DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 412, 413, 415, 422, 424, 485, and 488

[CMS–1607–P] RIN 0938–AS11

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program

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. Some of the proposed changes 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), the Protecting Access to Medicare Act of 2014, and other legislation. These proposed changes would be applicable to discharges occurring on or after October 1, 2014, unless otherwise specified in this proposed rule. 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 proposed updated rate-of-increase limits would be effective for cost reporting periods beginning on or after October 1, 2014.

We also are proposing to update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) and to implement certain statutory changes to the LTCH PPS under the Affordable Care Act and the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 and the Protecting Access to Medicare Act of 2014. In addition we are proposing to revise the interruption of stay policy for LTCHs and to retire the ''5 percent'' payment adjustment for co-located LTCHs. While many of the statutory mandates of the Pathway for SGR Reform Act will apply to discharges occurring on or after October 1, 2014, others will not begin to apply until 2016 and beyond. However, in light of the degree of forthcoming change, we discuss changes infra and request public feedback to inform our proposals for FY 2016 in this proposed rule as well.

In addition, we are proposing to make a number of changes relating to direct graduate medical education (GME) and indirect medical education (IME) payments. We are proposing to establish new requirements or revise requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, and LTCHs) that are participating in Medicare.

We are proposing to update policies relating to the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program. In addition, we are proposing changes to the regulations governing provider administrative appeals and judicial review relating to appropriate claims in provider cost reports; updates to the reasonable compensation equivalent (RCE) limits for services furnished by physicians to teaching hospitals excluded from the IPPS; regulatory revisions to broaden the specified uses of risk adjustment data and to specify the conditions for release of risk adjustment data to entities outside of CMS; and changes to the enforcement procedures for organ transplant centers.

We are proposing to align the reporting and submission timelines for clinical quality measures for the Medicare EHR Incentive Program for eligible hospitals and critical access hospitals (CAHs) with the reporting and submission timelines for the Hospital IQR Program. In addition, we provide guidance and clarification of certain policies for eligible hospitals and CAHs such as our policy for reporting zero denominators on clinical quality measures and our policy for case threshold exemptions.

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 30, 2014.

ADDRESSES: In commenting, please refer to file code CMS–1607–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1607–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 via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1607–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

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

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

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

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

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

For information on viewing public comments, we refer readers to the

beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Donald Thompson, (410) 786–4487, and Tiffany Swygert, (410) 786–4465, 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, and Medicare Disproportionate Share Hospital (DSH) 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.

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

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

Karen Nakano, (410) 786–6889, Hospital 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, Hospital Inpatient Quality Reporting—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

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

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

James Poyer, (410) 786–2261, PPS-Exempt Cancer Hospital Quality Reporting Issues.

Kellie Shannon, (410) 786–0416, Appropriate Claims in Provider Cost Reports; Administrative Appeals by Providers and Judicial Review Issues.

Amelia Citerone, (410) 786–3901, and Robert Kuhl (410) 786–4597, Reasonable Compensation Equivalent (RCE) Limits for Physician Services Provided in Providers.

Ann Hornsby, (410) 786–1181, and Jennifer Harlow, (410) 786–4549, Medicare Advantage Encounter Data Issues.

Thomas Hamilton, (410) 786–6763, Organ Transplant Center Issues.

Jennifer Phillips, (410) 786–1023, 2-Midnight Rule Benchmark Issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All public 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 public comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

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

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 the proposed rule and the final rule were published in the **Federal Register** as part of the annual proposed and final rules. However, beginning in FY 2012, some of the IPPS tables and LTCH PPS tables are no longer published in the **Federal Register**. Instead, these tables are 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/Medicare/medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled, ''FY 2015 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download''. The LTCH PPS tables for this FY 2015 proposed rule are available only through the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1607–P. For complete details on the availability of the tables referenced in this proposed rule, we refer readers to section VI. of the Addendum to this proposed rule.

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

Acronyms

3M 3M Health Information System
AAMC Association of American Medical Colleges
ACGME Accreditation Council for Graduate Medical Education
ACoS American College of Surgeons
AHA American Hospital Association
AHIC American Health Information Community
AHIMA American Health Information Management Association
AHRQ Agency for Healthcare Research and Quality
AJCC American Joint Committee on Cancer
ALOS Average length of stay
ALTHA Acute Long Term Hospital Association
AMA American Medical Association
AMGA American Medical Group Association
AMI Acute myocardial infarction
AOA American Osteopathic Association
APR DRG All Patient Refined Diagnosis Related Group System
APRN Advanced practice registered nurse
ARRA American Recovery and Reinvestment Act of 2009, Public Law 111–5
ASCA Administrative Simplification Compliance Act of 2002, Public Law 107–105
ASITN American Society of Interventional and Therapeutic Neuroradiology
ATRA American Taxpayer Relief Act of 2012, Public Law 112–240
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
CABG Coronary artery bypass graft [surgery]
CAH Critical access hospital
CARE [Medicare] Continuity Assessment Record & Evaluation [Instrument]
CART CMS Abstraction & Reporting Tool
CAUTI Catheter-associated urinary tract infection
CBSAs Core-based statistical areas
CC Complication or comorbidity
CCN CMS Certification Number
CCR Cost-to-charge ratio
CDAC [Medicare] Clinical Data Abstraction Center
CDAD *Clostridium difficile*-associated disease
CDC Center for Disease Control and Prevention
CERT Comprehensive error rate testing
CDI *Clostridium difficile* (C. difficile)
CFR Code of Federal Regulations
CLABSI Central line-associated bloodstream infection
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
COPD Chronis obstructive pulmonary disease

