withdrawal form to CMS.
- We will determine if an IPF has complied with our data submission requirements by validating each IPF's CCN and their aggregated data submission on the QualityNet Web site.
- IPFs must submit the aggregated numerator and denominator data for all age groups, for all measures, to avoid the 2.0 percentage point reduction.

As previously noted, we believe that this proposed aggregated data collection mode using a Web page will reduce burden to IPFs. We anticipate that IPFs already reporting de-identified patient level data to TJC would be able to easily aggregate and report these data on a secure Web page to CMS.

We welcome public comment on the proposed procedural requirements for the FY 2014 payment determination and subsequent years.

c. Proposed Reporting and Submission Requirements for the FY 2014 Payment Determination

IPFs choosing to participate in the IPFQR Program must meet the specific data collection and submission requirements as described on the QualityNet Web site (*http://www.qualitynet.org/*) and TJC's Specifications Manual for Joint Commission National Quality Measures (Specifications Manual) at: *http://www.manual.jointcommission.org/releases/TJC2012B/HospitalBasedInpatientPsychiatricServices.html*. We note that the Specifications Manual is updated at least twice a year (and may be updated more often as necessary), and IPFs are responsible for using the requirements in the most recent manual. The most current version can be found on the Web site at: *https://manual.jointcommission.org/bin/view/Manual/WebHome*. We are proposing that IPFs submit aggregate data on the measures on an annual basis, beginning FY 2014. As noted earlier, IPFs must submit the data to the Web-Based Measures Tool found in the Inpatient Psychiatric Facility section on the QualityNet Web site. However, the data input forms on the QualityNet Web site for such submission will require aggregate data for each separate quarter. Therefore, IPFs will need to track and maintain quarterly records for their data.

For the FY 2014 payment determination, we are proposing that IPFs report on the proposed measures for services provided between Q4 of CY 2012 and Q1 of CY 2013. These two quarters' data constitute the expected data available to CMS when we assess reporting compliance. The 6-month timeframe will allow us to establish a full calendar year of reporting by FY 2016 as discussed below. We are proposing that IPFs submit their aggregated data between July 1, 2013 and August 15, 2013. The following table summarizes this information.

PROPOSED QUALITY REPORTING AND SUBMISSION TIMEFRAMES FOR FY 2014

Payment determination (fiscal year)	Proposed reporting period for services provided (calendar year)	Proposed data submission timeframe
FY 2014	Q4 2012 (October 1, 2012–December 31, 2012). Q1 2013 (January 1, 2013–March 31, 2013)	July 1, 2013–August 15, 2013.

We welcome public comment on the proposed reporting and data submission requirements for the FY 2014 payment determination.

d. Proposed Reporting and Submission Requirements for the FY 2015 and FY 2016 Payment Determinations

We are proposing that IPFs report on measures for services provided in Q2, Q3, and Q4 of CY 2013 for the FY 2015 payment determination and in Q1, Q2, Q3, and Q4 of CY 2014 for the FY 2016 payment determination. For FY 2014 and FY 2015, we are proposing that IPFs report data on the proposed measures for inpatient psychiatric services provided for 6 and 9 months, respectively, to move towards data reporting of services provided within a full calendar year (12 months) by FY 2016. We have summarized this proposal in the following table.

PROPOSED QUALITY REPORTING AND SUBMISSION TIMEFRAMES FOR FY 2015 AND FY 2016 PAYMENT DETERMINATIONS

Payment determination (fiscal year)	Proposed reporting period for services provided (calendar year)	Proposed data submission timeframe
FY 2015	Q2 2013 (April 1, 2013–June 30, 2013) Q3 2013 (July 1, 2013–September 30, 2013). Q4 2013 (October 1, 2013–December 31, 2013).	July 1, 2014–August 15, 2014.
FY 2016	Q1 2014 (January 1, 2014–March 31, 2014) Q2 2014 (April 1, 2014–June 30, 2014). Q3 2014 (July 1, 2014–September 30, 2014). Q4 2014 (October 1, 2014–December 31, 2014).	July 1, 2015–August 15, 2015.

The reporting of data within the timeframes outlined previously will allow us to align the IPFQR Program with other quality reporting programs that base their data reporting on a calendar year.

We welcome public comment on the proposed reporting and data submission requirements for the FY 2015 and FY 2016 payment determinations.

e. Proposed Population, Sampling, and Minimum Case Threshold for FY 2014 and Subsequent Years

We are proposing that participating IPFs must meet specific population, sample size, and minimum reporting case threshold requirements as specified in TJC's Specifications Manual. The Specifications Manual is updated at least twice a year (and may be updated more often as necessary), and IPFs must follow the requirements in the most recent manual. The most current version can be found on the Web site at: *https://manual.jointcommission.org/bin/view/Manual/WebHome*.

We are proposing that the target population for the proposed measures include all patients, not solely Medicare beneficiaries. We believe it is important to require IPFs to submit measures on all patients because quality improvement is of industry-wide importance and should not be focused exclusively on a certain subset of patients. We are proposing that IPFs use the applicable sample size requirements found in the Specifications Manual. We note that the Specifications Manual gives providers the option of sampling their data quarterly or monthly. We note that the Specifications Manual does not require sampling procedures for measures HBIPS–2 and HBIPS–3. Therefore, IPFs are required to submit data on all cases for these two measures.

The Specifications Manual uses the term ''minimum required stratum sample size'' to refer to the required sample size for a given initial patient population stratum.[208] To comply with our proposed reporting requirements, if the initial patient population stratum size is below a certain number of cases,[209] for measures HBIPS–4, HBIPS–5, HBIPS–6, and HBIPS–7, IPFs must submit all applicable measure data rather than sample data. More details on sampling procedures are located in the Specifications Manual available at the Web site: *https://manual.jointcommission.org/bin/view/Manual/WebHome*.

IPFs that have no data to report for a given measure must enter zero for the population and sample counts. For example, an IPF that has no hours of physical restraint use (HBIPS–2) to report for a given quarter is still required to submit a zero for its quarterly aggregate population and sample count for HBIPS–2 in order to meet the reporting requirement. We believe it is important for IPFs to submit data on all measures even when the population size for a given measure is zero or small because it provides us with the opportunity to identify, assess, and evaluate the baseline for the number of cases for each measure in future years. This will also assist us in determining the minimum case threshold for future years in the rule. In cases where the measure rates are calculated based on low caseloads, when the submitted data are publicly displayed on the QualityNet Web site, we are proposing to clearly note that the affected measure rates were calculated based on low caseloads that may affect the result.

We invite public comment on the proposed population, sampling, and case thresholds and welcome any comments on methods and approaches for future years.

f. Proposed Data Accuracy and Completeness Acknowledgement Requirements for the FY 2014 Payment Determination and Subsequent Years

We are proposing to require IPFs to acknowledge their data accuracy and completeness once annually using a QualityNet Web site Web page. To affirm that the data provided to meet the FY 2014 IPFQR Program data submission requirement is accurate and complete to the best of a facility's knowledge, an IPF would be required to submit the Data Accuracy and Completeness Acknowledgment (DACA) form. We would provide a link to this form once IPFs have completed entry of all aggregated measure data. Data submission would not be complete until the IPF submits the DACA form. We are proposing that the deadline for submission of both measure data and the DACA form would be no later than August 15 prior to the applicable IPFQR Program payment determination year.

For the FY 2014 payment determination, for which participating IPFs are required to report data for discharges occurring between Q4 of CY 2012 and Q1 of CY 2013, we are proposing to make the submission deadline for the DACA no later than August 15, 2013. We are proposing that the DACA submission deadlines for FY 2015 and FY 2016 would be August 15 of CY 2014 and CY 2015, respectively. We are proposing August 15 as the DACA submission deadline for several reasons. First, requiring IPFs to acknowledge their data's accuracy and completeness by August 15 of the year before the respective payment determination year provides us with sufficient time to ensure compliance with the program by October 1, the start of the fiscal year, and, therefore, with sufficient time to calculate and apply the annual payment update. Second, we believe that it is reasonable to make the deadline for DACA the same as the data submission deadline in order to reduce reporting burden to hospitals. Lastly, using August 15 as the DACA deadline allows us to align our data acknowledgment deadline with other quality reporting programs, such as the Hospital IQR Program. The table below summarizes this information.

PROPOSED DATA ACCURACY AND COMPLETENESS ACKNOWLEDGMENT (DACA) DEADLINES FOR FY 2014, FY 2015, AND FY 2016 PAYMENT DETERMINATIONS

Payment determination (fiscal year)	Proposed reporting period for services provided (calendar year)	Proposed data accuracy and completeness acknowledgement deadline
FY 2014	Q4 2012 (October 1, 2012–December 31, 2012) Q1 2013 (January 1, 2013–March 31, 2013).	August 15, 2013.
FY 2015	Q2 2013 (April 1, 2013–June 30, 2013) Q3 2013 (July 1, 2013–September 30, 2013). Q4 2013 (October 1, 2013–December 31, 2013).	August 15, 2014.
FY 2016	Q1 2014 (January 1, 2014–March 31, 2014)	August 15, 2015.

[208] For example, for initial population stratum size of 211–877, the most current version of the Specifications Manual requires a minimum stratum sample size of 20 percent of the initial population stratum size. If the initial population size is 44–220, the minimum required stratum sample size is 44.

[209] In the most current version of the Specifications Manual this number is 44.

PROPOSED DATA ACCURACY AND COMPLETENESS ACKNOWLEDGMENT (DACA) DEADLINES FOR FY 2014, FY 2015, AND FY 2016 PAYMENT DETERMINATIONS—Continued

Payment determination (fiscal year)	Proposed reporting period for services provided (calendar year)	Proposed data accuracy and completeness acknowledgement deadline
	Q2 2014 (April 1, 2014–June 30, 2014). Q3 2014 (July 1, 2014–September 30, 2014). Q4 2014 (October 1, 2014–December 31, 2014).	

We invite public comment on our proposed DACA requirements.

8. Reconsideration and Appeals Procedures for the FY 2014 Payment Determination and Subsequent Years

In the event an IPF believes that its annual payment update has been incorrectly reduced for failure to report under the IPFQR Program, we are proposing a reconsideration process whereby IPFs can request a reconsideration of their payment update reduction. We are proposing to institute an annual reconsideration process similar to the Hospital IQR program (74 FR 43892). We would not utilize reconsideration policies and procedures related to the Hospital IQR Validation requirement because the IPFQR does not currently propose an annual validation requirement for IPFs. For FY 2014 and subsequent years, we are proposing that the deadline for IPFs to submit a request for reconsideration of their payment determination would be 30 days from the date identified on the payment determination notification letter. While we want to ensure that IPFs 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 IPFs' need to obtain final decisions on their requests in a timely manner. We believe that a 30-day timeframe best achieves this balance.

We believe that requiring providers to submit a request for reconsideration prior to filing an appeal before the Provider Reimbursement Review Board (PRRB) is more efficient for both CMS and IPFs because it decreases the number of appeals by resolving issues earlier in the process. We are proposing that, together with a request for reconsideration, an IPF must submit all documentation and evidence that supports its request for reconsideration. The documentation should include copies of any communication, such as emails, that the IPF believes demonstrates its compliance with the program requirements, as well as any other records that may support the IPF's rationale for seeking reconsideration.

We are proposing to codify the reconsideration procedures that IPFs must follow at new § 412.434 under 42 CFR Part 412, Subpart N. Under these procedures, an IPF must submit to CMS, no later than 30 days from the date identified on the IPFQR Program payment determination notification letter provided to the IPF, a Reconsideration Request form containing the following information:

- The IPF's CMS Certification Number (CCN).
- The name of the IPF.
- Contact information for the IPF's chief executive officer and QualityNet system administrator, including each individual's name, email address, telephone number, and physical mailing address.
- A summary of the reason(s), as set forth in the IPFQR Program Annual Payment Update Notification Letter, that CMS concluded the IPF did not meet the requirements of the IPFQR Program.
- A detailed explanation of why the IPF believes that it complied with the requirements of the IPFQR Program for the applicable fiscal year.
- Any evidence that supports the IPF's reconsideration request, such as e-mails and other documents.

Following receipt of a request for reconsideration, we will provide—

- An email acknowledgment, using the contact information provided in the reconsideration request, to the CEO and the QualityNet Administrator that the request has been received; and
- 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 that IPFs must submit a request for reconsideration, as described previously, and receive a decision on that request from CMS before they can file an appeal with the PRRB. If dissatisfied with the decision rendered at the reconsideration level, IPFs can appeal the decision with the PRRB under 42 CFR Part 405, Subpart R. We are proposing to codify this requirement at new § 412.434(c).

We intend to work with our Medicare administrative contractors to process updated IPF claims in an expeditious manner to pay IPFs when our annual payment update reduction decision is overturned in reconsideration or PRRB review. The timeframe for updating payment through retroactive claims processing widely varies, and is dependent on the number of IPFs, the number of affected claims, and the advance time needed by the Medicare administrative contractor.

We invite public comment on the proposed procedures for reconsideration and appeals.

9. Proposed Waivers From Quality Reporting Requirements for the FY 2014 Payment Determination and Subsequent Years

In our experience with other quality reporting and/or performance programs, we have noted occasions when providers have been unable to submit required quality data due to extraordinary circumstances that are not within their control (for example, natural disasters). It is our goal to avoid penalizing IPFs in such circumstances or to unduly increase their burden during these times. Therefore, we are proposing that, for FY 2014 and subsequent years, IPFs may request and we may grant waivers with respect to the reporting of required quality data when extraordinary circumstances beyond the control of the facility may warrant. When waivers are granted, IPFs will not incur payment reductions for failure to comply with the requirements of the IPFQR Program.

Under the proposed process, in the event of extraordinary circumstances not within the control of the IPF, such as a natural disaster, the IPF may request a reporting extension or a complete waiver of the requirement to submit quality data for one or more quarters. Such facilities would submit a request form to CMS that would be made available on the QualityNet Web site. The following information should be noted on the form:

- The IPF's CCN;
- The IPF's name;

• Contact information for the IPF's CEO and any other designated personnel, including name, email address, telephone number, and mailing address (the address must be a physical address, not a post office box);
• The IPF's reason for requesting an extension or waiver;
• Evidence of the impact of extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
• A date when the IPF will again be able to submit IPFQR Program data, and a justification for the proposed date.

We are proposing that the request form must be signed by the IPF's CEO, and must be submitted within 30 days of the date that the extraordinary circumstances occurred. Following receipt of the request form, we would: (1) Provide a written acknowledgement, using the contact information provided in the request, to the CEO and any additional designated IPF personnel, notifying them that the IPF's request has been received; and (2) provide a formal response to the CEO and any additional designated IPF personnel, using the contact information provided in the request, notifying them of our decision.

This proposal does not preclude us from granting waivers or extensions to IPFs that have not requested them when we determine that an extraordinary circumstance, such as an act of nature (for example, a hurricane or other natural disaster that could reasonably affect a facility's ability to compile or report data), affects an entire region or locale. If we make the determination to grant a waiver or extension to IPFs in a region or locale, we are proposing to communicate this decision through routine communication channels to IPFs and vendors, by means of memoranda, emails, and notices on the QualityNet Web site, among other means.

We invite public comment on this proposal.

10. Electronic Health Records (EHRs)

Although for initial reporting, the opportunity to utilize EHRs for automatic data collection is not applicable because the proposed measures will be submitted as aggregate data, we encourage IPFs to take steps towards adoption of EHRs (also referred to as electronic medical records) that will allow for reporting of clinical quality data from EHRs directly to a CMS repository. We encourage IPFs that are implementing, upgrading, or developing EHR systems to ensure that the technology obtained, upgraded, or developed conforms to standards adopted by HHS. Although the IPFQR Program is in its initial implementation stages, we suggest that IPFs take due care and be diligent to ensure that their EHR systems accurately capture quality data and that, ideally, such systems provide point-of-care decision support that promotes optimal levels of clinical performance.

In the future, we will continue to work with standard-setting organizations and other entities to explore processes through which EHRs could speed the collection of data and minimize the resources necessary for quality reporting.

We welcome public comment on the adoption of EHRs for the IPFQR Program in the future.

IX. MedPAC Recommendations and Other Related Studies and Reports for the IPPS and the LTCH PPS

A. MedPAC Recommendations for the IPPS for FY 2013

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 2012 ''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 2013 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*.

B. Studies and Reports on Reforming the Hospital Wage Index

1. Secretary's Report to Congress on Wage Index Reform

Section 3137(b) of the Affordable Care Act requires the Secretary of Health and Human Services to submit to Congress a report that includes a plan to comprehensively reform the Medicare wage index applied under section 1886(d) of the Act relating to the IPPS. In developing the plan, the Secretary was directed to take into consideration the goals for reforming the wage index that were set forth by MedPAC in its June 2007 report entitled ''Report to Congress: Promoting Greater Efficiency in Medicare.'' This report is available on via the Internet at: *http://www.medpac.gov/documents/jun07_entirereport.pdf*, and was discussed in the FY 2009 IPPS final rule (73 FR 48567 through 48574), the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43824 and 43825), and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50158 and 50159.

In developing the Report to Congress required by section 3137(b) of the Affordable Care Act, CMS contracted with Acumen L.L.C. (Acumen) to review the June 2007 MedPAC report and recommend a methodology for an improved Medicare wage index system. (The Acumen reports are available via the Internet on the Web site at: *http://www.acumenllc.com/reports/cms*. After consultation with relevant parties during the development of the plan (which included an April 12, 2011 special wage index reform open door forum, along with a review of electronically submitted comments and concerns), the Secretary submitted a ''Report to Congress—Plan to Reform the Medicare Hospital Wage Index'') that describes the concept of a Commuting Based Wage Index (CBWI) as a potential replacement to the current Medicare wage index methodology. The following is a summary of the highlights of the report. The complete report can be accessed on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html*.

As discussed in section III.B. of the preamble of this proposed rule, the current wage index methodology relies on labor markets that are based on statistical area definitions (Core-Based Statistical Areas (CBSAs)) established by the Office of Management and Budget (OMB). Hospitals are grouped by geographic location into either an urban labor market (that is, a metropolitan statistical area (MSA) or metropolitan division) or a statewide rural labor market (any area of a State that is not defined as urban). The current system establishes wage indexes for hospital labor market areas, not for individual hospitals. Many parties have argued that these definitions, in many instances, are not reflective of the true cost of labor for any given hospital, particularly for hospitals located on the periphery of labor markets or at labor market boundaries. Multiple exceptions and adjustments have been put into place in attempts to correct perceived inequities. However, many of these exceptions and adjustments may create or further exacerbate distortions in labor market values. The issue of ''cliffs,'' or significant differences in wage index values between proximate hospitals, can often be attributed to one hospital

benefiting from such an exception and adjustment when another hospital cannot.

On April 11, 2012, the Secretary submitted to Congress a report, ''Plan to Reform the Medicare Hospital Wage Index.'' This broad-based plan for reforming the hospital wage index included a fundamental change in the description and definition of labor market areas. The concept, referred to as the commuting based wage index (CBWI), would improve upon Medicare's existing wage index method by using commuting data to define hospital labor market areas. The CBWI is based on data on the number of hospital workers commuting from home to work to define a hospital's labor market. To derive the CBWI, commuting flows would be used to identify the specific areas (for example, zip code or census tracts) from which a hospital hires its workers and to determine the proportion of its workers hired from each area. A CBWI system could use either current hospital cost report data or other alternative sources, such as the Bureau of Labor Statistics (BLS) Occupational Employment Survey data, to calculate labor market area average wage values. While the current wage index system aggregates wage data within geographic CBSA-based areas where hospitals are located, the CBWI would aggregate wage data based upon where the hospital workers reside.

Once the hiring proportions by area and area wage levels are determined, the hospital's benchmark wage level would be calculated as the weighted average of these two elements. This value would then be divided by the national average. This calculation would result in a hospital-specific value, which reflects wage levels in the areas from which a hospital hires, accounting for variation in the proportion of workers hired from each area.

Using more precisely-defined labor markets, the CBWI values can vary for hospitals within the same CBSA or county and, thus, more precisely reflect wage differences within and across CBSA boundaries and address intra-area variation more precisely than the current system. Although the CBWI would allow wage index values to vary *within* a CBSA, the CBWI is less likely to produce large differences—or ''cliffs''—between wage index values for nearby hospitals in adjacent CBSA because nearby hospitals likely hire workers from areas in similar proportions.

Acumen found in its analysis that the CBWI system would more closely reflect hospitals' actual wages than the current CBSA-based system and the MedPAC proposal. As MedPAC suggested in its proposal, the exceptions and adjustments to the wage index system are the primary cause of the often significant ''cliffs'' between wage indexes of nearby hospitals. We believe the CBWI has the potential to reduce the need for exceptions and adjustments and further manipulation of wage index values (as is central to the MedPAC proposal) to prevent these ''cliffs'' between labor market areas.

The Report to Congress detailed several findings relevant to implementation of a CBWI:

- Because the CBWI accounts for specific differences in hospitals' geographic hiring patterns, it would yield wage index values that more closely correlate to actual labor costs than either the current wage index system (with or without geographic reclassification) or a system that attempts to reduce wage index differences across geographic boundaries, such as MedPAC's proposed wage index based on Bureau of Labor Statistics (BLS) data for health care industry workers.
- While a CBWI could be constructed with the most recent Census commuting data, were the CBWI to be adopted, a more up-to-date reporting system for collecting commuting data from hospitals would have to be established so that the wage index calculations would accurately reflect the commuting patterns of hospital employees. We believe that creating a system of more up-to-date commuting data could be achieved with a modest addition to the current reporting requirements.
- Concerns about a CBWI leading to hospitals altering hiring patterns and distorting labor markets do not appear to be worse than under the current system and could be managed with minimal policy adjustments.
- As current statutory provisions governing the Medicare wage index and exceptions to that wage index were designed for the current MSA-based wage index system, their applicability would need to be reviewed if a CBWI were to be adopted.
- The Medicare statute has traditionally applied payment changes in a budget neutral manner. If a CBWI were to be adopted in a budget neutrally manner, payments for some providers would increase while payments for other providers would decrease.

The Secretary was directed to ''consult with relevant affected parties'' during the development of the plan. In a special Medicare wage index open door forum held on April 12, 2011, hospital and hospital association representatives presented several concerns, which included issues with commuting data availability, the continuation of certain exceptions and adjustment policies, and the impacts of the CBWI upon other nonhospital payment systems. Several commenters expressed concern that a CBWI could encourage providers to alter or manipulate hiring practices in order to improve wage index calculations. However, based upon our findings and analysis, we believe it is dubious whether any alteration of a hospital's employment patterns would improve its competitive advantage over other hospitals that employ workers in the same area. We also share a concern expressed by multiple commenters regarding whether a CBWI should be applied to other nonhospital payment systems. Currently, several other payment systems are based upon the Medicare pre-reclassified hospital wage index. It is not clear whether it would be advantageous, or even possible, to apply a CBWI to these provider types.

2. Institute of Medicine (IOM) Study on Medicare's Approach to Measuring Geographic Variations in Hospitals' Wage Costs

In addition to submitting the aforementioned Report to Congress, in April 2010, the Secretary commissioned the Institute of Medicine (IOM) to evaluate Medicare's approach for measuring geographic variation in the wage costs faced by hospitals. The IOM's Phase I report, published in September 2011, is available via the Internet at: *http://iom.edu/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx.* In that report, IOM's Committee on Geographic Adjustment Factors in Medicare Payment proposed a set of recommendations for modifying the hospital wage index in both the method used in its construction and the data used in its calculation.

In constructing the wage index, the IOM recommends altering the current labor market definitions to account for the out-commuting patterns of health care workers who travel to a place of employment in an MSA other than the one in which they live. The IOM's recommendation is based on its theory that county-to-MSA commuting patterns reveal the degree of integration of labor markets across geographically drawn boundaries (that is, MSAs) and a commuting-based smoothing adjustment to the wage index would more accurately measure the market wage each hospital faces. The IOM model uses workers' out-commuting patterns to smooth wage index values for hospitals in different counties, similar

to the out-migration adjustment used in the current wage index system. The IOM also suggests that using out-commuting shares in the smoothing adjustment creates an index based on the wage levels of workers *living* in that area in which a hospital is located, as opposed to wage levels of workers *employed* in that area, as in the CBWI model. In calculating its smoothed wage index, the IOM uses the following four steps:

- Step 1—Compute a wage index for each MSA, adhering to Medicare's current approach for calculating the average hourly wage (AHW) paid by all IPPS hospitals located in the MSA (this step replicates the current pre-reclassification wage index).
- Step 2—Compute an area wage for each county equal to a weighted average of MSA-level AHWs, where the weight for each MSA measures the share of all hospital workers living in the county who commute to hospitals located in that MSA.
- Step 3—Assign all hospitals located in the county a hospital wage index value equal to the county area wage index.
- Step 4—Normalize wage indices to ensure budget neutrality, similar to the approach currently implemented by Medicare.

In addition, the IOM's wage index model uses hourly wage data from the BLS Occupational Employment Survey rather than from hospital cost reports. The IOM also recommends measuring hourly wages using data for all health care workers rather than only hospital workers and using a fuller set of occupations incorporated in the hospital wage index occupational mix adjustment. The IOM suggests that BLS data would reduce administrative burdens placed upon hospitals and, by broadening the array of reported occupations from what is currently covered in the hospital cost report, would achieve more accurate labor markets definitions and reduce year-to-year volatility. The IOM encourages CMS to establish an ongoing agreement with the BLS to use occupational survey data specific to health care workers to calculate average hourly wage values. The IOM suggests, for instance, that the 5-year American Community Survey is a potential source of the necessary commuting information, assuming CMS can arrange to obtain certain nonpublic ''micro-data'' from the BLS.

Preliminary findings demonstrate that the IOM hospital wage index method would result in the reduction in wage index ''cliffs,'' and would diminish the need to maintain current wage index exceptions and adjustments. The IOM also recommends that the hospital wage values should be applied to other nonhospital health care providers, shifting to a single measurement of geographic variation to be used in multiple Medicare provider payment systems. However, we believe that, by creating a wage index that measures the wage level only of workers who live near a hospital rather than of all workers who could potentially work at the hospital (including those who live far away from the hospital), IOM's approach may have some problematic implications. First, some of the wage information used by the IOM index is based on workers employed outside of the hospital's pertinent labor market. Second, the IOM index neglects market-relevant information regarding the wages of workers employed at the hospital who live outside the county of the hospital's location. If the in-commuting workers come from high wage areas, this information should contribute to increasing the hospital's wage index values. Likewise, if such workers live in low wage areas, they should contribute to decreasing the hospital's wage index values.

We are aware of numerous concerns from hospital and hospital association representatives regarding whether the BLS Occupational Employment Survey data is an acceptable source for hospital wage index calculations. (We refer readers to a discussion of the BLS occupational survey data in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43824 and 43825.) While the IOM proposal suggested a more refined use of BLS data than did the previous MedPAC recommendation, there may be significant operational challenges in accessing and compiling health care sector specific wage, occupational mix, and commuting data from the available datasets. Additional research would be required to determine whether the IOM recommendation for applying its hospital wage index to nonhospital providers would be appropriate.

To assist readers in understanding key concepts and differences in the wage index methodologies we discussed earlier in this section, we are presenting below a chart that includes a comparison of the CBWI, the IOM hospital wage index approaches, and MedPAC's recommendation from its June 2007 Report to Congress.

	Current wage index	IOM	MedPAC	CBWI
Labor Market Definition				
Labor Market Area	MSAs or Metropolitan Divisions/rural ''rest of State'' areas.	MSAs or Metropolitan Divisions/rural ''rest of State'' areas.	Blend of county and MSA labor market definitions (50/50).	Creates separate but linked labor-market for each hospital using small geographic areas (for example, zip codes).
Commuting Adjustment	Section 505 Out-Commuting Adjustment.	Adjusts hospitals' wage index values based on the out-commuting patterns of health care workers.	None	Uses in-commuting patterns relevant for individual hospitals to weight benchmark wages constructed for small geographic areas.

	Current wage index	IOM	MedPAC	CBWI
Other Adjustments	Multiple Reclassifications and/or Floors (for example, Frontier State floor, Lugar counties, MGCRB, and Section 508 reclassifications and special exceptions).	IOM proposes three smoothing specifications: (1) Apply to all counties; (2) Apply only to counties to which at least 10 percent of workers commute; (3) Apply only to counties to which at least 10 percent of workers commute and hospital wage index is higher than home-county hospital wage index.	Smoothing algorithm uses iterative process to eliminate large differences in index values across county boundaries.	None.
Measurement of Worker Wages				
Wage Data Source	Hospital cost reports	BLS Occupational Employment Survey.	BLS Occupational Employment Survey.	Any source of establishment wage data could potentially be used (for example, hospital cost reports, BLS Occupational Employment Survey).
Industry Sectors Used to Measure Wages.	Hospitals	Health care sector	All Industries (for example, hospitals, other health care, and nonhealth care sectors).	The CBWI could be implemented using any industry sector.
Occupational Mix	Occupational mix adjustment based on occupational categories of nurses reported on cost reports.	Occupational mix adjustment based on all occupations.	Occupational mix adjustment based on 30 occupations with the highest wage share in the hospital industry.	Occupational mix adjustment based on all occupations available in the wage data source selected.
Other Provider Settings				
Wage Index for Nonhospital Providers.	Pre-floor, pre-reclassification version of the current hospital wage index. A version of this index with an occupational mix adjustment has also been used for payments for other specialized hospital inpatient services.	Use identical hospital wage index methodology, except create an industry-specific occupational mix adjustment for each provider type.	No recommendation	Considerations include: (1) Collect commuting data for each provider type and apply CBWI; (2) Apply CBWI framework, but use hospital wage and commuting data; or (3) Measure using a weighted average of nearby-hospital CBWI values.

X. Proposed Quality Improvement Organization (QIO) Regulation Changes Related to Provider and Practitioner Medical Record Deadlines and Claims Denials

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51648 through 51649), we finalized changes to the utilization and quality control review regulation at 42 CFR 476.78 to require providers to submit medical records relating to services they have furnished in a shorter timeframe than the standard 30 calendar days in certain situations. Medical records must be submitted within 21 calendar days of serious reportable events or where other circumstances, as deemed by the Quality Improvement Organization (QIO), warrant earlier receipt of all required medical information. The changes were part of our effort to improve the QIO work, such as quality improvement assistance, beneficiary (or beneficiary representative) requested QIO quality of care reviews, and QIO medical necessity reviews to achieve the following three aims: (1) Improving individual care; (2) improving health care for populations; and (3) lowering costs through improvement efforts.

While these changes will enhance QIOs' efforts to effectively carry out their responsibilities in a timely manner, QIOs have historically experienced difficulty in obtaining medical information in a timely manner from providers and even more difficulty obtaining this information in a timely manner from practitioners. Without this information, QIOs are unable to carry out their review responsibilities. This is particularly problematic in cases in which Medicare beneficiaries may be awaiting a QIO's decision, for example, responses to complaints about the quality of care received. Although the regulations at 42 CFR Part 476 refer to practitioners' responsibilities in certain instances, § 476.78, which relates to the submission of medical information, addresses only the obligations of providers and not practitioners. No similar provisions exist within the QIO program regulations (that is, 42 CFR parts 475 through 480) that establish timeframes for the submission of medical information by practitioners. Moreover, § 476.90 addresses steps that

a QIO may take when providers or practitioners fail to cooperate with the QIO, including the QIO's authority to deny claims for the failure to respond to a QIO's request for information under paragraph (b) of § 476.90. However, § 476.90(b) limits the QIO's authority to deny claims to providers, and no similar provision exists for practitioners. In fact, a QIO's only recourse against practitioners is contained in § 476.90(a), which conveys a QIO's authority to recommend sanctions against practitioners, as well as providers, for the failure to present evidence of the medical necessity for or the quality of the care provided to a Medicare beneficiary. While recommending that sanctions be pursued against a practitioner is an option for QIOs, this is only appropriate when egregious circumstances exist, as described in 42 CFR 1004.30.

The responsibility of practitioners and providers to supply information to QIOs for use in completing their review activities is implicit throughout the QIO program statute. Most notably, section 1154(a)(7)(C) of the Act makes reference to the QIO's obligation to examine the pertinent records of any practitioner or provider of Medicare services if the QIO has the responsibility of reviewing those services. Section 1156(a) of the Act explicitly addresses the obligation of providers and practitioners to provide information to the QIO. It requires providers and practitioners to support the services or items they have furnished with evidence of their medical necessity and quality. Providers and practitioners must provide this evidence to the QIO in the form and fashion and at such time as may reasonably be required by a QIO in exercising its duties and responsibilities. A practitioner's or provider's failure to provide this evidence could result in the QIO reporting this failure to the Inspector General. One of the QIO's responsibilities, as described in section 1154(a)(2) of the Act, is to determine whether payment shall be made for Medicare services, based on its determination of whether a provider's or practitioner's services were reasonable and medically necessary, met professionally recognized quality standards, and/or were provided in the appropriate setting. It is not possible for a QIO to make a determination that services met these standards and that payment would be appropriate without the medical records it needs to conduct these reviews.

In light of the issues discussed above, in this proposed rule, we are proposing several changes to the regulations at §§ 476.1, 476.78, and 476.90 to more clearly convey the responsibilities of providers and practitioners in submitting medical information and to specify the QIO's authority should the information not be received.

- We are proposing to add a definition of ''providers'' under § 476.1 to clearly denote that certain requirements in Part 476 apply to health care facilities, institutions, and organizations involved in the delivery of health care services to Medicare beneficiaries.
- We are proposing to change the section heading of § 476.78 from ''Responsibilities of health care facilities'' to ''Responsibilities of providers and practitioners''. In addition, we are proposing to add references to ''practitioners'' in § 476.78(b)(2) so that the 21-day and 30-day timeframes for submittal of information apply equally to practitioners and providers. We also are proposing one minor technical change to § 476.78 that is unrelated to the application of timeframes to providers or practitioners. We are proposing to remove the sentence, ''QIOs pay providers paid under the prospective payment system for the costs of photocopying records required 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'', because it is merely a reference to paragraph (c) of § 476.78. Because the sentence does not provide substantive information, we believe it can be deleted without losing any of the necessary content of the paragraph.
- We are proposing changes to § 476.90 that will provide improved instructions to QIOs when attempting to resolve issues associated with practitioners and providers that fail to submit medical information within the timeframes set forth in § 476.78. These proposed changes include: Changing the section heading from ''Lack of cooperation by a health care facility or practitioner'' to ''Lack of cooperation by a provider or practitioner''; incorporating the broader term ''provider'' (as reflected in our proposed change to § 476.1) within § 476.90, as well as references to ''practitioners'', where appropriate. We note that we are proposing to add references to ''practitioners'' in § 476.90(a)(2) to denote that the QIO's authority includes the ability to make financial liability determinations for both providers and practitioners, and we are proposing to add the word ''may'' to clarify that the QIO has the discretion to report a provider's or practitioner's failure to provide evidence of the medical necessity or quality of care provided to the Inspector General. In addition, we are proposing modifications to § 476.90 (b) to denote that QIOs will also deny claims if practitioners fail to submit medical information as requested. We have based this proposed change on the fact that a QIO cannot make a determination about whether payment shall be made on the basis of its reviews, as described in section 1154(a)(2) of the Act, if the QIO does not have the medical records it needs to determine that payment would be appropriate. We also are proposing to add new language to § 476.90(b) to convey the right of providers and practitioners to request a reconsideration by the QIO of its decision to deny the claim based on the failure to receive the medical information, and that no further appeal rights exist beyond the QIO.
- We are proposing to make a technical correction to a cross-reference to ''§ 474.30(c)'' that appears in § 476.90(a)(1). This cross-reference is to the Office of Inspector General regulations that convey the obligations of providers and practitioners; these regulations are now located in 42 CFR 1004.10(c).

We are inviting public comment on our proposals, including the definition of ''providers'', the timeframes for practitioners and providers to follow in submitting medical information, the QIO's authority when medical information is not received, as well as the technical corrections.

XI. 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 2009 Medicare cost reports used to create the proposed FY 2013 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.L. of the preamble of this proposed rule.

Processing year	Wage data year	PPS fiscal year
2012	2009	2013
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 2013 IPPS Update.

2. CMS Occupational Mix Data Public Use File

This file contains the 2010 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.L. of the preamble of this proposed rule.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage*.

Period Available: FY 2013 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 2013 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 2013 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 2013 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 2013.

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 FY 2013 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/HIF/list.asp#TopOfPage*.

Periods Available: FY 1994 through FY 2013 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 2005 through FY 2013 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 2013 IPPS Update.

13. Hospital Readmissions Reduction Program File

This file contains information on the calculation of the Hospital Readmissions Reduction Program payment adjustment. Variables include the proxy excess readmission ratios for acute myocardial infarction, pneumonia and heart failure and the proxy readmissions payment adjustment for each provider included in the program.

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 2013 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. Statutory 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 2014 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, 2012, and 2013, we received 1, 4, 5, 3, 3, and 5 applications, respectively.

3. ICRs for the Occupational Mix Adjustment to the Proposed FY 2013 Index (Hospital Wage Index Occupational Mix Survey)

Section II.F. of the preamble of this proposed rule discusses the occupational mix adjustment to the proposed FY 2013 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.

4. Hospital Applications for Geographic Reclassifications by the MGCRB

Section III.H.3. of the preamble of this proposed rule discusses proposed 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 was previously approved under OMB control number 0938–0573. However, the information collection expired on December 31, 2011. We are currently seeking to reinstate the information collection and, as required by the PRA, will announce public notice and comment periods in the **Federal Register** separate from this notice of proposed rulemaking.

5. ICRs for Application for GME Resident Slots

The information collection requirements associated with the preservation of resident cap positions from closed hospitals, addressed under section IV.I.4. of this preamble, are not subject to the Paperwork Reduction Act (44 U.S.C. Chapter 35), as stated in section 5506 of the Affordable Care Act.

6. 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. The collection of information associated with the original starter set of quality measures was previously approved under OMB control number 0938–0918. We are currently seeking reinstatement of the information collection previously approved under that control number. However, we will be combining the proposed information collection requirements discussed below and addressed in section VIII.A. of this preamble, with the Hospital IQR Program PRA package that was previously approved under 0938–1022. This proposed rule will serve as the required 60-day Federal Register notice to solicit public comments. We welcome public comments on both the plan to combine the PRA packages and the proposed information collection requirements in this proposed rule.