CPI Consumer price index
CQM Clinical quality measure
CRNA Certified registered nurse anesthetist
CY Calendar year
DACA Data Accuracy and Completeness Acknowledgement
DPP Disproportionate patient percentage
DRA Deficit Reduction Act of 2005, Public Law 109–171
DRG Diagnosis-related group
DSH Disproportionate share hospital
EBRT External Bean Radiotherapy
ECI Employment cost index
eCQM Electronic clinical quality measure
EDB [Medicare] Enrollment Database
EHR Electronic health record
EMR Electronic medical record
EMTALA Emergency Medical Treatment and Labor Act of 1986, Public Law 99–272
EP Eligible professional
FAH Federation of American Hospitals
FDA Food and Drug Administration
FFY Federal fiscal year
FPL Federal poverty line
FQHC Federally qualified health center
FR **Federal Register**
FTE Full-time equivalent
FY Fiscal year
GAF Geographic Adjustment Factor
GME Graduate medical education
HAC Hospital-acquired condition
HAI Healthcare-associated infection
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCFA Health Care Financing Administration
HCO High-cost outlier
HCRIS Hospital Cost Report Information System
HHA Home health agency
HHS Department of Health and Human Services
HICAN Health Insurance Claims Account Number
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
HIPC Health Information Policy Council
HIS Health information system
HIT Health information technology
HMO Health maintenance organization
HPMP Hospital Payment Monitoring Program
HSA Health savings account
HSCRC [Maryland] Health Services Cost Review Commission
HSRV Hospital-specific relative value
HSRVcc Hospital-specific relative value cost center
HQA Hospital Quality Alliance
HQI Hospital Quality Initiative
IBR Intern- and Resident-to-Bed Ratio
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
IPFQR Inpatient Psychiatric Facility Quality Reporting [Program]
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
MAP Measure Application Partnership
MCC Major complication or comorbidity
MCE Medicare Code Editor
MCO Managed care organization
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
MU Meaningful Use [EHR Incentive Program]
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
NOP Notice of Participation
NQF National Quality Forum
NQS National Quality Strategy
NTIS National Technical Information Service
NTTAA National Technology Transfer and Advancement Act of 1991, Public Law 104–113
NVHRI National Voluntary Hospital Reporting Initiative
OACT [CMS] Office of the Actuary
OBRA 86 Omnibus Budget Reconciliation Act of 1986, 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
OQR [Hospital] Outpatient Quality Reporting
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
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
PSI Patient safety indicator
PS&R Provider Statistical and Reimbursement [System]
PQRS Physician Quality Reporting System
QIG Quality Improvement Group [CMS]
QIO Quality Improvement Organization
QRDA Quality Reporting Data Architecture
RCE Reasonable compensation equivalent
RFA Regulatory Flexibility Act, Public Law 96–354
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
RSMR Risk-standardized mortality rate
RSRR Risk-standard readmission rate
RTI Research Triangle Institute, International
RUCAs Rural-urban commuting area codes
RY Rate year
SAF Standard Analytic File
SCH Sole community hospital
SCIP Surgical Care Improvement Project
SFY State fiscal year
SIC Standard Industrial Classification
SNF Skilled nursing facility
SOCs Standard occupational classifications
SOM State Operations Manual
SSI Surgical site infection
SSI Supplemental Security Income
SSO Short-stay outlier
SUD Substance use disorder
TEFRA Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97–248
TEP Technical expert panel
THA/TKA Total hip arthroplasty/Total knee arthroplasty
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
UMRA Unfunded Mandate Reform Act, Public Law 104–4
VBP [Hospital] Value Based Purchasing [Program]
VTE Venous thromboembolism

Table of Contents

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This proposed rule would make payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it would make payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). It also would make policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded 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 2015 and subsequent fiscal years. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).
- Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; cancer hospitals; and short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.
- Sections 123(a) and (c) of 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 specify that payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services and that these payments are generally based on 101 percent of reasonable cost.
- Section 1866(k) of the Act, as added by section 3005 of the Affordable Care Act, which establishes a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as ''PPS-Exempt Cancer Hospitals.''
- Section 1886(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. A payment for indirect medical education (IME) is made under section 1886(d)(5)(B) 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.
- Section 1886(p) of the Act, as added by section 3008 of the Affordable Care Act, which establishes an adjustment to hospital payments for hospital-acquired conditions (HACs), or a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.
- Section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act and amended by section 10309 of the Affordable Care Act, which 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(r) of the Act, as added by section 3133 of the Affordable Care Act, which provides for a reduction to disproportionate share payments under section 1886(d)(5)(F) of the Act and for a new uncompensated care payment to eligible hospitals. Specifically, section 1886(r) of the Act now requires that, for ''fiscal year 2014 and each subsequent fiscal year,'' ''subsection (d) hospitals'' that would otherwise receive a ''disproportionate share payment . . . made under subsection (d)(5)(F)'' will receive two separate payments: (1) 25 percent of the amount they previously would have received under subsection (d)(5)(F) for DSH (''the empirically justified amount''), and (2) an additional payment for the DSH hospital's proportion of uncompensated care, determined as the product of three factors. These three factors are: (1) 75

percent of the payments that would otherwise be made under subsection (d)(5)(F); (2) 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured (minus 0.1 percentage points for FY 2014, and minus 0.2 percentage points for FY 2015 through FY 2017); and (3) a hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.

- Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for SGR Reform Act of 2013, which provided for the establishment of patient criteria for payment under the LTCH PPS for implementation beginning in FY 2016.
- Section 1206(b)(1) of the Pathway for SGR Reform Act of 2013, which further amended section 114(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, by retroactively reestablishing and extending the statutory moratorium on the full implementation of the 25-percent threshold payment adjustment policy under the LTCH PPS so that the policy will be in effect for 9 years (except for ''grandfathered'' hospital-within-hospitals (HwHs), which are permanently exempt from this policy); and section 1206(b)(2) (as amended by section 112(b) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93)), which together further amended section 114(d) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(c) and 10312(a) of the Affordable Care Act to establish a new moratoria (subject to certain defined exceptions) on the development of new LTCHs and LTCH satellite facilities and a new moratorium on increases in the number of beds in existing LTCHs and LTCH satellite facilities beginning January 1, 2015 and ending on September 30, 2017; and section 1206(d), which instructs the Secretary to evaluate payments to LTCHs classified under section 1886(b)(1)(C)(iv)(II) of the Act and to adjust payment rates in FY 2015 or FY 2016 under the LTCH PPS, as appropriate, based upon the evaluation findings.
- Section 1886(m)(5)(D)(iv) of the Act, as added by section 1206(c) of the Pathway for SGR Reform Act of 2013, which provides for the establishment, no later than October 1, 2015, of a functional status quality measure under the LTCHQR Program for change in mobility among inpatients requiring ventilator support.

To conform regulations to the statutory requirements of the Provider Reimbursement Review Board (Board) appeals based on untimely determinations of the Medicare Administrative Contractor (MAC), in this proposed rule, we are proposing to amend the regulations to eliminate the provider dissatisfaction requirement as a condition for Board jurisdiction over such appeals. We are proposing a similar amendment to the regulations for appeals to MAC hearing officers, to maintain consistency between the regulations for MAC and Board appeals. We also are proposing to codify in the cost reporting regulations our existing policy, implemented in section 115 of the Provider Reimbursement Manual, requiring providers to include an appropriate claim for an item in its cost report. In addition, we are proposing that providers' failure to include an appropriate claim for an item in its cost report will result in foreclosure of payment in the notice of program reimbursement and in any decision or order issued by a reviewing entity in an administrative appeal filed by the provider.

We are proposing to align the reporting and submission timelines for clinical quality measures for the Medicare EHR Incentive Program for eligible hospitals and critical access hospitals (CAHs) with the reporting and submission timelines for the Hospital IQR Program. In addition, we provide guidance and clarification of certain policies for eligible hospitals and CAHs such as our policy for reporting zero denominators on clinical quality measures and our policy for case threshold exemptions.

In addition, this proposed rule contains several proposals that are not directly related to these Medicare payment systems, such as regulatory revisions to broaden the specified uses and reasons for disclosure of risk adjustment data and to specify the conditions for release of risk adjustment data to entities outside of CMS and changes to the enforcement procedures for organ transplant centers. The specific statutory authority for these other proposals is discussed in the relevant sections below.

2. Summary of the Major Provisions

a. MS–DRG Documentation and Coding Adjustment

Section 631 of the American Taxpayer Relief Act (ATRA, Pub. L. 112–240) amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment to the standardized amount of Medicare payments to acute care hospitals to account for changes in MS–DRG documentation and coding that do not reflect real changes in case-mix, totaling $11 billion over a 4-year period of FYs 2014, 2015, 2016, and 2017. This adjustment represents the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Public Law 110–90.

While our actuaries estimated that a −9.3 percent adjustment to the standardized amount would be necessary if CMS were to fully recover the $11 billion recoupment required by section 631 of the ATRA in FY 2014, it is often our practice to delay or phase in rate adjustments over more than one year, in order to moderate the effects on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, we made a −0.8 percent recoupment adjustment to the standardized amount in FY 2014. We are proposing to make an additional −0.8 percent recoupment adjustment to the standardized amount in FY 2015.

b. Reduction of Hospital Payments for Excess Readmissions

We are proposing changes in policies to the Hospital Readmissions Reduction Program, which is established under section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. For FYs 2013 and 2014, these conditions are acute myocardial infarction, heart failure, and pneumonia. For FY 2014, we established additional exclusions to the three existing readmission measures (that is, the excess readmission ratio) to account for additional planned readmissions. We also established additional readmissions measures, Chronic Obstructive Pulmonary Disease (COPD), and Total Hip Arthroplasty and Total Knee Arthroplasty (THA/TKA), to be used in the Hospital Readmissions Reduction Program for FY 2015 and future years. We are proposing to expand the readmissions measures for FY 2017 and future years by adding a measure of patients readmitted following coronary artery bypass graft (CABG) surgery. We also are proposing to refine the readmission measures and related methodology for FY 2015 and subsequent years payment determinations. In addition, we are proposing that the readmissions payment adjustment factors for FY 2015

can be no more than a 3-percent reduction in accordance with the statute. We also are proposing to revise the calculation of aggregate payments for excess readmissions to include THA/TKA and COPD readmissions measures beginning in FY 2015.

c. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o) of the Act 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.

In this proposed rule, we are proposing to adopt quality measures for the FY 2017, FY 2019, and FY 2020 Hospital VBP Program years and to establish performance periods and performance standards for measures to be adopted for those fiscal years. We also are proposing to adopt additional policies related to performance standards and to revise the domain weighting previously adopted for the FY 2017 Hospital VBP Program.

d. Hospital-Acquired Condition (HAC) Reduction Program

In this proposed rule, we are proposing a change in the scoring methodology with the addition of a previously finalized measure for the FY 2016 payment adjustment under the HAC Reduction Program. Section 1886(p) of the Act, as added under section 3008(a) of the Affordable Care Act, establishes an adjustment to hospital payments for HACs, or a HAC Reduction program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce HACs, effective for discharges beginning on October 1, 2014 and for subsequent program years. This 1-percent payment reduction applies to a hospital whose ranking is in the top quartile (25 percent) of all applicable hospitals, relative to the national average, of conditions acquired during the applicable period and on all of the hospital's discharges for the specified fiscal year. The amount of payment shall be equal to 99 percent of the amount of payment that would otherwise apply to such discharges under section 1886(d) or 1814(b)(3) of the Act, as applicable.

e. Proposed Changes to the DSH Payment Adjustment and the Provision of Additional Payment for Uncompensated Care

Section 3133 of the Affordable Care Act modified the Medicare disproportionate share hospital (DSH) payment methodology beginning in FY 2014. Under section 1886(r) of the Act, which was added by section 3133 of the Affordable Care Act, starting in FY 2014, DSHs will receive 25 percent of the amount they previously would have received under the current statutory formula for Medicare DSH payments. The remaining amount, equal to 75 percent of what otherwise would have been paid as Medicare DSH payments, will be paid as additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH hospital will receive its additional amount based on its share of the total amount of uncompensated care for all Medicare DSH hospitals for a given time period. In this proposed rule, we are proposing updates to the uncompensated care amount to be distributed for FY 2015, and we are proposing changes to the methodology to calculate the uncompensated care payment amounts to be distributed such that we combine uncompensated care data for hospitals that have underwent a merger in order to calculate their relative share of uncompensated care.

f. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) 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 to add nine new measures for the Hospital IQR Program for the FY 2017 payment determination and subsequent years. We are proposing to remove five measures for the FY 2016 payment determination and subsequent years. We also are proposing to remove 15 chart-abstracted measures from the FY 2016 payment determination's measure set. However, we are proposing to retain an electronic clinical quality measure version of 10 of those chart-abstracted measures for the program.

g. Proposed Changes to the LTCH PPS

Section 1206(b) of the Pathway for SGR Reform Act provides for the retroactive reinstatement and extension, for an additional 4 years, of the moratorium on the full implementation of the 25-percent threshold payment adjustment under the LTCH PPS established under section 114(c) of the MMSEA, as further amended by subsequent legislation. In keeping with this mandate, we are proposing to reinstate this payment adjustment retroactively for LTCH cost reporting periods beginning on or after July 1, 2013 or October 1, 2013.

Section 1206(b)(2) of the Pathway for SGR Reform Act, as amended by section 112(b) of the Protecting Access to Medicare Act of 2014, provides for new statutory moratoria on the establishment of new LTCHs and LTCH satellite facilities (subject to certain defined exceptions) and a new statutory moratorium on bed increases in existing LTCHs effective for the period beginning April 1, 2014 and ending September 30, 2017.

In accordance with section 1206(d) of the Pathway for SGR Reform Act of 2013, we are proposing to apply a payment adjustment under the LTCH PPS to subclause (II) LTCHs beginning in FY 2015 that would result in payments to this type of LTCH resembling reasonable cost payments under the TEFRA payment system model.

We also are proposing to make changes to the LTCH interruption of stay policy, which is a payment adjustment that is applied when, during the course of an LTCH hospitalization, a patient is discharged to an inpatient acute care hospital, an IRF, or a SNF for treatment or services not available at the LTCH for a specified period followed by readmittance to the same LTCH.

3. Summary of Costs and Benefits

• Proposed Adjustment for MS–DRG Documentation and Coding Changes. We are proposing a −0.8 percent recoupment adjustment to the standardized amount for FY 2015 to implement, in part, the requirement of section 631 of the ATRA that the Secretary make an adjustment totaling $11 billion over a 4-year period of FYs 2014, 2015, 2016, and 2017. This recoupment adjustment represent the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Public Law 110–90.