We added additional quality measures to the Hospital IQR Program and submitted an 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. Section 1886(b)(3)(B)(viii)(III) of the Act, as 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 was previously approved under OMB control number 0938–1022.

For the FY 2015 payment determination, 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 are proposing to add one chart-abstracted measure (Elective Delivery Prior to 39 Weeks Gestation), one survey-based measure, and three claims-based measures. In addition, we are proposing to remove one chart-abstracted measure (SCIP–VTE–1: Surgery patients with recommended venous thromboembolism prophylaxis) and 16 claims-based measures.

In addition, in this request, for FY 2016 payment determinations, we are proposing to add one structural measure. We estimate that the proposed changes to our FY 2015 and FY 2016 payment determination measure set will result in a total collection burden to IPPS hospitals of approximately 6,273,199 hours per year.

With respect to the proposed new chart-abstracted measure for the FY 2015 payment determination, we are proposing to add the chart-abstracted measure, Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation. Hospitals would be required to submit data on patients who have elective vaginal deliveries or elective cesarean sections at >=37 and <39 weeks of gestation completed. We estimate that IPPS hospitals will incur an additional 117,474 burden hours resulting from the proposed addition of this measure. We estimate that hospitals will submit data on approximately 1,006,917 cases annually for this measure, and it will require, on average, 7 minutes to abstract the information from medical records for each case to calculate these measures.

The one proposed additional survey measure would be added to the existing HCAHPS survey. Burden for the HCAHPS data collection is currently approved through OMB control number 0938–0981.

The structural measure we are proposing for the FY 2016 payment determination, the Safe Surgery Checklist Use, would require hospitals to report their yes/no response regarding use of a safe surgery checklist. We estimate that it would take the 3,300 hospitals approximately 2 minutes each to answer this question each year, resulting in an estimated total increase of 110 hours for the total burden to hospitals each year.

We also are proposing to add three new claims-based measures for the FY 2015 payment determination. We do not believe that these claims-based measures would create any additional burden for hospitals because they 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 proposed removal of one chart abstracted measure, SCIP–VTE–1: Surgery Patients with Recommended Venous Thromboembolism Prophylaxis, beginning with the FY 2015 payment determination. In addition, in this proposed rule, beginning with the FY 2015 payment determination, we are proposing to remove 16 claims-based measures. We estimate that the proposed removal of the SCIP–VTE–1-measure will reduce the total burden to hospitals by a total of 150,000 hours.

7. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

As discussed in section VIII.B. of this preamble, pursuant to section 1866(k) of the Act, for purposes of FY 2014 and each subsequent fiscal years, a hospital described in section 1886(d)(1)(B)(v) of the Act shall submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. To comply with the statutory mandate, we are implementing the PCHQR Program in our sustained efforts to improving the quality of care for inpatient cancer patients. It is our aim and goal to facilitate high quality of care in a manner that is effective and meaningful, while remaining mindful of reporting burden posed on the PCHs. Therefore, we intend to reduce and avoid duplicative reporting efforts, whenever possible, by leveraging existing infrastructure.

For the FY 2014 program year, we are proposing five NQF-endorsed quality measures developed by the CDC and the American College of Surgeons' Commission on Cancer (ACoS/CoC).

Measure steward	Quality measures
ACoS/CoC	Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer (NQF#0223).

Measure steward	Quality measures
CDC	Combination Chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative Breast Cancer (NQF#0559). Adjuvant Hormonal Therapy (NQF#0220). National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF#0139). National Healthcare Safety Network (NHSN)Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF#0138).

We estimate that 11 PCHs will submit data on approximately 27,273 cases annually for these measures, and it will require, on average, 2.5 hours to abstract the information from medical records for each case to calculate these measures.

Although PCHs have not reported on quality measures to CMS, they have some familiarity with and experience in reporting of quality data. More specifically, out of the 11 existing PCHs, 10 are currently reporting the proposed cancer-specific measures to the ACoS/CoC. This equates to 91 percent of PCHs that already report the measures on a regular basis. Likewise, a majority of the PCHs have been submitting data to the CDC. We believe the fact that the majority of the PCHs have demonstrated the ability to report the measures indicates the proposed regulation do not significantly impact PCHs.

Furthermore, we estimate that reporting aggregated-level data through the CDC and the CMS contractor will not be costly to PCHs. In our burden calculation, we have included the time used for chart abstraction and for training personnel on collection of chart-abstracted data, aggregation of the data, as well as training for submitting the aggregate-level data through these entities (CDC and the CMS contractor). We estimate that the annual hourly burden to each PCH for the collection, submission, and training of personnel for submitting all quality measures is approximately 6293.5 hours in a year for each PCH. The average hourly burden to each PCH is approximately 524 hours per month. This proposed rule would affect all PCHs participating in Medicare. The facilities would have to register with QualityNet and take the proper training in order to be adequately prepared to use the QualityNet system to submit the Notice of Participation form. The anticipated burden to these providers consists of the following: (1) The initial registration with the CDC, CMS contractor, and CMS QualityNet; (2) training of the appropriate staff members on how to use the QualityNet reporting program; (3) the time required for collection and aggregation of data; and (4) the time required for entry of the data to the CDC and the CMS contractor database by the PCH's representative.

We believe the fact that the majority of the PCHs have demonstrated the ability to report the measures indicates the proposed regulation do not significantly impact PCHs. We are proposing the following approach for data reporting. First, patient-level data would be submitted by the PCHs to the CDC for the proposed HAI measures and to the CMS contractor for the proposed cancer-specific measures. Second, the NHSN and CMS contractor will submit aggregated and calculated measure rates to CMS.

We are proposing to implement some procedural requirements to meet the statutory mandate by setting requirements and align with current quality reporting programs. These procedural requirements would involve submission of data to comply with the PCHQR Program requirement.

8. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section VIII.C. of the preamble of this proposed rule, we discuss our proposal to add requirements for the FY 2015 Hospital VBP Program. Specifically, we are proposing to add two additional clinical process of care measures—AMI–10: Statin Prescribed at Discharge and SCIP–Inf-10: Surgery Patients with Perioperative Temperature Management—and two additional outcomes measures—an AHRQ Patient Safety Indicators composite measure and CLABSI: Central Line-Associated Blood Stream Infection. We also are proposing to add a measure of Medicare Spending per Beneficiary in the Efficiency domain. All of these measures are required for the Hospital IQR program; therefore, their 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.

9. ICRs for the Long-Term Care Hospital Quality Reporting (LTCHQR) Program

The FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756) adopted three quality measures for the FY 2014 Payment Determination: (1) Urinary Catheter Associated Urinary Tract Infection [CAUTI] rate per 1, 000 urinary catheter days, for Intensive Care Unit [ICU] Patients (NQF#0138); (2) Central Line Catheter-Associated Blood Stream Infection (CLABSI) Rate for ICU and High-Risk Nursery (HRN) Patients (NQF#0139); and (3) Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay) (NQF #0678). The three measures finalized for the FY 2014 payment determination were NQF-endorsed at the time, although not for the LTCH setting. We also stated the NQF was expected to review some of these measures for applicability to the LTCH setting, and we anticipated this review may result in modifications to any such measures.

As part of its endorsement maintenance process, under NQF's Patient Safety Measures Project (*http://www.qualityforum.org/projects/patient_safety_measures.aspx*), the NQF reviewed the CAUTI and CLABSI measures previously adopted and expanded the scope of endorsement to include additional care settings, including LTCHs. The original NQF-endorsed numbers were retained for these two expanded measures, but the measures were retitled to reflect the expansion of the scope of endorsement. The NQF #0138 Urinary Catheter-Associated Urinary Tract Infection [CAUTI] Rate Per 1,000 Urinary Catheter Days measure is now titled as National Health Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure. The NQF #0139 (Central Line Catheter-Associated Blood Stream Infection [CLABSI] Rate for ICU and High Risk Nursery (HRN) Patients is now titled National Health Safety Network (NHSN) Central Line Associated Blood Stream Infection (CLABSI) Outcome Measure (*http://www.qualityforum.org/News_And_Resources/Press_Releases/2012/NQF_Endorses_Patient_Safety_Measures.aspx*). These expanded measures allow for the calculation of standardized infection

ratio (SIR).[210,211,212,213] We are proposing that the CAUTI and CLABSI measures be adopted in their expanded form for the FY 2014 payment determination and all subsequent fiscal year payment determinations.

We also are proposing in the preamble of this proposed rule to retain the measure Percent of Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678), adopted in the FY 2012 IPPS/LTCH PPS final rule for the FY 2014 payment determination for all subsequent fiscal year payment determinations. We further noted that the Percent of Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) measure is undergoing NQF review for expansion in the scope of endorsement to include additional care settings, including the LTCHs.

In addition, we are proposing five additional quality measures for use in the LTCHQR Program which would affect the FY 2016 LTCHQR Program payment determination. These measures are: (1) Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680); (2) Percentage of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (short-stay) (NQF #0682); (3) Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431); (4) Ventilator Bundle (NQF #0302); and (5) Restraint Rate per 1000 Patient Days (not NQF-endorsed).

The information needed for the three proposed measures, NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure, NHSN Central line- associated Bloodstream Infection (CLABSI) Outcome Measure, and Influenza Vaccination Coverage among Healthcare Personnel, would be collected via the CDC/NHSN (*http://www.cdc.gov/nhsn/*). We are proposing that LTCHs report data on these measures according to measure specifications of these NQF-endorsed measures.

The NHSN is a secure, Internet-based surveillance system that 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 442 LTCHs in operation in the United States and, according to CDC, 80 of these LTCHs already submit HAI data to NHSN. For these LTCHs, we believe the burden related to complying with the requirements of the proposed quality reporting program would be reduced because of familiarity with the NHSN submission process.

Further, the initial setup and acclimation to the NHSN system will have already occurred through the implementation of the of the NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure and the NHSN Central Line- Associated Bloodstream Infection (CLABSI) Outcome Measure for the FY 2014 LTCHQR Program payment determination to the extent they are adopted in the FY 2013 IPPS/LTCH PPS final rule. Even though these measures have been recently reviewed by the NQF and expanded to post-acute care settings, including LTCHs, there has been no change in the way that the data for these measures is to be collected and reported to NHSN. Likewise, there has been no change in the registration and training requirements for providers that are new to the NHSN reporting system. In addition, LTCH providers will begin to use the NHSN system to report CAUTI and CLABSI data on October 1, 2012, to the extent they are adopted in the FY 2013 IPPS/LTCH PPS final rule. By the time that any new measures that are proposed above have been finalized and reporting of same begins, LTCH providers should be very familiar and comfortable with the NHSN reporting system. Thus, by that time, the additional burden related to the reporting of any additional measures should they be finalized in the FY 2013 IPPS/LTCH PPS final rule.

The burden associated with these proposed quality measures is the time and effort associated with collecting and submitting the data concerning CAUTI, CLABSI, and Influenza Vaccination Coverage among Healthcare Personnel to NHSN for LTCHs that are not currently reporting such data. As we have stated above, for LTCHs that already submit data regarding these measures to NHSN, we believe there should be little, if any, additional burden. For LTCHs that submit data to NHSN for other HAIs, but not data for these three proposed measures, there may be some added burden. However, we believe that this burden would be significantly decreased because these LTCHs will already be enrolled in the NHSN system for the submission of measures for the FY 2014 LTCHQR payment determination, provided the proposed CAUTI and CLABSI measures are finalized, and will be already familiar with the NHSN data submission process.

There are currently 442 LTCHs in the United States paid under the LTCH PPS. We estimate that each LTCH would submit approximately 12 NHSN submissions (6 CAUTI events and 6 CLABSI events) per month (144 events per LTCH annually). This equates to a total of approximately 63,648 submissions of HAI data to NHSN from all LTCHs per year. We estimate that each NHSN assessment would 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 database. 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 United States for reporting to NHSN is 26,520 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 $768,497 [214] While these proposed requirements would be subject to the Paperwork Reduction Act, we believe the associated burden hours are accounted for in the information collection request currently approved, OCN 0920–0666.

We analyzed the information collection requirements for the FY 2014 LTCHQR Program quality reporting measure ''Percent of Residents with Pressure Ulcers that are New or Worsened (NQF #0678)'' in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51781).

[210] Centers for Disease Control and Prevention. (2012, January). Central Line-Associated Bloodstream Infection (CLABSI) Event. Retrieved from *http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf.*

[211] National Quality Forum (2012). National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure. Retrieved from *http://www.qualityforum.org/QPS/0139.*

[212] Centers for Disease Control and Prevention. (2012, January). Catheter Associated Urinary Tract Infection Event. Retrieved from: *http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf.*

[213] National Quality Forum (2012). National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure. Retrieved from *http://www.qualityforum.org/QPS/0138.*

[214] Nursing Time—24 hours @ $41.59 per hour = $998.16; $998.16 × 442 LTCHs = approximately $441,187.

Admin Time—36 hours @ $20.57 per hour = $740.52; $740.52 × 442 LTCHs = approximately $327,310.

TOTAL = $441,187 + $327,310 = $768,497.

With respect to the remaining four proposed measures, Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine, Percentage of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (short-stay); Ventilator Bundle, and Restraint Rate per 1,000 Patient Days, we are proposing that we would post the specification for the measures, at a later date, on our Web site along with the specific data elements necessary to be collected. We are proposing to do so because, at this time, we have not completed development of the information collection instrument that LTCHs will use to submit the data for these measures. Because the forms are still under development, we cannot make a complete burden estimate at this time. We are proposing that reporting and submission of these four measures be incorporated into the existing data collection and submission framework, the LTCH CARE Data Set. This is the same data collection and submission framework that will be used by CMS to support providers for reporting on the Percent of Residents with Pressure Ulcers That Are New or Worsened measure.[215]

By building upon preexisting resources for data collection and submission, we intend to foster alignment between measures that helps to reduce the administrative burden related to data collection and submission. We anticipate that the initial setup and acclimation to the data collection by the LTCH CARE Data Set will have already occurred with the adoption of the Pressure Ulcer measure for the LTCHQR Program for the FY 2014 payment determination. Therefore, we believe the transition to reporting the four proposed measures via the LTCH CARE Data Set may be less burdensome.

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.

At this time, we have not completed development of the information collection instrument that LTCHs would have to submit to comply with the aforementioned reporting requirements regarding the measures proposed for data collection by the LTCH CARE Data Set for the FY 2016 LTCHQR payment determination. Because the forms are still under development, we cannot make a complete burden estimate at this time. Once the forms are available, we will prepare and submit the required Paperwork Reduction Act (PRA) package which will fully set forth the anticipated burden to LTCH providers as a result of the new data items (questions) that need to be added to the LTCH CARE Data Set. The PRA process provides for the publication of two PRA notices in the **Federal Register** which are followed by 60 and 30 day comment periods respectively. The PRA notice and comment process is similar to that provided for with the proposed and final rule notice and comment process. Therefore, even if it is not possible, at this time, for CMS to provide all of the necessary burden estimate information related to the new measures that we are proposing to add to the LTCHQR Program, stakeholders will still be afforded opportunities to submit public comments in accordance with the PRA rules and guidelines.

10. ICRs for the Ambulatory Surgical Center (ASC) Quality Reporting Program

In section VIII.E. of the preamble of this proposed rule, we discuss the proposed requirements for the ASC Quality Reporting Program for payment determinations affecting CY 2014 and subsequent years. In section XIV.K. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we finalized our proposal to implement a quality reporting program for ASCs beginning with the CY 2014 payment determination. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74554) for a detailed discussion of the ASC Quality Reporting Program collection of information requirements for the claims-based and structural measures for the CY 2014 and CY 2015 payment determinations.

In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74516), we finalized our proposal to consider an ASC to be participating in the ASC Quality Reporting Program for the CY 2014 payment determination if the ASC includes Quality Data Codes (QDCs) specified for the program on their CY 2012 claims relating to the finalized measures.

For the CY 2015 payment determination and subsequent payment determination years, we are proposing that once an ASC submits any quality measure data, it would be considered to be participating in the ASC Quality Reporting Program. Once an ASC submits quality measure data indicating its participation in the ASC Quality Reporting Program, in order to withdraw, an ASC must complete and submit an online form indicating that it is withdrawing from the quality reporting program.

For the CY 2015 payment determination and subsequent payment determination years, if the ASC submits quality measure data, there is no additional action required by the ASC to indicate participation in the program. The burden associated with the requirements to withdraw from the program is the time and effort associated with accessing, completing, and submitting the online form. Based on the number of hospitals that have withdrawn from the Hospital OQR Program over the past 4 years, we estimate that 2 ASCs would withdraw per year and that an ASC would expend 30 minutes to access and complete the form, for a total burden of 1 hour per year.

For the CY 2015 payment determination, we are proposing to require ASCs to identify and register a QualityNet administrator in order to set up accounts necessary to enter structural measure data. We estimate that, based upon previous experience with the Hospital OQR Program, it would take an ASC 10 hours to obtain, complete, and submit an application for a QualityNet administrator and then set up the necessary accounts for structural measure data entry. We estimate the total burden to meet these requirements to be 51,750 hours (10 hours × 5,175 ASCs). We previously discussed the burden associated with the data entry of structural measure information for the ASC Quality Reporting Program in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74554).

We are proposing to adopt a process for an extension or waiver for submitting information required under the program due to extraordinary circumstances that are not within the ASC's control. We are proposing that an ASC would complete a request form that would be available on the QualityNet Web site, supply requested information, and submit the request. The burden associated with these requirements is the time and effort associated with gathering required information as well as accessing, completing, and submitting the form. Based on the number of hospitals that have submitted a request for an extension or waiver from the Hospital OQR Program over the past 4 years, we estimate that 1 ASC per

[215] The LTCH CARE Data Set, the data collection instrument that will be used to submit data on this measure, is currently under Paperwork Reduction Act (PRA) review by the Office of Management and Budget. It is discussed in a PRA Notice which appeared in the **Federal Register** on September 2, 2011 (Volume 76, Issue 171). The file number for the LTCH PRA package is CMS–10409.

year would request an extension or waiver and that an ASC would expend 2 hours to gather required information as well as access, complete, and submit the form, for a total burden of 2 hours per year.

We also are proposing a reconsideration process that would apply to the CY 2014 payment determination and subsequent payment determination years under the ASC Quality Reporting Program. While there is burden associated with an ASC filing a reconsideration request, the regulations at 5 CFR 1320.4 for the Paperwork Reduction Act of 1995 exclude collection activities during the conduct of administrative actions such as redeterminations, reconsiderations, and/or appeals.

We are requesting public comments on these information collection requirements.

11. ICRs for the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

In section VIII.F. of the preamble of this proposed rule, we discuss the implementation of the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program.

Historically, IPFs have not been required to report quality data to CMS. However, they have been required to report quality measures to other entities such as TJC or State survey and certification organizations. Therefore, although IPFs have not reported on quality measures to CMS, they have some familiarity with and experience in reporting of quality data. More specifically, out of the 1,741 existing IPFs, 450 are currently reporting the proposed measures to TJC. This equates to 26.02 percent of IPFs that already report the measures on a regular basis. The fact that over one-quarter of the IPFs have demonstrated the ability to report the measures indicates the proposed regulation would not significantly impact IPFs.

Furthermore, we estimate that reporting aggregated-level data on QualityNet will not be costly to IPFs. In our burden calculation, we have included the time used for chart abstraction and for training personnel on collection of chart-abstracted data, aggregation of the data, as well as training for submitting the aggregate-level data through QualityNet. We estimate that the annual hourly burden to each IPF for the collection, submission, and training of personnel for submitting all quality measures is approximately 821 hours in a year for each IPF. The average hourly burden to each IPF is approximately 68 hours per month.

This proposed rule would affect all IPFs participating in Medicare. The facilities would have to register with QualityNet and take the proper training in order to be adequately prepared to use the QualityNet system to submit the data. The anticipated burden to these providers consists of the following: (1) The initial registration of the facility with QualityNet; (2) training of the appropriate staff members on how to use the QualityNet reporting program; (3) the time required for collection and aggregation of data; and (4) the time required for entry of the data into the QualityNet database by the IPF's representative.

This proposed rule would affect all IPFs that currently do not already report data to CMS. These facilities will have to register with CMS and take the proper training in order to be adequately prepared to use the CMS QualityNet System for data submission.

Those IPFs that already report quality measures to the TJC will be minimally affected because the abstraction methods, population, sampling, and reporting approaches are similarly adopted by CMS. Therefore, IPFs that report the proposed IPFQR Program quality measures will experience a minimum burden.

We are requesting public comments on these information collection requirements.

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–1588–P

Fax: (202) 395–6974; or

Email: *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 424

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 476

Health care, Health professional, Health record, Peer Review Organization (PRO), Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, 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 Public Law 106–113 (113 Stat. 1501A–332).

2. Section 412.1 is amended by adding new paragraphs (a)(5) and (a)(6) to read as follows:

§ 412.1 Scope of part.

(a) * * *

(5) This part implements section 1886(q) of the Act, which provides that, effective for discharges from an ''applicable hospital'' beginning on or after October 1, 2012, payments to those hospitals under section 1886(d) of the Act will be reduced to account for certain excess readmissions, under the Hospital Readmissions Reduction Program. This reduction will be made through an adjustment to the hospital's base operating DRG payment amounts under the prospective payment system for inpatient operating costs.

(6) This part implements section 1886(o)(1)(B) of the Act, which directs the Secretary to begin to make value-based incentive payments under the Hospital Value-Based Purchasing Program to hospitals for discharges

occurring on or after October 1, 2012, through an adjustment to the base operating DRG payment amounts under the prospective payment system for inpatient operating costs.

* * * * *

3. Section 412.64 is amended by—

a. Revising paragraph (d)(1)(iv).

b. Revising the introductory text of paragraph (h)(4).

c. Revising paragraph (h)(4)(v).

d. Adding a new paragraph (h)(4)(vi).

The revisions and addition 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 years 2012 and 2013, the percentage increase in the market basket index less a multifactor productivity adjustment (as determined by CMS) and less 0.1 percentage point for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) for hospitals in all areas.

* * * * *

(h) * * *

(4) For discharges on or after October 1, 2004 and before October 1, 2013, CMS establishes a minimum wage index for each all-urban State, as defined in paragraph (h)(5) of this section. This minimum wage index value is computed using the following methodology.

* * * * *

(v) The product determined under paragraph (h)(4)(iv) of this section is the minimum wage index value for the State, except as provided under paragraph (h)(4)(vi) of this section;

(vi) For discharges on or after October 1, 2012 and before October 1, 2013, the minimum wage index value for the State is the higher of the value determined under paragraph (h)(4)(iv) of this section or the value computed using the following alternative methodology:

(A) CMS estimates a percentage representing the average percentage increase in wage index for hospitals receiving the rural floor due to such floor.

(B) For each all-urban State, CMS makes a onetime determination of the lowest hospital wage index in the State (including all adjustments to the hospital's wage index, except for the rural floor, the rural floor budget neutrality, and the outmigration adjustment) and increases this wage index by the percentage determined under paragraph (h)(4)(vi)(A) of this section, the result of which establishes the alternative minimum wage index value for the State.

* * * * *

4. Section 412.92 is amended by—

a. Revising paragraph (b)(2)(i).

b. Adding paragraph (b)(2)(v).

b. Adding paragraph (b)(3)(iv).

The revision and additions read as follows:

§ 412.92 Special treatment: Sole community hospitals.

* * * * *

(b) * * *

(2) * * * (i) Sole community hospital status is effective 30 days after the date of CMS' written notification of approval, except as provided in paragraph (b)(2)(v) of this section.

* * * * *

(v) If a hospital that is classified as an MDH under § 412.108 applies for classification as a sole community hospital because its status under the MDH program expires with the expiration of the MDH program, and that hospital's sole community hospital status is approved, the effective date of approval of sole community hospital status is the day following the expiration date of the MDH program if the hospital—

(A) Applies for classification as a sole community hospital prior to 30 days before the expiration of the MDH program; and

(B) Requests that sole community hospital status be effective with the expiration of the MDH program.

(3) * * *

(iv) A sole community hospital must report to the fiscal intermediary or MAC any factor or information that could have affected its initial classification as a sole community hospital. If CMS determines that a sole community hospital has failed to comply with this requirement, CMS may cancel the hospital's classification as a sole community hospital effective with the date the hospital failed to meet the criteria for such classification, consistent with the provisions of § 405.1885 of this chapter.

* * * * *

5. 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, or inpatient hospice services.

* * * * *

6. Section 412.140 is amended by revising paragraphs (a)(3)(i), (b), and (d)(2) to read as follows:

§ 412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Review (IQR) Program.

(a) * * *

(3) * * *

(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 calendar year preceding the first quarter of the calendar year in which data submission is required for any given fiscal year.

* * * * *

(b) *Withdrawal from the Hospital IQR Program.* A subsection (d) hospital may withdraw from the Hospital IQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet Web site. The hospital must submit the withdrawal form by May 15 prior to the start of the payment year affected. For example, if a hospital seeks to withdraw from the FY 2015 payment determination, the hospital must submit the withdrawal form to CMS by May 15, 2014.

* * * * *

(d) * * *

(2) A hospital meets the validation requirement with respect to a fiscal year if it achieves a passing score, as determined by CMS, on applicable measure sets.

* * * * *

7. Subpart I is added to read as follows:

SUBPART I—ADJUSTMENTS TO THE BASE OPERATING DRG PAYMENT AMOUNTS UNDER THE PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT OPERATING COSTS

Sec.
412.150 Basis and scope of subpart.

Payment Adjustments Under the Hospital Readmissions Reduction Program

412.152 Definitions for the Hospital Readmissions Reduction Program.
412.154 Payment adjustments under the Hospital Readmissions Reduction Program.
412.155–412.159 [Reserved]

Incentive Payments Under the Hospital Value-Based Purchasing Program

412.160 Definitions for the Hospital Value-Based Purchasing Program.
412.162 Process for reducing the base operating DRG payment amount and applying the value-based incentive payment amount adjustment under the Hospital Value-Based Purchasing (VBP) Program.
412.163 Process for posting hospital-specific performance information under the Hospital Value-Based Purchasing (VBP) Program.
412.164 Measures selection under the Hospital Value-Based Purchasing (VBP) Program.
412.165 Performance standards under the Hospital Value-Based Purchasing (VBP) Program.
412.166 Performance scoring under the Hospital Value-Based Purchasing (VBP) Program.
412.167 Appeal under the Hospital Value-Based Purchasing (VBP) Program.
412.168–412.169 [Reserved]

SUBPART I—ADJUSTMENTS TO THE BASE OPERATING DRG PAYMENT AMOUNTS UNDER THE PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT OPERATING COSTS

§ 412.150 Basis and scope of subpart.

(a) Section 1886(q) of the Act requires the Secretary to establish a Hospital Readmissions Reduction program, under which payments to applicable hospitals are reduced in order to account for certain excess readmissions, effective for discharges beginning on October 1, 2012. The rules for determining the payment adjustment under the Hospital Readmission Reductions Program are specified in §§ 412.152 and 412.154.

(b) Section 1886(o) of the Act requires the Secretary to establish a Value-Based Purchasing (VBP) Program for inpatient hospitals (Hospital VBP Program), which requires CMS to make value-based incentive payments to hospitals that meet performance standards for applicable performance periods, effective for discharges beginning on October 1, 2012. The rules for determining the payment adjustment under the Hospital Value-Based Purchasing Program are specified in §§ 412.160 through 412.167.

Payment Adjustments Under the Hospital Readmissions Reduction Program

§ 412.152 Definitions for the Hospital Readmissions Reduction Program.

As used in this section and in § 412.154, the following definitions apply:

Aggregate payments for all discharges is, for a hospital for the applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period.

Aggregate payments for excess readmissions is, for a hospital for the applicable period, the sum, for the applicable conditions, of the product for each applicable condition of:

(1) The base operating DRG payment amount for the hospital for the applicable period for such condition;

(2) The number of admissions for such condition for the hospital for the applicable period; and

(3) The excess readmission ratio for the hospital for the applicable period minus 1.

Applicable condition is a condition or procedure selected by the Secretary among conditions and procedures for which:

(1) Readmissions represent conditions or procedures that are high volume or high expenditures; and

(2) Measures of such readmissions have been endorsed by the entity with a contract under section 1890 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).

Applicable hospital is a hospital described in section 1886(d)(1)(B) of the Act or a hospital in Maryland that is paid under section 1814(b)(3) of the Act and that, absent the waiver specified by section 1814(b)(3) of the Act, would have been paid under the hospital inpatient prospective payment system.

Applicable period is, with respect to a fiscal year, the 3-year period (specified by the Secretary) from which data are collected in order to calculate excess readmission ratios and adjustments under the Hospital Readmissions Reduction Program.

Base operating DRG payment amount is the wage-adjusted DRG operating payment plus any applicable new technology add-on payments under subpart F of this part. This amount is determined without regard to any payment adjustments under the Hospital Value-Based Purchasing Program, as specified under § 412.162. This amount does not include any additional payments for indirect medical education under § 412.105, the treatment of a disproportionate share of low-income patients under § 412.106, outliers under subpart F of this part, and a low volume of discharges under § 412.101.

Excess readmissions ratio is a hospital-specific ratio for each applicable condition for an applicable period, which is the ratio (but not less than 1.0) 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.

Floor adjustment factor is the value that the readmissions adjustment factor cannot be less than for a given fiscal year. The floor adjustment factor is set at 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years.

Readmission is 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 of 30 days from the date of such discharge.

Readmissions adjustment factor is equal to the greater of:

(1) 1 minus the ratio of the aggregate payments for excess readmissions to aggregate payments for all discharges; or

(2) The floor adjustment factor.

Wage-adjusted DRG operating payment is the applicable average standardized amount adjusted for resource utilization by the applicable MS–DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index (and by the applicable cost-of-living adjustment for hospitals located in Alaska and Hawaii).

§ 412.154 Payment adjustments under the Hospital Readmissions Reduction Program.

(a) *Scope.* This section sets forth the requirements for determining the payment adjustments under the Hospital Readmissions Reduction Program for applicable hospitals to account for excess readmissions in the hospital.

(b) *Payment adjustment.* (1) *General.* To account for excess readmissions, except as provided for in paragraph (d) of this section, an applicable hospital's base operating DRG payment amount is adjusted for each discharge occurring during the fiscal year. The payment adjustment for each discharge is determined by subtracting the product of the base operating DRG payment amount (as defined in § 412.152) for such discharge by the hospital's readmission payment adjustment factor for the fiscal year (determined under paragraph (e) of this section) from the base operating DRG payment amount for such discharge.

(2) *Special treatment for sole community hospitals.* In the case of a sole community hospital that receives payments under § 412.92(d) based on the hospital-specific rate, the difference between the hospital-specific rate

payment and the Federal rate payment determined under subpart D of this part is not affected by this payment adjustment.

(c) *Methodology to calculate the readmissions payment adjustment factor.* A hospital's readmission payment adjustment factor is the higher of the ratio described in paragraph (c)(1) of this section or the floor adjustment factor set forth in paragraph (c)(2) of this section.

(1) *Ratio.* The ratio is equal to 1 minus the ratio of the aggregate payments for excess readmissions as defined in § 412.152 and the aggregate payments for all discharges as defined in § 412.152.

(2) *Floor adjustment factor.* The floor adjustment factor is:

(i) For FY 2013, 0.99;

(ii) For FY 2014, 0.98; and

(iii) For FY 2015 and subsequent fiscal years, 0.97.

(d) *Hospitals paid under section 1814(b)(3) of the Act (certain Maryland hospitals).* The Secretary will consider whether to exempt Maryland hospitals that are paid under section 1814(b)(3) of the Act and that, absent the provisions of section 1814(b)(3) of the Act, would be paid under section 1886(d) of the Act from the Hospital Readmissions Reduction Program, provided that the State submits an annual report to the Secretary describing how a similar program to reduce hospital readmissions in that State achieves or surpasses the measured results in terms of health outcomes and cost savings for the Hospital Readmissions Reduction Program as applied to hospitals described in section 1886(d)(1)(B) of the Act.

(1) CMS will establish criteria for evaluation of Maryland's annual report to the Secretary to determine whether Maryland will be exempted from the program for a given fiscal year.

(2) Maryland's annual report to the Secretary and request for exemption from the Hospital Readmissions Reduction Program must be resubmitted and reconsidered annually.

(e) *Limitations on review.* There is no administrative or judicial review under this subpart of the following:

(1) The determination of base operating DRG payment amounts.

(2) The methodology for determining the adjustment factor under paragraph (c) of this section, including the excess readmissions ratio, aggregate payments for excess readmissions, and aggregate payments for all discharges.

(3) The applicable period.

(4) The applicable conditions.

(f) *Reporting of hospital-specific information.* CMS will make information available to the public regarding readmissions rates of each applicable hospital (as defined in § 412.152) under the Hospital Readmissions Reduction Program.

(1) To ensure that an applicable hospital has the opportunity to review and submit corrections for its excess readmission ratios for the applicable conditions for a fiscal year that are used to determine its readmissions payment adjustment factor under paragraph (c) of this section, CMS will provide each applicable hospital with confidential hospital-specific reports and discharge level information used in the calculation of its excess readmission ratios.

(2) Applicable hospitals will have a period of 30 days after receipt of the information provided in paragraph (f)(1) of this section to review and submit corrections for the excess readmission ratios for each applicable condition that are used to calculate the readmissions payment adjustment factor under paragraph (c) of this section for the fiscal year.

(3) The administrative claims data used to calculate an applicable hospital's excess readmission ratios for the applicable conditions for a fiscal year are not subject to review and correction under paragraph (f)(1) of this section.

(4) CMS will post the excess readmission ratios for the applicable conditions for a fiscal year for each applicable hospital on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov*).

§§ 412.155–412.159 [Reserved]

Incentive Payments Under the Hospital Value-Based Purchasing Program

§ 412.160 Definitions for the Hospital Value-Based Purchasing Program.

As used in this section and in §§ 412.162 through 412.167:

Achievement threshold means the median performance level among all hospitals on a measure during the baseline period or performance period, as applicable, for each measure for a fiscal year.

Applicable percent means the following:

(1) For FY 2013, 1.0 percent;

(2) For FY 2014, 1.25 percent;

(3) For FY 2015, 1.50 percent;

(4) For FY 2016, 1.75 percent; and

(5) For FY 2017 and subsequent fiscal years, 2.0 percent.

Base operating DRG payment amount means the following:

(1) With respect to a subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Act), the wage-adjusted DRG operating payment plus any applicable new technology add-on payments under subpart F of this part. This amount is determined without regard to any payment adjustments under the Hospital Readmissions Reduction Program, as specified under § 412.154. This amount does not include any additional payments for indirect medical education under § 412.105, the treatment of a disproportionate share of low-income patients under § 412.106, outliers under subpart F of this part, or a low volume of discharges under § 412.101.

(2) With respect to a Medicare-dependent, small rural hospital that receives payments under § 412.108(c) or a sole community hospital that receives payments under § 412.92(d), the wage-adjusted DRG operating payment plus any applicable new technology add-on payments under subpart F of this part. This amount does not include any additional payments for indirect medical education under § 412.105, the treatment of a disproportionate share of low-income patients under § 412.106, outliers under subpart F of this part, or a low volume of discharges under § 412.101. This amount also does not include the difference between the hospital-specific payment rate and the Federal payment rate determined under subpart D of this part.

(3) With respect to a hospital that is paid under section 1814(b)(3) of the Act, the payment amount under section 1814(b)(3) of the Act.

Benchmark means the arithmetic mean of the top decile of performance among all hospitals on a measure during the baseline period or performance period, as applicable, for each measure for a fiscal year.

Cited for deficiencies that pose immediate jeopardy means that, during the applicable performance period, the Secretary cited the hospital for immediate jeopardy on at least two surveys using the Form CMS–2567, Statement of Deficiencies and Plan of Correction.

Domain means a category of quality measures given weighting for purposes of performance scoring as a component of the Total Performance Score.

Domain score means the points awarded to a hospital for scored measures in a domain.

Hospital means a hospital described in section 1886(d)(1)(B) of the Act, but does not include a hospital, with respect to a fiscal year, for which one or more of the following applies:

(1) The hospital is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) of the Act for the fiscal year;

(2) The hospital was cited for deficiencies that pose immediate jeopardy by the Secretary during the performance period for the fiscal year;

(3) There are not a minimum number of measures that apply to the hospital for the performance period for the fiscal year; or

(4) There are not a minimum number of cases for the measures that apply to the hospital for the performance period for the fiscal year.

Immediate jeopardy has the same meaning as that term is defined in § 489.3 of this chapter.

Improvement threshold means an individual hospital's performance level on a measure during the baseline period for a fiscal year.

Performance period means the time period during which data are collected for the purpose of calculating hospital performance on measures under the Hospital VBP Program.

Performance standards are the levels of performance that hospitals must achieve in order to earn points under the Hospital VBP Program.

Total Performance Score means the numeric score ranging from 0 to 100 awarded to each hospital based on its performance under the Hospital VBP Program with respect to a fiscal year.

Value-based incentive payment percentage means the percentage of the total base operating DRG payment amount for each discharge that a hospital has earned, based on its Total Performance Score, the applicable percent, and the exchange function slope, with respect to a fiscal year.

Value-based payment adjustment factor is calculated by subtracting the applicable percent from the value-based incentive payment percentage, converting the result to a number, and adding one.

Wage-adjusted DRG operating payment is the applicable average standardized amount adjusted for resource utilization by the applicable MS–DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index (and by the applicable cost-of-living adjustment for hospitals located in Alaska and Hawaii).

§ 412.162 Process for reducing the base operating DRG payment amount and applying the value-based incentive payment amount adjustment under the Hospital Value-Based Purchasing (VBP) Program.

(a) *General.* If a hospital meets or exceeds the performance standards that apply to the Hospital VBP Program for a fiscal year, CMS will make value-based incentive payments to the hospital under the requirements and conditions specified in this section.