While our actuaries estimated that a −9.3 percent recoupment adjustment to the standardized amount would be necessary if CMS were to fully recover the $11 billion recoupment required by

section 631 of the ATRA in FY 2014, it is often our practice to delay or phase in rate adjustments over more than one year, in order to moderate the effects on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases and the adjustment we made for FY 2014, we are proposing to make a −0.8 percent recoupment adjustment to the standardized amount in FY 2015. We estimated that this level of adjustment, combined with leaving the −0.8 percent adjustment made for FY 2014 in place, will recover up to $2 billion in FY 2015. Taking into account the approximately $1 billion recovered in FY 2014, this will leave approximately $8 billion remaining to be recovered by FY 2017.

• Reduction to Hospital Payments for Excess Readmissions. The provisions of section 1886(q) of the Act which establishes the Hospital Readmissions Reduction Program are not budget neutral. For FY 2015, a hospital's readmissions payment adjustment factor is the higher of a ratio of a hospital's aggregate payments for excess readmissions to its aggregate payments for all discharges, or 0.97 (that is, or a 3-percent reduction). In this proposed rule, we estimate that the reduction to a hospital's base operating DRG payment amount to account for excess readmissions of selected applicable conditions under the Hospital Readmissions Reduction Program will result in a 0.2 percent decrease in payments to hospitals for FY 2015 relative to FY 2014.

• Value-Based Incentive Payments Under the Hospital Value-Based Purchasing (VBP) Program. We estimate that there will be no net financial impact to the Hospital VBP Program for FY 2015 in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given fiscal year must be equal to the total amount of base operating DRG payment amount reductions for that year, as estimated by the Secretary. The estimated amount of base operating DRG payment amount reductions for FY 2015, and therefore the estimated amount available for value-based incentive payments for FY 2015 discharges, is approximately $1.4 billion. We believe that the program's benefits will be seen in improved patient outcomes, safety, and in the patient's experience of care. However, we cannot estimate these benefits in actual dollar and patient terms.

• Proposed Payment Adjustment Under the HAC Reduction Program for FY 2015. Under section 1886(p) of the Act, (as added by section 3008 of the Affordable Care Act), the incentive to reduce hospital-acquired conditions with a payment adjustment to applicable hospitals under the HAC Reduction Program is made beginning FY 2015. We estimate that, under this proposal, 753 hospitals would be subject to the 1-percent reduction, and that overall payments will decrease approximately 0.3 percent or $330 million.

• Proposed Changes Relating to the Medicare DSH Payment Adjustment and Provision of Additional Payment for Uncompensated Care. Under section 1886(r) of the Act (as added by section 3313 of the Affordable Care Act), disproportionate share payments to hospitals under section 1886(d)(5)(F) of the Act are reduced and an additional payment to eligible hospitals is made beginning in FY 2014. Hospitals that receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the current statutory formula for Medicare DSH payments. The remainder, equal to 75 percent of what otherwise would have been paid as Medicare DSH payments, will be the basis for additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured and additional statutory adjustments. Each hospital that receives Medicare DSH payments will receive an additional payment based on its share of the total uncompensated care amount reported by Medicare DSHs. The reduction to Medicare DSH payments is not budget neutral.

For FY 2015, we are proposing that the 75 percent of what otherwise would have been paid for Medicare DSH is adjusted to approximately 80.4 percent of the amount for changes in the percentage of individuals that are uninsured and additional statutory adjustments. In other words, Medicare DSH payments prior to the application of section 3133 of the Affordable Care Act are adjusted to approximately 60.3 percent (the product of 75 percent and 80.4 percent) and that resulting payment amount is used to create an additional payment for a hospital's relative uncompensated care. As a result, we project that the proposed reduction of Medicare DSH payments and the inclusion of the additional payments for uncompensated care will reduced payments overall by 1.1 percent as compared to the Medicare DSH payments and uncompensated care payments distributed in FY 2014. The proposed additional payments have redistributive effects based on a hospital's uncompensated care amount relative to the uncompensated care amount to all hospitals that are estimated to receive Medicare DSH payments, and the payment amount is not tied to a hospital's discharges.

• Hospital Inpatient Quality Reporting (IQR) Program. In this proposed rule, we are proposing to add nine new measures for the FY 2017 payment determination and subsequent years. We are proposing to remove five measures from the hospital IQR Program for the FY 2016 payment determination and subsequent years. We also are proposing to remove 15 chart-abstracted from the FY 2016 payment determination's measure set, but we are proposing to retain an electronic clinical quality measure version of 10 of those measures for the program. We estimate that our proposals for the adoption and removal of measures will decrease hospital costs by $39.8 million.

• Proposed Update to the LTCH PPS Standard Federal Rate and Other Payment Factors. Based on the best available data for the 423 LTCHs in our database, we estimate that the proposed changes to the payment rates and factors we are presenting in the preamble and Addendum of this proposed rule, including the proposed update to the standard Federal rate for FY 2015, the proposed changes to the area wage adjustment for FY 2015, and the expected changes to short-stay outliers and high-cost outliers, would result in an increase in estimated payments from FY 2014 of approximately $44 million (or 0.8 percent). In addition, we estimate that net effect of the projected impact of certain other proposed LTCH PPS policy changes (that is, the reinstatement of the moratorium on the full implementation of the ''25 percent threshold'' payment adjustment; the reinstatement of the moratorium on the development of new LTCHs and LTCH satellite facilities and additional LTCH beds; the proposed revision of the ''greater than 3-day interruption of stay'' policy; the proposed revocation of onsite discharges and readmissions policy; and the proposed payment adjustment for ''subclause (II)'' LTCHs) is estimated to result in a reduction in LTCH PPS payments of approximately $14 million.

The impact analysis of the proposed payment rates and factors presented in this proposed rule under the LTCH PPS, in conjunction with the estimated payment impacts of certain other proposed LTCH PPS policy changes would result in a net increase of $30 million to LTCH providers. Additionally, we estimate that the costs to LTCHs associated with the completion of the proposed data for the LTCHQR Program at $3.96 million or approximately $1 million more than FY 2014.

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. The Affordable Care Act revised the Medicare DSH payment methodology and provides for a new additional Medicare payment that considers the amount of uncompensated care beginning on October 1, 2013.

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 April 1, 2015, 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 on March 31, 2015, under current law.) 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; certain cancer hospitals; and short-tern acute care hospitals located in Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and American Samoa. Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA, Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for 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, certain cancer hospitals, short-tern acute care hospitals

located in Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and American Samoa, and RNHCIs continue to be paid solely under a reasonable cost-based system subject to a rate-of-increase ceiling on inpatient operating costs, as updated annually by the percentage increase in the IPPS operating market basket.

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 section 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). During the 5-year (optional) transition period, a LTCH's payment under the PPS was based on an increasing proportion of the LTCH Federal rate with a corresponding decreasing proportion based on reasonable cost principles. Effective for cost reporting periods beginning on or after October 1, 2006, 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 with FY 2009, annual updates to the LTCH PPS are published in the same documents that update the IPPS (73 FR 26797 through 26798).

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v)(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. Summary of Provisions of Recent Legislation Discussed in This Proposed Rule

The Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, 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).

The American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240), enacted on January 2, 2013, also made a number of changes that affect the IPPS. We announced changes related to certain IPPS provisions for FY 2013 in accordance with sections 605 and 606 of Public Law 112–240 in a notice issued in the **Federal Register** on March 7, 2013 (78 FR 14689).

The Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), enacted on December 26, 2013, also made a number of changes that affect the IPPS and the LTCH PPS. We implemented changes related to the low-volume hospital payment adjustment and MDH provisions for FY 2014 in accordance with sections 1105 and 1106 of Public Law 113–67 in an interim final rule with comment period that appeared in the **Federal Register** on March 18, 2014 (79 FR 15022).

The Protecting Access to Medicare Act of 2014 (Pub. L. 113–93), enacted on April 1, 2014, also made a number of changes that affect the IPPS and LTCH PPS.

1. 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)

In this proposed rule, we are proposing policy changes to implement (or, as applicable, continuing to implement in FY 2015) 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 for FY 2015:

- Section 3001(a) of Public Law 111–148, which requires the establishment of a hospital inpatient value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards for the performance period for that fiscal year.
- Section 3004 of Public Law 111–148, which provides for the submission of quality data by LTCHs in order for them to receive the full annual update to the payment rates beginning with the FY 2014 rate year.
- Section 3005 of Public Law 111–148, which provides for the establishment of a quality reporting program for PPS-exempt cancer hospitals beginning with FY 2014, and for subsequent program years.
- Section 3008 of Public Law 111–148, which establishes the Hospital-Acquired Condition (HAC) Reduction Program and requires the Secretary to make an adjustment to hospital payments for applicable hospitals, effective for discharges beginning on October 1, 2014, 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 3133 of Public Law 111–148, as amended by section 10316 of Public Law 111–148 and section 1104 of Public Law 111–152, which modifies the methodologies for determining Medicare DSH payments and creates a new additional payment for uncompensated care effective for discharges beginning on or after October 1, 2013.
- 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 2015.

• 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.

2. American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240)

In this proposed rule, we are proposing policy changes to implement section 631 of the American Taxpayer Relief Act of 2012 that are applicable to the IPPS for FY 2015, which amended section 7(b)(1)(B) of Public Law 110–90 and requires a recoupment adjustment to the standardized amounts under section 1886(d) of the Act based upon the Secretary's estimates for discharges occurring in FY 2014 through FY 2017 to fully offset $11 billion (which represents the amount of the increase in aggregate payments from FYs 2008 through 2013 for which an adjustment was not previously applied).

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

In this proposed rule, we are proposing policy changes to implement, or the need for future policy changes, to carry out provisions under section 1206 of the Pathway for SGR Reform Act of 2013. These include:

• Section 1206(a), which provides the establishment of patient criteria for ''site neutral'' payment rates under the LTCH PPS, portions of which will begin to be implemented in FY 2016.

• Section 1206(b)(1), which further amended section 114(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 by retroactively reestablishing, and extending, the statutory moratorium on the full implementation of the 25-percent threshold payment adjustment policy under the LTCH PPS so that the policy will be in effect for 9 years (except for grandfathered HwHs, which are permanently exempt from this policy).

• Section 1206(b)(2), which amended section 114(d) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(c) and 10312(a) of the Affordable Care Act to establish new moratoria (subject to certain defined exceptions) on the development of new LTCHs and LTCH satellite facilities and a new moratorium on increases in the number of beds in existing LTCHs and LTCH satellite facilities.

• Section 1206(d), which instructs the Secretary to evaluate payments to LTCHs classified under section 1886(d)(1)(B)(iv)(II) of the Act and to adjust payment rates in FY 2015 or 2016 under the LTCH PPS, as appropriate, based upon the evaluation findings.

4. Protecting Access to Medicare Act of 2014 (Pub. L. 113–93)

In this proposed rule, we are proposing policy changes to implement, or make conforming changes to regulations in accordance with, the following provisions (or portions of the following provisions) of the Protecting Access to Medicare Act of 2014 that are applicable to the IPPS and the LTCH PPS for FY 2015:

• Section 105, which extends the temporary changes to the Medicare inpatient hospital payment adjustment for low-volume subsection (d) hospitals through March 31, 2015.

• Section 106, which extends the MDH program through March 31, 2015.

• Section 112, which makes certain changes to Medicare LTCH provisions, including modifications to the statutory moratoria on the establishment of new LTCHs and LTCH satellite facilities and on increases in bed size in LTCH and LTCH satellite facilities.

• Section 212, which prohibits the Secretary from requiring implementation of ICD–10 code sets before October 1, 2015.

D. Summary of the Provisions 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 for FY 2015. We also are setting forth proposed changes relating to payments for IME and GME 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 2015.

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—

• Proposed changes to MS–DRG classifications based on our yearly review, including a discussion of the conversion of MS–DRGs to ICD–10 and the status of the implementation of the ICD–10–CM and ICD–10–PCS systems.

• Proposed application of the documentation and coding adjustment for FY 2015 resulting from implementation of the MS–DRG system.

• 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 2015.

• A discussion of the FY 2015 status of new technologies approved for add-on payments for FY 2014 and a presentation of our evaluation and analysis of the FY 2015 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Pub. L. 108–173, obtained in a town hall meeting).

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

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

• Proposed changes in CBSAs as a result of new OMB labor market area delineations and proposed policies related to the proposed changes in CBSAs.

• The proposed FY 2015 wage index update using wage data from cost reporting periods beginning in FY 2011.

• Analysis and implementation of the proposed FY 2015 occupational mix adjustment to the wage index for acute care hospitals, including the proposed application of the rural floor, the proposed imputed rural floor, and the proposed frontier State floor.

• 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 2015 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 2015 hospital wage index and proposed revisions to that timetable.

• Determination of the labor-related share for the proposed FY 2015 wage index.