(b) *Value-based incentive payment amount.* (1) *Available amount.* The value-based incentive payment amount for a discharge is the portion of the payment amount that is attributable to the Hospital VBP Program. The total amount available for value based incentive payments to all hospitals is equal to the total amount of base-operating DRG payment reductions, as estimated by the Secretary, according to section 1886(o)(6)(C)(ii)(I) of the Act.

(2) *Calculation of the value-based incentive payment amount.* The value-based incentive payment is determined by multiplying the base operating DRG payment amount and the value-based incentive payment percentage.

(3) *Calculation of the he value-based incentive payment percentage.* The value-based incentive payment percentage is calculated as the product of: The applicable percent as specified in paragraph (d) of this section, the hospital's Total Performance Score divided by 100, and the exchange function slope.

(c) *Methodology to calculate the value-based incentive payment adjustment factor.* (1) *General.* The base operating DRG payment amount payment amount for each discharge is adjusted under the Hospital VBP Program by multiplying the base operating DRG payment amount by the value-based incentive payment adjustment factor.

(2) *Calculation Methodology.* The value-based incentive payment adjustment factor for each discharge is determined by subtracting the applicable percent as specified in paragraph (d) of this section from the value-based incentive payment percentage and then adding that difference to one.

(d) *Hospitals paid under section 1814 of the Act (Maryland hospitals).* (1) The Secretary may exempt Maryland hospitals from the requirements of the Hospital VBP Program for a fiscal year if the State submits an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under the Hospital VBP Program.

(e) *Limitations on review.* There is no administrative or judicial review of the following:

(1) The methodology used to determine the amount of the value-based incentive payment under section 1886(o)(6) of the Act and the determination of such amount.

(2) The determination of the amount of funding available for value-based incentive payments under section 1886(o)(7)(A) of the Act and the payment reduction under section 1886(o)(7)(B)(i) of the Act.

(3) The establishment of the performance standards under section 1886(o)(3) of the Act and the performance period under section 1886(o)(4) of the Act.

(4) The measures specified under section 1886(b)(3)(B)(viii) of the Act and the measures selected under section 1886(o)(2) of the Act.

(5) The methodology developed under section 1886(o)(5) of the Act that is used to calculate hospital performance scores and the calculation of such scores.

(6) The validation methodology that is specified under section 1886(b)(3)(B)(viii)(XI) of the Act.

§ 412.163 Process for posting hospital-specific performance information under the Hospital Value-Based Purchasing (VBP) Program.

(a) CMS will make information available to the public regarding the performance of each hospital (as defined in § 412.160(h) of the subpart) under the Hospital VBP Program.

(b) To ensure that a hospital has the opportunity to review and submit corrections for the information to be made public under this section, CMS will provide each hospital with confidential hospital-specific reports and discharge level information used in the calculation of its performance with respect to each measure, condition, and domain, and the calculation of its Total Performance Score.

(c) Hospitals will have a period of 30 days after CMS provides the information specified in paragraph (b) of this section to review and submit corrections for the information.

(d) CMS will post the information specified in paragraph (b) for each hospital on the *Hospital Compare* Web site.

§ 412.164 Measures selection under the Hospital Value-Based Purchasing (VBP) Program.

(a) CMS will select measures, other than measures of readmissions, for purposes of the Hospital VBP Program. Such measures will be a subset of the measures specified under section 1886(b)(3)(B)(viii) of the Act (the Hospital Inpatient Quality Reporting Program).

(b) CMS will post data on each measure on the *Hospital Compare* Web site for at least 1 year prior to the beginning of a performance period for the measure under the Hospital VBP Program.

§ 412.165 Performance standards under the Hospital Value-Based Purchasing (VBP) Program.

(a) *Points awarded based on hospital performance.* (1) CMS will award points to hospitals for performance on each measure for which the hospital reports the applicable minimum number of cases during the applicable performance period.

(2) CMS will award from 1 to 9 points for achievement to each hospital whose performance on a measure during the applicable performance period meets or exceeds the achievement threshold but is less than the benchmark for that measure.

(3) CMS will award from 0 to 9 points for improvement to each hospital whose performance on a measure during the applicable performance period exceeds the improvement threshold but is less than the benchmark for that measure.

(4) CMS will award 10 points to a hospital whose performance on a measure during the applicable performance period meets or exceeds the benchmark for that measure.

(b) [Reserved]

§ 412.166 Performance scoring under the Hospital Value-Based Purchasing (VBP) Program.

The hospital's Total Performance Score for a program year is calculated as follows:

(a) CMS will calculate a domain score for a hospital when it reports the minimum number of measures in the domain.

(b) CMS will sum all points awarded for each measure in a domain to calculate an unweighted domain score.

(c) CMS will normalize the domain scores to ensure that the domain score is expressed as a percentage of points earned out of 100.

(d) CMS will weight the domain scores with the finalized domain weights for each fiscal year.

(e) The sum of the weighted domain scores is the hospital's Total Performance Score for the fiscal year.

§ 412.167 Appeal under the Hospital Value-Based Purchasing (VBP) Program.

(a) A hospital may appeal the following issues:

(1) CMS' decision to deny a hospital's correction request that the hospital submitted under the review and corrections process;

(2) Whether the achievement/improvement points were calculated correctly;

(3) Whether CMS properly used the higher of the achievement/improvement points in calculating the hospital's measure/dimension score;

(4) Whether CMS correctly calculated the domain scores, including the normalization calculation;

(5) Whether CMS used the proper lowest dimension score in calculating the hospital's HCAHPS consistency points;

(6) Whether CMS calculated the HCAHPS consistency points correctly;

(7) Whether the correct domain scores were used to calculate the Total Performance Score;

(8) Whether each domain was weighted properly;

(9) Whether the weighted domain scores were properly summed to arrive at the Total Performance Score; and,

(10) Whether the hospital's open/closed status (including mergers and acquisitions) is properly specified in CMS' systems.

(b) Appeals must be submitted within 30 days of CMS' decision to deny a corrections request under § 412.163 or within 30 days of the conclusion of the review and corrections period, as applicable, and must contain the following information:

(1) Hospital's CMS Certification Number (CCN).

(2) Hospital name.

(3) Hospital's basis for requesting an appeal. This must identify the hospital's specific reason(s) for appealing the hospital's Total Performance Score or performance assessment with respect to the performance standards.

(4) CEO contact information, including name, email address, telephone number, and mailing address (must include the physical address, not just the post office box).

(5) QualityNet System Administrator contact information, including name, email address, telephone number, and mailing address (must include the physical address, not just the post office box).

(c) *Limitations on review.* There is no administrative or judicial review of the following:

(1) The methodology used to determine the amount of the value-based incentive payment under section 1886(o)(6) of the Act and the determination of such amount.

(2) The determination of the amount of funding available for value-based incentive payments under section 1886(o)(7)(A) of the Act and the payment reduction under section 1886(o)(7)(B)(i) of the Act.

(3) The establishment of the performance standards under section 1886(o)(3) of the Act and the performance period under section 1886(o)(4) of the Act.

(4) The measures specified under section 1886(b)(3)(B)(viii) of the Act and the measures selected under section 1886(o)(2) of the Act.

(5) The methodology developed under section 1886(o)(5) of the Act that is used to calculate hospital performance scores and the calculation of such scores.

(6) The validation methodology that is specified under section 1886(b)(3)(B)(viii)(XI) of the Act.

§§ 412.168–412.169 [Reserved]

8. Section 412.424 is amended by adding a new paragraph (d)(1)(vi) to read as follows:

§ 412.424 Methodology for calculating the Federal per diem payment amount.

* * * * *

(d) * * *

(1) * * *

(vi) *Applicable percentage change for fiscal year 2014 payment determination and for subsequent years.* (A) In the case of an inpatient psychiatric facility that is paid under the prospective payment system in § 412.1(a)(2) that does not submit quality data to CMS, in the form and manner and at a time specified by CMS, the applicable annual update to a Federal standard rate is reduced by 2.0 percentage points.

(B) Any reduction in the applicable annual update to a Federal standard rate will apply only to the fiscal year involved and will not be taken into account in computing the annual payment update for a subsequent year.

* * * * *

9. Section 412.434 is added to subpart N to read as follows:

§ 412.434 Reconsideration and appeals procedures of Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program decisions.

(a) An inpatient psychiatric facility may request reconsideration of a decision by CMS that the inpatient psychiatric facility has not met the requirements of the IPFQR Program for a particular fiscal year. An inpatient psychiatric facility must submit a reconsideration request to CMS no later than 30 days from the date identified on the IPFQR Program Annual Payment Update Notification Letter provided to the inpatient psychiatric facility.

(b) A reconsideration request must contain the following information:

(1) The inpatient psychiatric facility's CMS Certification Number (CCN);

(2) The name of the inpatient psychiatric facility;

(3) Contact information for the inpatient psychiatric facility's chief executive officer and QualityNet system administrator, including each individual's name, email address, telephone number, and physical mailing address;

(4) A summary of the reason(s), as set forth in the IPFQR Program Annual Payment Update Notification Letter, that CMS concluded the inpatient psychiatric facility did not meet the requirements of the IPFQR Program;

(5) A detailed explanation of why the inpatient psychiatric facility believes that it complied with the requirements of the IPFQR Program for the applicable fiscal year; and

(6) Any evidence that supports the inpatient psychiatric facility's reconsideration request, such as emails and other documents.

(c) An inpatient psychiatric facility 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.

10. Section 412.523 is amended by—

a. Adding a new paragraph (c)(3)(ix).

b. Revising paragraph (d)(3).

The addition and revision read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) * * *

(ix) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2012, and ending September 30, 2013.* (A) The standard Federal rate for the long-term care hospital prospective payment system beginning October 1, 2012, and ending September 30, 2013, is the standard Federal rate for the previous long-term care hospital prospective payment system fiscal year updated by 2.1 percent, and further adjusted, as appropriate, as described in paragraph (d) of this section.

(B) With respect to discharges occurring on or after October 1, 2012 and before December 29, 2012, payments are based on the standard Federal rate in paragraph (c)(3)(ix)(A) of this section without regard to the adjustment provided for under paragraph (d)(3)(ii) of this section.

* * * * *

(d) * * *

(3) (i) *General.* The Secretary reviews payments under this prospective payment system and may make a one-time prospective adjustment to the long-term care hospital prospective payment system rates no earlier than December 29, 2012, so that the effect of any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years.

(ii) *Adjustment to the standard Federal rate.* The standard Federal rate determined in paragraph (c)(3) of this section is permanently reduced by 3.75 percent to account for the estimated difference between projected aggregate payments in FY 2003 made under the prospective payment system implemented under this subpart and the projected aggregate payments that would have been made in FY 2003 under Part 413 of this chapter without regard to the implementation of the prospective payment system implemented under this subpart, excluding the effects of sections 1886(b)(2)(E) and (b)(3)(J) of the Act. This adjustment is transitioned over 3 years beginning in FY 2013.

(iii) *Special rule for certain discharges occurring during FY 2013.* The adjustment applied under paragraph (d)(3)(ii) of this section is not applicable when making payments under this subpart for discharges occurring on or after October 1, 2012, and on or before December 28, 2012.

* * * * *

11. Section 412.529 is amended by revising paragraph (d)(4)(i)(C) to read as follows:

§ 412.529 Special payment provisions for short-stay outliers.

* * * * *

(d) * * *

(4) * * *

(i) * * *

(C) The payment amount specified under paragraph (d)(4)(i)(B) of this section may not exceed the full amount comparable to what would otherwise be paid under the hospital inpatient prospective payment system determined under paragraph (d)(4)(i)(A) of this section.

* * * * *

12. Section 412.534 is amended by—

a. In the following paragraphs, removing the date ''October 1, 2012'' and adding in its place the date ''October 1, 2013'':

1. Paragraph (c)(1) heading;
2. Paragraph (c)(1)(i);
3. Paragraph (c)(1)(ii);
4. Paragraph (c)(2) heading;
5. Paragraph (d)(1) heading;
6. Paragraph (d)(1)(i);
7. Paragraph (d)(2) heading;
8. Paragraph (e)(1) heading;
9. Paragraph (e)(1)(i); and
10. Paragraph (e)(2) heading.

b. Revising the heading of paragraph (c)(3).

c. Revising the heading of paragraph (d)(3).

d. Revising the heading of paragraph (e)(3).

e. Revising paragraph (h)(4).

f. Revising paragraph (h)(5).

The revisions read as follows:

§ 412.534 Special payment provisions for long-term care hospitals within hospitals and satellites of long-term care hospitals.

* * * * *

(c) * * *

(3) *For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012 and for cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013.* * * *

(d) * * *

(3) *For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012 and for cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013.* * * *

(e) * * *

(3*) For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012 and for cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013.* * * *

(h) * * *

(4) For a long-term care hospital described in § 412.23(e)(2)(i) that meets the criteria in § 412.22(f), the policies set forth in this paragraph (h) and in § 412.536 do not apply for discharges occurring in cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012 and for cost reporting periods beginning on and after October 1, 2012 and before October 1, 2013.

(5) For a long-term care hospital or satellite facility that, as of December 29, 2007, was co-located with an entity that is a provider-based, off-campus location of a subsection (d) hospital which did not provide services payable under section 1886(d) of the Act at the off-campus location, the policies set forth in this paragraph (h) and in § 412.536 of this part do not apply for discharges occurring in cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012 and for cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013.

13. Section 412.536 is amended by revising the introductory text of paragraph (a)(2) to read as follows:

§ 412.536 Special payment provisions for long-term care hospitals and satellites of long-term care hospitals that discharged Medicare patients admitted from a hospital not located in the same building or on the same campus as the long-term care hospital or satellite of the long-term care hospital.

(a) * * *

(2) For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2012, and for cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013, the policies set forth in this section are not applicable to discharges from:

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

14. 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 Public Law 106–133 (113 Stat. 1501A–332).

15. Section 413.24 is amended by revising paragraph (a) to read as follows:

§ 413.24 Adequate cost data and cost finding.

(a) *Principle.* Providers receiving payment on the basis of reimbursable cost must provide adequate cost data. This must be based on their financial and statistical records which must be capable of verification by qualified auditors. The cost data must be based on an approved method of cost finding and on the accrual basis of accounting, except for—

(1) Governmental institutions which operate on a cash basis method of accounting. Cost data based on such basis of accounting will be acceptable, subject to appropriate treatment of capital expenditures.

(2) Costs of qualified defined benefit pension plans shall be reported on a cash basis method of accounting, as described at § 413.100(c)(2)(vii)(D) for cost reporting periods beginning on or after October 1, 2011.

* * * * *

16. Section 413.79 is amended by—

a. Revising paragraph (e)(1).

b. Revising paragraph (f)(7)(i)(B).

c. Redesignating paragraphs (n)(2)(ii) and (n)(2)(iii) as paragraphs (n)(2)(iii) and paragraph (n)(2)(iv), respectively.

d. Adding new paragraph (n)(2)(ii).

e. Revising redesignated paragraphs (n)(2)(iii) and (n)(2)(iv).

The revisions and addition read as follows:

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

* * * * *

(e) * * *

(1) If a hospital had no allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, and it establishes a new medical residency training program on or after January 1, 1995, the hospital's unweighted FTE resident cap under paragraph (c) of this section may be adjusted based on the product of the highest number of FTE residents in any program year during the third year of the first program's existence for all new residency training programs and the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program. The adjustment to the cap may not exceed the number of accredited slots available to the hospital for the new program. If a hospital that had no allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, begins training residents in a new program for the first time on or after October 1, 2012, the hospital's unweighted FTE resident cap under paragraph (c) of this section may be adjusted based on the product of the highest number of FTE residents in any program year during the fifth academic year of the first program's existence for all new residency training programs and the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program. The adjustment to the cap may not exceed the number of accredited slots available to the hospital for the new program.

(i) If the residents are spending an entire program year (or years) at one hospital and the remainder of the program at another hospital, the adjustment to each respective hospital's cap is equal to the product of the highest number of FTE residents in any program year during the third year of the first program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program and the number of years the residents are training at each respective hospital. If a hospital begins training residents in a new program for the first time on or after October 1, 2012, and if the residents are spending an entire program year (or years) at one hospital and the remainder of the program at another hospital, the adjustment to each respective new teaching hospital's cap is equal to the product of two amounts. The first amount is the product of the highest total number of FTE residents in any program year during the fifth year of the first program's existence at all of the participating hospitals involved and the number of years in which residents are expected to complete the program, based on the minimum accredited length for the type of program. The second amount is the ratio of the number of FTE residents in the new program that the hospital may count over the entire 5-year period to the total number of FTE residents that all of the participating hospitals may count over the entire 5-year period.

(ii) Prior to the implementation of the hospital's adjustment to its FTE cap beginning with the fourth year of the hospital's residency program(s), the hospital's cap may be adjusted during each of the first 3 years of the hospital's new residency program using the actual number of residents participating in the new program. The adjustment may not exceed the number of accredited slots available to the hospital for each program year. If a hospital begins training residents in a new program for the first time on or after October 1, 2012, prior to the implementation of the hospital's adjustment to its FTE cap beginning with the sixth year of the hospital's residency program(s), the hospital's cap may be adjusted during each of the first 5 years of the hospital's new residency program using the actual number of FTE residents participating in the new program. The adjustment may not exceed the number of accredited slots available to the hospital for each program year.

(iii) Except for rural hospitals, the cap will not be adjusted for new programs established more than 3 years after the first program begins training residents. If a hospital begins training residents in a new program for the first time on or after October 1, 2012, except for rural hospitals, the cap will not be adjusted for new programs established more than 5 years after the first program begins training residents.

(iv) Effective for affiliation agreements entered into on or after October 1, 2005, an urban hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap only if the adjustment that results from the affiliation is an increase to the urban hospital's FTE cap.

(v) A rural hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME

affiliated group for purposes of establishing an aggregate FTE cap.

* * * * *

(f) * * *

(7) * * *

(i) * * *

(B) Specify the effective period of the emergency Medicare GME affiliation agreement (which must, in any event, terminate at the conclusion of four academic years following the academic year in which the section 1135 emergency period began).

* * * * *

(n) * * *

(2) * * *

(ii) A hospital that receives an increase in the otherwise applicable FTE resident cap under paragraph (n)(1) of this section must fill at least half of its section 5503 slots in at least one of the following timeframes or lose its section 5503 slots under paragraph (n)(2)(iv) of this section: Its first 12-month cost reporting period of the 5-year period; and/or its second 12-month cost reporting period of the 5-year period; and/or its third 12-month cost reporting period of the 5-year period. Such a hospital that receives an increase in the otherwise applicable FTE resident cap under paragraph (n)(1) of this section also must fill all of the slots it received by its final cost reporting period beginning during the timeframe of July 1, 2011 through June 30, 2016, or under paragraph (n)(2)(iv) of this section, lose all of its section 5503 slots after June 30, 2016.

(iii) CMS may determine whether a hospital has met the requirements under paragraphs (n)(2)(i) and (n)(2)(ii) of this section during the 5-year period of July 1, 2011, through June 30, 2016, in such manner and at such time as CMS determines appropriate, including at the end of such 5-year period.

(iv) In a case where the Medicare contractor determines that a hospital did not meet the requirements under paragraphs (n)(2)(i) and (n)(2)(ii) of this section in a cost reporting period within the 5-year time period, the Medicare contractor will reduce the otherwise applicable FTE resident cap of the hospital by the amount by which such limit was increased under paragraph (n)(1) of this section from the earliest cost reporting period that is reopenable in which it would be determined that the hospital did not meet the requirements.

* * * * *

17. Section 413.100 is amended by adding a new paragraph (c)(2)(vii)(D) to read as follows:

§ 413.100 Special treatment of certain accrued costs.

* * * * *

(c) * * *

(2) * * *

(vii) * * *

(D) Exception: Qualified defined benefit pension plans, which are funded deferred compensation arrangements, shall be reported on a cash accounting basis as follows:

(1) The allowable pension cost shall be equal to the amount of actual pension contributions funded during the hospital's current Medicare cost reporting period, plus any contributions funded in a prior period and carried forward, subject to the limit under paragraph (c)(2)(vii)(D)(2) of this section.

(2) Except as provided in paragraph (c)(2)(vii)(D)(3) of this section, the allowable pension cost shall not exceed 150 percent of the average contribution(s) funded during the three consecutive Medicare cost reporting periods that produce the highest average contribution(s), out of the five most recent Medicare cost reporting periods (ending with the current cost reporting period). Contributions in excess of the limit may be carried forward to future period(s). In the case of a newly adopted pension plan, the 5-year look-back period and/or the 3-year averaging period will be limited to the number of cost reporting periods the provider sponsored a qualified defined benefit pension plan.

(3) A waiver of the limit imposed under paragraph (c)(2)(vii)(D)(2) of this section may be granted for a specific Medicare cost reporting period for all or a portion of the contributions in excess of the limit imposed under paragraph (c)(2)(vii)(D)(2) of this section if it is determined that such excess costs are reasonable and necessary for that period.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

18. The authority citation for Part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

19. Section 424.30 is revised to read as follows:

§ 424.30 Scope.

This subpart sets forth the requirements, procedures, and time limits for claiming Medicare payments. Claims must be filed in all cases except when services are furnished on a prepaid capitation basis by an MA organization, or through cost settlement with a health maintenance organization (HMO), a competitive medical plan (CMP), a health care prepayment plan (HCPP), or a demonstration. However, claims must be filed by hospitals seeking IME payment under § 412.105(g) of this chapter, and/or direct GME payment under § 413.76(c) of this chapter, and/or nursing or allied health education payment under § 413.87 of this chapter associated with services furnished on a prepaid capitation basis by an MA organization. Hospitals that must report patient data for services furnished on a prepaid capitation basis by an MA organization, or through cost settlement with a health maintenance organization (HMO), a competitive medical plan (CMP), a health care prepayment plan (HCCP), or a demonstration, for purposes of the DSH payment adjustment under § 412.106 of this chapter are required to file claims by submitting no pay bills for such patients. Special procedures for claiming payment after the beneficiary has died and for certain bills paid by organizations are set forth in subpart E of this part.

PART 476—UTILIZATION AND QUALITY CONTROL REVIEW

20. 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)).

21. Section 476.1 is amended by adding a definition of ''Provider'' in alphabetical order, to read as follows:

§ 476.1 Definitions.

* * * * *

Provider means a health care facility, institution, or organization, including but not limited to a hospital, involved in the delivery of health care services for which payment may be made in whole or in part under Title XVIII of the Act.

* * * * *

22. Section 476.78 is amended by revising the section heading and the introductory text of paragraph (b)(2) to read as follows:

§ 476.78 Responsibilities of providers and practitioners.

* * * * *

(b) * * *

(2) Providers and practitioners 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. When the QIO does postadmission, preprocedure review,

the provider must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis. Providers and practitioners must—

* * * * *

23. Section 476.90 is revised to read as follows:

§ 476.90 Lack of cooperation by a provider or practitioner.

(a) If a provider or practitioner refuses to allow a QIO to enter and perform the duties and functions required under its contract with CMS, the QIO may—

(1) Determine that the provider or practitioner has failed to comply with the requirements of 42 CFR 1004.10(c) and report the matter to the HHS Inspector General; or

(2) Issue initial denial determinations for those claims it is unable to review, make the determination that financial liability will be assigned to the provider or practitioner, and may report the matter to the HHS Inspector General.

(b) If a QIO gives a provider or practitioner sufficient notice and a reasonable amount of time to respond to a request for information about a claim, and if the provider or practitioner does not respond in a timely manner, the QIO will deny the claim. A provider or practitioner may request that the QIO reconsider its decision to deny the claim. No further appeal rights are available.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

24. The authority citation for Part 489 is revised to read as follows:

Authority: Secs. 1102, 1819, 1820(e), 1861, 1864(m), 1866, 1869, 1871 and section 1886(o) of the Social Security Act (42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, 1395hh, and 1395ww(o)).

25. Section 489.5 is added to read as follows:

§ 489.5 Definitions for purposes of the Hospital Value-Based Purchasing Program.

For purposes of the Hospital Value-Based Purchasing Program established under section 1886(o) of the Act—

(a) *Cited for deficiencies that pose immediate jeopardy* means that, during the applicable performance period, the hospital had more than one survey by the State survey agency for which it was cited for an immediate jeopardy on the Form CMS 2567, Statement of Deficiencies and Plan of Correction.

(b) *Immediate jeopardy* has the same meaning as the definition at § 489.3.

(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 2, 2012.

Marilyn Tavenner

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: April 13, 2012,

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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, 2012 and Proposed Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2012

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 2013 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 2013. 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, 2012.

In addition, we are setting forth a description of the methods and data we used to determine the proposed standard Federal rate that would be applicable to Medicare LTCHs for FY 2013.

In general, except for SCHs 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.

We note that, as discussed in section IV.G. of the preamble of this proposed rule, 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, the MDH program was to be in effect through the end of FY 2011 only.) Therefore, due to the expiration of the MDH program beginning with FY 2013, we are not including MDHs in our proposal to update the hospital-specific rates for FY 2013.

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 2013. 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 2013. 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 2013. 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 2013. 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 2013

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 2013.

In summary, the 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 2.1 percent for all areas (that is, the FY 2013 estimate of the

market basket rate-of-increase of 3.0 percent less an adjustment of 0.8 percentage point 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) and 10319(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 0.1 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less an adjustment of 0.8 percentage point for multifactor productivity, and less 0.1 percentage point).

- A proposed update of 2.1 percent to the Puerto Rico-specific standardized amount (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 0.8 percentage point 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 2012 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 to remove the FY 2012 outlier offset and apply an offset for FY 2013, 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 Public Law 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, FY 2009. We are also proposing an adjustment to the standardized amounts to offset the estimated amount of the increase in aggregate payments) due to the effect of documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2010.

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 2012, for FY 2013, 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 proposed FY 2013 wage index for the rural floor. We note that, as finalized in the FY 2012 IPPS/LTCH PPS final rule, we extended the imputed floor through FY 2013 (76 FR 51593). Therefore, for this proposed rule, we are continuing to include the imputed floor in calculating the uniform, national rural floor budget neutrality adjustment to the wage indices. Thus, the imputed floor is reflected in the proposed FY 2013 wage index. Additionally, while we are proposing an alternative temporary methodology for computing the imputed floor index in section II.G.2. of the preamble of this proposed rule, we did not include this proposed alternative in our calculation of rural floor budget neutrality because of its negligible impact, although we intend to include it in the calculation if the policy is finalized.

We note that, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51788 through 51790), we finalized an adjustment of 1.1 percent to the standardized amount (that is, a factor of 1.011) in light of the Cape Cod decision. The adjustment is a one-time permanent adjustment that is left permanently on the standardized amount.

A. Calculation of the Proposed Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. 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 2013, we are proposing to continue to use a labor-related share of 68.8 percent for discharges occurring on or after October 1, 2012, 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 proposing to apply 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 proposing to apply the wage index to a labor-related share of 68.8 percent of the national standardized amount. For FY 2013, 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 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 2013 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.H. 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 proposed FY 2013 applicable percentage increase (which is based on the first quarter 2012 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 2013) of 0.8 percent, which is calculated based on IHS Global Insight, Inc.'s (IGI's) first quarter 2012 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 further proposing to update the standardized amount for FY 2013 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) 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 2012 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 2013 is 3.0 percent. Thus, for FY 2013, the proposed update to the average standardized amount is 2.1 percent for hospitals in all areas (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 0.8 percentage point 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) of the Act, the estimated proposed update to the operating standardized amount is 0.1 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent, less 2.0 percentage points for failure to submit data under the IQR program, less an adjustment of 0.8 percentage point 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 proposed 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 2.1 percent.

Although the update factors for FY 2013 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 2013 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 2013 standardized amount to remove the effects of the FY 2012 geographic reclassifications and outlier payments before applying the proposed FY 2013 updates. We then apply budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on proposed FY 2013 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.

In order to appropriately estimate aggregate payments in our modeling, we make several inclusions and exclusions so that the appropriate universe of claims and charges are included. We discuss IME Medicare Advantage payment amounts, fee-for-service only claims, and charges for antihemophilic blood factor and organ acquisition below.

First, consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total ''operating DRG payments,'' which does not include IME and DSH payments. We refer the reader to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.

Second, consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is a fee-for-service claim).

Third, consistent with our methodology established in the FY 2011 IPPS/LTCH PPS 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.

Section 3021 of the Affordable Care Act, codified at section 1115A of the Social Security Act, authorizes CMS to test innovative payment and service delivery models with the goal of reducing Medicare program expenditures while preserving or enhancing the quality of care furnished to individuals. Because initiatives established under this authority could result in IPPS hospitals receiving a payment different from what they otherwise would receive under the IPPS, we believe it is important to identify how these initiatives are addressed in the context of our budget neutrality calculations.

The Bundled Payments for Care Improvement (BPCI) initiative, developed by CMS' Center for Medicare and Medicaid Innovation under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), will test four payment models that link payments for multiple services during an episode of care. On August 23, 2011, CMS invited providers to apply to help develop and test four models of bundling payments under the BPCI. We refer the reader to section IV.H.4. of the preamble to this proposed rule for a discussion on the BPCI initiative. We note that under Models 1, 2, and 4, participating IPPS hospitals could receive a payment for all or selected IPPS claims under the BPCI that differs from payments they would otherwise receive under the IPPS. We also note that Model 3 addresses payments for related readmissions and postacute care services. Therefore, we believe it is not necessary to propose to address the treatment of any data for participating hospitals in Model 3.

For purposes of computing the budget neutrality calculations to compute the average standardized amount, we intend to include all applicable data from subsection (d) hospitals participating in BPCI models 1,

2, and 4 in our IPPS payment modeling and ratesetting calculations (which includes recalibration of the MS–DRG weights, ratesetting, calculation of the budget neutrality factors, and the impact analysis). In essence, we would continue to treat these hospitals the same as prior fiscal years for purposes of the FY 2013 (and subsequent years) IPPS payment modeling and ratesetting process without regard to a hospital's participation within these three bundled payment models (that is, we would treat these hospitals as if they are not be participating in Model 1, Model 2, or Model 4 under the BPCI initiative). We believe it is appropriate to include all applicable data from these subsection(d) hospitals in our IPPS payment modeling and ratesetting calculations because these hospitals are still receiving IPPS payments under section 1886(d) of the Act (in addition to the reconciliation payment the hospital may receive under Model 2 of the BPCI initiative). Moreover, the Secretary has the authority to make appropriate adjustments for payment amounts at section 1886(d)(5)(I)(i) of the Act to include all applicable data from these ''subsection(d)'' hospitals in our IPPS ratesetting calculations. We believe it is appropriate to use the Secretary's authority under section 1886(d)(5)(I)(i) of the Act to include all IPPS short term acute care hospitals and their data within the IPPS ratesetting calculations since excluding these hospitals would diminish the number of providers used to determine the IPPS rates which could cause fluctuations to the IPPS rates and could produce instability to the IPPS rates.

The Affordable Care Act established the Hospital Readmissions Reduction Program and the Hospital Value-Based Purchasing Program which adjust payments to certain IPPS hospitals beginning with discharges on or after October 1, 2012. Because the adjustments made under these programs affect the estimation of aggregate IPPS payments, we believe it is appropriate to include adjustments for these programs within our budget neutrality calculations. We discuss the treatment of these two programs in the context of budget neutrality adjustments below.

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 ''Hospital Readmissions 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. Under the Hospital Readmissions Reduction Program at section 1886(q) of the Act, payments for discharges from an ''applicable hospital'' will be in an amount equal to the product of the ''base operating DRG payment amount'' and an ''adjustment factor'' that accounts for excess readmissions for the hospital for the fiscal year, for discharges beginning on October 1, 2012. (The statute also specifies that hospitals that receive any applicable add-on payments for IME, DSH, outliers and low-volume hospitals provided for under sections 1886(d)(5)(A), (d)(5)(B), (d)(5)(F), and (d)(12) of the Act, respectively, are not affected by the adjustment for excess readmissions under the Hospital Readmissions Reduction Program.) In other words, payment under section 1886(q) is the base operating DRG payment amount multiplied by the adjustment factor, in addition to any outliers, IME, DSH, or low-volume payment adjustment the hospital may otherwise receive. We refer readers to section IV.A. of the preamble of this proposed rule for full details of our proposal implementing the Hospital Readmissions Reduction Program for FY 2013, including definitions of the ''base operating DRG payment amount.'' Under current law, the Hospital Readmissions Reduction Program under section 1886(q) of the Act is not budget neutral.

Section 1886(o) of the Act requires the Secretary to establish a hospital value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards established for a performance period for such fiscal year to payments for hospital discharges occurring on or after October 1, 2012. As specified under section 1886(o)(7)(B)(i) of the Act, the cost of these value-based incentive payments are funded by a reduction applied to each eligible hospital's base-operating DRG payment amount, for each discharge occurring in the fiscal year, beginning with FY 2013. For FY 2013, the reduction amount is equal to 1.00 percent, As required by section 1886(o)(7)(A) of the Act, the total amount of allocated funds available for value-based incentive payments is equal to the total amount of estimated base-operating DRG payment reductions (that is, 1.0 percent of eligible hospitals' base-operating DRG payment amount for FY 2013). We refer the reader to section VIII.C. of the preamble of this proposed rule for full details of our proposal implementing the Hospital VBP Program for FY 2013, including definitions of the ''base operating DRG payment amount.''

Unlike the Hospital Readmissions Reduction Program (where an adjustment factor is applied to reduce the base operating DRG payment amount for excess readmissions), the Hospital VBP Program has no effect on overall payments. As mentioned above, for FY 2013, the funding pool for value-based incentive payments is 1.0 percent of eligible hospitals' base-operating DRG payment which is equal to the total amount of estimated base-operating DRG payment reductions. In other words, the funding pool that CMS sets aside for the Hospital VBP Program is then equally redistributed by applying the hospital VBP adjustment. However, both the hospital readmissions payment adjustment (reduction) and the hospital VBP adjustment (redistribution) are applied on a claim by claim basis by adjusting, as applicable, the base operating DRG payment amount for individual IPPS hospitals which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations. For example, when we calculate the budget neutrality factor for DRG reclassification and recalibration of the relative weights, we compare (section II.4.a. of this Addendum contains for full details) aggregate payments estimated using the prior year's GROUPER and weights to estimated payments using the new grouper and weights. Other factors, such as the DSH and IME payment adjustments, are the same on both sides of the comparison because we are only seeking to ensure that aggregate payments do not increase or decrease as a result of the proposed changes of DRG reclassification and recalibration. In order to properly sum aggregate payments on each side of the comparison, we would need to apply the hospital readmissions payment adjustment and the hospital VBP adjustment on each side of the comparison. Therefore, to assure that aggregate payments are estimated correctly in light of the effects of the Hospital Readmissions Reduction Program and Hospital VBP Program, we are proposing that we would apply the readmissions payment adjustment and the Hospital VBP payment adjustment on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

For this proposed rule, for the purpose of modeling the proposed aggregate payments for excess readmissions and the proposed readmissions adjustment factors, we are using excess readmission ratios for the applicable hospitals from the 3-year period of July 1, 2007 to June 30, 2010 (the 3-year period preceding the FY 2013 ''applicable period'' of July 1, 2008 to June 30, 2011 that was finalized in last year's rulemaking (76 FR 51671 through 51672), because the underlying data from this period have already be available to the public on the Hospital Compare Web site (as of July 2011). The data from the 3-year applicable period of July 1, 2008 to June 30, 2011, for FY 2013 have not been through the review and correction process required by section 1886(q)(6) of the Act (as proposed in section IV.A.3.d. of the preamble of this proposed rule). For the final rule, we intend to use excess readmission ratios based on admissions for the finalized applicable period of July 1, 2008 to June 30, 2011, to calculate the aggregate payments for excess readmissions and ultimately to calculate the readmissions payment adjustment factors, as applicable hospitals will have had the opportunity to review and correct these data before the data are made public under our proposal set forth in this rule regarding the reporting of hospital-specific readmission rates consistent with section 1886(q)(6) of the Act.

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.H. 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 2013, we are proposing to adjust 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.F. of the preamble of this proposed rule.

For FY 2013, 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 2011 discharge data to simulate payments and compared aggregate payments using the FY 2012 labor-related share percentages, the FY 2012 relative weights, and the FY 2012 pre-reclassified wage data and applied the estimated readmissions payment adjustment and estimated VBP payment adjustment to aggregate payments using the FY 2012 labor-related share percentages, the proposed FY 2013 relative weights, and the FY 2012 pre-reclassified wage data and applied the same estimated readmissions payment and estimated VBP adjustments. Based on this comparison, we computed a proposed budget neutrality adjustment factor equal to 0.998546. As discussed in section IV. of this Addendum, we also are proposing to apply the DRG reclassification and recalibration budget neutrality factor of 0.998546 to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2012.

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 0.998546 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 proposed budget neutrality factor for wage index and labor-related share changes, we used FY 2011 discharge data to simulate payments and compared aggregate payments using proposed FY 2013 relative weights and FY 2012 pre-reclassified wage indices, applied the FY 2012 labor-related share of 68.8 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0) and applied the estimated readmissions payment adjustment and estimated VBP payment adjustment when estimating aggregate payments using the proposed FY 2013 relative weights and the proposed FY 2013 pre-reclassified wage indices, applied the proposed labor-related share for FY 2013 of 68.8 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0) and applied the same estimated readmissions payment adjustment and estimated VBP payment adjustment. 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 2012 to FY 2013. By applying this methodology, we determined a proposed budget neutrality factor of 1.000563 for changes to the wage index. Finally, we multiplied the proposed DRG reclassification and recalibration budget neutrality factor of 0.998546 (derived in the first step) by the proposed budget neutrality factor of 1.000563 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 0.999108.

b. Reclassified Hospitals—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 2013, we used FY 2011 discharge data to simulate payments and compared total IPPS payments with proposed FY 2013 relative weights, proposed FY 2013 labor-related share percentages, and proposed FY 2013 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act and applied the estimated readmissions payment adjustment and the estimated VBP payment adjustment to total IPPS payments with proposed FY 2013 relative weights, proposed FY 2013 labor-related share percentages, and proposed FY 2013 wage data after such reclassifications and applied the same estimated readmissions payment adjustment and the estimated VBP payment adjustment. Based on these simulations, we calculated a proposed adjustment factor of 0.991436 to ensure that the effects of these provisions are budget neutral, consistent with the statute.