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

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

- Proposed changes in postacute care transfer policies as a result of proposed new MS–DRGs.
- Proposed changes to the inpatient hospital updates for FY 2015, including incorporation of the adjustment for hospitals that are not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act.
- 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 2015.
- The statutorily required IME adjustment factor for FY 2015 and proposed IME Medicare Part C payments to SCHs that are paid according to their hospital-specific rates.
- Effect of expiration of the MDH program on April 1, 2015.
- Proposed changes to the methodologies for determining Medicare DSH payments and the additional payments for uncompensated care.
- Proposed changes to the measures and payment adjustments under the Hospital Readmissions Reduction Program.
- Proposed changes to the requirements and provision of value-based incentive payments under the Hospital Value-Based Purchasing Program.
- Proposed requirements for payment adjustments to hospitals under the HAC Reduction Program for FY 2015.
- Proposed IME and direct GME policy changes regarding the effective date of the FTE resident cap, 3-year rolling average, and IRB ratio cap in new programs in teaching hospitals; effect of new OMB labor market area delineations on certain teaching hospitals training residents in rural areas; clarification of effective date of provisions on counting resident time in nonprovider settings; proposed changes to the process for reviewing applications for and awarding slots made available under section 5506 of the Affordable Care Act by teaching hospitals that close; and clarification regarding direct GME payment to FQHCs and RHCs that train residents in approved programs.
- Discussion of the Rural Community Hospital Demonstration Program and a proposal for making a budget neutrality adjustment for the demonstration program.
- Discussion of the requirements for transparency of hospital charges under the Affordable Care Act.
- Discussion of and solicitation of comments on an alternative payment methodology under the Medicare program for short inpatient hospital stays.
- Discussion of the process for submitting suggested exceptions to the 2-midnight benchmark.

4. Proposed FY 2015 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 2015 and other related proposed policy changes.

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

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

- Proposed changes to payments to certain excluded hospitals for FY 2015.
- Proposed updates to the RCE limits for services furnished by physicians to excluded hospitals.
- Proposed CAH related changes regarding reclassifications as rural.
- Proposed changes to the physician certification requirements for services furnished in CAHs.

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 2015.
- Proposed revisions to the LTCH PPS geographic classifications based on the new OMB delineations.
- Proposals to implement section 1206(b)(1) of the Pathway for SGR Reform Act, which provides for the retroactive reinstatement and extension, for an additional 4 years, of the statutory moratorium on the full implementation of the 25-percent threshold payment adjustment established under section 114(c) of the MMSEA, as further amended by subsequent legislation.
- Proposals to implement section 1206(b)(2) of the Pathway for SGR Reform Act, as amended by section 112(b) of the Protecting Access to Medicare Act of 2014, which provides for moratoria (subject to certain defined exceptions) on the establishment of new LTCHs and LTCH satellite facilities and a moratorium on bed increases in LTCHs effective for the period beginning April 1, 2014, and ending September 30, 2017.
- Proposed changes to the LTCH interruption of stay policy by revising the fixed-day thresholds under the ''greater than 3-day interruption of stay policy'' to apply a uniform 30-day threshold as an ''acceptable standard'' for determining a linkage between an index discharge and a readmission.
- Proposal to remove the discharge and readmission requirement, ''Special Payment Provisions for Patients Who Are Transferred to Onsite Providers and Readmitted to an LTCH'' (the ''5 percent payment threshold'') beginning in FY 2015.
- Proposal to apply a payment adjustment under the LTCH PPS to subclause (II) LTCHs beginning in FY 2015 that would result in payments to this type of LTCH resembling reasonable cost payment under the TEFRA payment system model, consistent with the provisions of section 1206(d) of the Pathway for SGR Reform Act of 2013.

7. Proposed Changes to Regulations Governing Administrative Appeals by Providers and Judicial Review of Provider Claims

In section VIII. of the preamble of this proposed rule, we set forth proposals to revise the regulations governing administrative appeals and judicial review of provider claims in Medicare cost reports.

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

In section IX. 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.
- Proposed changes to the requirements for the quality reporting program for PPS-exempt cancer hospitals (PCHQR Program).
- Proposed changes to the requirements under the LTCH Quality Reporting (LTCHQR) Program.

9. Proposed Uses and Release of Medicare Advantage Risk Adjustment Data

In section X. of the preamble of this proposed rule, we set forth proposed regulatory revisions to broaden the specified uses of risk adjustment data and to specify the conditions for release of risk adjustment data to entities outside of CMS.

10. Proposed Changes to Enforcement Provisions for Organ Transplant Centers

In section XI. of the preamble of this proposed rule, we are proposing to revise the regulations governing organ transplant centers that request approval, based on mitigating factors for initial approval and re-approval, for participation in Medicare when the centers have not met one or more of the conditions of participation.

11. Determining 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 2015 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 addressed the proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2015 for certain hospitals excluded from the IPPS.

12. Determining 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 2015 LTCH PPS standard Federal rate. We are proposing to establish the adjustments for wage levels (including proposed changes to the LTCH PPS labor market area delineations based on the new OMB delineations), 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.

13. 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, and PCHs.

14. 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 provided our recommendations of the appropriate percentage changes for FY 2015 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.

15. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2014 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We address these recommendations in Appendix B of this proposed rule. For further information relating specifically to the MedPAC March 2014 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 diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

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), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51485 through 51487), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53273), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50512).

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 2015 MS–DRG Documentation and Coding Adjustment

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

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. (In FY 2014, there are 751 MS–DRGs.) 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 (Pub. L. 110–90). Section 7(a) of Public Law 110–90 reduced the documentation and coding adjustment made as a result of the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to −0.6 percent for FY 2008 and −0.9 percent for FY 2009, and we finalized the FY 2008 adjustment through rulemaking, effective 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 effective October 1, 2008 (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 section 7(a) of 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. Adjustment to the Average Standardized Amounts Required by Public Law 110–90

a. Prospective Adjustment 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.

b. Recoupment or Repayment Adjustments in FYs 2010 Through 2012 Required by Section 7(b)(1)(B) 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 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.

3. 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 IPPS/RY 2010 LTCH PPS 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 IPPS/LTCH PPS 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 was sound.

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 CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/* by clicking on MedPAR Limited Data Set (LDS)-Hospital (National). This CMS 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 (refer to the Web site for the required payment amount) 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.

4. Prospective Adjustments for FY 2008 and FY 2009 Authorized by Section 7(b)(1)(A) of Public Law 110–90

In the FY 2010 IPPS/RY 2010 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 of case-mix changes based on FY 2009 claims data could be completed. We refer readers to the FY 2010 IPPS/RY 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 5.4 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 believed the law provided some discretion as to the manner in which we applied the prospective adjustment of −3.9 percent. As we discussed 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 the −3.9 percent prospective adjustment in FY 2011 because we finalized a −2.9 percent recoupment adjustment for that fiscal 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 noted that, as a result, payments in FY 2011 (and in each future fiscal year until we implemented the requisite adjustment) would be higher than they would have been if we had implemented an adjustment under section 7(b)(1)(A) of Public Law 110–90.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51489 and 51497), we indicated that, because further delay of this prospective adjustment would 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 to the standardized amount instead of the full −3.9 percent.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53274 through 53276), we completed the prospective portion of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 by finalizing a −1.9 percent adjustment to the standardized amount for FY 2013. We stated that 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 believed that it was imperative to implement the full remaining adjustment, as any further delay would result in an overstated standardized amount in FY 2013 and any future fiscal years until a full adjustment was made.

We noted again that delaying full implementation of the prospective portion of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 until FY 2013 resulted in payments in FY 2010 through FY 2012 being overstated. These overpayments could not be recovered by CMS as section 7(b)(1)(B) of Public Law 110–90 limited recoupments to overpayments made in FY 2008 and FY 2009.

5. Recoupment or Repayment Adjustment 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. Our actuaries estimated that there was a 5.8 percentage point difference resulting 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 payment rate adjustments over more than one year in order to moderate the effect on payment 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). 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. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53276), we made a final +2.9 percent adjustment to the standardized amount, completing the recoupment portion of section 7(b)(1)(B) of Public Law 110–90. We note that with this positive adjustment, according to our estimates, all overpayments made in FY 2008 and FY 2009 have been fully recaptured with appropriate interest, and the standardized amount has been returned to the appropriate baseline.

6. Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA)

Section 631 of the ATRA amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment or adjustments totaling $11 billion by FY 2017. This adjustment represents the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. As discussed earlier, this delay in implementation resulted in overstated payment rates in FYs 2010, 2011, and 2012. The resulting overpayments could not have been recovered under Public Law 110–90.

Similar to the adjustments authorized under section 7(b)(1)(B) of Public Law 110–90, the adjustment required under section 631 of the ATRA is a one-time recoupment of a prior overpayment, not

a permanent reduction to payment rates. Therefore, any adjustment made to reduce payment rates in one year would eventually be offset by a positive adjustment, once the necessary amount of overpayment is recovered.

As we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515 through 50517), our actuaries estimate that a −9.3 percent adjustment to the standardized amount would be necessary if CMS were to fully recover the $11 billion recoupment required by section 631 of the ATRA in FY 2014. It is often our practice to phase in payment rate adjustments over more than one year, in order to moderate the effect on payment rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, and after consideration of the public comments we received, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515 through 50517), we implemented a −0.8 percent recoupment adjustment to the standardized amount in FY 2014. We stated that if adjustments of approximately −0.8 percent are implemented in FYs 2014, 2015, 2016, and 2017, using standard inflation factors, we estimate that the entire $11 billion will be accounted for by the end of the statutory 4-year timeline. As estimates of any future adjustments are subject to slight variations in total savings, we did not provide for specific adjustments for FYs 2015, 2016, or 2017 at that time. We stated that we believed that this level of adjustment for FY 2014 was a reasonable and fair approach that satisfies the requirements of the statute while mitigating extreme annual fluctuations in payment rates. In addition, we again noted that this −0.8 percent recoupment adjustment, and future adjustments under this authority, will be eventually offset by an equivalent positive adjustment once the full $11 billion recoupment requirement has been realized.

Consistent with the approach discussed in the FY 2014 rulemaking for recouping the $11 billion required by section 631 of the ATRA, we are proposing an additional −0.8 percent recoupment adjustment to the standardized amount for FY 2015. We estimated that this level of adjustment, combined with leaving the −0.8 percent adjustment made for FY 2014 in place, will recover up to $2 billion in FY 2015. Taking into account the approximately $1 billion recovered in FY 2014, this will leave approximately $8 billion remaining to be recovered by FY 2017. We continue to believe that if adjustments of approximately −0.8 percent are implemented in FYs 2014, 2015, 2016, and 2017, using standard inflation factors, the entire $11 billion will be accounted for by the end of the statutory 4-year timeline. As we explained in the FY 2014 rulemaking, estimates of any future adjustments are subject to slight variations in total savings; therefore, we are not proposing specific adjustments for FY 2016 and FY 2017 at this time. We continue to believe that our proposed −0.8 percent adjustment for FY 2015 is a reasonable and fair approach that will help satisfy the requirements of the statute while mitigating extreme annual fluctuations in payment rates. In addition, we again note that this −0.8 percent recoupment adjustment, and future adjustments under this authority, will be eventually offset by an equivalent positive adjustment once the full $11 billion recoupment requirement has been realized.

7. Prospective Adjustment for the MS–DRG Documentation and Coding Effect Through FY 2010

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515 through 50517), we discussed the possibility of applying an additional prospective adjustment to account for the cumulative MS–DRG documentation and coding effect through FY 2010. In that final rule, we stated that if we were to apply such an adjustment, we believe the most appropriate additional adjustment is −0.55 percent. However, we decided not to apply such an adjustment in FY 2014, in light of the need to make the retrospective adjustments required by the ATRA. We continue to believe that if we were to apply an additional prospective adjustment for the cumulative MS–DRG documentation and coding effect through FY 2010, the most appropriate additional adjustment is −0.55 percent. However, we are not proposing such an adjustment in FY 2015, in light of the ongoing recoupment required by the ATRA. We will consider whether such an additional adjustment is appropriate in future years' rulemaking.

E. Refinement of the MS–DRG Relative Weight Calculation

1. Background

Beginning in FY 2007, we implemented relative weights for DRGs based on cost report data instead of charge information. We refer readers to the FY 2007 IPPS final rule (71 FR 47882) for a detailed discussion of our final policy for calculating the cost-based DRG relative weights and to the FY 2008 IPPS final rule with comment period (72 FR 47199) for information on how we blended relative weights based on the CMS DRGs and MS–DRGs.

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 addition, we refer readers to RTI's July 2008 final report titled ''Refining Cost to Charge Ratios for Calculating APC and MS–DRG Relative Payment Weights'' (*http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf*).

In the FY 2009 IPPS 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 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 for ''Implantable Devices Charged to Patients'' was created in July 2009. 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) 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 cost centers for CT scans, MRIs, and cardiac catheterization in order for hospitals to report separately the costs and charges for those services and in order for CMS to calculate unique CCRs to estimate the 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, MRIs, 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, MRIs, and cardiac catheterization.) The new standard cost centers for CT scans, MRIs, and cardiac catheterization are effective for cost reporting periods beginning on or after May 1, 2010, on the revised cost report Form CMS–2552–10.

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 Form 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, MRIs, 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). In preparation for the FY 2012 IPPS/LTCH PPS rulemaking, 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 Devices 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.

During the development of the FY 2013 IPPS/LTCH PPS proposed and final rules, hospitals were still in the process of transitioning from the previous cost report Form CMS–2552–96 to the new cost report Form CMS–2552–10. Therefore, we were 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; that is, those cost reports on Form CMS–2552–96. Data from the Form CMS–2552–10 cost reports were not available because cost reports filed on the Form CMS–2552–10 were not accessible in the HCRIS. Further complicating matters was that, due to additional unforeseen technical difficulties, the corresponding information regarding charges for implantable devices on hospital claims was 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 believed that we had no choice but to continue computing the relative weights with the current CCR that combines the costs and charges for supplies and implantable devices. We stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53281 through 53283) that when we do have the necessary data for supplies and implantable devices on the claims in the MedPAR file to create distinct CCRs for the respective cost centers for supplies and implantable devices, we hoped that we would also have data for an analysis of creating distinct CCRs for CT scans, MRIs, and cardiac catheterization, which could then be finalized through rulemaking. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53281), we stated that prior to proposing to create these CCRs, we would first thoroughly analyze and determine the impacts of the data, and that distinct CCRs for these new cost centers would be used in the calculation of the relative weights only if they were first finalized through rulemaking.