The proposed FY 2013 budget neutrality adjustment factor is applied to the standardized amount after removing the effects of the FY 2012 budget neutrality adjustment factor. We note that the proposed FY 2013 budget neutrality adjustment reflects proposed FY 2013 wage index reclassifications approved by the MGCRB or the Administrator.

c. Rural Floor and Imputed Floor Budget Neutrality Adjustment

As noted above, as discussed in section III.G. 2.b. of the preamble of this proposed rule, in the FY 2012 final rule, we extended the imputed floor through FY 2013. 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) and the imputed floor under § 412.64(h)(4) of the regulations are not affected. In addition, we note in section III.G.2.b. of the preamble of this proposed rule, we are proposing an alternative temporary methodology for computing the imputed floor index. We did not apply this proposed alternative in our calculation of the proposed uniform, national rural floor budget neutrality adjustment to the wage indices because the projected impact of this proposal is less than $5 million and, therefore, would have a negligible impact on the adjustment. If this proposed alternative methodology policy is finalized, we intend to include it in the calculation of the uniform, national rural floor budget neutrality adjustment in the final rule. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.G. of the preamble of this proposed rule, the budget neutrality adjustment for the rural and imputed floors is a national adjustment to the wage index.

Since FY 2012, there is one hospital in rural Puerto Rico. Therefore, similar to our

calculation in the FY 2012 IPPS/LTCH final rule (76 FR 51593), for FY 2013, 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 is used to adjust the labor-related share of the Puerto Rico-specific standardized amount for hospitals in Puerto Rico that receive 25 percent of the Puerto Rico-specific standardized amount). Because this rural Puerto Rico hospital still has no established wage data, 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 the FY 2012 final rule.

To calculate the proposed national rural floor and imputed floor budget neutrality factor and Puerto Rico-specific rural floor budget neutrality adjustment factor, we used FY 2011 discharge data and proposed FY 2013 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 rural floor and imputed floor and Puerto Rico-specific rural floor applied to national and Puerto Rico-specific simulated payments with the national rural floor and imputed floor and Puerto Rico-specific rural floor applied to determine the proposed national rural budget neutrality adjustment factor of 0.992243 and the proposed Puerto Rico-specific budget neutrality adjustment factor of 0.990686. The national adjustment was applied to the national wage indices to produce a national rural floor budget neutral wage index and the 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 Case-Mix Budget Neutrality Adjustment

Below we summarize the proposed adjustments to the FY 2013 rates to account for the effect of changes in documentation and coding that do not reflect real changes in case-mix. We refer the reader to section II.D. of the preamble to this proposed rule for a complete discussion (including our historical adjustments to the rates) on our proposals to eliminate the estimated effect of changes in documentation and coding that do not reflect real changes in case-mix.

(1) Prospective Adjustments for Documentation and Coding in FY 2008 and FY 2009 Authorized by Section 7(b)(1)(A) of Public Law 110–90 and Section 1886(d)(3)(vi) of the Act

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.

For FY 2013, we are proposing a −1.9 percent adjustment to the standardized amount to complete the adjustment required under section 7(b)(1)(A) of Public Law 110–90. We refer the reader to section II.D. of the preamble to this proposed rule for a complete discussion on our historical adjustments and our proposed FY 2013 adjustment to the standardized amount pursuant to section 7(b)(1)(A) of Pub. L. 110–90.

(2) Prospective Adjustments for Documentation and Coding in FY 2010 Authorized by Section 1886(d)(3)(vi) of the Act

Section 1886(d)(3)(A)(vi) of the Act authorizes adjustments to the average standardized amounts if the Secretary determines such adjustments to be necessary for any subsequent fiscal years in order to eliminate the effect of coding or classification changes that do not reflect real changes in case mix. After review of comments and recommendations received from MedPAC, we analyzed claims data in FY 2010 to determine whether any additional adjustment would be required to ensure that the introduction of MS–DRGs was implemented in a budget neutral manner. As discussed in section II.D. of the preamble of this proposed rule, our analysis showed a documentation and coding effect in FY 2010 of 0.8 percent, and we are proposing an additional −0.8 percent adjustment to account for the effects of documentation and coding that did not reflect an increase in case-mix severity in FY 2010.

(3) Recoupment or Repayment Adjustment for Documentation and Coding in FY 2008 and FY 2009 Authorized by Section 7(b)(1)(B) of Public Law 110–90

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. As discussed in section II.D.5. of the preamble of this proposed rule, we determined that an aggregate adjustment of −5.8 percent in FYs 2011 and 2012 would be necessary in order to meet these statutory requirements.

In the FY 2011 IPPS/LTCH PPS final rule, for FY 2011, we made an adjustment to the standardized amount of −2.9 percent, representing approximately half of the required adjustment. For FY 2012, in accordance with the timeframes set forth by section 7(b)(1)(B) of Pub. L. 110–90, and consistent with the discussion in the FY 2011 IPPS/LTCH PPS final rule, we completed 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 (76 FR 51489 and 51498). Therefore, the required recoupment for overpayments due to documentation and coding effects on discharges occurring in FYs 2008 and 2009 has been completed within the required statutory timeframes. However, to avoid continuing the −2.9 percent adjustment finalized in FY 2012, we are proposing for FY 2013 to make a final +2.9 percent adjustment to the standardized amount. This adjustment removes the onetime −2.9 percent adjustment implemented in FY 2012.

(4) Documentation and Coding Adjustment to the Puerto Rico-Specific 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, in section II.D.9. of the preamble of this proposed rule, we are proposing to make no further adjustment for FY 2013. For a complete discussion on our proposed policy, we refer readers to section II.D.9. of the preamble of this proposed rule.

We note that, based upon our analysis of FY 2010 claims data; we found no significant additional effect of documentation and coding that would warrant any additional adjustment to the Puerto Rico-specific rate.

e. Rural Community Hospital Demonstration Program Adjustment

As discussed in section IV.K. 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 Pub. L. 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 allowed 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 2012 IPPS/LTCH PPS final rule (76 FR 51700 through 51705), 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 2013, for the 23 hospitals participating in the demonstration project, we are proposing to adjust the national IPPS rates according to the methodology set forth elsewhere in this proposed rule. For this proposed rule, the estimated amount for the adjustment to the national IPPS rates for FY 2013 is $35,077,708. Accordingly, to account for the estimated costs of the demonstration for the specific time periods as explained in detail in section IV.K. of the preamble of this proposed rule, for FY 2013, we computed a proposed factor of 0.999629 for the rural community hospital demonstration program budget neutrality adjustment that would be applied to the IPPS standardized rate.

We note that if updated data become available prior to the FY 2013 final rule, we are proposing to use them, to the extent appropriate, to estimate the costs of the demonstration program in FY 2013. Therefore, this estimated budget neutrality offset amount may change in the final rule depending on the availability of updated data. In addition, if settled cost reports for all of the demonstration hospitals that participated in the applicable fiscal year (2007, 2008, 2009, or 2010) are available prior to the FY 2013 IPPS/LTCH PPS final rule, we are proposing to incorporate into the FY 2013 budget neutrality offset amount the difference between the final cost of the demonstration in any of these years (as described previously) and the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule.

f. 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 2013 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 2013 Outlier Fixed-Loss Cost Threshold

For FY 2013, 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 2013, 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 2013 outlier threshold, we simulated payments by applying proposed FY 2013 rates and policies using cases from the FY 2011 MedPAR files. Therefore, in order to determine the proposed FY 2013 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2011 to FY 2013.

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 2010 in combination with the first quarter of FY 2011 (July 1, 2010 through December 31, 2010) to the last quarter of FY 2011 in combination with the first quarter of FY 2012 (July 1, 2011 through December 31, 2011). This rate-of-change was 6.8 percent (1.068003) or 14.06 percent (1.140630) over 2 years. As we have done in the past, we established the proposed FY 2013 outlier threshold using hospital CCRs from the December 2011 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 2013, we are proposing to continue to use the same methodology to calculate the CCR adjustment by using the FY 2011 operating cost per discharge increase in combination with the actual FY 2011 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 2011 actual (otherwise referred to as ''final'') operating market basket percentage increase reflects historical data, whereas the published FY 2011 operating market basket update factor was based on IGI's 2010 second quarter forecast with historical data through the first quarter of 2010. We also note that while the FY 2011 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 2011 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 2013, we determined the adjustment by taking the percentage increase in the operating costs per discharge from FY 2009 to FY 2010 (1.0160) from the cost report and dividing it by the final operating market basket percentage increase from FY 2010 (1.0210). 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 2007 to FY 2008 percentage increase of operating costs per discharge of 1.0505 divided by the FY 2008 final operating market basket percentage

increase of 1.0400, the FY 2008 to FY 2009 percentage increase of operating costs per discharge of 1.0295 divided by the FY 2009 final operating market basket percentage increase of 1.0260). For FY 2013, we averaged the differentials calculated for FY 2008, FY 2009, and FY 2010, which resulted in a mean ratio of 1.0029. We multiplied the 3-year average of 1.0029 by the FY 2011 final operating market basket percentage increase of 1.0270, which resulted in an operating cost inflation factor of 2.99 percent or 1.029948. We then divided the operating cost inflation factor by the 1-year average change in charges (1.068003) and applied an adjustment factor of 0.964368 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 2009 to FY 2010 (1.0102) from the cost report and dividing it by the final capital market basket percentage increase from FY 2010 (1.010). 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 2007 to FY 2008 percentage increase of capital costs per discharge of 1.0809 divided by the FY 2008 final capital market basket percentage increase of 1.0150, the FY 2008 to FY 2009 percentage increase of capital costs per discharge of 1.0499 divided by the FY 2009 final capital market basket percentage increase of 1.0150). For FY 2013, we averaged the differentials calculated for FY 2008, FY 2009, and FY 2010, which resulted in a mean ratio of 1.0332. We multiplied the 3-year average of 1.0332 by the FY 2011 final capital market basket percentage increase of 1.0120, which resulted in a capital cost inflation factor of 4.56 percent or 1.045567. We then divided the capital cost inflation factor by the 1-year average change in charges (1.068003) and applied an adjustment factor of 0.978993 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 2013, we applied the proposed FY 2013 rates and policies using cases from the FY 2011 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.G.3. of the preamble 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 2013, 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 2013. If we did not take into account this provision, our estimate of total FY 2013 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.

Our estimate of the cumulative effect of changes in documentation and coding due to the adoption of the MS–DRGs of 5.4 percent from FY 2008 and FY 2009 and 0.8 percent from FY 2010 is already included within the claims data (FY 2011 MedPAR files) used to calculate the proposed FY 2013 outlier threshold. 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 2011 MedPAR claims data, and we do not believe there is any need to inflate FY 2011 claims data for any additional case-mix growth projected to have occurred since FY 2010.

In addition, 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.

As described in sections IV.A. and VIII.B., respectively, of the preamble of this proposed rule, section 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program. We do not believe it is appropriate to include the hospital VBP payment adjustment and the readmissions payment adjustment in the outlier threshold calculation or the outlier offset to the standardized amount. Specifically, consistent with our proposed definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under proposed § 412.152 and the Hospital VBP Program (that is, the wage-adjusted DRG operating payment amount) under proposed § 412.160, outlier payments under section 1886(d)(5)(F) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the operating base DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP adjustment). Consequently, we are proposing to exclude the hospital VBP payment adjustment and the readmissions payment adjustment from the calculation of the outlier fixed-loss cost threshold.

Using this methodology, we are proposing an outlier fixed-loss cost threshold for FY 2013 equal to the prospective payment rate for the DRG, plus any IME and DSH payments, and any add-on payments for new technology, plus $27,425.

We note that the proposed FY 2013 outlier fixed-loss cost threshold represents a $5,040 (or 22.5 percent) increase from the final FY 2012 final outlier fixed-loss cost threshold of $22,385. Since FY 2009, the outlier fixed-loss cost threshold has been between $20,185 and $23,140. Therefore, we are concerned about this large increase in the outlier fixed-loss cost threshold from FY 2012.

We further note that the 2-year charge inflation factor of 14.06 percent applied to the FY 2011 MedPAR claims used to compute the FY 2013 outlier fixed-loss cost threshold is higher than the 2-year charge inflation factor of 7.94 percent applied to the FY 2010 MedPAR claims used to compute the FY 2012 final outlier fixed-loss cost threshold. We believe that a large increase in the charge inflation factor for FY 2013 (from FY 2012) increased projected total outlier payments. With an increase in projected outlier payments, in order for CMS to meet the 5.1 percent target, it would be necessary to reduce the amount of outlier payments by raising the outlier fixed-loss cost threshold. Therefore, in addition to being concerned about the large increase in the fixed-loss threshold proposed for FY 2013 compared to FY 2012, we are concerned about this large charge inflation increase and how it potentially affected the proposed FY 2013 outlier fixed-loss cost threshold. As described above, to determine the 1-year average annualized rate-of-change in charges per case, we currently use a methodology that compares the average charge per case from the most recent 6-month period of

MedPAR data that are available to the same 6-month period of MedPAR data from the prior year. We adopted this methodology in the FY 2005 IPPS final rule (69 FR 49277) as a result of the special circumstances surrounding the revisions to the outlier payment methodology at that time. In that rule, we stated that we would continue to consider other methodologies for determining charge inflation when calculating the outlier threshold in the future. We welcomed comment on possible modifications to our current methodologies, including the possibility of looking at a larger time period beyond 6 months to determine the average charge per case to measure the charge inflation factor.

In addition, as pointed out by commenters in last year's final rule (76 FR 51793 through 51795), CMS has not met the 5.1 percent target for some time and the commenters have recommended enhancements to the methodology to improve the calculation of the outlier fixed-loss cost threshold. Commenters have focused on CMS underestimating actual outlier payments. Since FY 2009, we have used the same methodology to calculate the outlier fixed-loss cost threshold. While we have been reluctant to make changes to our methodology, as discussed below, our estimate for FY 2011 is that outlier payments will be approximately 4.7 percent of actual total DRG payments and for FY 2012 outlier payments will be approximately 6.0 percent of actual total DRG payments. While these estimates differ—with one being under the target and one above the target—they draw attention to the potential for improving our estimation methodology so that we meet the 5.1 percent target. We welcome public comment on ways to enhance the accuracy of our methodology of the calculation of the FY 2013 outlier fixed-loss cost threshold, especially additional analyses that could inform potential technical improvements.

(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 2013 would result in outlier payments that will equal 5.1 percent of operating DRG payments and 5.99 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 2013 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 2013 outlier threshold are as follows:

	Operating standardized amounts	Capital federal rate
National	0.948992	0.940035
Puerto Rico	0.953161	0.923900

We are proposing to apply the outlier adjustment factors to the proposed FY 2013 rates after removing the effects of the FY 2012 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, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the fiscal intermediary or MAC computes operating CCRs greater than 1.137 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), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available only via the Internet) 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, 2012, these statewide average ratios would replace the ratios posted on the Internet at *http://www.cms.gov/AcuteInpatientPPS/FR2012/list.asp#TopOfPage*. Table 8B listed in section VI. of this Addendum (and available via the Internet) contains the proposed comparable statewide average capital CCRs. Again, the CCRs in Tables 8A and 8B would be used during FY 2013 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, as mentioned above, we published an additional manual update (Change Request 7192) to our outlier policy on December 3, 2010 which also updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update outlines the outlier reconciliation process for hospitals and Medicare contractors. To download and view the manual instructions on outlier reconciliation, we refer readers to the CMS Web site: *http://www.cms.hhs.gov/manuals/downloads/clm104c03.pdf.*

(3) FY 2011 and FY 2012 Outlier Payments

In the FY 2012 IPPS final rule (76 FR 51795 through 51796), we stated that, based on available data, we estimated that actual FY 2011 outlier payments would be approximately 4.7 percent of actual total DRG payments. This estimate was computed based on simulations using the FY 2010 MedPAR file (discharge data for FY 2010 claims). That is, the estimate of actual outlier payments did not reflect actual FY 2011 claims, but instead reflected the application of FY 2011 rates and policies to available FY 2010 claims.

Our current estimate, using available FY 2011 claims data, is that actual outlier payments for FY 2011 were approximately 4.7 percent of actual total DRG payments. Thus, the data indicate that, for FY 2011, the percentage of actual outlier payments relative to actual total payments is lower than we projected for FY 20110. 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 2011 are equal to 5.1 percent of total DRG payments.

We currently estimate that actual outlier payments for FY 2012 will be approximately 6.0 percent of actual total DRG payments, approximately 0.9 percentage points higher than the 5.1 percent we projected when setting the outlier policies for FY 2012. This estimate of 6.0 percent is based on simulations using the FY 2011 MedPAR file (discharge data for FY 2011 claims).

5. Proposed FY 2013 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 proposed national standardized amounts that we are proposing to apply to all hospitals, except hospitals located in Puerto Rico, for FY 2013. 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 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 proposing to apply a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we will apply a labor-related share of 62 percent for all hospitals (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 applicable percentage increase of 2.1 percent for FY 2013, and a proposed update of 0.1 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 proposed labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2013 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 2012 national standardized amount. The second column shows the proposed changes from the FY 2012 standardized amounts for hospitals that satisfy the quality data submission requirement and therefore receive the full proposed update of 2.1 percent. The third column shows the proposed changes for hospitals receiving the proposed reduced update of 0.1 percent. The first row of the table shows the updated (through FY 2012) average standardized amount after restoring the FY 2012 offsets for outlier payments, demonstration budget neutrality, the geographic reclassification budget neutrality and the retrospective documentation and coding adjustment under section 7(b)(1)(B) of Public Law 110–90. The DRG reclassification and recalibration wage index budget neutrality factors are cumulative. Therefore, those FY 2012 factors are not removed from this table.

COMPARISON OF FY 2012 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2013 STANDARDIZED AMOUNT WITH FULL AND REDUCED UPDATE

	Full update (2.1 percent); wage index is greater than 1.0000	Full update (2.1 percent); wage index is less than or equal to 1.0000	Reduced update (0.1 percent); wage index is greater than 1.0000	Reduced update (0.1 percent); wage index is less than or equal to 1.0000
FY 2012 Base Rate, after removing geographic reclassification budget neutrality, demonstration budget neutrality, cumulative FY 2008 and FY 2009 documentation and coding adjustment, FY 2012 documentation and coding recoupment, and outlier offset (based on the labor-related share percentage for FY 2012).	Labor: $4,060.65 ..... Nonlabor: $1,841.46 ..	Labor: $3,659.31 ..... Nonlabor: $2,242.80 ..	Labor: $4,060.65 ..... Nonlabor: $1,841.46 ..	Labor: $3,659.31. Nonlabor: $2,242.80.
Proposed FY 2013 Update Factor	1.021	1.021	0.001	0.001.
Proposed FY 2013 DRG Recalibration and Wage Index Budget Neutrality Factor.	0.999108	0.999108	0.999108	0.999108.
Proposed FY 2013 Reclassification Budget Neutrality Factor.	0.991436	0.991436	0.991436	0.991436.
Proposed FY 2013 Rural Demonstration Budget Neutrality Factor.	0.999629	0.999629	0.999629	0.999629.
Proposed FY 2013 Outlier Factor	0.948992	0.948992	0.948992	0.948992.
Documentation and coding adjustments required under sections 7(b)(1)(A) and 7(b)(1)(B) of Pub. L. 110–90.	0.9405	0.9405	0.9405	0.9405.
Proposed Rate for FY 2013	Labor: $3,664.03 ..... Nonlabor: $1,661.59 ..	Labor: $3,301.88 ..... Nonlabor: $2,023.74 ..	Labor: $3,592.26 ..... Nonlabor: $1,629.04 ..	Labor: $3,237.21. Nonlabor: $1,984.09.

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 proposed labor-related and nonlabor-related shares that we used to calculate the proposed prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2013. This section addresses two types of adjustments to the standardized amounts that are made in determining the 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 2013 wage index.

2. Proposed Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make ''such adjustments * * * as the Secretary deems appropriate'' to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described above. To account for higher nonlabor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii by an adjustment factor. For FY 2011 and in prior fiscal years, we used the most recent 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* to update this nonlabor portion.

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. As we discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51797), we did not believe it was appropriate to use 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 continued to use the same COLA factors (published by OPM) that we used to adjust payments in FY 2011 (which were based on OPM's 2009 COLA factors) to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii.

We believe it was appropriate to use ''frozen'' COLA factors to adjust payments in FY 2012 while we explored alternatives for updating the COLA adjustment in the future. In this proposed rule, for FY 2013, we are now proposing to continue to use the same ''frozen'' COLA factors used in FY 2012 and to update the COLA factors for Alaska and Hawaii beginning in FY 2014 based on a comparison of the growth in the Consumer Price Indices (CPIs) for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). Specifically, for FY 2014, we would update the COLA factors published by OPM that we used to adjust payments in FY 2011 (which are based on OPM's 2009 COLA factors) as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay. Because BLS publishes CPI data for only Anchorage and Honolulu, we are proposing to use the comparison of the growth in the overall CPI relative to the growth in the CPI for those cities to update the COLA adjustment factors for all areas in Alaska and Hawaii, respectively. We believe that the relative price differences between these cities and the U.S. (as measured by the CPIs mentioned above) are appropriate proxies for the relative price differences between the ''other areas'' of Alaska and Hawaii and the U.S.

BLS publishes the CPI for All Items for Anchorage, Honolulu, and for the average U.S. city. However, we are proposing to create reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. The current composition of the CPI for All Items for all of the respective areas is approximately 40 percent commodities and 60 percent services. However, the IPPS nonlabor-related share is compromised of approximately 60 percent commodities and 40 percent services. Therefore, we are proposing to create reweighted indexes for Anchorage, Honolulu, and the average U.S. city using the respective CPI commodities index and CPI services index using the 60/40 share obtained from the IPPS market basket. We believe this proposed methodology is appropriate because we would continue to make a COLA adjustment for hospitals located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standardized amount by a COLA factor. We note that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent, and since at least 1984, we have exercised our discretionary authority to adjust Alaska and Hawaii payments by incorporating this cap. In keeping with this historical policy, our proposal for FY 2014 would continue to use such a cap, as our proposal is based on OPM's COLA factors (updated by the proposed methodology described above).

Lastly, we are proposing to update the COLA factors based on our proposed methodology every 4 years, at the same time as the update to the labor-related share of the IPPS market basket. The labor-related share of the IPPS market basket is currently not scheduled to be updated until FY 2014. Accordingly, under this proposal, we would begin applying this proposed methodology to update the COLA factors to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii for FY 2014. At the time of development of the FY 2014 proposed rule, we expect to have CPI data available through 2012. Therefore, the proposed FY 2014 COLA factors for Alaska and Hawaii would be based on the 2009 OPM COLA factors updated through 2012 by the comparison of the growth in the reweighted CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the reweighted CPI for the average U.S. city.

However, in this proposed rule, for FY 2013, we are proposing to use the same COLA factors used to adjust payments in FY 2012 (as originally used to adjust payments in FY 2011, which are based on OPM's 2009 COLA factors) to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. The table below shows the COLA factors that we are proposing to use for FY 2013:

TABLE OF PROPOSED 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

D. Calculation of the Proposed Prospective Payment Rates

General Formula for Calculation of the 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, for FY 2013 equals the Federal rate. (As noted above, due to the expiration of the MDH program, beginning with FY 2013, we are not including MDHs in our proposal to update the hospital-specific rates for FY 2013.)

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 2013 equals the higher of the applicable Federal rate, or the hospital-specific rate as described below. The prospective payment rate for hospitals located in Puerto Rico for FY 2013 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.D. of the preamble of this proposed rule. Finally, the base operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP adjustment as described under sections 1886 (q) and 1886(o) of the Act.

2. Hospital-Specific Rate (Applicable Only to SCHs)

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. 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).

We note that, in the FY 2012 IPPS/LTCH final rule (76 FR 51799), we finalized an adjustment of 0.9 percent to the hospital-specific rate (that is, a factor of 1.009) to remove the effects of the rural floor from the hospital-specific rates for FYs 1998 through 2005. The adjustment is a onetime permanent adjustment to the hospital-specific rates.

b. Updating the FY 1982, FY 1987, FY 1996 and FY 2006 Hospital-Specific Rate for FY 2013

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs 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 equal to the update factor for all other IPPS hospitals, the update to the hospital specific rates for SCHs 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 is 2.1 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 0.8 percentage point for multifactor productivity and less 0.1 percentage point) for hospitals that submit quality data or 0.1 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less an adjustment of 0.8 percentage point for multifactor productivity, and less 0.1 percentage point) 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, we refer readers to section IV.B. of the preamble of this proposed rule.

In addition, because SCHs 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, a SCH's hospital-specific rate is adjusted by the proposed DRG reclassification and recalibration budget neutrality factor of 0.998546, as discussed in section III. of this Addendum. The resulting rate is used in determining the payment rate an SCH would receive for its discharges beginning on or after October 1, 2012.

c. Documentation and Coding Adjustment to the FY 2013 Hospital-Specific Rate for SCHs

As discussed in section II.D. of the preamble of this proposed rule, because hospitals paid based in whole or in part on the hospital-specific rate (that is, SCHs and former MDHs) 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, we have determined that a cumulative adjustment of −5.4 percent is required to eliminate the full effect of changes in documentation and coding that occurred in FY 2008 and FY 2009 on future payments to SCHs. Currently, we have made cumulative adjustments to the hospital-specific rates to account for 4.9 percent of the 5.4 percent effect of changes in documentation and coding that occurred in FY 2008 and FY 2009. (For FY 2011, we established a prospective adjustment of −2.9 percent to the hospital-specific rates, and, for FY 2012, we established a prospective adjustment to the hospital-specific rates of −2.0 percent.) In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51499), we indicated that, because the −2.0 percent adjustment we made in FY 2012 did not reflect the entire remaining requirement adjustment amount of −2.5 percent, an additional −0.5 percent adjustment to the hospital-specific rates would be required in future rulemaking.

In this proposed rule, we are proposing a −0.5 percent prospective adjustment to the hospital-specific rate to account for the remainder of the 5.4 percent effect of documentation and coding that occurred in FY 2008 and FY 2009. We continue to believe that hospitals paid based on their hospital-specific rate (that is, SCHs) had the same opportunity to benefit for improvements in documentation and coding that did not reflect an increase in patient severity, and we continue to believe that any resulting adjustments should be applied similarly to all subsection (d) hospitals, when possible.

As discussed in section II.D., after review of comments and recommendations received from MedPAC, we analyzed claims data in FY 2010 to determine whether any additional adjustment (beyond the estimated 5.4 percent for FYs 2008 and 2009 discussed above) to the hospital-specific rate would be required to ensure that the introduction of MS–DRGs was implemented in a budget neutral manner. We analyzed FY 2010 claims data (for this proposed rule, we analyzed FY 2010 claims paid through December 2011), and determined that there is an additional documentation and coding effect of 0.8 percent.

Consistent with our proposal for IPPS hospitals based upon a review of FY 2010 claims data using the same methodology, we also are proposing an additional −0.8 percent adjustment to the hospital-specific rates to account for documentation and coding that did not reflect an actual increase in case-mix in FY 2010. We believe that a full prospective adjustment is the most appropriate means to take into account the effect of documentation and coding changes on payments, while maintaining equity as much as possible between different IPPS hospitals paid using the MS–DRG. Therefore, as discussed in more detail the preamble to this proposed rule, we are proposing a combined adjustment of −1.3 percent (−0.5 percent + −0.8 percent) to the hospital-specific rates, accounting for all documentation and coding effects observed between FY 2008 though FY 2010.

3. General Formula for Calculation of Prospective Payment Rates for Hospitals Located in Puerto Rico Beginning on or After October 1, 2012, and Before October 1, 2013

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 is then 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 2013

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 2013, which will be effective for discharges occurring on or after October 1, 2012.

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 exceptions under § 412.348. (We note that, as discussed in below in section III.A.4. of this Addendum, there is no longer a need for an exceptions payment adjustment factor.) Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for 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. Effective October 1, 2004, in accordance with section 504 of Pub. L. 108–173, 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 25 percent of the applicable standardized amount specific to Puerto Rico hospitals and 75 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, 2004, we also 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 capital rate and 75 percent of the national capital Federal rate (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 2013. In particular, we explain why the proposed FY 2013 capital Federal rate increases approximately 0.7 percent, compared to the FY 2012 capital Federal rate. As discussed in the impact analysis in Appendix A of this proposed rule, we estimate that capital payments per discharge will decrease 0.2 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 2013 under that framework is 1.3 percent based on the best data available at this time. The proposed update factor under that framework is based on a projected 1.3 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 2011 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 2013 CIPI projection in that same section of this Addendum. We note that, as discussed in section V.C. of the preamble of this proposed rule, we are proposing to apply a −0.8 percent adjustment to the capital rate in FY 2013 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 2013.

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 2013, we are projecting a 0.5 percent total increase in the case-mix index. We estimated that the real case-mix increase will also equal 0.5 percent for FY 2013. 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 2013 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, in order to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, we have data available to evaluate the effects of the FY 2011 DRG reclassification and recalibration as part of our update for FY 2013. We estimate that FY 2011 DRG reclassification and recalibration resulted in no change in the case-mix when compared with the case-mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, we are proposing to make a 0.0 percent adjustment for reclassification and recalibration in the update framework for FY 2013.

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 0.0 percentage point was calculated for the proposed FY 2013 update. That is, current historical data indicate that the forecasted FY 2011 CIPI (1.2 percent) used in calculating the FY 2011 update factor is the same as the actual realized price increases (1.2 percent). Because we estimate forecast error for the FY 2011 CIPI, we are proposing to make a 0.0 percent adjustment for forecast error in the update for FY 2013.

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.

We calculate case-mix constant intensity as the change in total cost per discharge, 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.

In this proposed rule, we are proposing to continue to use Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2013 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2013, we are proposing to use an intensity measure that is based on an average of cost per discharge data from the 5-year period beginning with FY 2005 and extending through FY 2010. Based on these data, we estimated that case-mix constant intensity declined during FYs 2005 through 2010. 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 2013. Therefore, we are proposing to make a 0.0 percent adjustment for intensity in the update for FY 2013.

Above, we described the basis of the components used to develop the proposed 1.3 percent capital update factor under the capital update framework for FY 2013 as shown in the table below.

PROPOSED CMS FY 2013 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index	1.3
Intensity	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	−0.5
Projected Case-Mix Change	0.5
Subtotal	1.3
Effect of FY 2011 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Update	1.3

b. Comparison of CMS and MedPAC Update Recommendation

In its March 2012 Report to Congress, MedPAC did not make a specific update recommendation for capital IPPS payments for FY 2013. (MedPAC's Report to the Congress: Medicare Payment Policy, March 2012, 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 2012, we estimated that outlier payments for capital would equal 6.18 percent of inpatient capital-related payments based on the capital Federal rate in FY 2012. 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 6.00 percent for inpatient capital-related payments based on the proposed capital Federal rate in FY 2013. Therefore, we are proposing to apply an outlier adjustment factor of 0.9400 in determining the capital Federal rate for FY 2013. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2013 will be somewhat lower than the percentage for FY 2012. This decrease in estimated capital outlier payments is primarily due to the proposed increase in the outlier threshold used to identify outlier cases for both inpatient operating and inpatient capital-related payments, which is discussed in section II.A. of this Addendum. That is, because the outlier threshold used to identify outlier cases is higher, cases will receive lower outlier payments and fewer cases will 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 2013 outlier adjustment of 0.9400 is a 0.19 percent change from the FY 2012 outlier adjustment of 0.9382. Therefore, the proposed net change in the outlier adjustment to the capital Federal rate for FY 2013 is 1.0019 (0.9400/0.9382). Thus, the proposed outlier adjustment will increase the FY 2013 capital Federal rate by 0.19 percent compared with the FY 2012 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.

To determine the proposed factors for FY 2013, we compared (separately for the national capital rate and the Puerto Rico capital rate) estimated aggregate capital Federal rate payments based on the FY 2012 MS–DRG classifications and relative weights and the FY 2012 GAF to estimated aggregate capital Federal rate payments based on the FY 2012 MS–DRG classifications and relative weights and the proposed FY 2013 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 1.0006 for FY 2013 to the previous cumulative FY 2012 adjustment of 0.9905, yielding an adjustment of 0.9911, through FY 2013. For the Puerto Rico GAFs, we are proposing to apply an incremental budget neutrality adjustment of 1.0044 for FY 2013 to the previous cumulative FY 2012 adjustment of 1.0043, yielding a cumulative adjustment of 1.0087 through FY 2013.

We then compared estimated aggregate capital Federal rate payments based on the FY 2012 DRG relative weights and the proposed FY 2013 GAFs to estimate aggregate capital Federal rate payments based on the cumulative effects of the proposed FY 2013 MS–DRG classifications and relative weights and the proposed FY 2013 GAFs. The proposed incremental adjustment for DRG classifications and proposed changes in relative weights is 0.9996 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 0.9907 nationally and 1.0083 for Puerto Rico. We note that all the values are calculated with unrounded numbers.

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 2012, we established a GAF/DRG budget neutrality factor of 1.0004 (76 FR 51803). For FY 2013, we are proposing to establish a GAF/DRG budget neutrality factor of 1.0002. 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 adjustment from FY 2012 to FY 2013 is 1.0002. The proposed cumulative change in the capital Federal rate due to this adjustment is 0.9907 (the product of the incremental factors for FYs 1995 through 2012 and the proposed incremental factor of 1.0002 for FY 2013). (For a listing of the DRG and GAF budget neutrality adjustment factors, we refer readers to section V. of the Addendum to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51803).)

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 2013 geographic reclassification decisions made by the MGCRB compared to FY 2012 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.

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, as discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51804), 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). Therefore, beginning with FY 2012, there is no longer a need for an exceptions payment adjustment factor.

5. Proposed Capital Standard Federal Rate for FY 2013

For FY 2012, we established a capital Federal rate of $421.42 (76 FR 51804). We are proposing to establish an update of 1.3 percent in determining the FY 2013 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 Pub. L. 110–90, we are proposing to make an additional 0.8 percent reduction to the national capital Federal payment rate in FY 2013 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 0.9404 in determining the proposed FY 2013 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 −1.0 percent adjustment for FY 2012, plus the proposed −0.8 percent adjustment for FY 2013, computed as 1 divided by $(1.006 \times 1.009 \times 1.029 \times 1.010 \times 1.008)$. (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 1.3 percent update and other budget neutrality factors discussed above, we are proposing to establish a national capital Federal rate of $424.42 for FY 2013. The proposed national capital Federal rate for FY 2013 was calculated as follows:

- The proposed FY 2013 update factor is 1.0130, that is, the proposed update is 1.3 percent.
- The proposed FY 2013 budget neutrality adjustment factor that is applied to the proposed capital standard Federal payment rate for proposed changes in the MS–DRG classifications and relative weights and proposed changes in the GAFs is 1.0002.
- The proposed FY 2013 outlier adjustment factor is 0.9400.
- The proposed cumulative adjustment factor for FY 2013 applied to the national capital Federal rate for changes in documentation and coding under the MS–DRGs is 0.9404.

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. (As discussed in section III.A.4. of this Addendum, there is no longer a need for an exceptions payment adjustment factor in determining the capital Federal rate.)

We are providing the following chart that shows how each of the proposed factors and adjustments for FY 2013 affects the computation of the proposed FY 2013 national capital Federal rate in comparison to the FY 2012 national capital Federal rate. The proposed FY 2013 update factor has the effect of increasing the capital Federal rate by 1.3 percent compared to the FY 2012 capital Federal rate. The proposed GAF/DRG budget neutrality factor has the effect of increasing the capital Federal rate by 0.02 percent. The proposed FY 2013 outlier adjustment factor has the effect of increasing the proposed capital Federal rate by 0.19 percent compared to the FY 2012 capital Federal rate. The proposed factor for changes in documentation and coding under the MS–DRGs for FY 2013 has the net effect of decreasing the proposed FY 2013 national capital Federal rate by 0.08 percent as compared to the FY 2012 national capital Federal rate. The combined effect of all the proposed changes would increase the proposed national capital Federal rate by approximately 0.7 percent compared to the FY 2012 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2012 CAPITAL FEDERAL RATE AND PROPOSED FY 2013 CAPITAL FEDERAL RATE

	FY 2012	Proposed FY 2013	Change	Percent change
Update Factor [1]	1.0150	1.0130	1.0130	1.30
GAF/DRG Adjustment Factor [1]	1.004	1.0002	1.0002	0.02
Outlier Adjustment Factor [2]	0.9382	0.9400	1.0019	0.19
MS–DRG Documentation and Coding Adjustment Factor	[3] 0.9479	[4] 0.9404	0.9921	−0.79
Capital Federal Rate [5]	$421.42	$424.42	1.0071	0.71

[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 2012 to FY 2013 resulting from the application of the proposed 1.0002 GAF/DRG budget neutrality factor for FY 2013 is a net change of 1.0002.

[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 2013 outlier adjustment factor is 0.9404/0.9382, or 1.0019.

[3] 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 −1.0 percent in FY 2012.

[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, the −2.9 percent in FY 2011, the −1.0 percent in FY 2012, and the proposed −0.8 percent in FY 2013.

[5] 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, 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 budget neutrality adjustments for the proposed national GAF and for the proposed Puerto Rico GAF, and the proposed budget neutrality factor for proposed MS–DRG reclassifications and recalibration (which is the same nationally and for Puerto Rico) is discussed above in section III.A.3. of this Addendum.

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).

For FY 2012, the special capital rate for hospitals located in Puerto Rico was $203.86 (76 FR 51805). As discussed in section V.C.3. of the preamble of 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 2013. Therefore, with the changes we are proposing to make to the other factors used to determine the proposed capital rate, the proposed FY 2013 special capital rate for hospitals in Puerto Rico is $206.82.

B. Calculation of the Proposed Inpatient Capital-Related Prospective Payments for FY 2013

For purposes of calculating payments for each discharge during FY 2013, 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 2013 are in section II.A. of this Addendum. For FY 2013, 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 $27,425.

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 2013

Based on the latest forecast by IHS Global Insight, Inc. (first quarter of 2012), we are forecasting the FY 2006-based CIPI to increase 1.3 percent in FY 2013. This reflects a projected 1.8 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 1.9 percent increase in other capital expense prices in FY 2013, partially offset by a projected 2.2 percent decline in vintage-weighted interest expenses in FY 2013. The weighted average of these three

factors produces the proposed 1.3 percent increase for the FY 2006-based CIPI as a whole in FY 2013.

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.)

In this proposed rule, we are proposing that the FY 2013 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 2013 IPPS operating market basket, in accordance with applicable regulations at § 413.40. In this proposed rule, the estimated percentage increase in the FY 2013 IPPS operating market basket is estimated to be 3.0 percent. We also are proposing to use the most recent data available to determine the estimated percentage increase for the FY 2013 IPPS operating market basket. Based on IHS Global Insight, Inc.'s first quarter 2012 forecast, with historical data through the 2011 fourth quarter, the IPPS operating market basket update is 3.0 percent for FY 2013. Therefore, for cancer and children's hospitals and RNHCIs, the proposed FY 2013 rate-of-increase percentage that would be applied to the FY 2012 target amounts in order to determine the proposed FY 2013 target amount is 3.0 percent.

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 2013. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Proposed Changes to the Payment Rates for the LTCH PPS for FY 2013

A. Proposed LTCH PPS Standard Federal Rate for FY 2013

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 2013.

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 update 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 made an adjustment for 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). For FY 2012, we updated the standard Federal rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by section 1886(m)(3)(A) of the Act.

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 described in section 1886(b)(3)(B)(xi)(II) of the Act (which we refer to as ''the multifactor productivity (MFP) adjustment'') as discussed in section VII.D.2.d. of the preamble of this proposed rule.

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.D.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 use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

For FY 2012, 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 of 2.9 percent, the 1.1 percentage point reductions required by sections 1886(m)(3)(A)(i) and (m)(4)(C) of the Act. Accordingly, at § 412.523(c)(3)(viii) of the regulations, we established an annual update of 1.8 percent to the standard Federal rate for FY 2012 (76 FR 51769 through 51771 and 51807).

In this proposed rule, for FY 2013, as discussed in greater detail in section VII.D.2. of the preamble of this proposed rule, we are proposing to establish an annual update to the LTCH PPS standard Federal rate based on the full estimated increase in the proposed LTCH PPS market basket, less the MFP adjustment consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.1 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(C) of the Act. Specifically, in this proposed rule, based on the best available data, we are proposing an annual update to the standard Federal rate of 2.1 percent, which is based on the full estimated increase in the proposed LTCH PPS market basket of 3.0 percent, less the proposed MFP adjustment of 0.8 percentage point consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.1 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(C) of the Act.

2. Development of the Proposed FY 2013 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. Consistent with our historical practice, we are proposing to apply the annual update to the LTCH PPS standard Federal rate from the previous year. In determining the proposed standard Federal rate for FY 2013, we also are proposing to make certain regulatory adjustments. Specifically, we are proposing to make a one-time prospective adjustment to the standard Federal rate under § 412.523(d)(3), as discussed in greater detail in section VII.E.4. of the preamble of this proposed rule (which would not be applicable to payments for discharges occurring prior to December 29, 2012, consistent with the statute.) In addition, in determining the proposed FY 2013 standard Federal rate, we are proposing to apply a budget neutrality adjustment for the proposed changes to the area wage adjustment (that is, proposed changes to the wage data and labor-related share) in accordance with § 412.523(d)(4).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51769 through 51771 and 51807), we established an annual update to the LTCH PPS standard Federal rate of 1.8 percent for FY 2012 based on the full estimated LTCH PPS market basket increase of 2.9 percent, less the MFP adjustment of 1.0 percentage point consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.1 percentage point required by sections 1886(m)(3)(A)(ii) and(m)(4)(C) of the Act. Accordingly, at § 412.523(c)(3)(viii), we established an annual update to the standard Federal rate for FY 2012 of 1.8 percent. That is, we applied an update factor of 1.018 to the FY 2011 Federal rate of $39,599.95 to determine the FY 2012 standard Federal rate. Furthermore, for FY 2012, we applied an area wage level budget neutrality factor of 0.99775 to the standard Federal rate to ensure that any changes to the area wage level adjustment (that is, the 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 established a standard Federal rate for FY 2012 of $40,222.05 (calculated as $39,599.95 × 1.018 × 0.99775), which is applicable to LTCH PPS discharges occurring on or after October 1, 2011, through September 30, 2012.

In this proposed rule, for FY 2013, as noted above and as discussed in greater detail in section VII.D.2. of the preamble of this proposed rule, consistent with our historical practice, we are proposing to establish an annual update to the proposed LTCH PPS standard Federal rate of 2.1 percent, based on the full estimated increase in the proposed LTCH PPS market basket of 3.0 percent less the proposed MFP adjustment of 0.8 percentage point consistent with section 1886(m)(3)(A)(i) and less the 0.1 percentage point required by sections 1886(m)(3)(A)(ii) and(m)(4)(C) of the Act. Furthermore, as discussed in section VII.E.4. of the preamble of this proposed rule, in determining the proposed standard Federal rate for FY 2013, we are proposing to make a one-time prospective adjustment to the standard Federal rate under § 412.523(d)(3) (which would not be applicable to payments for discharges occurring prior to December 29, 2012, consistent with the statute).

In this proposed rule, under proposed § 412.523(c)(3)(ix)(A), we are proposing to apply a factor of 1.021 to the FY 2012 standard Federal rate of $40,222.05 (as established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51807)) to determine the proposed FY 2013 standard Federal rate. In addition, as discussed in section VII.E.4. of the preamble of this proposed rule, the standard Federal rate would be further adjusted by the proposed one-time prospective adjustment factor for FY 2013 of 0.98734 under proposed § 412.523(d)(3)(ii). However, consistent with the statute, we are proposing at § 412.523(c)(3)(ix)(B) that, for payments for discharges occurring on or after October 1, 2012, and before December 29, 2012, payments are based on the standard Federal rate in paragraph (c)(3)(ix)(A) of this section without regard to the one-time prospective adjustment provided for under proposed § 412.523(d)(3)(ii). In addition, as discussed in greater detail in section V.B.5. of this Addendum, for FY 2013, we are proposing to apply an area wage level budget neutrality factor of 0.99903 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, in this proposed rule, under proposed § 412.523(c)(3)(ix)(A), we are proposing to establish a standard Federal rate for FY 2013 of $40,507.48 (calculated as $40,222.05 × 1.021 × 0.98734 × 0.99903). Furthermore, consistent with section 114(c)(4) of the MMSEA, as amended by sections 3106(a) and 10312 of the Affordable Care Act, the proposed one-time prospective adjustment to the standard Federal rate for FY 2013 of 0.98734 would not apply to payments for discharges occurring before December 29, 2012. Therefore, payment for discharges occurring on or after October 1, 2012 and on or before December 28, 2012, would not reflect that proposed adjustment and instead would be paid based on a standard Federal rate of $41,026.88 (calculated as $40,507.48 divided by 0.98734).

B. Proposed Adjustment for Area Wage Levels Under the LTCH PPS for FY 2013

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. For additional information on the development and initial implementation 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

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 (67 FR 56015 through 56019). Specifically, the application of the LTCH PPS area wage level adjustment at § 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.

Currently, the labor market area definitions used under the LTCH PPS are based on the Executive OMB's CBSA designations, which are based on 2000 Census data (as adopted in the RY 2006 LTCH PPS final rule (70 FR 24184 through 24185)). We adopted this policy 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 currently used for acute care hospitals under the IPPS at § 412.64(b) (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).) Each year, we update the LTCH PPS CBSA-based labor market area definitions to reflect any changes OMB has made to the CBSA designations (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 for FY 2011 in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50444 through 50445), and adopted their continued use for FY 2012 in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51808). In 2013, OMB plans to announce new area delineations based on its 2010 standards (75 FR 37246) and the 2010 Census data. Therefore, in this proposed rule, for FY 2013 wage index, we are proposing to continue to use the same labor market areas that we adopted for FY 2012 (76 FR 51808).

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 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: Labor-Related, Administrative and Business Support Services, and All Other: Labor-Related Services) and a labor-related portion of capital costs using the applicable LTCH PPS market basket.

For FY 2012, we revised and rebased the market basket used under the LTCH PPS by adopting the newly created FY 2008-based rehabilitation, psychiatric, and long-term care hospital (RPL) market basket. Accordingly, the current LTCH PPS labor-related share is based on the relative importance of the labor-related share of operating costs and capital costs of the RPL market basket based on FY 2008 data, as those were the best available data at that time that reflected the cost structure of LTCHs. For FY 2012, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808), we established a labor-related share of 70.199 percent based on the best available data at that time for the FY 2008-based RPL market basket for FY 2012. (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).)

As discussed in section VII.C. of the preamble of this proposed rule, we are proposing to revise and rebase the market basket used under the LTCH PPS by adopting the newly created FY 2009-based LTCH-specific market basket. Consistent with this proposal, we are proposing to determine the labor-related share for FY 2013 as the sum of the proposed FY 2013 relative importance of each labor-related cost category of the proposed FY 2009-based LTCH-specific market basket. Consistent with the current labor-related share determined from the relative importance of each labor-related cost category of the FY 2008-based RPL market basket, we are proposing to determine the LTCH PPS labor-related share for FY 2013 based on the relative importance of the labor-related share of operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Business Support Services, and All Other: Labor-Related Services) and the labor-related share of capital costs of the proposed LTCH-specific market basket based on FY 2009 data, as we believe these are currently the best data available to reflect the cost structure of LTCHs.

In this proposed rule, we are proposing a labor-related share under the LTCH PPS for FY 2013 based on IGI's first quarter 2012 forecast of the proposed FY 2009-based LTCH-specific market basket for FY 2013, as these are the most recent available data at this time that reflect the cost structure of LTCHs. As discussed in greater detail in section VII.C.3.f. of this preamble, the sum of the proposed relative importance for FY 2013 for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Business Support Services, and All-Other: Labor-Related Services) is 58.978 percent and the proposed labor-related share of capital costs is 4.239 percent. Therefore, in this proposed rule, 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 63.217 percent (58.978 percent plus 4.239 percent) under the LTCH PPS for FY 2013, which would be effective for discharges occurring on or after October 1, 2012, and through September 30, 2013. Consistent with our historical practice of using the best data available, we also are proposing that if more recent data become available to determine the labor-related share used under the LTCH PPS for FY 2013, we would use those data for determining the FY 2013 LTCH PPS labor-related share in the final rule. (For additional details on the development of the proposed LTCH PPS labor-related share for FY 2013, we refer readers to section VII.C.3.f. of the preamble of this proposed rule.)

4. Proposed LTCH PPS Wage Index for FY 2013

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 2012 LTCH PPS final rule (76 FR 51808 through 51809), we calculated the FY 2012 LTCH PPS wage index values using the same data used for the FY 2012 acute care hospital IPPS (that is, data from 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, as these were the most recent complete data available at that time. In that same final rule, we indicated that we computed the FY 2012 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). This IPPS wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus or campuses are located. We also continued to use our existing policy for determining 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 2013, 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 2009, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act. We are proposing to use FY 2009 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 2013 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.D. of the preamble of this proposed rule). Furthermore, in determining the proposed FY 2013 LTCH PPS wage index values in this proposed rule, we are proposing to continue to use our existing policy for determining wage index values in areas where there are no IPPS wage data.

Specifically, 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 2013. (We refer readers to 73 FR 26817 through 26818 for an explanation of and rationale for our policy for determining LTCH PPS wage index values for areas that have no IPPS wage data.)

There are currently no LTCHs located in labor areas without IPPS hospital wage data (or IPPS hospitals) for FY 2013. However, we calculate 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. Under our existing 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, and the LTCH PPS wage index value for rural areas with no IPPS wage data is determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2009 IPPS wage data that we are proposing to use to determine the proposed FY 2013 LTCH PPS wage index values in this proposed rule, there are no IPPS hospital 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 2013 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 rural areas without IPPS hospital wage data will vary in the future.

Based on the FY 2009 IPPS wage data that we are proposing to use to determine the proposed FY 2013 LTCH PPS wage index values in this proposed rule, there are no rural areas without IPPS hospital wage data. Therefore, for this proposed rule, it is not necessary to propose to use our established methodology to calculate a LTCH PPS wage index value for rural areas with no IPPS wage data. We note that, as IPPS wage data are dynamic, it is possible that rural areas without IPPS hospital wage data will vary in the future. In addition, we are proposing that if there are rural areas without IPPS hospital wage data based on the updated data, we would use our established methodology to calculate a LTCH PPS wage index value for such rural areas with no IPPS wage data in the final rule.

The proposed FY 2013 LTCH wage index values that would be applicable for LTCH discharges occurring on or after October 1, 2012, through September 30, 2013, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of the Addendum of this proposed rule and available via the Internet on the CMS Web site.

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. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809), under § 412.525(c)(2), we established that any changes to the wage index values or labor-related share will be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected, that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage level adjustment budget neutrality factor that will be applied to the standard Federal rate to ensure that any changes to the area wage level adjustment are budget neutral such that any changes to the wage index values or labor-related share will not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we established that we will apply an area wage level adjustment budget neutrality factor in determining the standard Federal rate and we also established a methodology for calculating an area wage level adjustment budget neutrality factor.

For FY 2013, in accordance with § 412.523(d)(4), we are proposing to apply an area wage level adjustment budget neutrality factor to adjust the standard Federal rate to account 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 using the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). Specifically, we are proposing to determine a proposed area wage level adjustment budget neutrality factor that is applied to the standard Federal rate under at § 412.523(d)(4) for FY 2013 using the following methodology:

Step 1—We simulate estimated aggregate LTCH PPS payments using the FY 2012 wage index values (as established in Tables 12A and 12B listed in the Addendum to the FY 2012 IPPS/LTCH PPS final rule and available on the Internet) and the FY 2012 labor-related share of 70.199 percent (as established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51767 and 51808).

Step 2—We simulate estimated aggregate LTCH PPS payments using the proposed FY 2013 wage index values (as shown in Tables 12A and 12B listed in the Addendum to this proposed rule and available on the Internet) and the proposed FY 2013 labor-related share of 63.217 percent (based on the latest available data as discussed in section VII.C.3.f. of this preamble).

Step 3—We calculate the ratio of these estimated total LTCH PPS payments by dividing the estimated total LTCH PPS payments using the FY 2012 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS payments using the proposed FY 2013 area wage level adjustments (calculated in Step 2) to determine the proposed area wage level adjustment budget neutrality factor for FY 2013.

Step 4—We then apply the proposed FY 2013 area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2013 LTCH PPS standard Federal rate after the application of the proposed FY 2013 annual update (discussed in section V.A.2. of the Addendum to this proposed rule).

For this proposed rule, using the steps in the methodology described above, we determined a proposed FY 2013 area wage level adjustment budget neutrality factor of 0.99903. Accordingly, in section V.A.2. of the Addendum to this proposed rule, to determine the proposed FY 2013 LTCH PPS standard Federal rate, we applied a proposed area wage level adjustment budget neutrality factor of 0.99903, in accordance with § 412.523(d)(4). Accordingly, the proposed FY 2013 LTCH PPS standard Federal rate shown in Table 1E of the Addendum to this proposed rule reflects this proposed adjustment factor.

C. Proposed LTCH PPS Cost-of-Living Adjustment for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), we established a cost-of-living adjustment (COLA) for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States (67 FR 56022). 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.

As we discuss in section VII.D.4. of the preamble of this proposed rule, historically, we have used the most recent updated COLA factors obtained from the OPM Web site at *http://www.opm.gov/oca/cola/rates.asp* to adjust the payments for LTCHs in Alaska and Hawaii. Recent statutory changes transition the Alaska and Hawaii COLAs to locality pay (phased in over a 3-year period beginning in January 2010 with COLA rates frozen as of October 28, 2009, and then proportionately reduced to reflect the phase-in of locality). As stated previously, we do not believe it is appropriate to use either the 2010 or 2011 reduced factors to adjust the nonlabor-related portion of the standard Federal rate for LTCHs in Alaska and Hawaii for Medicare payment purposes. Therefore, for FY 2012, we continued to use the same COLA factors (published by OPM) that we used to adjust payments in FY 2011 (which were 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 it was appropriate to use ''frozen'' COLA factors to adjust payments in FY 2012 while we explored alternatives for updating the COLA adjustment in the future. As we discuss in greater detail in section VII.D.4. of the preamble of this proposed rule, we are proposing to continue to use the same ''frozen'' COLA factors used in FY 2012 for FY 2013. Furthermore, we are proposing to update the COLA factors for Alaska and Hawaii beginning in FY 2014 based on a comparison of the growth in the CPIs for Anchorage, Alaska and Honolulu, Hawaii relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). (For additional details on our proposal to update the COLA factors for Alaska and Hawaii beginning in FY 2014, we refer readers to section VII.D.4. of the preamble of this proposed rule.)

In this proposed rule, for FY 2013, 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 the same COLA factors used to adjust payments in FY 2012 (which are based on OPM's 2009 COLA factors) by multiplying the nonlabor-related portion of the standard Federal payment rate by the proposed factors listed in the chart below.

PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII HOSPITALS FOR THE LTCH PPS FOR FY 2013

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

PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII HOSPITALS FOR THE LTCH PPS FOR FY 2013—Continued

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

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 for 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, in this proposed rule, using our established methodology for determining the LTCH total CCR ceiling (described above), based on IPPS total CCR data from the December 2011 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, 2012, through September 30, 2013. Consistent with our historical policy of using the best available data, we also are proposing that if more recent data became available, we would use such data to establish a total CCR ceiling for FY 2013 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 2011 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, 2012, through September 20, 2013, in Table 8C listed in section VI. of the Addendum to this proposed rule (and available via the Internet). 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 urban and rural hospitals that would be effective for FY 2013 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. 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, consistent with our existing methodology, in determining the proposed urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, in this proposed rule, we are proposing to continue to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We 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 2013

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 2013 (based on the 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 additional detail on the rationale for setting the HCO payment ''target'' at 8 percent of total estimated LTCH PPS payments, we refer readers to the to the FY 2003 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 2013, we use the most recent available LTCH claims data and CCR data at this time. Specifically, for this proposed rule, we are using LTCH claims data from the December 2011 update of the FY 2011 MedPAR file and CCRs from the December 2011 update of the PSF to determine a proposed fixed-loss amount that would result in estimated outlier payments projected to be equal to 8 percent of total estimated payments in FY 2013 because these data are the most recent complete LTCH data available at this time. 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 2013 in the final rule.

Under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of BIPA, we established a fixed-loss amount of $17,931 for FY 2012. For this proposed rule, we are proposing to establish a fixed-loss amount of $15,728 for FY 2013. Thus, we are proposing to make an additional payment for an HCO case that is equal to 80 percent of the difference between the estimated cost of the case and the proposed outlier threshold (the sum of the proposed adjusted Federal LTCH payment for the proposed MS–LTC–DRG and the proposed fixed-loss amount of $15,728). We also note that the proposed fixed-loss amount of $15,728 for FY 2013 is lower than the FY 2012 fixed-loss amount of $17,931. Based on our payment simulations using the most recent available data at this time, the proposed decrease in the fixed-loss amount for FY 2013 is 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 less than the current regulatory 8-percent requirement because a higher fixed-loss amount would result in fewer cases qualifying as outlier cases. In addition, maintaining the higher fixed-loss amount would result in 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 believe that proposing to lower 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 an SSO case (as defined in the regulations at § 412.529 in conjunction with § 412.503) and also as an 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 an HCO. Thus, for an SSO case in FY 2013, 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 $15,728 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 2013

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 applicable LTCH PPS wage index (proposed FY 2013 values 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 applicable cost-of-living factor (proposed FY 2013 factors shown in the chart in section V.C. 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 2013 of $40,507.48 (however, payment for discharges occurring on or after October 1, 2012, and before December 29, 2012 would not reflect that proposed adjustment consistent with the statute, and instead would be paid based on a standard Federal rate of $41,026.88), 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 standard rate for FY 2013 in the following example:

Example: During FY 2013, a Medicare patient is in a LTCH located in Chicago, Illinois (CBSA 16974) and discharged on January 1, 2013. The proposed FY 2013 LTCH PPS wage index value for CBSA 16974 is 1.0623 (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 2013 of 1.5986 (Table 11 listed in section VI. of the Addendum of this proposed rule and available via the Internet).

To calculate the LTCH's proposed total adjusted Federal prospective payment for this Medicare patient in FY 2013, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted proposed FY 2013 standard Federal rate ($40,507.48) by the proposed labor-related share (63.217 percent) and the proposed wage index value (1.0623). This wage-adjusted amount is then added to the nonlabor-related portion of the unadjusted proposed standard Federal rate (36.783 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 (1.5886) to calculate the total adjusted proposed Federal LTCH PPS prospective payment for FY 2013 ($67,305.58). The table below illustrates the components of the calculations in this example.

Proposed Unadjusted Standard Federal Prospective Payment Rate.	$40,507.48
Proposed Labor-Related Share.	× 0.63217
Proposed Labor-Related Portion of the Federal Rate.	= $25,607.61
Proposed Wage Index (CBSA 16974).	× 1.0623
Proposed Wage-Adjusted Labor Share of Federal Rate.	= $27,202.96
Proposed Nonlabor-Related Portion of the Federal Rate ($40,507.48 x 0.36783).	+ $14,899.87
Proposed Adjusted Federal Rate Amount.	= $42,102.83
Proposed MS–LTC–DRG 28 Relative Weight.	× 1.5986
Total Proposed Adjusted Federal Prospective Payment.	= $67,305.58

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, similar to FY 2012, for the FY 2013 rulemaking cycle, the IPPS and LTCH tables will not be published as part of the annual IPPS/LTCH PPS proposed and final rulemakings and will be available only through the Internet. Specifically, IPPS tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 5, 6A, 6B, 6C, 6D, 6E, 6F, 6G, 6I, 6I.1, 6.I.2, 6J, 6J.1, 6K, 7A, 7B, 8A, 8B, 9A, 9C, 10 and new tables 15 and 16 and LTCH PPS tables 8C, 11, 12A, 12B, 13A, and 13B 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 proposed and final rules. As discussed in section II.G.9. of the preamble of this proposed rule, for FY 2013, there were no changes to the ICD–9–CM coding system, effective October 1, 2012, due to the partial code freeze in anticipation of the transition to the ICD–10 coding system or for new technology. Therefore, there will be no new, revised, or deleted diagnosis and procedure codes effective October 1, 2012, that are usually announced in Tables 6A (New Diagnosis Codes), 6B (New Procedure Codes), 6C (Invalid Diagnosis Codes), 6D (Invalid Procedure Codes), 6E (Revised Diagnosis Code Titles), and 6F (Revised Procedure Codes). Therefore, these tables will not be published as part of this FY 2013 rulemaking cycle. As discussed in section IV.E. of this proposed rule, effective FY 2013 and forward, the low-volume hospital definition and payment adjustment methodology under section 1886(d)(12) of the Act will return to the pre-Affordable Care Act definition and payment adjustment methodology (we refer readers to section IV.E. for complete details on the low-volume hospital payment adjustment). Therefore, we are no longer including a table (previously Table 14) in this proposed rule that lists the low volume payment adjustments.

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 2013 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 2013 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 2011; Proposed Hospital Wage Indexes for Federal Fiscal Year 2013; Hospital Average Hourly Wages for Federal Fiscal Years 2011 (2007 Wage Data), 2012(2008 Wage Data), and 2013 (2009 Wage Data); and 3–Year Average of Hospital Average Hourly Wages

Table 3A.—Proposed FY 2013 and 3–Year Average Hourly Wage for Acute Care Hospitals in Urban Areas by CBSA

Table 3B.—Proposed FY 2013 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 2013

Table 4B.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Rural Areas by CBSA and by State—FY 2013

Table 4C.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals That Are Reclassified by CBSA and by State—FY 2013

Table 4D.—States Designated as Frontier, with Acute Care Hospitals Receiving at a Minimum the Proposed Frontier State Floor Wage Index[1]; Urban Areas With Acute Care Hospitals Receiving the Proposed Statewide Rural Floor Wage Index—FY 2013

Table 4E.—Urban CBSAs and Constituent Counties for Acute Care Hospitals—FY 2013

Table 4F.—Proposed Puerto Rico Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals by CBSA—FY 2013

Table 4J.—Proposed Out-Migration Adjustment for Acute Care Hospitals—FY 2013

Table 5.—List of Proposed Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2013

Table 6G—Additions to the CC Exclusions List—FY 2013

Table 6I.—Proposed Complete MCC List—FY 2013

Table 6I.2.—Proposed Deletions to the MCC List—FY 2013

Table 6J.—Proposed Complete CC List—FY 2013

Table 6J.1.—Proposed Additions to the CC List—FY 2013

Table 6K.—Proposed Complete List of CC Exclusions—FY 2013

Table 7A.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2011 MedPAR Update—December 2011 GROUPER V29.0 MS–DRGs

Table 7B.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2011 MedPAR Update—December 2011 GROUPER V30.0 MS–DRGs

Table 8A.—Proposed FY 2013 Statewide Average Operating Cost to Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)

Table 8B.—Proposed FY 2013 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals

Table 9A.—Hospital Reclassifications and Redesignations—FY 2013

Table 9C.—Hospitals Redesignated as Rural Under Section 1886(d)(8)(E) of the Act—FY 2013

Table 10.—Proposed New Technology Add-On Payment Thresholds for Applications for FY 2014

Table 15.—FY 2013 Proposed Readmissions Adjustment Factors

Table 16.—Proposed Hospital Inpatient Value-Based Purchasing Program (VBP) Program Adjustment Factors for FY 2013

The following LTCH PPS tables for this FY 2013 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–1588–P.

Table 8C.—Proposed FY 2013 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, 2012 through September 30, 2013 under the LTCH PPS

Table 12A.—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2012 through September 30, 2013

Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring From October 1, 2012 through September 20, 2013

Table 13A.—Composition of Proposed Low-Volume Quintiles for MS–LTC–DRGs—FY 2013

Table 13B.—Proposed No-Volume MS–LTC–DRG Crosswalk for FY 2013

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 2013

Full update (2.1 percent)		Reduced update (0.1 percent)	
Labor-related	Nonlabor-related	Labor-related	Nonlabor-related
$3,664.03	$1,661.59	$3,592.26	$1,629.04

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 2013

Full update (2.1 percent)		Reduced update (0.1 Percent)	
Labor-related	Nonlabor-related	Labor-related	Nonlabor-related
$3,301.88	$2,023.74	$3,237.21	$1,984.09

TABLE 1C—PROPOSED ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR PUERTO RICO, LABOR/NONLABOR—FY 2013

	Rates if wage index is greater than 1		Rates if wage index is less than or equal to 1	
	Labor	Nonlabor	Labor	Nonlabor
National	$3,664.03	$1,661.59	$3,301.88	$2,023.74
Puerto Rico	1,583.10	966.17	1,580.55	968.72

TABLE 1D—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2013

	Rate
National	$424.42
Puerto Rico	206.82

TABLE 1E—PROPOSED LTCH STANDARD FEDERAL PROSPECTIVE PAYMENT RATE—FY 2013

	Rate
Standard Federal Rate*	$40,507.48

*Consistent with section 114(c)(4) of the MMSEA as amended by sections 3106(a) and 10312 of the Affordable Care Act, the proposed one-time prospective adjustment to the standard Federal rate for FY 2013 of 0.98734 would not apply to payments for discharges occurring before December 29, 2012. Therefore, payment for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, would not reflect that proposed adjustment and instead would be paid based on a standard Federal rate of $41,026.88 (calculated as $40,507.48 divided by 0.98734).

Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (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 2013 acute care hospital operating and capital payments will redistribute amounts in excess of $100 million to acute care hospitals. The applicable percentage increase to the IPPS rates required by the statute, in conjunction with other payment changes in this proposed rule, will result in an estimated $904 million increase in proposed FY 2013 operating payments (or 0.9 percent change) and an estimated $8 million decrease in proposed FY 2013 capital payments (or -0.1 percent change). The proposed impact analysis of the capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience an increase in payments by $100 million in FY 2013 relative to FY 2012.

Our operating impact estimate includes the proposed 0.2 percent documentation and coding adjustment applied to the IPPS standardized amounts (which accounts for the proposed −2.7 percent documentation and coding adjustment and 2.9 percent adjustment to restore the one-time recoupment adjustment made to the national standardized amount for FY 2012). In addition, our operating impact estimate includes the proposed 2.1 percent hospital update to the standardized amount (which includes the 3.0 percent proposed market basket update less 0.8 percentage point for the proposed multifactor productivity adjustment and less 0.1 percentage point required under the Affordable Care Act). The proposed 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 analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. 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.

C. 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 delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe the changes in this proposed rule will 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 changes will ensure that the outcomes of the prospective payment systems are reasonable and equitable while avoiding or minimizing unintended adverse consequences.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our proposed policy changes, as well as statutory changes effective for FY 2013, 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.

E. Hospitals Included in and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital-related costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 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 45 such hospitals in Maryland remain excluded from the IPPS pursuant to the waiver under section 1814(b)(3) of the Act.

As of March 2012, there are 3,405 IPPS acute care hospitals to be included in our analysis. This represents about 67 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,349 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs rather than under the IPPS. There are also 1,232 IPPS-excluded hospitals and 2,090 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 proposed impact of the update and policy changes to the LTCH PPS for FY 2013 is discussed in section I.J. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of March 2012, there were 3,337 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, 230 rehabilitation hospitals and 906 rehabilitation units, and 442 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 469 psychiatric hospitals and 1,148 psychiatric units are paid the Federal per diem amount under the IPF PPS. As stated above, IRFs and IPFs are not affected by the rate updates discussed in this proposed rule. The impacts of the proposed changes on LTCHs are discussed in section I.J. 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 2013. For these hospitals (cancer and children's hospitals), consistent with the authority provided in section 1886(b)(3)(B)(ii) of the Act, the proposed update is the FY 2013 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 2012 first quarter forecast, with historical data through the 2011 fourth quarter, we are estimating that the proposed FY 2013 update based on the IPPS operating market basket is 3.0 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 proposed to be 0.8 percentage point) and a 0.1 percentage point reduction to the market basket update resulting in a proposed 2.1 percent applicable percentage increase for IPPS hospitals. RNCHIs, children's hospitals and cancer hospitals are not subject to the reductions 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 2013 IPPS operating market basket, estimated at 3.0 percent, without the reductions required under the Affordable Care Act.

The impact of the 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.

G. Quantitative Effects of the Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this proposed rule, we are announcing proposed policy changes and payment rate updates for the IPPS for FY 2013 for operating costs of acute care hospitals. The proposed FY 2013 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2013 operating payments will increase by 0.9 percent compared to FY 2012. In addition to the applicable percentage increase, this amount reflects the proposed FY 2013 adjustments for documentation and coding described in section II.D. of the preamble of this proposed rule: 0.2 percent for the IPPS national standardized amounts and -1.3 percent for the IPPS hospital-specific rates. The impacts do not reflect changes in the number of 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 the 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 proposed changes in payments per case presented below are taken from the FY 2011 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 proposed change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2011 MedPAR file, we simulated proposed 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 proposed 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. Proposed estimated payment impacts of the capital IPPS for FY 2013 are discussed in section I.I. of this Appendix.

We discuss the following changes below:

- The effects of the proposed application of the documentation and coding adjustment and applicable percentage increase (including the 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.
- 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 2009, compared to the FY 2008 wage data.
- The effects of the proposed 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 2013.
- The effects of the proposed rural floor and imputed 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 proposed frontier State 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 the proposed implementation of section 505 of Public Law 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 effects of the proposed policies for implementation of the Hospital Readmissions Reduction Program under section 3025 of the Affordable Care Act, that adjusts hospital's base operating DRG amount by an adjustment factor to account for a hospital's excess readmissions.
- The effects of the expiration of the special payment status for MDHs under section 3124 of the Affordable Care Act under which MDHs that currently receive the higher of payments made under the Federal standardized amount or the payments made under the Federal standardized amount plus 75 percent of the difference between the Federal standardized amount and the hospital-specific rate will be paid based on the Federal standardized amount starting in FY 2013.
- The proposed total estimated change in payments based on the FY 2013 proposed policies relative to payments based on FY 2012 policies that include the applicable percentage increase of 2.1 percent (or proposed 3.0 percent market basket update with a proposed reduction of 0.8 percentage point 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 2013 changes, our analysis begins with a FY 2012 baseline simulation model using: The proposed FY 2013 applicable percentage increase of 2.1 percent and the documentation and coding adjustment of 0.2 to the Federal standardized amount and the 1.3 percent documentation and coding adjustment to the hospital-specific rate; the FY 2012 MS–DRG GROUPER (Version 29.0); the most current CBSA designations for hospitals based on OMB's MSA definitions; the FY 2012 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, 48 hospitals did not receive the full market basket rate-of-increase for FY 2012 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 2013 using a reduced update for these 48 hospitals. However, we do not have enough information at this time to determine which hospitals will not receive the full update factor for FY 2013.

Each proposed policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2013 model incorporating all of the proposed changes. This simulation allows us to isolate the effects of each proposed change.

Our final comparison illustrates the proposed percent change in payments per case from FY 2012 to FY 2013. 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 2013 using an applicable percentage increase of 2.1 percent. This includes our forecasted IPPS operating hospital market basket increase of 3.0 percent with a reduction of 0.8 percentage point for the proposed 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 an update of 0.1 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 are also equal to the applicable percentage increase, or 2.1 percent. In addition, we are proposing to update the Puerto Rico-specific amount by an applicable percentage increase of 2.1 percent.

A second significant factor that affects the changes in hospitals' payments per case from FY 2012 to FY 2013 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 2012 that are no longer reclassified in FY 2013. Conversely, payments may increase for hospitals not reclassified in FY 2012 that are reclassified in FY 2013.

A third significant factor is that we currently estimate that actual outlier payments during FY 2012 will be 6.0 percent of total MS–DRG payments. Our updated FY 2012 outlier estimate accounts for changes to the FY 2012 IPPS payments required under the Affordable Care Act. When the FY 2012 final rule was published, we projected FY 2012 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 higher than expected outlier payments during FY 2012 (as discussed in the Addendum to this proposed rule) are reflected in the analyses below comparing our current proposed estimates of FY 2012 payments per case to estimated proposed FY 2013 payments per case (with outlier payments projected to

equal 5.1 percent of total MS–DRG payments).

2. Analysis of Table I

Table I displays the results of our analysis of the proposed changes for FY 2013. 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 3,405 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 2,485 hospitals located in urban areas included in our analysis. Among these, there are 1,365 hospitals located in large urban areas (populations over 1 million), and 1,120 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 920 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' proposed 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 2,500; 1,375; 1,125; 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 2,376 nonteaching hospitals in our analysis, 789 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 proposed changes on rural hospitals by special payment groups (SCHs, RRCs, and MDHs). There were 199 RRCs, 340 SCHs, 195 former MDHs, and 101 hospitals that are both SCHs and RRCs, and 17 hospitals that were former 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 2009 or FY 2008 Medicare cost reports.

The next two groupings concern the proposed geographic reclassification status of hospitals. The first grouping displays all proposed urban hospitals that were reclassified by the MGCRB for FY 2013. The second grouping shows the proposed MGCRB rural reclassifications. The final category shows the impact of the proposed policy changes on the 18 cardiac hospitals.

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TABLE I.— IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2013

	No. of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment[2] (2)	Proposed FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	Proposed FY 2013 Wage Data with Application of Wage Budget Neutrality[4] (4)	Proposed FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	Proposed FY 2013 MGCRB Reclassifications[6] (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Proposed Application of the Frontier Wage Index[8] (8)	Proposed FY 2013 Out-Migration Adjustment[9] (9)	Expiration of MDH Status (10)	Proposed Hospital Readmissions Reduction Program (11)	All Proposed FY 2013 Changes[12] (12)
All Hospitals	3,405	2.2	0	0	0	0	0	0.1	0	-0.1	-0.3	0.9
By Geographic Location:												
Urban hospitals	2,485	2.3	0	0	0.1	-0.2	0	0.1	0	0	-0.3	1
Large urban areas	1,365	2.3	0	0.2	0.2	-0.3	0	0	0	0	-0.3	1.2
Other urban areas	1,120	2.3	0	-0.2	-0.1	-0.1	0.1	0.1	0	-0.1	-0.2	0.9
Rural hospitals	920	1.8	-0.1	-0.3	-0.3	2.1	-0.3	0	0.1	-0.9	-0.3	-0.5
Bed Size (Urban):												
0-99 beds	627	2.3	0	0.1	0.2	-0.6	0.2	0.2	0	-0.4	-0.2	1
100-199 beds	773	2.3	0	0.1	0.2	0	0.3	0	0	-0.1	-0.3	1.1
200-299 beds	448	2.3	0	0.1	0.1	-0.2	0	0.1	0	0	-0.3	1.2
300-499 beds	432	2.3	0	0	0	-0.2	0	0.1	0	0	-0.3	1.2
500 or more beds	205	2.3	0	-0.1	0	-0.3	-0.1	0	0	0	-0.3	0.8
Bed Size (Rural):												
0-49 beds	317	1.8	-0.1	-0.3	-0.4	0.8	-0.3	0.1	0.3	-1.4	-0.3	-1.9
50-99 beds	346	1.7	-0.1	-0.3	-0.4	1.2	-0.3	0	0.2	-2.2	-0.3	-2.4
100-149 beds	152	1.8	-0.1	-0.3	-0.3	2.6	-0.3	0	0	-0.3	-0.4	0.3
150-199 beds	58	1.8	-0.1	-0.2	-0.3	2.3	-0.3	0.1	0	0	-0.3	0.6
200 or more beds	47	1.8	0	-0.2	-0.1	3	-0.3	0	0	0	-0.3	1.1

	No. of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment[2] (2)	Proposed FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	Proposed FY 2013 Wage Data with Application of Wage Budget Neutrality[4] (4)	Proposed FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	Proposed FY 2013 MGCRB Reclassifications[6] (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Proposed Application of the Frontier Wage Index[8] (8)	Proposed FY 2013 Out-Migration Adjustment[9] (9)	Expiration of MDH Status (10)	Proposed Hospital Readmissions Reduction Program (11)	All Proposed FY 2013 Changes[12] (12)
Urban by Region:												
New England	120	2.3	0	1	1	0.7	3.1	0	0	0	-0.4	-0.4
Middle Atlantic	318	2.3	0	0	0	0.1	-0.2	0	0	0	-0.5	0.5
South Atlantic	377	2.3	0	-0.4	-0.4	-0.4	-0.4	0	0	0	-0.3	0.8
East North Central	396	2.3	0	0.1	0.2	-0.2	-0.4	0	0	0	-0.3	1.2
East South Central	151	2.3	0	-0.8	-0.7	-0.5	-0.3	0	0	0	-0.4	0.5
West North Central	165	2.2	0	0.6	0.6	-0.6	-0.4	0.7	0	-0.1	-0.2	1.8
West South Central	370	2.3	0	-0.2	-0.2	-0.6	-0.4	0	0	-0.1	-0.2	1.1
Mountain	157	2.1	0	-0.2	-0.2	-0.3	-0.1	0.2	0	0	-0.1	1.2
Pacific	380	2.3	-0.1	0.7	0.6	-0.2	0.9	0	0	0	-0.2	2.4
Puerto Rico	51	2.2	0	0.3	0.2	-0.8	0.2	0	0	0	0	1.7
Rural by Region:												
New England	23	1.9	-0.1	-0.1	-0.2	2.3	-0.4	0	0	-3.5	-0.1	-2.1
Middle Atlantic	69	1.6	-0.1	-0.2	-0.3	1.8	-0.3	0	0	-1.3	-0.3	-0.5
South Atlantic	164	1.9	-0.1	-0.6	-0.7	2.7	-0.3	0	0.1	-0.6	-0.4	-0.3
East North Central	120	1.7	0	-0.1	-0.1	1.5	-0.2	0	0.1	-1.7	-0.2	-0.9
East South Central	170	2.2	0	-0.4	-0.4	2.9	-0.4	0	0.1	-0.1	-0.4	-0.1
West North Central	98	1.2	0	-0.2	-0.2	1.2	-0.2	0.2	0.1	-1.2	-0.2	-0.7
West South Central	181	2	0	0	0	2.2	-0.3	0	0.2	-0.2	-0.5	-0.5
Mountain	65	1.2	0	0	0	0.5	-0.1	0.8	0	0	-0.1	0.6
Pacific	29	1.3	-0.1	-0.1	-0.2	1	-0.2	0	0	-0.1	-0.1	0

	No. of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment[2] (2)	Proposed FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	Proposed FY 2013 Wage Data with Application of Wage Budget Neutrality[4] (4)	Proposed FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	Proposed FY 2013 MGCRB Reclassifications[6] (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Proposed Application of the Frontier Wage Index[8] (8)	Proposed FY 2013 Out-Migration Adjustment[9] (9)	Expiration of MDH Status (10)	Proposed Hospital Readmissions Reduction Program (11)	All Proposed FY 2013 Changes[12] (12)
Puerto Rico	1	2.2	0.7	0.8	1.4	-0.9	-0.4	0	0	0	0	3.7
By Payment Classification:												
Urban hospitals	2,500	2.3	0	0	0	-0.2	0	0.1	0	0	-0.3	1
Large urban areas	1,375	2.3	0	0.2	0.2	-0.3	0	0	0	0	-0.3	1.1
Other urban areas	1,125	2.3	0	-0.2	-0.1	0	0.1	0.1	0	0	-0.2	1
Rural areas	905	1.8	0	-0.2	-0.2	1.7	-0.3	0	0.1	-1	-0.3	-0.5
Teaching Status:												
Nonteaching	2,376	2.2	0	-0.1	-0.1	0.3	0.1	0	0	-0.3	-0.3	0.7
Fewer than 100 residents	789	2.3	0	0.1	0.1	-0.1	-0.1	0.1	0	0	-0.3	1.1
100 or more residents	240	2.3	0	0.1	0.1	-0.2	0	0	0	0	-0.3	0.8
Urban DSH:												
Non-DSH	758	2.3	0	0.2	0.2	-0.2	0	0	0	-0.3	-0.3	0.5
100 or more beds	1,523	2.3	0	0	0	-0.2	0	0.1	0	0	-0.3	1.1
Less than 100 beds	327	2.3	0	0	0.1	-0.1	0.2	0.1	0	-0.4	-0.2	1.2
Rural DSH:												
SCH	269	1.1	-0.1	0	-0.2	0.5	-0.1	0	0	0	-0.3	-0.8
RRC	210	1.9	0	-0.1	-0.1	2.6	-0.3	0	0	-0.5	-0.3	0.6
100 or more beds	32	2.3	-0.1	-0.4	-0.4	1.3	-0.4	0	0.2	-0.8	-0.5	-0.3
Less than 100 beds	286	2.3	0	-0.6	-0.6	1	-0.3	0.1	0.4	-2.2	-0.4	-2.6
Urban teaching and DSH:												
Both teaching and DSH	815	2.3	0	0	0.1	-0.3	-0.1	0.1	0	0	-0.3	1

	No. of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment[2] (2)	Proposed FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	Proposed FY 2013 Wage Data with Application of Wage Budget Neutrality[4] (4)	Proposed FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	Proposed FY 2013 MGCRB Reclassifications[6] (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Proposed Application of the Frontier Wage Index[8] (8)	Proposed FY 2013 Out-Migration Adjustment[9] (9)	Expiration of MDH Status (10)	Proposed Hospital Readmissions Reduction Program (11)	All Proposed FY 2013 Changes[12] (12)
Teaching and no DSH	147	2.3	-0.1	0.5	0.4	-0.1	0.2	0	0.1	0	-0.3	0.7
No teaching and DSH	1,035	2.3	0	-0.1	-0.1	0	0.3	0	0	0	-0.3	1.3
No teaching and no DSH	503	2.3	0	0.1	0.1	-0.4	-0.1	0.1	0	0	-0.3	0.9
Special Hospital Types:												
RRC	199	2.3	0	0.1	0.2	3	-0.4	0.1	0	-0.8	-0.3	0.9
SCH	340	1.1	-0.1	-0.2	-0.3	0.3	0	0.1	0.1	0	-0.2	-0.4
Former MDH	195	2.3	0	-0.4	-0.4	0.4	-0.2	0	0.3	-6.1	-0.5	-7
SCH and RRC	101	1.2	-0.1	0.1	0	0.7	-0.1	0.1	0	0	-0.2	0.4
Former MDH and RRC	17	2.3	0.1	0.3	0.4	1.2	-0.4	0	0	-15.2	-0.3	-14.8
Type of Ownership:												
Voluntary	1,970	2.2	0	0.1	0.1	0	0	0.1	0	-0.1	-0.3	0.8
Proprietary	866	2.3	0.1	-0.3	-0.2	0.1	-0.1	0	0	-0.1	-0.3	1.1
Government	560	2.2	0	-0.2	-0.2	-0.1	-0.1	0	0	-0.1	-0.3	0.9
Medicare Utilization as a Percent of Inpatient Days:												
0-25	377	2.2	0	0.1	0.1	-0.3	0	0	0	0	-0.2	1.8
25-50	1,834	2.3	0	0	0	-0.2	0	0.1	0	0	-0.3	1
50-65	968	2.2	0	0	0.1	0.7	0.1	0	0	-0.4	-0.3	0.4
Over 65	168	2.1	-0.1	-0.3	-0.3	0.6	0.1	0.1	0.1	-1.2	-0.5	-0.5

	No. of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment [2] (2)	Proposed FY 2013 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	Proposed FY 2013 Wage Data with Application of Wage Budget Neutrality[4] (4)	Proposed FY 2013 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	Proposed FY 2013 MGCRB Reclassifications[6] (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Proposed Application of the Frontier Wage Index[8] (8)	Proposed FY 2013 Out-Migration Adjustment[9] (9)	Expiration of MDH Status (10)	Proposed Hospital Readmissions Reduction Program (11)	All Proposed FY 2013 Changes[12] (12)
Proposed FY 2013 Reclassifications by the Medicare Geographic Classification Review Board:												
All Reclassified Hospitals	755	2.2	0	0.2	0.2	2.2	0.3	0	0	-0.1	-0.3	0.9
Non-Reclassified Hospitals	2,650	2.3	0	-0.1	0	-0.7	-0.1	0.1	0	-0.1	-0.3	0.9
Urban Hospitals Reclassified	420	2.3	0	0.3	0.4	1.9	0.5	0	0	0	-0.4	1.1
Urban Nonreclassified Hospitals, FY 2013:	2,025	2.3	0	-0.1	0	-0.7	-0.1	0.1	0	0	-0.3	1
All Rural Hospitals Reclassified FY 2013:	335	1.8	0	-0.2	-0.2	3.1	-0.3	0	0	-0.5	-0.3	0.2
Rural Nonreclassified Hospitals FY 2013:	524	1.7	-0.1	-0.3	-0.4	-0.2	-0.3	0.1	0.3	-1.3	-0.3	-1.8
All Section 401 Reclassified Hospitals:	46	1.8	0	0.5	0.5	-0.6	-0.1	0	0	-2.6	-0.2	-1.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	62	2	-0.1	-0.2	-0.2	2.9	-0.4	0	0	-3.1	-0.3	-2.4
Specialty Hospitals												
Cardiac specialty Hospitals	18	2.3	0.1	-0.2	-0.1	-0.8	0	0.6	0	0	-0.1	2.7

[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 2011, 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 2.1 percent adjustment to the national standardized amount (the 3.0 percent proposed market basket update reduced by the 0.8 percentage point for the proposed multifactor productivity adjustment and the 0.1 percentage point reduction under the Affordable Care Act) and the 0.2 percent documentation and coding adjustment to the national standardized amount (-2.7 documentation and coding adjustment and 2.9 percent return to the rate to account for the one-time documentation and coding recoupment from FY 2012). In addition, it displays the payment impact of the proposed hospital rate update of 2.1 percent and the proposed documentation and coding adjustment of -1.3 percent to the hospital-specific rate.

[3] This column displays the payment impact of the proposed changes to the Version 30.0 GROUPER and the recalibration of the MS-DRG weights based on FY 2011 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the proposed recalibration budget neutrality factor of 0.998546, in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the proposed update to wage index data using FY 2009 cost report data. This column displays the payment impact of the application of proposed the wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The proposed wage budget neutrality factor is 1.000563.

[5.] This column displays the combined payment impact of the proposed changes in Columns 3 through 4 and the proposed 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 proposed cumulative wage and recalibration budget neutrality factor of 0.999108 is the product of the wage budget neutrality factor and the recalibration budget neutrality factor.

[6] Shown here are the proposed effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2013 payment impact of going from no reclassifications to the proposed reclassifications scheduled to be in effect for FY 2013. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the proposed geographic budget neutrality factor of 0.991436.

[7.] This column displays the proposed effects of the rural floor and imputed floor, including the Affordable Care Act requirement that the floor budget neutrality is at a 100 percent national level adjustment. This column does not reflect the alternative temporary methodology proposed beginning in FY 2013; we note that the impact of that proposal is discussed separately and would have a negligible impact on budget neutrality. The proposed rural floor and imputed floor budget neutrality factor is 0.992243.

[8] This column shows the proposed 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.

[9.] This column displays the proposed 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.

[10.] This column displays the impact of the expiration of MDH status, under section 3124 of the Affordable Care Act, a non-budget neutral payment provision.

[11.] This column displays the impact of the proposed implementation of the Hospital Readmissions Reduction Program, section 3025 of the Affordable Care Act, a non-budget neutral provision that adjusts a hospital's payment for excess readmissions.

[12.] This column shows the proposed changes in payments from FY 2012 to FY 2013. It reflects the impact of the proposed FY 2013 hospital update, the proposed adjustments due to the documentation and coding. It also reflects proposed changes in hospitals' reclassification status in FY 2013 compared to FY 2012. It incorporates all of the changes displayed in Columns 2, 5, 6, 7, 8, 9, 10 and 11 (the changes displayed in Columns 3 and 4 are included in Column 5). The sum of these impacts may be different from the percentage changes shown here due to rounding and interactive effects.

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a. Effects of the Proposed Hospital Update and Proposed 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 3.0 percent proposed market basket update, the reduction of 0.8 percentage point for the proposed 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 2013 documentation and coding adjustment of 0.2 percent on the national standardized amount, which includes the −2.7 percent prospective adjustment for documentation and coding and a 2.9 percent adjustment to restore the one-time recoupment adjustment made to the national standardized amount for FY 2012. As a result, we a proposing a 2.3 percent update to the national standardized amount.

This column also includes the proposed 0.8 percent update to the hospital-specific rates, which includes the proposed 2.1 percent for the proposed hospital update and proposed −1.3 documentation and coding adjustment.

Overall, hospitals will experience a 2.2 percent increase in payments primarily due to the effects of the proposed hospital update and proposed documentation and coding adjustment on the national standardized amount. Hospitals that are paid under the hospital-specific rate, namely SCHs, will see a 0.8 percent increase in payments; therefore, hospital categories with SCHs paid under the hospital-specific rate will see increases in payments less than 2.2 percent.

b. Effects of the Proposed Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 3)

Column 3 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 proposed FY 2013 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2013, the MS–DRGs are calculated using the FY 2011 MedPAR data grouped to the Version 30.0 (FY 2013) 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 3 indicates that changes due to the proposed MS–DRGs and relative weights will result in a 0.0 percent change in payments with the application of the proposed recalibration budget neutrality factor of 0.998546 on to the standardized amount. Due to the proposed changes to the MS–DRG GROUPER in this proposed rule, there were some shifts in payments due to changes in the relative weights with rural hospitals experiencing a 0.1 percent decrease in payments.

c. Effects of the Proposed Wage Index Changes (Column 4)

Column 4 shows the impact of proposed 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 wage index for acute care hospitals for FY 2013 is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2008 and before October 1, 2009. The estimated impact of the updated wage data and labor share on hospital payments is isolated in Column 4 by holding the other payment parameters constant in this simulation. That is, Column 4 shows the percentage change in payments when going from a model using the FY 2012 wage index, based on FY 2008 wage data, the current labor-related share and having a 100-percent occupational mix adjustment applied, to a model using the FY 2013 pre-reclassification wage index with the labor-related share, also having a 100-percent occupational mix adjustment applied, based on FY 2009 wage data (while holding other payment parameters such as use of the Version 30.0 MS–DRG GROUPER constant). The occupational mix adjustment is based on the 2010 occupational mix survey.

In addition, the column shows the proposed 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 2013, 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 1.000563, and the overall payment change is 0 percent.

Column 4 shows the impacts of updating the wage data using FY 2009 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 4. Among the regions, the largest increase is in the urban New England region, which experiences a 1.0 percent increase. The largest decline from updating the wage data is seen in the rural East South Central region (−0.8 percent decrease).

In looking at the wage data itself, the national average hourly wage increased 3.1 percent compared to FY 2012. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the national 3.1 percent increase in average hourly wage. Of the 3,405 hospitals with wage data for both FYs 2012 and 2013, 1,537, or 45.1 percent, experienced an average hourly wage increase of 3.1 percent or more.

The following chart compares the shifts in wage index values for hospitals for FY 2013 relative to FY 2012. Among urban hospitals, none 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. Among rural hospitals, none 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, 924 rural hospitals will experience increases or decreases of less than 5 percent, while 2,481 urban hospitals will experience increases or decreases of less than 5 percent. No urban hospitals will experience decreases in their wage index values of more than 5 percent and less than 10 percent. No urban hospitals will experience decreases in their wage index values of greater than 10 percent. No rural hospitals will experience a decrease of more than 10 percent. No 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-related 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	0	0
Increase more than 5 percent and less than 10 percent	0	0
Increase or decrease less than 5 percent	2,481	924

Percentage change in area wage index values	Number of hospitals	
	Urban	Rural
Decrease more than 5 percent and less than 10 percent	0	0
Decrease more than 10 percent	0	0

d. Combined Effects of the Proposed MS–DRG and Wage Index Changes (Column 5)

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 1.000563, and a proposed recalibration budget neutrality factor of 0.998546 (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 cumulative wage and recalibration budget neutrality factor. The proposed cumulative wage and recalibration budget neutrality adjustment is 0.999108, or approximately −0.9 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 proposed 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 updated wage data with budget neutrality applied will result in 0.1 percent increase in payments for urban hospitals and 0.3 percent decrease in payments for rural hospitals. Urban Pacific hospitals will experience a 0.6 percent increase in payments due to increases in their wages compared to the national average, while the urban East South Central area and rural South Atlantic will experience a −70.7 decrease in payments because of below average increases in wages.

e. Effects of Proposed MGCRB Reclassifications (Column 6)

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 proposed changes in Column 6 reflect the per case payment impact of moving from this baseline to a simulation incorporating the proposed MGCRB decisions for FY 2013 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 proposing to apply an adjustment of 0.991436 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 the proposed geographic reclassification will increase payments to rural hospitals by an average of 2.1 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 2.9 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 0.7 percent and 0.1 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 proposed reclassifications for FY 2013.

f. Effects of the Proposed Rural and Imputed Floor, Including Application of National Budget Neutrality (Column 7)

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. We apply a uniform budget neutrality adjustment to the wage index. In addition, the imputed floor, which is budget neutral, was extended in FY 2012 for 2 additional years. The current imputed floor only benefits hospitals located in New Jersey. We note that we have proposed an alternative temporary methodology for the imputed floor that will have a negligible impact on budget neutrality. The impact of this proposal is discussed separately. While it is not included in the determination of budget neutrality for this proposed rule, if finalized, we intend to include it in the determination of budget neutrality in the final rule. The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally, and the imputed floor is part of the rural floor budget neutrality factor applied to the wage index nationally. The proposed FY 2013 rural floor budget neutrality factor applied to the wage index is 0.992243, which will reduce wage indexes by −0.77 percent.

Column 7 shows the projected impact of the rural floor and imputed floor with the national rural floor budget neutrality factor applied to the wage index. The column compares the proposed post-reclassification FY 2013 wage index of providers before the rural floor and imputed floor adjustment and the proposed post-reclassification FY 2013 wage index of providers with the rural floor and imputed 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 −0.3 percent decrease in payments as a result of the proposed 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 0.1 percent increase in payments because those providers benefit from the rural floor. Urban hospitals in the New England region can expect a 3.1 percent increase in payments primarily due to the application of the rural floor in Massachusetts and the application of 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 value, including rural floor budget neutrality, of 1.3047. 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. We estimate that Massachusetts hospitals will receive

approximately a 5.5 percent increase in IPPS payments due to the application of rural floor.

Urban Puerto Rico hospitals are expected to experience a 0.2 percent increase in payments as a result of the application of a Puerto Rico rural floor. Urban Puerto Rico hospitals will receive a rural floor as a result of a one IPPS hospital located in rural Puerto Rico setting a rural floor. We are applying a proposed rural floor budget neutrality factor to the Puerto Rico-specific wage index of 0.987885 or −1.2 percent. The Puerto Rico-specific wage index adjusts the Puerto Rico-specific standardized amount, which represents 25 percent of payments to Puerto Rico hospitals.

There are 29 hospitals in New Jersey that benefit from the extension of the imputed floor and will receive the imputed floor wage index value, including rural floor budget neutrality of 1.1010, which we estimate will increase their payments by approximately $18 million. Urban Middle Atlantic hospitals will experience a −0.2 percent decrease in payments which reflects the increase in payments for New Jersey hospitals receiving the imputed floor and a decrease for all other urban hospitals in the in the Middle Atlantic region.

We note that the impact of the proposal under section III.G.2.b. of the preamble of this proposed rule to establish an alternative temporary methodology for the imputed floor is not included in the table. Based on FY 2012 wage data, we estimate that four Rhode Island hospitals will benefit from this alternative temporary methodology for the imputed floor and receive an additional $4.8 million in payments.

In response to a public comment addressed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593), we are providing the proposed payment impact of the rural floor and imputed floor with budget neutrality at the State level. Column 1 of the table below displays the number of IPPS hospitals located in each State. Column 2 displays the number of hospitals in each State that would receive the rural floor or imputed floor wage index for FY 2013. Column 3 displays the percentage of total payments each State would receive or contribute to fund the proposed rural floor and imputed floor with national budget neutrality. The column compares the proposed post-reclassification FY 2013 wage index of providers before the rural floor and imputed floor adjustment and the proposed post-reclassification FY 2013 wage index of providers with the rural floor and imputed floor adjustment. Column 4 displays the proposed estimated payment amount that each State would gain or lose due to the proposed application of the rural floor and imputed floor with national budget neutrality. Again, we note that the proposal under section III.G.2.b. to establish an alternative temporary methodology for the imputed floor that would benefit four hospitals located in Rhode Island is not included in this table.

FY 2013 IPPS Proposed Estimated Payments Due to Rural Floor and Imputed Floor With National Budget Neutrality

State	Number of hospitals (1)	Proposed number of hospitals receiving rural floor or imputed floor (2)	Proposed percent change in payments due to application of rural floor and imputed floor with budget neutrality (3)	Proposed difference (in millions) (4)
Alabama	95	4	−0.4	−$7.1
Alaska	6	4	1.6	2.1
Arizona	56	8	−0.4	−6.1
Arkansas	45	0	−0.4	−4.5
California	308	178	1.3	113.9
Colorado	46	7	0.7	6.3
Connecticut	32	9	−0	−0.3
Delaware	5	0	−0.4	−1.8
Florida	166	8	−0.3	−23.3
Georgia	108	0	−0.4	−11.0
Hawaii	14	0	−0.3	−0.8
Idaho	14	0	−0.3	−0.7
Illinois	129	1	−0.4	−22.8
Indiana	89	0	−0.4	−10.0
Iowa	34	0	−0.4	−3.8
Kansas	55	0	−0.3	−2.6
Kentucky	65	0	−0.4	−7.4
Louisiana	97	6	−0.4	−6.2
Maine	20	0	−0.4	−2.1
Massachusetts	61	60	5.6	182.7
Michigan	96	0	−0.4	−18.6
Minnesota	51	0	−0.4	−7.3
Mississippi	64	0	−0.4	−4.7
Missouri	76	2	−0.4	−8.5
Montana	12	1	−0.2	−0.5
Nebraska	23	0	−0.3	−1.8
Nevada	24	0	−0.4	−2.9
New Hampshire	13	9	0.8	3.6
New Jersey	65	29	0.5	17.7
New Mexico	27	0	−0.3	−1.2
New York	168	0	−0.5	−41.0
North Carolina	87	0	−0.4	−13.9
North Dakota	6	0	−0.3	−0.6
Ohio	137	11	−0.3	−13.1
Oklahoma	85	0	−0.4	−4.8
Oregon	33	0	−0.4	−3.0

FY 2013 IPPS PROPOSED ESTIMATED PAYMENTS DUE TO RURAL FLOOR AND IMPUTED FLOOR WITH NATIONAL BUDGET NEUTRALITY—Continued

State	Number of hospitals (1)	Proposed number of hospitals receiving rural floor or imputed floor (2)	Proposed percent change in payments due to application of rural floor and imputed floor with budget neutrality (3)	Proposed difference (in millions) (4)
Pennsylvania	154	14	−0.3	−13.8
Puerto Rico	52	13	0.2	0.2
Rhode Island	11	0	−0.5	−1.9
South Carolina	56	7	−0.3	−5.0
South Dakota	18	0	−0.2	−0.6
Tennessee	97	10	−0.3	−6.5
Texas	324	2	−0.4	−28.3
Utah	32	0	−0.3	−1.2
Vermont	6	0	−0.3	−0.6
Virginia	79	1	−0.4	−9.5
Washington	48	6	−0.4	−5.8
Washington, DC	7	0	−0.4	−1.9
West Virginia	33	2	−0.3	−2.6
Wisconsin	65	5	−0.3	−4.6
Wyoming	11	0	−0.1	−0.1

g. Effects of the Proposed Application of the Frontier State Wage Index (Column 8)

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, four States (Montana, North Dakota, South Dakota, and Wyoming) are considered frontier States and 51 hospitals located in those States will receive a frontier wage index of 1.0. Although Nevada is also, by definition, a frontier State and was assigned a frontier floor value of 1.0000 for FY 2012, its FY 2013 proposed rural floor value of 1.0293 is greater and, therefore, is the State's proposed minimum wage index for FY 2013. As a result, hospitals located in Nevada will not experience a change in payment as a result of this provision. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $53 million.

Urban hospitals located in the West North Central region and urban hospitals located in the Mountain region will receive an increase in payments by 0.7 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 0.8 percent and 0.2 percent, respectively.

h. Effects of the Proposed Wage Index Adjustment for Out-Migration (Column 9)

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 proposed outmigration adjustment. Rural DSH providers with less than 100 beds will experience a 0.4 percent increase in payments. There are 213 providers that will receive the out-migration adjustment in FY 2013. This out-migration wage adjustment is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase to be approximately $18 million.

i. Effects of the Expiration of MDH Special Payment Status (Column 10)

Column 10 shows our estimate of the changes in payments due to the expiration of MDH status, a nonbudget neutral payment provision, under section 3124 of the Affordable Care Act. Hospitals that qualified to be MDHs receive the higher of payments made under the Federal standardized amount or the payments made under the Federal standardized amount plus 75 percent of the difference between the Federal standardized amount and the hospital specific rate (a hospital-specific cost-based rate). Because this provision was not budget neutral, the expiration of this payment provision results in a −0.1 percent decrease in payments overall. There are currenty 212 MDHs, of which 104 were estimated to be paid under the blended payment of the federal standardized amount and hospital specific rate. Because those 104 MDHs will no longer receive the blended payment and will be paid only under the Federal standardized amount in FY 2013, it is estimated that those hospitals will experience an overall decrease in payments of approximately $114 million.

MDHs were generally rural hospitals, so the expiration of th MHD program will result in an overall decrease in payments to rural hospitals of 0.9 percent. Rural New England hospitals can expect a decrease in payments of 3.5 percent because 8 out of the 23 rural New England hospitals are MDHs that will lose their special payment status under the expiration at the end of FY 2012. MDHs can expect a decrease in payments of −6.1 percent.

j. Proposed Effects of the Hospital Readmissions Reduction Program (Column 11)

Column 11 shows our estimates of proposed effects of the proposed policies for implementation of the Hospital Readmissions Reduction Program, which was established under section 3025 of the Affordable Care Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payments to account for excess readmissions, which is based on a hospital's risk-adjusted readmission rate during a 3-year period for three applicable conditions: Acute Myocardial Infarction, Heart Failure, and Pneumonia. This provision is not budget neutral. A hospital's readmission adjustment is the higher of a ratio of the hospital's aggregate payments for excess readmissions to their aggregate payments for all discharges, or a floor, which has been defined in statute as 0.99 (or a 1-

percent reduction) for FY 2013. A hospital's base operating DRG payment (that is, wage-adjusted DRG payment amount, as proposed in section IV.A. of the preamble of this proposed rule) is the portion of the IPPS payment subject to the readmissions payment adjustment (DSH, IME, outliers and low-volume add-on payments are not subject to the readmissions adjustment). In this proposed rule, we estimate that 2,210 hospitals will have their base operating DRG payments reduced by the readmissions adjustment, resulting in a 0.3 percent decrease in payments to hospitals overall.

Urban hospitals in the Middle Atlantic, rural hospitals in the West South Central region, rural DSH hospitals with more than 100 beds, and hospitals with Medicare utilization of over 65 percent are estimated to experience the highest decreases of 0.5 percent among the different hospital categories. Urban and rural hospitals in the Mountain Region and Rural Pacific hospitals are expected to experience the smallest decreases of 0.1 percent in payments. Puerto Rico hospitals are estimated to show a 0 percent change in payments because they are exempt from the provision.

k. Effects of All FY 2013 Proposed Changes (Column 12)

Column 12 shows our estimate of the changes in payments per discharge from FY 2012 and FY 2013, resulting from all proposed changes reflected in this proposed rule for FY 2013. It includes combined effects of the previous columns in the table.

The average increase in payments under the IPPS for all hospitals is approximately 0.9 percent for FY 2013 relative to FY 2012. As discussed in section II.D. of the preamble of this proposed rule, this column includes the proposed FY 2013 documentation and coding adjustment of 0.2 percent on the national standardized amount (the proposed −2.7 documentation and coding adjustment and 2.9 percent adjustment to restore the one-time recoupment adjustment made to national standardized amount) and the proposed −1.3 percent documentation and coding adjustment on the hospital-specific rates. In addition, this column includes the proposed annual hospital update of 2.1 percent to the national standardized amount. This proposed annual hospital update includes the 3.0 percent proposed market basket update, the proposed reduction of 0.8 percentage point for the proposed 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 documentation and coding adjustment, results in a 2.2 percent increase in payments in FY 2013 relative to FY 2012. In addition, Column 8 describes an estimated 0.1 percent increase in payments due to the proposed frontier State wage index. Column 10 describes the estimated 0.1 percent decrease in payments due to the expiration of the MDH status under section 3124 of the Affordable Care Act. Column 11 shows the estimated 0.3 percent decrease in payments due to the establishment of the Hospital Readmissions Reduction Program, which reduces a hospital's base operating DRG payments by a readmission adjustment factor based on a hospital's performance on readmissions for specified conditions. In addition, although not shown in the impacts table, payments are estimated to decrease by 0.1 due to the expiration of section 508 reclassifications that had been extended for 6 months of FY 2012 under section 302 of the Temporary Payroll Tax Cut Continuation Act of 2011 (Pub. L. 112–78), as amended by section 3001 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96). Section 508 was not a budget-neutral provision. The impact of moving from our proposed estimate of FY 2012 outlier payments, 6.0 percent, to the estimate of FY 2013 outlier payments, 5.1 percent, results in a decrease of 0.9 percent in FY 2013 payments relative to FY 2012. 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 12 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 2013 is estimated to increase by 0.9 percent. The payment increase among the hospital categories are largely attributed to the proposed updates to the rate including the hospital update. Hospitals in urban areas will experience an estimated 1.1 percent increase in payments per discharge in FY 2013 compared to FY 2012. Hospital payments per discharge in rural areas are estimated to increase by 0.5 percent in FY 2013 as compared to FY 2012 due to the expiration of MDH status.

Among urban census divisions, the Urban New England hospitals will experience a −0.4 percent change in payments because many of the urban providers in this region had benefited from section 508 reclassifications in FY 2012 that will expire for FY 2013. Urban hospitals in the Pacific will see the largest payment increases (2.4 percent) because the hospitals are benefitting from the rural floors in their States.

Among the rural regions, the providers in the New England Region will experience the decreases in payments of −2.1 percent, due to the expiration of MDH status. Rural hospitals in the Pacific Region are estimated to experience a 0.0 percent change because the rural providers in this region benefit from higher than average wage data and MGCRB reclassification, which offsets decreases due to the rural floor and the expiration of MDH status.

Among special categories of hospitals, former MDHs will receive an estimated payment decrease of −7 percent due to the expiration of the MDH status. SCHs are paid the higher of their Federal rate and the hospital-specific rate. Overall, SCHs are estimated to experience a decrease in payments by 0.4 percent due to decreases in their wage data and the implementation of the Hospital Readmissions Reduction Program.

Proposed rural hospitals reclassified for FY 2013 are anticipated to receive a 0.5 percent payment increase. Rural hospitals that are not reclassifying are estimated to receive a payment decrease of −1.8 percent due to lower wage data, the proposed application of rural floor budget neutrality and expiration of MDH status. Urban reclassified hospitals will experience the average payment increase at 1.1 percent due to the benefits under MGCRB reclassification and the proposed rural floor. Urban nonreclassified hospitals will experience a payment increase of 1.0 percent.

Cardiac hospitals are expected to experience a payment increase 2.7 percent in FY 2013 relative to FY 2012 primarily due to benefits to the changes in the relative weights.

3. Impact Analysis of Table II

Table II presents the projected impact of the proposed changes for FY 2013 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the proposed estimated average payments per discharge for FY 2012 with the proposed average payments per discharge for FY 2013, as calculated under our models. Thus, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the 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 12 of Table I.

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2013 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM (PAYMENTS PER DISCHARGE)

	Number of hospitals (1)	Proposed average FY 2012 payment per discharge (2)	Proposed average FY 2013 payment per discharge (3)	All proposed FY 2013 changes (4)
All hospitals	3,405	10,447	10,539	0.9
By Geographic Location:				
Urban hospitals	2,485	10,859	10,971	1
Large urban areas (populations over 1 million)	1,365	11,469	11,602	1.2

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2013 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM (PAYMENTS PER DISCHARGE)—Continued

	Number of hospitals (1)	Proposed average FY 2012 payment per discharge (2)	Proposed average FY 2013 payment per discharge (3)	All proposed FY 2013 changes (4)
Other urban areas (populations of 1 million or fewer)	1,120	10,110	10,198	0.9
Rural hospitals	920	7,790	7,752	−0.5
Bed Size (Urban):				
0–99 beds	627	8,277	8,361	1
100–199 beds	773	9,126	9,227	1.1
200–299 beds	448	9,882	9,996	1.2
300–499 beds	432	11,091	11,219	1.2
500 or more beds	205	13,475	13,581	0.8
Bed Size (Rural):				
0–49 beds	317	6,222	6,106	−1.9
50–99 beds	346	7,270	7,093	−2.4
100–149 beds	152	7,529	7,551	0.3
150–199 beds	58	8,487	8,537	0.6
200 or more beds	47	9,615	9,725	1.1
Urban by Region:				
New England	120	11,860	11,818	−0.4
Middle Atlantic	318	11,946	12,009	0.5
South Atlantic	377	9,984	10,060	0.8
East North Central	396	10,147	10,266	1.2
East South Central	151	9,601	9,651	0.5
West North Central	165	10,544	10,736	1.8
West South Central	370	10,216	10,333	1.1
Mountain	157	11,013	11,145	1.2
Pacific	380	13,609	13,942	2.4
Puerto Rico	51	5,369	5,458	1.7
Rural by Region:				
New England	23	10,441	10,219	−2.1
Middle Atlantic	69	8,291	8,246	−0.5
South Atlantic	164	7,526	7,503	−0.3
East North Central	120	8,014	7,942	−0.9
East South Central	170	7,167	7,161	−0.1
West North Central	98	8,248	8,193	−0.7
West South Central	181	6,868	6,830	−0.5
Mountain	65	8,603	8,658	0.6
Pacific	29	10,599	10,594	0
Puerto Rico		2,104	2,182	3.7
By Payment Classification:				
Urban hospitals	2,500	10,838	10,952	1
Large urban areas (populations over 1 million)	1,375	11,449	11,577	1.1
Other urban areas (populations of 1 million or fewer)	1,125	10,082	10,178	1
Rural areas	905	7,991	7,947	−0.5
Teaching Status:				
Non-teaching	2,376	8,721	8,784	0.7
Fewer than 100 Residents	789	10,259	10,374	1.1
100 or more Residents	240	15,474	15,600	0.8
Urban DSH:				
Non-DSH	758	9,075	9,121	0.5
100 or more beds	1,523	11,370	11,494	1.1
Less than 100 beds	327	7,582	7,671	1.2
Rural DSH:				
SCH	269	7,827	7,764	−0.8
RRC	210	8,855	8,912	0.6
100 or more beds	32	6,913	6,889	−0.3
Less than 100 beds	286	6,158	5,995	−2.6
Urban teaching and DSH:				
Both teaching and DSH	815	12,443	12,570	1
Teaching and no DSH	147	10,014	10,087	0.7
No teaching and DSH	1,035	9,259	9,375	1.3
No teaching and no DSH	503	8,643	8,717	0.9
Rural Hospital Types:				
RRC	199	8,848	8,924	0.9
SCH	340	8,281	8,251	−0.4
Former MDH	195	6,423	5,975	−7
SCH and RRC	101	9,678	9,717	0.4
Former MDH and RRC	17	8,678	7,396	−14.8
Type of Ownership:				
Voluntary	1,970	10,592	10,680	0.8

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2013 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM (PAYMENTS PER DISCHARGE)—Continued

	Number of hospitals (1)	Proposed average FY 2012 payment per discharge (2)	Proposed average FY 2013 payment per discharge (3)	All proposed FY 2013 changes (4)
Proprietary	866	9,262	9,365	1.1
Government	560	11,108	11,210	0.9
Medicare Utilization as a Percent of Inpatient Days:				
0–25	377	14,766	15,027	1.8
25–50	1,834	10,949	11,056	1
50–65	968	8,543	8,573	0.4
Over 65	168	7,926	7,889	−0.5
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
Proposed FY 2013 Reclassifications:				
All Reclassified Hospitals FY 2013	755	10,018	10,106	0.9
All Non-Reclassified Hospitals FY 2013	2,650	10,585	10,678	0.9
Urban Reclassified Hospitals FY 2013:	420	10,811	10,931	1.1
Urban Non-reclassified Hospitals FY 2013	2,025	10,882	10,996	1
Rural Reclassified Hospitals FY 2013	335	8,349	8,370	0.2
Rural Nonreclassified Hospitals FY 2013:	524	6,950	6,825	−1.8
All Section 401 Reclassified Hospitals:	46	9,905	9,760	−1.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	62	7,383	7,202	−2.4
Specialty Hospitals				
Cardiac Hospitals	18	10,898	11,194	2.7

H. Effects of Other 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.

1. 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. 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 are proposing to add two additional HACs for FY 2013: Surgical Site Infection (SSI) Following Cardiac Implantable Electronic Device (CIED) Procedures and Iatrogenic Pneumothorax with Venous Catheterization. Similar to the current HACs, only a very small number of discharges would have only one secondary diagnosis that would lead to a higher payment. Therefore, there will likely be very few discharges where the MS–DRG is reassigned for these proposed conditions and this would result in a minimal payment impact.

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 2013	$24
FY 2014	26
FY 2015	28
FY 2016	30
FY 2017	33

2. 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 five applications for add-on payments for new medical services and technologies for FY 2013, as well as the status of the new technology that was approved to receive new technology add-on payments in FY 2012. 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 five applications we received for consideration for new technology add-on payments for FY 2013 will meet the specified criteria. Consequently, it is premature to estimate the potential payment impact of these five applications for any potential new technology add-on payments for FY 2013. We note that if any of the five applications are found to be eligible for new technology add-on payments for FY 2013 in the FY 2013 IPPS/LTCH PPS final rule, we would discuss the estimated payment impact for FY 2013 in that final rule. In the preamble to this proposed rule, we are proposing not to

continue making new technology add-on payments for the AutoLITT™ in FY 2013. Therefore, we are not providing an impact analysis for the AutoLITT™ in this proposed rule.

3. Effects of Proposed Policy Changes Relating to SCHs

In section IV.B.2. of the preamble of this proposed rule, we discuss our proposal to clarify the regulations related to the termination of a hospital's status as an SCH. We are proposing to add a provision to the regulations to clarify that if CMS determines that the hospital was incorrectly classified as an SCH, SCH status would be cancelled retroactively, consistent with the provisions at 42 CFR 405.1885. We also are proposing that if a hospital that was incorrectly designated as an SCH notifies CMS of that error, the SCH classification status will be terminated effective with the date of the notice to CMS. We believe it would be difficult to quantify the payment impact of these proposed clarifications because we cannot estimate the number of SCHs that would be affected by these proposals. However, we believe any impact would be insignificant because the proposal only affects hospitals that were incorrectly classified as SCHs. We are soliciting public comments on these issues.

In section IV.B.3. of the preamble of this proposed rule, we discuss our proposal to add a provision to the regulations to allow hospitals that are currently classified as MDHs to apply for classification as SCHs upon the expiration of the MDH program on September 30, 2012. We are proposing that, for any MDH that applies for SCH classification at least 30 days prior to the expiration of the MDH program and requests that SCH classification status be effective with the expiration of the MDH program, and the hospital is approved for SCH status, the effective for SCH status would be the day following the expiration of the MDH program. We believe it would be difficult to quantify the payment impact of this proposal because we cannot estimate the number of MDHs that would be applying for SCH status.

4. Effects of the Proposed Payment Adjustment for Low-Volume Hospitals for FY 2013

In section IV.D. of the preamble to this proposed rule, we discuss the provisions of the Affordable Care Act that expanded the definition of low-volume hospital and modified the methodology for determining the payment adjustment for hospitals meeting that definition for FYs 2011 and 2012. In accordance with section 1886(d)(12) of the Act, beginning with FY 2013, the low-volume hospital definition and payment adjustment methodology will revert back to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act. Therefore, effective for FY 2013 and subsequent years, in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospitals and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year.

Based on FY 2011 claims data (December 2011 update of the MedPAR file), we estimate that approximately 600 hospitals in our database qualified as a low-volume hospital for FY 2012, but will no longer meet the mileage and discharges criteria to qualify as a low-volume hospital under section 1886(d)(12) of the Act for FY 2013. Because we estimate that these hospitals will no longer qualify for the low-volume hospital adjustment in FY 2013 (due to the statutory change in the qualifying criteria), we project that these hospitals will experience a decrease in payments of approximately $300 million in FY 2013 as compared to the payments that they would have otherwise received in FY 2013 in absence of the statutory change in the low-volume hospital qualifying criteria.

5. Effects of Proposed Policy Changes Relating to Payment Adjustments for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medical Education (IME)

In section IV.F. of the preamble of this proposed rule, we discuss our proposal to include ancillary labor and delivery beds in the available bed count used to determine the DSH payment adjustment and the IME payment adjustment. The impact of the proposed changes to the DSH payment adjustment should be negligible, as the DSH payment adjustment is determined mainly by the demographic composition of an individual hospital's patient population, and not its overall bed count. However, we note that some hospitals' bed counts do not meet the minimum threshold required to qualify for the DSH payment adjustment. For these hospitals that do not meet the minimum bed count required to qualify for the DSH payment adjustment, an increase in the number of available beds could now allow them to qualify for the DSH payment adjustment. For purposes of the IME payment adjustment, an increase in a hospital's number of available beds would result in a decrease in the resident-to-bed ratio. The inclusion of bed days associated with labor and delivery patients in the available bed count for IME would increase the available beds, decrease the resident-to-bed ratio, and, consequently, decrease IME payments to teaching hospitals, depending on the number of these hospitals' labor and delivery beds. Based on labor and delivery patient days currently reported in the Medicare hospital cost report database, we estimate that the inclusion of labor and delivery beds in the available bed day count would decrease IME payments by $170 million in FY 2013.

6. Effects of the Proposed Policy Changes Relating to GME and IME

a. Effects of Clarification and Proposal Regarding Timely Filing Requirements Under Fee-for-Service Medicare

In section IV.E.2. of the preamble of this proposed rule, we discuss a clarification related to the time limits for filing claims for Medicare Advantage patients under fee-for-service Medicare for IME, direct GME, and nursing and allied health education payment purposes. This clarification is intended to make clear to hospitals that they must follow the regulations governing the time limits for filing claims at § 424.44 in order to receive IME, and/or direct GME, and/or nursing or allied health education program payments associated with Medicare Advantage enrollees. Because we are not proposing to make any policy changes (but rather clarifying the timely filing requirements), there is no financial impact for this clarification.

In section IV.E.2. of the preamble of this proposed rule, we also are proposing to adopt a policy under which hospitals that are required to submit no pay bills for the purpose of calculating the DPP that is used in determining the DSH payment adjustment must do so within the time limits for filing claims at § 424.44. We do not anticipate that this proposal would have any impact, as providers are already submitting no pay bills for purposes of the DPP.

b. Effects of Proposed Policy Changes Relating to New Teaching Hospitals: New Program Growth From 3 Years to 5 Years

In section IV.I.2. of the preamble of this proposed rule, we discuss our proposal to extend the period a new teaching hospital has to establish its caps for direct GME and IME payment purposes from 3 years to 5 years. We are proposing to revise the regulations to state that if a new teaching hospital participates in training residents in a new program for the first time on or after October 1, 2012, that new teaching hospital's caps will be based on the product of the highest number of FTE residents training in any program year during the fifth academic year of the first program's existence for all new residency training programs and the number of years in which residents are expected to complete the program based on the minimum accredited length for the type of program. The cap would be applied beginning with the sixth academic year of the first new program. We believe this expansion of the cap-building period from 3 years to 5 years would make our policies for the establishment of a hospital's cap more compatible with current accreditation requirements that hospitals must meet to establish new residency training programs. We estimate that this proposal would cost approximately $175 million over the next 10 years. However, because this proposal to change the cap growth period from 3 years to 5 years would only affect new programs begun on or after October 1, 2012, we estimate that no cost would be incurred until FY 2016. This estimate assumes that there could be 20 new teaching hospitals each year.

c. Effects of Proposed Changes Relating to 5-Year Period Following Implementation of Reductions and Increases to Hospitals' FTE Resident Caps for GME Payment Purposes Under Section 5503 of the Affordable Care Act

In section IV.I.3. of the preamble of this proposed rule, we discuss our proposals related to the 5-year period following implementation of reductions and increases to hospitals' FTE resident caps for GME payment purposes under section 5503 of the Affordable Care Act. Section 5503 of the Affordable Care Act amended the Medicare statute by adding a new section 1886(h)(8) of

the Act, which provides for reductions in the statutory FTE resident caps for direct GME and IME under Medicare for certain hospitals, and authorizes a ''redistribution'' to certain hospitals of the estimated number of FTE resident slots resulting from the reductions. The amendments made by section 5503 also specifies that a hospital that receives an increase in its cap shall ensure, during the 5-year period beginning on the date of such increase (July 1, 2011), that certain requirements, referred to as the primary care average and 75-percent threshold, are met in order to retain those slots. Otherwise, the Medicare statute authorizes the Secretary to reduce the FTE caps of the hospital by the same number of FTE residents by which the hospital's FTE caps were increased if the hospital fails to meet either of those requirements.

Because a statutorily directed criteria for consideration in awarding slots under section 5503 included the requirement that hospitals applying for slots demonstrate the likelihood of filling the slots within the first three cost reporting periods beginning on or after July 1, 2011, and we relied on that information in awarding slots, we believe it is reasonable and authorized under section 1886(h)(8)(B)(ii) of the Act to expect that hospitals that received slots under section 5503 begin to use their slots by Year 3 of the 5-year period in order to give full effect to the requirements under section 1886(h)(8)(B)(ii) of the Act. Therefore, we are proposing that a hospital that received section 5503 slots must fill at least half of its section 5503 slots, IME and direct GME respectively, in at least one of the following timeframes: The first 12-month cost reporting period of the 5-year period, and/or in its second 12-month cost reporting period and/or in its third 12-month cost reporting period of the 5-year period, or lose its section 5503 slots. We also are proposing that the hospital must fill all of the slots it received by its final cost reporting period beginning during the timeframe of July 1, 2011 through June 30, 2016, or lose all of its section 5503 slots after June 30, 2016.

We believe the impact of these proposals regarding the timing of the use of these section 5503 slots is budget neutral. We believe that hospitals will take the steps necessary to comply with the section 5503 requirements to ensure, to the best of their ability, that they will not lose their section 5503 slots. We believe that section 5503 slots are valuable enough to a hospital that it is worthwhile for the hospital to comply with the proposed regulations (that is, to fill at least half of its section 5503 slots in its first 12-month cost reporting period of the 5-year period, and/or in its second 12-month cost reporting period and/or in its third 12-month cost reporting period of the 5-year period, and also fill all of the slots it received by its final cost reporting period beginning during the timeframe of July 1, 2011 through June 30, 2016), because not doing so would mean the loss of all of its section 5503 slots after Year 5 ends. Therefore, we anticipate that, as a result of these proposals, the hospitals that previously might not have made an effort to fill their section 5503 slots in a timely manner will now do so, and, assuming they continue to meet the primary care average and 75-percent threshold requirements, those hospitals would be allowed to keep their section 5503 slots. Thus, there would be neither an additional cost due to these proposals nor savings related to these proposals.

d. Preservation of Resident Cap Positions From Closed Hospitals (Section 5506 of the Affordable Care Act)

In section IV.I.4. of the preamble of this proposed rule, we discuss our proposals and clarifications of existing policy related to section 5506 of the Affordable Care Act. Section 5506 amended the Medicare statute to add a provision that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria up to the number of the closed hospital's FTE resident caps. The Secretary is directed to ensure that the total number of FTE resident cap slots distributed is not to exceed the amount of slots in the closed hospital's direct GME and IME FTE resident caps, respectively. The regulations and application process regarding section 5506 were implemented in the November 24, 2010 **Federal Register** (75 FR 72212). The provisions included in the preamble of this proposed rule are generally administrative in nature, related to the rules regarding the application of section 5506, minor proposed changes or clarifications to the ranking criteria on the applications, and minor proposed changes or clarifications regarding the effective dates of slots awarded under section 5506. Therefore, there is no financial impact for these section 5506 provisions.

7. Effects of Proposed Changes Relating to the Reporting Requirements for Pension Costs for Medicare Cost-Finding Purposes

In section IV.J. of the preamble of this proposed rule, we discuss our proposal to amend two existing regulations to conform these regulations to the final policy we adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51693 through 51597) with regard to pension costs for Medicare cost-finding purposes. Because we are proposing to make only conforming changes to the regulations and not further modifying the policy we finalized, there is no impact on hospitals for these proposed changes for FY 2013.

8. Effects of Implementation of Rural Community Hospital Demonstration Program

In section IV.K. of the preamble of this proposed rule, we discuss our implementation of section 410A of Public Law 108–173, as amended, which requires the Secretary to conduct a demonstration that would modify reimbursement for inpatient services for up to 30 rural community 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.K. of the preamble of this proposed rule, in the IPPS final rules for each of the previous 8 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.

We are proposing to adjust the national IPPS rates according to the methodology set forth elsewhere in this proposed rule. In this proposed rule, the proposed adjustment to the national IPPS rates to account for estimated demonstration cost for FY 2013 for the 7 ''pre-expansion'' participating hospitals that are currently participating in the demonstration and the 16 additional hospitals participating as a result of the expansion of the demonstration under the Affordable Care Act is $35,077,708. In addition, in this FY 2013 proposed rule, we are proposing that if settled cost reports for all of the demonstration hospitals that participated in the applicable budget year (FY 2007, 2008, 2009, or 2010) are available prior to the FY 2013 IPPS/LTCH PPS final rule, we would include in the budget neutrality offset amount any additional amount by which the final settled costs of the demonstration for the year (FY 2007, 2008, 2009, or 2010) exceeded the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule. The estimated amount of $35,077,708 that we are proposing in this FY 2013 proposed rule does not account for any differences between the cost of the demonstration program for hospitals participating in the demonstration for FYs 2007 through 2010 and the amounts that were offset by the budget neutrality adjustment for these years because the specific numeric value associated with this component of the adjustment to the national IPPS rates cannot be known at this time. This is because the large majority of settled cost reports beginning in FYs 2007 through 2010 for the hospitals participating during in the demonstration during those years also are not available at this time.

9. Effects of Proposed Change in Effective Date for Policies Relating to Hospital Services Furnished Under Arrangements

In section IV.L. of the preamble of this proposed rule, we discuss that, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51711 through 51714), we limited the circumstances under which a hospital may furnish services to Medicare beneficiaries ''under arrangements.'' Under the revised policy, ''routine services'' (that is, bed, board,

and nursing and other related services) must be provided in the hospital in which the patient is a registered inpatient in order for the services to be considered as being provided by the hospital. Routine services furnished to Medicare beneficiaries as inpatients of the hospital are considered services furnished by the hospital. Only diagnostic and therapeutic services (that is, ancillary services) may be provided under arrangements outside the hospital. We have become aware that a number of affected hospitals need additional time to restructure existing arrangements and establish necessary operational protocols to comply with this requirement. Therefore, in this proposed rule, we are proposing to postpone the effective date of the revised policy change from services provided on or after October 1, 2011, to cost reporting periods beginning in FY 2014. We have determined that the impact of this proposed effective date change would be negligible.

I. Effects of Proposed Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented below, we used data from the December 2011 update of the FY 2011 MedPAR file and the December 2011 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 2011 update of the most recently available hospital cost report data (FYs 2009 and 2010) 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.C.2. of the preamble to this proposed rule, we are proposing to make a −0.8 percent documentation and coding adjustment to the national capital rate for FY 2013 in addition to the −0.6 percent adjustment established for FY 2008, the −0.9 percent adjustment for FY 2009, the −2.9 percent adjustment for FY 2011, and the −1.0 percent adjustment for FY 2012. This results in a proposed cumulative adjustment factor of 0.9404 that we applied in determining the proposed FY 2013 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 and coding for FYs 2008 and 2009 that do not reflect real changes in case-mix under the MS–DRGs. (We currently estimate that there was no additional effect of documentation and coding from the adoption of the Ms-DRGs in FY 2010 for hospitals located in Puerto Rico.) Therefore, as we did for FY 2012, we are not proposing to adjust the Puerto Rico-specific capital rate in FY 2013 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 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 2011 update of the FY 2011 MedPAR file, we simulated payments under the capital IPPS for FY 2012 and FY 2013 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 capital IPPS payments in FY 2013 is as follows:

(Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may 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 0.5 percent in both FYs 2012 and 2013.
- We estimate that the Medicare discharges would be approximately 12.8 million in FY 2012 and 13.3 million in FY 2013.
- The capital Federal rate was updated beginning in FY 1996 by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1.a. of the Addendum to this proposed rule, the proposed update is 1.3 percent for FY 2013.
- In addition to the proposed FY 2013 update factor, the proposed FY 2013 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality factor of 1.0002, and a proposed outlier adjustment factor of 0.9400.
- For FY 2013, as discussed above and in section V.C.2. of the preamble to this proposed rule, we are proposing to apply a cumulative adjustment of 0.9404 in determining the proposed FY 2013 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 proposed cumulative adjustment of 0.9404 reflects the additional −0.8 percent adjustment in FY 2013 for the effects of documentation and coding in FY 2010 (and is in addition to the adjustments previously made for the effects in FYs 2008 and 2009).

2. Results

We used the actuarial model described above to estimate the potential impact of our proposed changes for FY 2013 on total capital payments per case, using a universe of 3,405 hospitals. As described above, the individual hospital payment parameters are taken from the best available data, including the December 2011 update of the FY 2011 MedPAR file, the December 2011 update to the PSF, and the most recent cost report data from the December 2011 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2012 and estimated total payments per case for FY 2013 based on the proposed FY 2013 payment policies. Column 2 shows estimates of payments per case under our model for FY 2012. Column 3 shows estimates of payments per case under our model for FY 2013. Column 4 shows the proposed total percentage change in payments from FY 2012 to FY 2013. The proposed change represented in Column 4 includes the 1.3 percent update to the proposed capital Federal rate and other proposed changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2013 are expected to decrease as compared to capital payments per case in FY 2012. However, the proposed capital rate for FY 2013 would increase approximately 0.7 percent as compared to the FY 2012 capital Federal 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 certain exceptions. The regional variations in the proposed estimated change in capital payments are consistent with the proposed changes in payments due to changes in the wage index (and policies affecting the wage index) shown in Table I in section I of this Appendix.

We also are estimating a slight decrease in outlier payments in FY 2013 as compared to FY 2012. This is primarily because of the proposed increase to the outlier fixed-loss amount (discussed in section II.A.4.f. of the Addendum to this proposed rule). In addition, this estimated decrease in outlier payments is based on the FY 2011 claims from the December 2011 update of the MedPAR file, we are currently estimating that FY 2012 capital outlier payments are more than the projected 6.18 percent that we used to determine the outlier offset that we applied in determining the FY 2012 capital Federal rate.

The net impact of these proposed changes, as discussed above, is an estimated −0.2 percent change in capital payments per discharge from FY 2012 to FY 2013 for all hospitals (as shown below in Table III).

The geographic comparison shows that, on average, all hospitals are expected to experience a decrease in capital IPPS payments per case in FY 2013 as compared to FY 2012. These decreases are primarily due to proposed changes in the GAFs (primarily resulting from policies affecting

the wage index)), and the estimated decrease in capital outlier payments. Capital IPPS payments per case for large urban hospitals are estimated to decrease 0.1 percent, while other urban hospitals are expected to experience a 0.4 percent decrease. Rural hospitals, on average, are not expected to experience any change in capital payments per discharge from FY 2012 to FY 2013.

The comparisons by region show that most urban regions, except for the Pacific region and Puerto Rico, will experience, on average, decreases in capital IPPS payments. The estimated decrease in capital payments per discharge from FY 2012 to FY 2013 in urban areas ranges from a 0.1 percent decrease for the East North Central urban region to a 1.0 percent decrease for the New England urban region. The two exceptions to decreases in capital payments per case are the Pacific urban region and the Puerto Rico urban region, which are expected to experience a 1.1 percent and 0.5 percent increase, respectively. As we indicated in the FY 2012 IPPS/LTCH PPS final rule, the GAFs for Puerto Rico result in a positive effect in estimated capital IPPS payment because of the application of a Puerto Rico rural floor. FY 2012 was the first year an IPPS hospital was located in rural Puerto Rico, therefore, setting a rural floor. The GAFs are also having a positive effect on capital IPPS payments per discharge in the Pacific urban region, primarily due to proposed changes in the wage index for hospitals located in that area as discussed in section I of this Appendix.

For rural regions, the estimated change in capital payments per discharge from FY 2012 to FY 2013 ranges from a 1.6 percent decrease for the Pacific rural region to a 0.7 percent increase for the Middle Atlantic rural region. The East South Central and Mountain rural regions are not expected to experience any change in their capital payments per discharge from FY 2012 to FY 2013. The Puerto Rico rural region is estimated to experience a 3.3 percent increase in capital payments per discharge in FY 2013 compared to FY 2012.

Hospitals of all type of ownership (that is, voluntary hospitals, government hospitals, and proprietary hospitals) are estimated to experience a 0.2 percent decrease in capital payments per case from FY 2012 to FY 2013.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2013. 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 2013, we show the average capital payments per case for reclassified hospitals for FY 2013. Only urban reclassified hospitals are expected to experience an increase in capital payments, 0.1 percent, in FY 2013 as compared to FY 2012. Urban non-reclassified hospitals are estimated to experience a decrease of 0.3 percent. Rural reclassified hospitals are estimated to experience no change in capital payments per discharge from FY 2012 to FY 2013, while rural nonreclassified hospitals are estimated to have a 0.1 percent decrease in capital payments per case. Similarly, other reclassified hospitals (that is, hospitals reclassified under section 1886(d)(8)(B) of the Act) are expected to experience a decrease of 0.1 percent in capital payments from FY 2012 to FY 2013.

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE

[FY 2012 payments compared to proposed FY 2013 payments]

	Number of hospitals	Average FY 2012 payments/case	Proposed average FY 2013 payments/case	Change
By Geographic Location:				
All hospitals	3,405	799	797	−0.2
Large urban areas (populations over 1 million)	1,365	880	880	−0.1
Other urban areas (populations of 1 million of fewer)	1,120	784	781	−0.4
Rural areas	920	552	552	0.0
Urban hospitals	2,485	837	835	−0.2
0–99 beds	627	670	667	−0.4
100–199 beds	773	722	720	−0.2
200–299 beds	448	769	770	0.1
300–499 beds	432	848	848	0.0
500 or more beds	205	1,016	1,010	−0.6
Rural hospitals	920	552	552	0.0
0–49 beds	317	438	438	0.1
50–99 beds	346	505	506	0.0
100–149 beds	152	545	544	−0.1
150–199 beds	58	619	617	−0.3
200 or more beds	47	672	673	0.2
By Region:				
Urban by Region	2,485	837	835	−0.2
New England	120	907	898	−1.0
Middle Atlantic	318	886	884	−0.2
South Atlantic	377	781	776	−0.6
East North Central	396	804	804	−0.1
East South Central	151	730	725	−0.7
West North Central	165	836	841	0.7
West South Central	370	796	791	−0.6
Mountain	157	868	864	−0.4
Pacific	380	1,016	1,026	1.1
Puerto Rico	51	384	386	0.5
Rural by Region	920	552	552	0.0
New England	23	744	743	−0.1
Middle Atlantic	69	569	573	0.7
South Atlantic	164	541	540	−0.2
East North Central	120	576	577	0.1
East South Central	170	507	507	0.0
West North Central	98	585	582	−0.4
West South Central	181	491	491	0.1
Mountain	65	580	580	0.0
Pacific	29	723	712	−1.6
Puerto Rico	1	150	155	3.3

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE—Continued

[FY 2012 payments compared to proposed FY 2013 payments]

	Number of hospitals	Average FY 2012 payments/case	Proposed average FY 2013 payments/case	Change
By Payment Classification:				
All hospitals	3,405	799	797	−0.2
Large urban areas (populations over 1 million)	1,375	879	879	−0.1
Other urban areas (populations of 1 million of fewer)	1,125	783	780	−0.3
Rural areas	905	563	561	−0.2
Teaching Status:				
Non-teaching	2,376	680	679	−0.2
Fewer than 100 Residents	789	790	790	0.0
100 or more Residents	240	1,137	1,133	−0.4
Urban DSH:				
100 or more beds	1,523	863	861	−0.1
Less than 100 beds	327	583	585	0.2
Rural DSH:				
Sole Community (SCH/EACH)	269	519	517	−0.4
Referral Center (RRC/EACH)	210	624	623	−0.3
Other Rural:				
100 or more beds	32	506	504	−0.5
Less than 100 beds	286	446	447	0.2
Urban teaching and DSH:				
Both teaching and DSH	815	933	932	−0.2
Teaching and no DSH	147	812	810	−0.3
No teaching and DSH	1,035	720	720	0.0
No teaching and no DSH	503	741	736	−0.7
Rural Hospital Types:				
Non special status hospitals	2,391	841	839	−0.2
RRC/EACH	61	733	736	0.4
SCH/EACH	34	722	724	0.2
SCH, RRC and EACH	16	769	764	−0.6
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY 2013 Reclassifications:				
All Urban Reclassified	420	833	834	0.1
All Urban Non-Reclassified	2,025	840	838	−0.3
All Rural Reclassified	335	596	596	0.0
All Rural Non-Reclassified	524	482	481	−0.1
Other Reclassified Hospitals (Section 1886(d)(8)(B))	55	550	550	−0.1
Type of Ownership:				
Voluntary	1,970	813	812	−0.2
Proprietary	866	718	717	−0.2
Government	560	817	816	−0.2
Medicare Utilization as a Percent of Inpatient Days:				
0–25	377	1,044	1,047	0.3
25–50	1,834	839	837	−0.3
50–65	968	666	665	−0.1
Over 65	168	611	611	0.1

J. Effects of Proposed Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VII. of the preamble and section V. of the Addendum to this proposed rule, we set forth the proposed annual update to the payment rates for the LTCH PPS for FY 2013. 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 rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this proposed rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

Currently, our database of 427 LTCHs includes the data for 82 nonprofit (voluntary ownership control) LTCHs and 322 proprietary LTCHs. Of the remaining 23 LTCHs, 14 LTCHs are government-owned and operated and the ownership type of the other 9 LTCHs is unknown. In the impact analysis, we used the proposed rate, factors, and policies presented in this proposed rule, including the proposed 2.1 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 one-time prospective adjustment of 0.98734 (approximately −1.3 percent), which would not apply to payments for discharges occurring on or before December 28, 2012 (consistent with the statute), the proposed update to the MS–LTC–DRG classifications and relative weights, the proposed update to the wage index values and labor-related share, the expiration of the statutory delay in the application of very short-stay outlier policy at § 412.529(c)(3), effective for discharges occurring on or after December 29, 2012 (that is, the option for certain short-stay outlier cases to be paid under the ''blended payment'' will be replaced with the ''IPPS comparable per diem amount'' as discussed in section VII.E.3. of the preamble of this proposed rule), and the best available claims and CCR data to estimate the proposed change in payments for FY 2013.

The standard Federal rate for FY 2012 was $40,222.05. For FY 2013, we are proposing to establish a standard Federal rate of $40,507.48 that reflects the proposed 2.1 percent annual update to the standard

Federal rate, and the proposed area wage budget neutrality factor of 0.99903, which ensures that the proposed changes in the wage indexes and labor-related share do not influence aggregate payments. Furthermore, consistent with section 114(c)(4) of the MMSEA, as amended by sections 3106(a) and 10312 of the Affordable Care Act, the proposed one-time prospective adjustment to the standard Federal rate for FY 2013 of 0.98734 (approximately −1.3 percent) would not apply to payments for discharges occurring before December 29, 2012. Therefore, payment for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, would not reflect that proposed adjustment and, instead, would be paid based on a standard Federal rate of $41,026.88.

Based on the best available data for the 427 LTCHs in our database, we estimate that the proposed update to the standard Federal rate for FY 2013 (discussed in section V.A.2. of the Addendum to this proposed rule) and the proposed changes to the area wage adjustment for FY 2013 (discussed in section V.B. of the Addendum to this proposed rule), in addition to an estimated increase in HCO payments and an estimated decrease in SSO payments, would result in an increase in estimated payments from FY 2012 of approximately $100 million. Based on the 427 LTCHs in our database, we estimate that the FY 2013 LTCH PPS payments would be approximately $5.282 billion, as compared to estimated FY 2012 LTCH PPS payments of approximately $5.181 billion. Because the combined distributional effects and estimated changes to the Medicare program payments are over approximately $100 million, this proposed rule is considered a major economic rule, as defined in this section. We note that the approximately $100 million for the projected increase in estimated aggregate proposed LTCH PPS payments from FY 2012 to FY 2013 does not reflect changes in LTCH admissions or case-mix intensity in estimated LTCH PPS payments, which also will affect overall payment changes. It also does not include the estimated effect of the proposed 1-year extension of the moratorium on the application of the ''25-percent threshold'' payment adjustment policy on LTCH PPS payments, which is discussed below in section I.J.b.3. of this Appendix.

The projected 1.9 percent increase in estimated proposed payments per discharge from FY 2012 to FY 2013 is attributable to several factors, including the proposed 2.1 percent annual update to the standard Federal rate, the proposed one-time prospective adjustment of −0.98734 (approximately −1.3 percent) to the standard Federal rate, which is not applicable to payments for discharges occurring on or before December 28, 2012, consistent with the statute, and projected increases in estimated HCO and decreases in SSO payments due to a change in the SSO payment methodology effective for discharges occurring on or after December 29, 2012 (as described in section VII.E.3. of the preamble of this proposed rule). As Table IV shows, the change attributable solely to the proposed annual update to the standard Federal rate (2.1 percent), including the proposed one-time prospective adjustment (approximately −1.3 percent) which is not applicable to payments for discharges occurring before December 29, 2012, is projected to result in an increase of 0.9 percent in payments per discharge from FY 2012 to FY 2013, on average, for all LTCHs. This estimated increase of 0.9 percent reflects the proposed 2.1 percent annual update for payments to FY 2013 discharges occurring from October 1, 2012 through December 28, 2012, and the proposed −1.3 percent one-time prospective adjustment factor, which would not apply in determining payments for discharges occurring on or before December 28, 2012, and also includes estimated payments to SSO cases that are paid using special methodologies that are not affected by the annual update to the standard Federal rate. Therefore, the projected increase in payments to the Federal rate is less than the proposed 2.1 percent annual update for FY 2013. 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 2013 based on the most recent available data. In addition, we are proposing to decrease the labor-related share from 70.199 percent to 63.217 percent under the LTCH PPS for FY 2013, 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 2009-based LTCH-specific market basket. We also are proposing an area wage level budget neutrality factor of 0.99903, which reduces the proposed standard Federal rate by approximately 0.1 percent. Therefore, the proposed changes to the wage data and labor-related share do not result in a change in estimated aggregate LTCH PPS payments.

We are projecting that LTCHs would experience a decrease in aggregate payments of 0.4 percent in FY 2013 as a result of the expiration of the statutory delay in the application of the very short-stay outlier policy at § 412.529(c)(3), effective for discharges occurring on or after December 29, 2012. Generally, very short-stay outliers are cases that have a length of stay that is less than or equal to one standard deviation from the geometric mean average length of stay of the same DRG under the IPPS. Under the moratorium, very short stay outliers are paid the lowest of: (1) The LTC–DRG payment; (2) 100 percent of cost; (3) 120 percent of the LTCH per diem payment; or (4) a blend of 120 percent of the LTCH per diem amount and the ''IPPS comparable per diem amount'' (the ''blended payment''). With the expiration of the moratorium, in the case of very short-stay outliers, effective for discharges on or after December 29, 2012, the ''blended payment'' will be replaced with only the ''IPPS comparable per diem amount,'' which results in a decrease in payments for these cases.

Table IV below shows the impact of the proposed payment rate and the proposed policy changes on LTCH PPS payments for FY 2013 presented in this proposed rule by comparing estimated FY 2012 payments to estimated FY 2013 payments. The projected increase in payments per discharge from FY 2012 to FY 2013 is 1.9 percent (shown in Column 9). This projected increase in payments is attributable to the impacts of the proposed change to the standard Federal rate (0.9 percent in Column 6), the end of the moratorium on delaying the implementation of the very short-stay outlier policy (−0.4 percent in Column 8), as well as the effect of the estimated increase in proposed payments for HCO cases and SSO cases (1.1 percent, 0.2 percent, respectively). That is, estimated total HCO payments are projected to increase from FY 2012 to FY 2013 in order to ensure that the estimated HCO payments would be 8 percent of the total estimated LTCH PPS payments in FY 2013. An analysis of the most recent available LTCH PPS claims data (that is, FY 2011 claims data from the December 2011 update of the MedPAR file) indicates that the FY 2012 HCO threshold of $17,931 (as established in the FY 2012 IPPS/LTCH PPS final rule) may-result in HCO payments in FY 2012 that fall below the estimated 8 percent. Specifically, we currently estimate that HCO payments would be approximately 6.9 percent of the estimated total LTCH PPS payments in FY 2012. We estimate that the impact of the increase in HCO payments would result in approximately a 1.1 percent increase in estimated payments from FY 2012 to FY 2013, on average, for all LTCHs. Furthermore, in calculating the estimated increase in payments from FY 2012 to FY 2013 for HCOs, we increased estimated costs by the applicable market basket percentage increase as projected by our actuaries. This increase in estimated costs also results in a projected increase in SSO payments of 0.2 percent relative to last year. However, the expiration of the statutory moratorium on the application of the very short-stay outlier policy, effective December 29, 2012, which replaces the ''blended payment'' option with the ''IPPS comparable per diem amount'' option for certain SSO cases (as described in section VII.E.3. of the preamble of this proposed rule) is expected to result in a −0.4 percent change in aggregate payments. The net result of these projected changes in SSO payments in FY 2013 is an estimated change in aggregate payments of −0.2 percent. 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 FY 2013 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 (approximately 59 percent) are based on the estimated cost of the 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.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 3.6 percent increase in estimated payments per discharge for FY 2013 as compared to FY 2012 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 27 rural LTCHs in our database (out of 427 LTCHs) for which complete data were available.

The estimated increase in LTCH PPS payments from FY 2012 to FY 2013 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 decrease in the labor-related share from 70.199 to 63.217. 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 1.1 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 2013 as compared to FY 2012.

3. Anticipated Effects of Proposed LTCH PPS Payment Rate Changes and Policy Changes

a. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal 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 I.J.1. of this Appendix, we project an increase in aggregate LTCH PPS payments in FY 2013 relative to FY 2012 of approximately $100 million based on the 427 LTCHs in our database.

b. Expiration of Statutory Delay on Full Implementation of the ''25 Percent Threshold'' Payment Adjustment and Proposed 1-Year Extension

As discussed in section VII.E.2. of the preamble of this proposed rule, the statutory delay in the full application of the ''25 percent threshold'' payment adjustment for LTCHs at § 412.534 and § 412.536 will expire for cost reporting periods beginning on or after July 1, 2012, or October 1, 2012, as applicable. We are proposing a 1-year extension of the moratorium on the application of the ''25 percent threshold'' payment adjustment policy as provided by section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(a) and 10312(a) of the Affordable Care Act, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013. We estimate that this proposal will result in a payment impact of approximately $170 million to LTCHs.

c. 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 2013, it is necessary to estimate payments per discharge for FY 2012 using the rates, factors (including the FY 2012 GROUPER (Version 29.0), and relative weights and the policies established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51733 through 51781 and 51838 through 51844). 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 30.0) for FY 2013 (as discussed in section VII. of the preamble and section V. of the Addendum to this proposed rule). These estimates of FY 2012 and FY 2013 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 2012 payments to estimated FY 2013 payments (on a per discharge basis) for each category of LTCHs. We are proposing a standard Federal rate for FY 2013 of $40,507.48 that includes the proposed 2.1 percent annual update, the proposed area wage budget neutrality factor, and the proposed one-time prospective adjustment to the standard Federal rate for FY 2013 of 0.98734 (approximately −1.3 percent) that would not apply to payments for discharges occurring on or before December 29, 2012, consistent with statute. Payment for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, would not reflect that proposed one-time prospective adjustment and instead would be paid based on a standard Federal rate of $41,026.88.

Therefore, we modeled payments so that claims with discharge dates prior to January would be paid on the basis of a rate that does not reflect the proposed one-time prospective adjustment, and claims with discharges in January or after would reflect our proposed standard Federal rate for FY 2013 that reflects the proposed one-time prospective adjustment. Furthermore, because the statutory moratorium on application of the very short-stay outlier policy will expire effective for discharges occurring on or after December 29, 2012, we modeled payments so that claims that would qualify for a payment under the very short-stay outlier policy with discharge dates in October, November, and December are paid based on the ''blended payment'' option, if applicable, and claims that would qualify for a payment under the very short-stay outlier policy with discharges in January through September are paid based on the ''IPPS comparable per diem amount,'' if applicable (as described in section VII.E.3. of the preamble of this proposed rule).

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 included 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 2011 MedPAR file to estimate payments for FY 2012 and to estimate payments for FY 2013 for 427 LTCHs. We believe that the discharges based on the FY 2011 MedPAR data for the 427 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.

d. 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 2011 MedPAR files. For modeling estimated LTCH PPS payments for FY 2012, we used the FY 2012 standard Federal rate (that is, $40,222.05 effective for LTCH discharges occurring on or after October 1, 2011, through September 30, 2012).

For modeling estimated LTCH PPS payments for FY 2013, we used the proposed FY 2013 standard Federal rate of $40,507.48, which includes the proposed one-time prospective adjustment of 0.98734 for payments for discharges occurring on or after December 29, 2012 and through September 30, 2013. As noted above, consistent with section 114(c)(4) of the MMSEA, as amended by sections 3106(a) and 10312 of the Affordable Care Act, the proposed one-time prospective adjustment to the standard Federal rate for FY 2013 of 0.98734 (approximately −1.3 percent) would not apply to payments for discharges occurring before December 29, 2012. Therefore, payment for discharges occurring on or after October 1, 2012 and on or before December 28, 2012 would not reflect that proposed adjustment and instead would be paid based on a standard Federal rate of $41,026.88; therefore, for the purpose of payment modeling, claims with discharges occurring October through December were modeled using this proposed payment rate.

The proposed FY 2013 standard Federal rate of $40,507.48 includes the proposed application of an area wage level budget neutrality factor of 0.99903 (as discussed in section V.B.5. of the Addendum to this proposed rule). As noted above, consistent with section 114(c)(4) of the MMSEA, as amended by sections 3106(a) and 10312 of the Affordable Care Act, this proposed rate would not apply to payments for discharges occurring before December 29, 2012. Therefore, payment for discharges occurring on or after October 1, 2012 and on or before December 28, 2012 would be paid based on a standard Federal rate of $41,026.88, which also includes the proposed area wage level budget neutrality factor of 0.99903.

Furthermore, in modeling estimated LTCH PPS payments for both FY 2012 and FY 2013 in this impact analysis, we applied the FY 2012 and the proposed FY 2013 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 2012 payments using the current LTCH PPS labor-related share of 70.199 percent (76 FR 51766) and the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2012 IPPS/LTCH PPS final rule (and available via the Internet (76 FR 51813)). We also applied the FY 2012 COLA factors shown in the table in section V.C. of the Addendum to that final rule (76 FR 51810) to the FY 2012 nonlabor-related share (29.801 percent) for LTCHs located in Alaska and Hawaii. Similarly, we adjusted for differences in area wage levels in determining the estimated FY 2013 payments using the proposed LTCH PPS FY 2013 labor-related share of 63.217 percent and the proposed FY 2013 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 2013 COLA factors shown in the table in section V.C. of the Addendum of this proposed rule to the proposed FY 2013 nonlabor-related share (36.783 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.D. of the Addendum to this proposed rule). In modeling proposed payments for SSO and HCO cases in FY 2013, we applied an inflation factor of 1.055 (determined by OACT) to estimate the costs of each case using the charges reported on the claims in the FY 2011 MedPAR files and the best available CCRs from the December 2011 update of the PSF. Furthermore, in modeling estimated LTCH PPS payments for FY 2013 in this impact analysis, we used the proposed FY 2013 fixed-loss amount of $15,728 (as discussed in section V.D. of the Addendum to this proposed rule). Finally, in modeling payments for SSO cases, we included the expiration of the statutory moratorium on application of the very short-stay outlier, effective for discharges occurring on or after December 29, 2012, under which the ''blended payment'' option of the SSO payment formula will be replaced with the ''IPPS comparable per diem amount'' for very short-stay outlier cases as discussed in section VII.E.3. of the preamble of this proposed rule.

These impacts reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from the FY 2012 to FY 2013 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 2012 (as described above).
- The fifth column shows the estimated payment per discharge for FY 2013 (as described above).
- The sixth column shows the percentage change in estimated payments per discharge from FY 2012 to FY 2013 due to the proposed update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this proposed rule) and proposed one-time prospective adjustment (which is not applicable to payments for discharges occurring before December 29, 2012, consistent with the statute).
- The seventh column shows the percentage change in estimated payments per discharge from FY 2012 to FY 2013 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 this proposed rule).
- The eighth column shows the percentage change in estimated payments per discharge from FY 2012 to FY 2013 due to the expiration of the SSO policy that allowed for qualifying SSO cases to be paid under a blended payment amount based on the LTCH per diem rate and IPPS comparable per diem rate.
- The ninth column shows the percentage change in estimated payments per discharge from FY 2012 (Column 4) to FY 2013 (Column 5) for all proposed changes (and includes the effect of estimated proposed changes to HCO and SSO payments).

TABLE IV—IMPACT OF PROPOSED PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR FY 2013

(Estimated FY 2012 payments compared to estimated proposed FY 2013 payments*)

LTCH Classification	Number of LTCHs	Number of LTCH PPS cases	Average FY 2012 LTCH PPS payment per case	Average FY 2013 LTCH PPS proposed payment per case [1]	Percent change in estimated payments per discharge from FY 2012 to proposed FY 2013 for the proposed annual update to the federal rate [2]	Percent change in estimated payments per discharge from FY 2012 to FY 2013 for proposed changes to the area wage level adjustment with proposed budget neutrality [3]	Percent change in estimated payments per discharges due to expiration of statutory moratorium on application of the 'very' short-stay SSO payment methodology [4]	Percent change in payments per discharge from FY 2012 to FY 2013 for all proposed changes [5]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
ALL PROVIDERS	427	134,114	38,633	39,381	0.9	0.0	−0.4	1.9
BY LOCATION:								
RURAL	27	6,259	34,325	35,571	1.0	1.1	−0.3	3.6
URBAN	400	127,855	38,844	39,568	0.9	0.0	−0.4	1.9
LARGE	202	73,668	40,827	41,519	0.9	−0.2	−0.4	1.7
OTHER	198	54,187	36,147	36,916	1.0	0.2	−0.5	2.1
BY PARTICIPATION DATE:								
BEFORE OCT. 1983	17	5,848	34,189	35,120	0.9	−0.2	−0.2	2.7
OCT. 1983–SEPT. 1993	44	15,786	41,530	42,286	0.9	−0.1	−0.5	1.8
OCT. 1993–SEPT. 2002	185	62,594	37,886	38,616	1.0	0.0	−0.4	1.9
AFTER OCTOBER 2002	173	48,737	39,142	39,895	1.0	0.0	−0.5	1.9
UNKNOWN PARTICIPATION DATE	8	1,149	40,546	41,096	0.9	−0.3	−0.7	1.4
BY OWNERSHIP TYPE:								
VOLUNTARY	82	19,532	38,899	39,900	0.9	0.2	−0.5	2.6
PROPRIETARY	322	111,475	38,451	39,148	1.0	0.0	−0.4	1.8
GOVERNMENT	14	1,718	44,353	45,172	0.9	−0.4	−0.6	1.8
UNKNOWN OWNERSHIP TYPE	9	1,389	42,411	43,693	0.9	0.9	−0.6	3.0
BY REGION:								
NEW ENGLAND	15	7,333	33,793	34,643	0.9	−0.2	−0.2	2.5
MIDDLE ATLANTIC	31	7,970	41,678	42,233	1.0	−0.1	−0.4	1.3
SOUTH ATLANTIC	60	16,367	41,373	41,951	0.9	−0.1	−0.5	1.4
EAST NORTH CENTRAL	69	20,669	40,014	40,782	1.0	0.2	−0.5	1.9
EAST SOUTH CENTRAL	30	8,411	38,938	39,929	0.9	0.7	−0.4	2.5
WEST NORTH CENTRAL	26	5,374	40,845	41,733	0.9	0.6	−0.5	2.2
WEST SOUTH CENTRAL	139	50,543	34,502	35,415	1.0	0.3	−0.4	2.6
MOUNTAIN	32	5,956	41,996	42,450	0.9	−0.7	−0.4	1.1
PACIFIC	25	11,491	48,388	48,603	0.8	−1.3	−0.4	0.4
BY BED SIZE:								
BEDS: 0–24	31	3,478	34,245	35,055	1.0	0.6	−0.4	2.4
BEDS: 25–49	198	44,578	38,194	38,992	1.0	0.3	−0.5	2.1
BEDS: 50–74	115	36,438	38,667	39,421	1.0	0.0	−0.4	2.0
BEDS: 75–124	46	20,178	41,700	42,290	0.9	−0.3	−0.4	1.4
BEDS: 125–199	23	16,055	37,051	37,804	0.9	−0.1	−0.4	2.0
BEDS: 200+	14	13,387	38,416	39,201	0.9	−0.4	−0.4	2.0

[1] Estimated FY 2013 LTCH PPS payments based on the proposed payment rate and policy changes presented in the preamble and the Addendum to this proposed rule.

[2] Percent change in estimated payments per discharge from FY 2012 to FY 2013 for the proposed annual update to the standard Federal rate and the proposed one-time prospective adjustment to the standard Federal rate (which would not apply to payments for discharges occurring before December 29, 2012, consistent with the statute), as discussed in section V.A.2. of the Addendum to this proposed rule.

[3] Percent change in estimated payments per discharge from FY 2012 to FY 2013 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 discharges due to the expiration of the statutory moratorium on application of the very short-stay outlier, effective for discharges occurring on or after December 29, 2012, under which the ''blended payment'' option of the SSO payment formula will be replaced with the ''IPPS comparable per diem amount'' for very short-stay outlier cases as discussed in section VII.E.3. of the preamble of this proposed rule.

[5] Percent change in estimated payments per discharge from FY 2012 LTCH PPS (shown in Column 4) to FY 2013 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 6) and the proposed changes to the area wage level adjustment with budget neutrality (Column 7) 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.

e. Results

Based on the most recent available data for 427 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 2012 to FY 2013 as a result of the proposed payment rate and policy changes presented in this proposed rule, including the expiration of the statutory moratorium on application of the very short-stay outlier policy which utilizes the ''IPPS comparable per diem amount'' payment option, effective for discharges occurring on or after December 29, 2012 (discussed in section VII.E.3. of the preamble of this proposed rule) and an estimated increase in HCO payments. This estimated 1.9 percent increase in LTCH PPS payments per discharge from the FY 2012 to FY 2013 for all LTCHs (as shown in Table IV) was determined by comparing estimated FY 2013 LTCH PPS payments (using the proposed rate and policies discussed in this proposed rule) to estimated FY 2012 LTCH PPS payments (as described above in section I.J.1. of this Appendix).

We are proposing to establish a standard Federal rate of $40,507.48 for FY 2013. Specifically, we are proposing to update the standard Federal rate for FY 2013 by 2.1 percent, which is based on the latest estimate of the proposed LTCH PPS market basket increase (3.0 percent), the proposed reduction of 0.8 percentage point for the multifactor productivity adjustment, and the 0.1 percentage point reduction consistent with sections 1886(m)(3) and (m)(4) of the Act. In addition, we are proposing to apply a one-time prospective adjustment of 0.98734 (approximately −1.3 percent) to the standard Federal rate. However, this proposed reduction would not apply to payments for discharges occurring before December 29, 2012, consistent with section 114(c)(4) of the MMSEA, as amended by sections 3106(a) and 10312 of the Affordable Care Act. Therefore, payments for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, would not reflect that proposed adjustment and instead would be paid based on a standard Federal rate of $41,026.88. 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 2.1 percent for the proposed annual update to the standard Federal rate and the proposed 0.8 percent update to the standard Federal rate that includes the proposed one-time prospective adjustment of approximately −1.3 percent which would not apply to payments for discharges occurring before December 29, 2012, consistent with the statute, is projected to result in approximately a 0.9 percent increase in estimated payments per discharge for all LTCHs from FY 2012 to FY 2013. That is, for approximately the first 3 months of FY 2013, payments would not reflect the proposed one-time prospective adjustment such that payments would be based on the proposed annual update to the standard Federal rate of 2.1 percent, and for the remaining 9 months of FY 2013, payments would be based on a standard Federal rate that reflects the proposed FY 2013 annual update of 2.1 percent and the proposed one-time prospective adjustment of approximately −1.3 percent. In addition, our estimate of the proposed changes in payments due to the proposed updates to the standard Federal rate also reflects estimated payments for SSO cases that are paid using special methodologies that are not affected by the update to the standard Federal rate. For these reasons, we estimate that payments would increase by 0.9 percent due to the proposed update to the Federal rate.

(1) 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 5 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 2012 to FY 2013 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 3.6 percent, while for urban LTCHs, we estimate the increase would be 1.9 percent. Large urban LTCHs are projected to experience an increase of 1.7 percent in estimated payments per discharge from FY 2012 to FY 2013, while other urban LTCHs are projected to experience an increase of 2.1 percent in estimated payments per discharge from FY 2012 to FY 2013, as shown in Table IV.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) Before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) 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 2012 to FY 2013, 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 higher than average percent increase (2.7 percent) in estimated payments per discharge from FY 2012 to FY 2013, 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 projected to experience a 1.8 percent increase in estimated payments from FY 2012 to FY 2013. 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 2012 to FY 2013.

(3) 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 2013 LTCH payments per discharge would experience a higher than the average increase (2.6 percent) in comparison to estimated payments in FY 2012 primarily because we project the estimated increase in HCO payments to be higher than the average increase for these LTCHs. The majority (75 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 2012 to FY 2013. Finally, government-owned and operated LTCHs are also expected to experience a nearly average increase in payments of 1.8 percent in estimated payments per discharge from FY 2012 to FY 2013.

(4) Census Region

Estimated payments per discharge for FY 2013 are projected to increase for LTCHs located in all regions in comparison to FY 2012. 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, East South Central and New England regions (2.6 percent, 2.5 percent and 2.5 percent respectively as shown in Table IV). The estimated percent increase in payments per discharge from FY 2012 to FY 2013 for those regions is largely attributable to the proposed changes in the area wage level adjustment or proposed updates to the MS–LTC–DRGs classifications and relative weights.

In contrast, LTCHs located in the Pacific region are projected to experience the smallest increase in estimated payments per discharge from FY 2012 to FY 2013. The average estimated increase in payments of 0.4 percent for LTCHs in the Pacific region is primarily due to estimated decreases in payments associated with the proposed changes to the area wage level adjustment.

(5) Bed Size

LTCHs are grouped into six categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds.

We project that small LTCHs (0–24 beds) would experience a 2.4 percent increase in payments due to increases in the area wage adjustment while large LTCHs (200+ beds) would experience a 2.0 percent increase in payments. LTCHs with between 75 and 124 beds are expected to experience a slightly below average increase in payments per discharge from FY 2012 to FY 2013 (1.4 percent) primarily due to an estimated decreases in their payments from FY 2012 to FY 2013 due to the proposed area wage level adjustment.

4. 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 2013 relative to FY 2012 of approximately $100 million (or approximately 1.9 percent) for the 427 LTCHs in our database. In addition, the effects of the proposed extension of the moratorium on the application of the ''25 percent threshold'' payment adjustment policy, as provided by section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(a) and 10312(a) of the Affordable Care Act, for cost reporting periods beginning or after October 1, 2012, and before October 1, 2012, will result in a payment impact of approximately $170 million to LTCHs.

5. 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 will enhance the efficiency of the Medicare program.

K. Effects of Proposed Requirements for Hospital Inpatient Quality Reporting (IQR) Program

In section VIII.A. of this proposed rule, we discuss our requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for FY 2015. We now estimate that approximately 95 hospitals may not receive the full annual percentage increase in any fiscal year. At the time that analysis was prepared, 70 hospitals did not receive the full annual percentage increase in FY 2012.

We are proposing that, for the FY 2015 payment determination, we would remove one chart-abstracted measure and 16 claims-based measures, beginning with January 1, 2012 discharges. We believe that these proposed changes would not have a significant effect on our estimate. We believe that most of these estimated 95 hospitals will 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 2015.

In section VIII.A.6. of this preamble, we are proposing, for the FY 2015 payment determination, supplements to the chart validation process for the Hospital IQR Program. As a part of these supplements, we are proposing, for FY 2015 payment determinations and subsequent years, to separate validation for chart-abstracted and HAI measures and to also validate two additional HAI measures, CAUTI and SSI.

Starting with the FY 2015 payment determination, we are proposing a modest increase to the current Hospital IQR Program validation sample of 18 cases per quarter (currently three each for SCIP, AMI, HF, PN, ED/IMM, and candidate CLABSI) to 27 cases per quarter (3 each for SCIP, AMI, HF, PN, ED/IMM, and up to 4 each for CLABSI, CAUTI, and SSI). However, in order not to increase the Hospital IQR validation program's overall burden to hospitals, while expanding some of the requirements, and targeting hospitals with higher levels of concern for data quality, we are proposing to reduce the total sample size of hospitals included in the annual validation random sample from 800 eligible hospitals to 600 eligible hospitals. This includes 400 hospitals in the base sample and up to 200 hospitals in the target sample.

The requirement of an additional 9 charts per hospital submitted for validation, combined with the decreased sample size, will result in approximately 1,800 additional charts per quarter being submitted to CMS by all selected hospitals. We provide payment to 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 estimate that we would expend approximately $66,600 per quarter to collect the additional charts we need to validate all measures.

The total requirement of 27 charts per hospital would result in approximately 16,200 charts per quarter being submitted to CMS. Using the assumptions discussed above, for the FY 2015 Hospital IQR Program, we estimate that we would have expenditures of approximately $599,400 per quarter related to the validation requirement. Given that we pay for the data collection effort, we believe that a requirement for 27 charts per hospital per quarter represents a minimal burden to participating hospitals selected for validation.

L. Effects of Proposed PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section VIII.B. of the preamble of this proposed rule, we discuss our proposal to implement the quality data reporting program for PPS-exempt hospitals (PCHs), which we refer to as the PCHQR program, as required under section 1866(k) of the Act, as added by section 3005 of the Affordable Care Act. These quality reporting requirements would affect all PCHs participating in Medicare. PCHs would be required to register with the CDC, the CMS contractor, and QualityNet Web sites and take the proper training in order to be adequately prepared to use the respective systems to submit the data. The anticipated burden to these PCHs consists of the following: (1) The initial registration of the facility with CDC, the CMS contractor, and CMS; (2) training of the appropriate staff members on how to use the CDC agency-based data collection mechanism (CDC/NHSN), the CMS contractor-based collection mechanism for the cancer-specific quality measure data, and CMS (QualityNet) program; (3) the time required for collection and aggregation of data; (4) the time required for entry of the data into the CDC's NHSN data warehouse, CMS contractor's quality measure data warehouse, and QualityNet databases by the PCH's representative.

All PCHs that currently do not already report data to the NHSN would be required to register with the CDC, the CMS contractor, and the CMS/QualityNet and take the proper training in order to be adequately prepared to use the CDC's NHSN data warehouse, the CMS contractor's collection mechanism for data submission, and the CMS QualityNet Web site.

Those PCHs that already report the proposed HAI measures to the NHSN would not be significantly affected because we intend to align our reporting infrastructure with that used by the NHSN. However, for PCHs that do not currently report the two proposed HAI measures to the NHSN, at this time, we have no way to estimate how many PCHs will participate in the PCHQR program. Therefore, we are unable to estimate the burden for these PCHs.

Aside from the statutory requirements, it is important to note that one of our priorities is to help achieve better health and better health care for individuals through collection of valid, reliable, and relevant measures of quality health care data. Such data can be shared with appropriate health care related organizations and used to the further the development of health care quality, which, in turn, helps to further our objectives and goals. Health care organizations can use their health care quality data for many purposes such as in their risk management programs, health care acquired infection prevention programs and research and development of medical programs, among others.

Even more importantly, we intend to share the information obtained from the PCHQR Program with the public as is required under the statute. These data will be displayed on the *Hospital Compare* Web site. The goals of making these data available to the public in a public user-friendly and relevant format, include, but are not limited to: (1) Keeping the public informed of the quality of care that is being provided in PCHs as a whole; (2) keeping the public informed of the quality of care being provided in specific PCHs; (3) allowing the public to compare and contrast the data about specific PCHs, thus enabling the public to make informed health care decisions regarding PCHs; and (4) providing information about current trends in health care. There are many other public uses for these quality data concerning PCHs. Further, keeping the public informed of quality of care provided in health care has always been of high priority to CMS.

We also seek to align the new PCHQR Program reporting requirements with current HHS high priority conditions and topics and to ultimately provide a comprehensive assessment of the quality of health care delivered in a variety of settings.

M. Effects of 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) 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.

We previously published a detailed analysis of the FY 2013 Hospital VBP Program's impact, based on scoring for two quality domains, in the Hospital Inpatient VBP Program final rule (76 FR 26542 through 26545). Because we are not proposing in this proposed rule to make any changes to the FY 2013 Hospital VBP Program, we do not believe we must provide an additional regulatory impact analysis for the FY 2013 Hospital VBP Program. We are proposing the operational details of the payment adjustment in the preamble of this proposed rule. We believe that these proposals do not have a regulatory impact or financial impact beyond policies already finalized. They are proposals regarding how CMS intends to ensure that the value-based incentive payments made to all hospitals in a fiscal year are equal, in total, to the reduced base operating DRG payment amounts.

In section VIII.C. of the preamble of this proposed rule, we discuss our proposal to add requirements for the Hospital VBP Program. In addition to certain operational and payment details for the FY 2013 Hospital VBP Program, we are making a number of additional proposals related to the FY 2015 and the FY 2016 Hospital VBP Program, including proposed measures, performance periods, performance standards, domain weighting, and other topics.

Specifically, with respect to the FY 2015 Hospital VBP Program, we are proposing to add one additional clinical process of care measure, AMI–10: Statin Prescribed at Discharge, and two additional outcome measures, an AHRQ Patient Safety Patient Safety Indicators composite measure and CLABSI: Central Line-Associated Blood Stream Infection. We also are proposing to add a measure of Medicare Spending per Beneficiary in the Efficiency domain.

With respect to the FY 2016 Hospital VBP Program, we are proposing to adopt four measures: three 30-day mortality measures adopted for FY 2014 and proposed for FY 2015—MORT–30–AMI, MORT–30–HF, and MORT–30–PN—and the AHRQ PSI composite measure. All of these measures are required for the Hospital IQR Program; therefore, their 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.

For future program years, we intend to consider the impacts of Hospital VBP Program policies in the applicable IPPS/LTCH PPS rulemaking vehicle. Because we are not proposing to alter the underlying scoring methodology finalized for the FY 2013 Hospital VBP Program in this proposed rule, we do not believe it appropriate to revise the regulatory impact analysis published in the Hospital Inpatient VBP final rule referenced above. We intend to provide an updated analysis of the Hospital VBP Program's impacts for the FY 2014 program year in the FY 2014 IPPS/LTCH PPS rulemaking.

N. Effects of Proposed New Measures To Be Added to the LTCH Quality Reporting (LTCHQR) Program

In section VIII.D. of the preamble of this proposed rule, we discuss the implementation of section 3004(a) of the Affordable Care Act, which added section 1886(m)(5) to the Act. Section 1886(m)(5) of the Act, further provides that in the case of an LTCH that does not submit data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a rate year, any annual update to the standard Federal rate for discharges for the hospital during the rate year, and after application of section 1886(m)(3) of the Act, shall be reduced by 2 percentage points. The initial requirements for this LTCH Quality Reporting (LTCHQR) Program were finalized in the section VII.C. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51839 through 51840), we estimated that only a few LTCHs would not receive the full payment update in any fiscal year as a result of not submitting data under the LTCH quality reporting program. At this time, the LTCHQR Program has not been fully implemented, as data collection will not begin until October 1, 2012. However, we believe that statements we made in the FY 2012 IPPS/LTCH PPS final rule regarding the number and types of LTCHs that may not receive the full payment update as a result of failing to submit data to the Secretary under the LTCHQR Program remain valid. We believe that a majority of LTCHs will submit data because they will view the new quality reporting program as an important step in improving the quality of care patients receive in these facilities. We believe that most LTCHs will quickly and easily adapt to this new quality reporting program and find that the benefits of this program outweigh the burdens.

In section VIII.D.3.d. of the preamble of this proposed rule, for FY 2015, we have proposed to retain the three quality measures that were finalized for use in the LTCHQR Program in the FY 2012 IPPS/LTCH PPS final rule. These measures are: (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. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51780 through 51781), we estimated that the total yearly cost to all LTCH that are paid under the LTCH PPS 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) would be approximately $756,326. In section XI.B.9. of the preamble of this proposed rule, we use this same estimate.

It is important to note that, as part of its endorsement maintenance process under NQF's Patient Safety Measures Project (*http://www.qualityforum.org/projects/patient safety_measures.aspx*), the NQF reviewed the CAUTI and CLABSI measures that we adopted in the FY 2012 IPPS/LTCH final rule. As a result of this review, the NQF expanded the scope of endorsement of these measures to include additional care settings, including LTCHs. We are proposing, in this proposed rule, that the CAUTI and CLABSI measures be adopted in their expanded form for the FY 2014 payment determination. and all subsequent fiscal year payment determinations. We do not anticipate that the expansion of the CAUTI and CLABSI measures will cause any increase in the burden to providers because there will be no change in the way that these data are collected or reported.

In the FY 2012 IPPS/LTCH PPS final rule and in the preamble of this proposed rule, we estimate that the total cost to all LTCHs 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 would be $756,326. We believe that this remains a valid estimation of the total financial burden that all LTCHs will incur as a result of the LTCHQR Program, even considering that the CAUTI and CLABSI measures were reviewed and expanded by the NQF.

We do not believe that that the burden estimate that we made in the FY 2012 IPPS/LTCH PPS final rule is affected by the expansion of the CAUTI and CLABSI measures because these expanded measures are essentially the same measures that were adopted in the FY 2012 IPPS/LTCH PPS final rule, except that the measure names have been changed and the measures have been expanded so as to be applicable to the LTCH setting. The expanded CAUTI and CLABSI measures make no changes to the way that this data is to be collected and reported by LTCHs. Thus, use of the expanded CAUTI and CLABSI measures will place no additional financial burden on LTCHs. In addition, we believe that this financial burden should remain relatively stable over the first several years of this quality reporting program, subject to normal inflationary increases, such as increased labor wage rates.

In section VIII.D.3.d. of the preamble of this proposed rule, for the FY 2016 LTCHQR Program, we are proposing to add five additional quality measures. These proposed quality measures are: (1) Percent of Nursing Home Residents Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680); (2) Percent of Residents Assessed and Appropriately Given the Pneumococcal Vaccine (Short-Stay) (NQF #0682); (3) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431); (4) Ventilator Bundle (NQF #0302); and (5) Restraint Rate per 1,000 Patient Days (not NQF-endorsed).

As we noted previously, the LTCHQR Program has not been fully implemented, as data collection will not begin until October 1, 2012. At this time, we provide estimates of the costs associated with the collection and submission of data in section XI.B.9 of the preamble of this proposed rule.

We invite public comment on the impact that the proposed measures would have on LTCHs.

O. Effects of Proposed Quality Reporting Requirements for Ambulatory Surgical Centers (ASCs)

In section XIV.K. of the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74517), we finalized quality reporting measures for the CYs 2014, 2015, and 2016 payment determinations under the ASC Quality Reporting Program. In section VIII.E. of the preamble of this proposed rule, we discuss our proposals to adopt requirements for ASCs to report quality data under the ASC Quality Reporting Program in order to be eligible to receive the full ASC annual payment update. We are unable at this time to estimate the number of ASCs that may not receive the full ASC annual payment update in CYs 2014, 2015, and 2016 because we do not have data that would allow us to make a reasonable estimate. ASCs have not yet submitted quality data to CMS; therefore, there are no data from previous program operations on which to base an estimate. Further, data from other quality programs would not allow us to make a reasonable estimate. Although we might be able to make a reasonable estimate based on data from other programs with respect to the structural and process of care measures, we are unable to estimate the number of ASCs that would not be eligible to receive the full ASC annual payment update with respect to the submission of QDCs for the claims-based measures. There are two other quality data reporting programs that utilize QDCs reported on claims similar to what we finalized in the ASC Quality Reporting Program: the Physician Quality Reporting System (PQRS) and the E-Prescribing Incentive Program. However, these programs do not have comparable reporting incentives. PQRS currently has no penalty for not meeting reporting requirements, and the E-Prescribing Incentive Program until CY 2012 was solely incentive-based, rather than penalty-based.

P. Effects of Proposed Requirements for the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

In section VIII.F. of the preamble of this proposed rule, we discuss our proposals to implement the IPFQR Program.

1. General Background and Intent for Implementation of the Proposed IPFQR Program

We intend to achieve several goals as we develop and implement the proposed IPFQR Program. One goal of the proposed IPFQR Program is to implement the statutory requirements of section 1886(s)(4) of the Act as added by sections 3401(f)(4) and 10322(a) of the Affordable Care Act. However, in addition, it is important to note that one of our priorities is to help achieve better health and better health care for individuals through collection of valid, reliable, and relevant measures of quality health care data. Such data can be shared with appropriate health care related organizations and used to further the development of health care quality, which, in turn, helps to further CMS' objectives and goals. Health care organizations can use such health care quality data for many purposes such as in their risk management programs, health care acquired infection prevention programs and research and development of medical programs, among others.

More importantly, as required by the Act, we intend to share the information obtained from the IPFQR Program with the public. These data will be displayed on the CMS Web site. The goals of making these data available to the public in a properly risk-adjusted, public user-friendly and relevant format, include, but are not limited to: (1) Keeping the public informed of the quality of care that is being provided in IPFs as a whole; (2) keeping the public informed of the quality of care being provided in specific IPFs; (3) allowing the public to compare and contrast the data about specific IPFs, thus enabling the public to make informed health care decisions regarding IPFs; and (4) providing information about current trends in health care. There are certainly many other public uses for these quality data concerning IPFs. However, giving the public access to information about the quality of care in specific facilities and keeping the public informed of trends in health care has always been of high priority to CMS.

CMS also seeks to align the new IPFQR Program reporting requirements with current HHS high priority conditions and topics and to ultimately provide a comprehensive assessment of the quality of health care delivered in a variety of settings.

2. Anticipated Effects

This proposed rule would affect all IPFs participating in Medicare. The facilities will have to register with QualityNet and take the proper training in order to be adequately prepared to use the QualityNet system to submit the data. The anticipated burden to these providers consists of the following: (1) The initial registration of the facility with QualityNet; (2) training of the appropriate staff members on how to use the QualityNet reporting program; (3) the time required for collection and aggregation of data; and (4) the time required for entry of the data into the QualityNet database by the IPF's representative.

We have estimated the burdens associated with IPFs reporting aggregated-level data on QualityNet. In our burden calculation, we have included the time used for chart abstraction and for training personnel on collection of chart-abstracted data, aggregation of the data, as well as training for submitting the aggregate-level data through QualityNet. We estimate that the annual hourly burden to each IPF for the collection, submission, and training of personnel for submitting all quality measures is approximately 821 hours in a year for each IPF. Thus, the average hourly burden to each IPF is approximately 68 hours per month. At this time we have no way to estimate how many IPFs will participate in the program. Therefore, we cannot estimate the financial impact.

We are proposing to adopt the quality measures, abstraction methods, population, sampling, and reporting approaches used by TJC. One reason we selected this proposed approach was to minimize the burden on IPFs. There were 1,741 existing IPFs, of which 450 (approximately 26 percent) are currently reporting the proposed measures to TJC. For these IPFs, we estimate that the burden will be minimal.

Q. Effects of Proposed Requirements for Provider and Practitioner Medical Record Deadlines and Claims Denials

In section X. of the preamble of this proposed rule, we discuss changes for practitioners to follow in responding to requests for medical records from Quality Improvement Organizations (QIOs). The proposed changes would require practitioners to adhere to the 21-day and 30-day timeframes in the regulations, which are currently only applicable to providers. In addition, the proposed changes would give QIOs the authority to effectuate claim denials for practitioners who fail to submit the medical records within these timeframes. QIOs have authority to carry out claim denials for providers who fail to submit medical records, but similar provisions do not exist for practitioners. In fact, to this point, the QIOs' only option for practitioners who fail to submit medical records has been to refer the matter to the HHS Inspector General, and it would seem appropriate to identify a step, short of recommending sanctions, for the QIOs to pursue.

On average, QIOs request approximately 2,000 medical records from practitioners each year. In general, requests for medical records from both practitioners and providers are ultimately fulfilled, but the average response time is considerably longer for practitioners than for providers. Because we are working to improve the QIOs' response time in completing various review activities, the proposed application of the timeframes to practitioners is an important step in our efforts. In addition, given that the QIOs have the need for and the statutory authority to request medical records within a reasonable period of time, they have relied on the same 21-day and 30-day timeframes for practitioners. We believe that having the regulatory timeframe and authority to carry out technical denials for providers have generally resulted in providers complying with medical record requests within the required timeframes. In line with this, we believe that having this same regulatory authority for practitioners will result in practitioners complying with medical record requests within their required timeframes, which should, in turn, greatly will reduce the potential for any technical denials. Moreover, because vendors are increasingly being used by providers and practitioners to respond to requests for medical records, the increasing effectiveness of this process could well further diminish any impact of the proposed regulatory changes. While we believe the impact would be insignificant, at this time, we cannot determine the precise number of claim denials that could occur for practitioners as a result of these proposed changes.

R. Alternatives Considered

This proposed rule contains a range of proposed 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.

S. Overall Conclusion

1. Acute Care Hospitals

Table I of section I.G. 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 increase of 0.9 percent in operating payments. We estimate that operating payments would increase by approximately $904 million in FY 2013 relative to FY 2012. In addition, we estimate a savings of $24 million associated with the HACs policies in FY 2013, which is an additional $2 million in savings than in FY 2012. In FY 2012, pursuant to section 1109 of the Affordable Care Act, we distributed an additional $250 million to qualifying hospitals resulting in a decrease of $250 million in payments to hospitals in FY 2013 relative to FY 2012. Furthermore, we estimate that the expiration of the expansion of low-volume payments under sections 3125 and 10314 of the Affordable Care Act in FY 2013 will result in a decrease in payments of $300 million compared to low-volume payments made in FY 2012. Finally, we estimate that our proposal to count labor and delivery bed days in the available bed day count for IME and DSH payments will reduce IME payments by approximately $170 million for FY 2013. These estimates, added to our FY 2013 operating estimate of $904 million, would result in an increase of $182 million for FY 2013. We estimate that capital payments will experience a −0.1 percent decrease in payments per case, as shown in Table III of section I.I. of this Appendix. We project that there would be an $8 million decrease in capital payments in FY 2013 compared to FY 2012. The proposed cumulative operating and capital payments should result in a net increase of $174 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.

2. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments per discharge in FY 2013. In the impact analysis, we are proposing to use the rates, factors, and policies presented in this proposed rule, including updated wage index values and relative weights, and the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2013. Accordingly, based on the best available data for the 427 LTCHs in our database, we estimate that FY 2013 LTCH PPS payments would increase approximately $100 million relative to FY 2012. In addition, we estimate that extension of the moratorium on the application of the ''25 percent threshold'' payment adjustment policy, as provided by section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(a) and 10312(a) of the Affordable Care Act, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013, will result in a payment impact of approximately $170 million to LTCHs.

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/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 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 2012 TO FY 2013

Category	Transfers
Annualized Monetized Transfers.	$174 million.
From Whom to Whom	Federal Government to IPPS Medicare Providers.
Total	$174 million.

B. LTCHs

As discussed in section I.J. 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 in FY 2013 relative to FY 2012 of approximately $100 million for the 427 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/sites/default/files/omb/assets/regulatory_matters_pdf/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 427 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 2012 LTCH PPS TO THE FY 2013 LTCH PPS

Category	Transfers
Annualized Monetized Transfers.	Positive transfer—Estimated increase in expenditures: $100 million.

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $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 I.J. 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 regulatory flexibility analysis. In this proposed rule, we are soliciting public comments on our estimates and analysis of the impact of our proposals on those small entities.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 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 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 in section I.G. of this Appendix for the quantitative effects of the proposed policy changes under the IPPS for operating costs.)

V. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2012, that threshold level is approximately $136 million. This proposed rule will not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

VI. 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 rate for SCHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we have made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2013, we plan to include the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2013

A. Proposed FY 2013 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 2013 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 2012 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 data 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.H.1. 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 0.8 percent.

Therefore, based on IGI's first quarter 2012 forecast of the FY 2013 market basket increase, we are proposing an applicable percentage increase to the FY 2012 operating standardized amount of 2.1 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 0.8 percentage point 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 0.1 percent (that is, the FY 2013 estimate of the market basket rate-of increase of 3.0 percent less 2.0 percentage points for failure to submit quality data, less an adjustment of 0.8 percentage point for economy-wide productivity, and less an additional adjustment of 0.1 percentage point).

B. Proposed Update for SCHs for FY 2013

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2013 applicable percentage increase in the hospital-specific rate for SCHs 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 rate for SCHs 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 rate applicable to SCHs of 2.1 percent for hospitals that submit quality data or 0.1 percent for hospitals that fail to submit quality data.

C. Proposed FY 2013 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 2.1 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.

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 that the FY 2013 rate-of-increase percentage to be applied to the target amount for children's hospitals, cancer hospitals, and RNHCIs would be the percentage increase in the IPPS operating market basket. For this proposed rule, the current estimate of the FY 2013 IPPS operating market basket percentage increase is 3.0 percent.

E. Proposed Update for LTCHs

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section VII. of the preamble of this proposed rule, we are proposing to establish an update to the LTCH PPS standard Federal rate for FY 2013 based on the full LTCH PPS market basket increase estimate (for this proposed rule, estimated to be 3.0 percent), subject to an adjustment based on changes in economy-wide productivity and an additional reduction of 0.1 percentage point. The productivity adjustment described in section 1886(b)(3)(B)(xi)(ii) of the Act is currently estimated to be 0.8 percent for FY 2013. In addition, section 1886(m)(3)(A)(ii) of the Act requires that any annual update for FY 2013 be reduced by the ''other adjustment'' at section 1886(m)(4)(C) of the Act, which is 0.1 percentage point. Therefore, based on IGI's

first quarter 2012 forecast of the proposed FY 2013 market basket increase, we are proposing an annual update to the LTCH PPS standard Federal rate of 2.1 percent (that is, the current FY 2013 estimate of the proposed market basket rate-of-increase of 3.0 percent less an adjustment of 0.8 percentage point for economy-wide productivity and less 0.1 percentage point). Accordingly, we are proposing to apply an update factor of 1.021 in determining the proposed LTCH PPS standard Federal rate for FY 2013. Furthermore, we are proposing to phase in a one-time prospective adjustment to the standard Federal rate under § 412.523(d)(3) by applying a factor of 0.98734 (or approximately −1.3 percent), which would not be applicable to payments for LTCH PPS discharges occurring on or before December 28, 2012 (consistent with current law).

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update equal to one percent for FY 2013. 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 2.1 percent (that is, the FY 2013 estimate of the market basket rate-of-increase of 3.0 percent less an adjustment of 0.8 percentage point for MFP and less 0.1 percentage point). We are recommending that the same applicable percentage increase apply to SCHs 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 certain other types of hospitals excluded from the IPPS. Consistent with our proposal for these facilities, we are recommending an update for children's hospitals, cancer hospitals, and RNHCIs of 3.0 percent.

For FY 2013, consistent with policy proposal set forth in section VII. of the preamble of this proposed rule, we are recommending an update of 2.1 percent to the LTCH PPS standard Federal rate.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2012 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, 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 use the difference between the increase of the applicable percentage increase under the IPPS for FY 2013 and MedPAC's recommendation of a 1.0 percent update to gradually recover past overpayments due to documentation and coding changes.

Response: With regard to MedPAC's recommendation of an update to the hospital inpatient rates equal to one percent, for FY 2013, 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) of the Act, as amended by these sections, sets the requirements for the FY 2013 applicable percentage increase. Therefore, we have proposed an applicable percentage increase for FY 2013 of 2.1 percent, provided the hospital submits quality data, consistent with these statutory requirements.

With regard to MedPAC's recommendation that Congress should require the Secretary to use the difference between the increase of the applicable percentage increase under the IPPS for FY 2013 and MedPAC's recommendation of a 1.0 percent update to gradually recover post overpayments due to documentation and coding changes, we refer readers to section II.D. of the preamble of this proposed rule for a complete discussion of the proposed FY 2013 documentation and coding adjustments. In section II.D. of the preamble of this proposed rule, we are proposing a prospective adjustment of 2.7 percent to the FY 2013 standardized amount to remove the remaining effect of documentation and coding that occurred in FY 2008, FY 2009, and FY 2010. We note that section 7(b)(1)(B) of Pub. L. 110–90 authorized recoupments of overpayments due to documentation and coding improvements for FY 2008 and FY 2009, and under this authority, such recoupments had to be made no later than FY 2012. Accordingly, any recoupments of overpayments due to documentation and coding improvements beyond the authority of section 7(b)(1)(B) of Public Law 110–90 would require changes to current law by Congress.

We also 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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