At the time of the development of the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27506 through 27507), we had a substantial number of hospitals completing all, or some, of these new cost centers on the FY 2011 Medicare cost reports, compared to prior years. We stated that we believed that the analytic findings described using the FY 2011 cost report data and FY 2012 claims data supported our original decision to break out and create new cost centers for implantable devices, MRIs, CT scans, and cardiac catheterization, and we saw no reason to further delay proposing to implement the CCRs of each of these cost centers. Therefore, beginning in FY 2014, we proposed to calculate the MS–DRG relative weights using 19 CCRs, creating distinct CCRs from cost report data for implantable devices, MRIs, CT scans, and cardiac catheterization (78 FR 27509).

We refer readers to the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27507 through 27509) and final rule (78 FR 50518 through 50523) in which we presented data analyses using distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. The FY 2014 IPPS/LTCH PPS final rule also set forth our responses to public comments we received on our proposal to implement these CCRs. As explained in more detail in the FY 2014 IPPS/LTCH PPS final rule, we finalized our proposal to use 19 CCRs to calculate MS–DRG relative weights beginning in FY 2014—the then existing 15 cost centers and the 4 new CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. Therefore, beginning in FY 2014, we calculated the IPPS MS–DRG relative weights using 19 CCRs, creating distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization.

2. Discussion for FY 2015

To calculate the proposed MS–DRG relative weights for FY 2015, we use two data sources: the MedPAR file as the

claims data source and the HCRIS as the cost report data source. We adjust the charges from the claims to costs by applying the 19 national average CCRs developed from the cost reports. The description of the calculation of the proposed 19 CCRs and the proposed MS–DRG relative weights for FY 2015 is included in section II.H. of the preamble of this proposed rule.

F. Proposed Adjustment to MS–DRGs for Preventable Hospital-Acquired Conditions (HACs), Including Infections for FY 2015

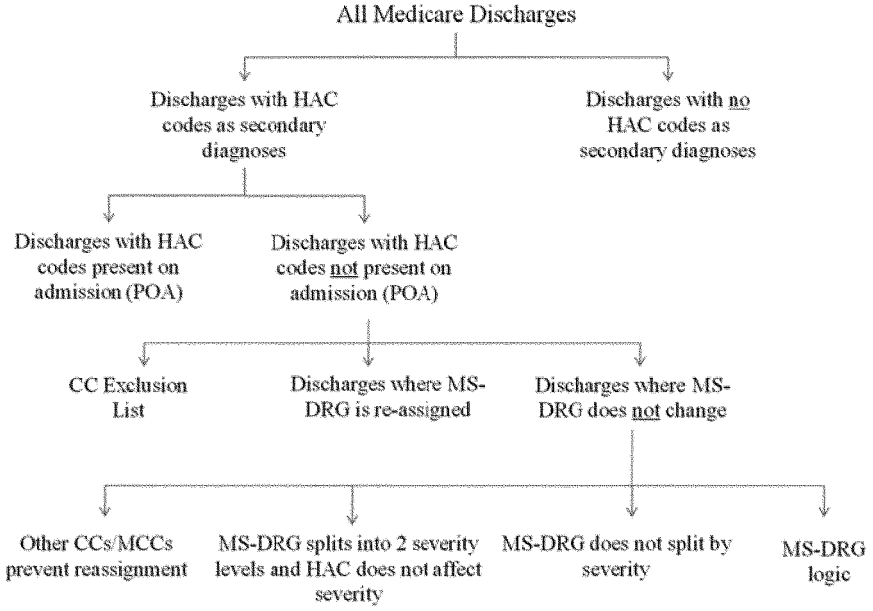
1. Background

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 complication or comorbidity (CC) or a major complication or comorbidity (MCC). The presence of a CC or an MCC generally results in a higher payment.

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 the 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, under 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 or 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 affected 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); the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25810 through 25816) and final rule (76 FR 51504 through 51522); the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27892 through 27898) and final rule (77 FR 53283 through 53303); and the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27509 through 27512) and final rule (78 FR 50523 through 50527). A complete list of the 11 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*.

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).

Currently, as we have discussed in the prior rulemaking cited under section II.I.2. of the preamble of this proposed rule, the POA indicator reporting requirement only applies to IPPS hospitals because they are subject to this HAC provision. Non-IPPS hospitals, including CAHs, LTCHs, IRFs, IPFs, cancer hospitals, children's hospitals, RNHCIs, and the Department of Veterans Affairs/Department of Defense hospitals, are exempt from POA reporting.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50525), we noted that hospitals in Maryland operating under a statutory waiver are not paid under the IPPS, but rather were paid under the provisions of section 1814(b)(3) of the Act and therefore exempt from reporting POA indicators. However, we believed it was appropriate to require them to use POA indicator reporting on their claims so that we can include their data and have as complete a dataset as possible when we analyze trends and make further payment policy determinations, such as those authorized under section 1886(p) of the Act. Therefore, in the FY 2014 IPPS/LTCH PPS final rule, we finalized our policy that hospitals in Maryland that formerly operated under section 1814(b)(3) of the Act were no longer exempted from the POA indicator reporting requirement beginning with claims submitted on or after October 1, 2013, including all claims for discharges on or after October 1, 2013. We note that, while this requirement was not effective until October 1, 2013, hospitals in Maryland could submit data with POA indicators before that date with the expectation that these data will be accepted by Medicare's claims processing systems. (We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50712) for a discussion of our FY 2014 final policies to implement section 1886(p) of the Act that are applicable to Maryland hospitals.)

Subsequent to our FY 2014 rulemaking, the State of Maryland entered into an agreement with CMS, effective January 1, 2014, to participate in CMS' new Maryland All-Payer Model, a 5-year hospital payment model. This model is being implemented under section 1115A of the Act, as added by section 3021 of the Affordable Care Act, which authorizes the testing of innovative payment and service delivery models, including models that allow States to ''test and evaluate systems of all-payer payment reform for the medical care of residents of the State, including dual eligible individuals.'' Section 1115A of the Act authorizes the Secretary to waive such requirements of titles XI and XVIII of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models.

Under the agreement with CMS, Maryland will limit per capita total hospital cost growth for all payers, including Medicare. In order to implement the new model, effective January 1, 2014, Maryland elected to no longer have Medicare make payments to Maryland hospitals in accordance with section 1814(b)(3) of the Act. Maryland also represented that it is no longer in continuous operation of a demonstration project reimbursement system since July 1, 1977, as specified under section 1814(b)(3) of the Act. Because Maryland hospitals are no longer paid under section 1814(b)(3) of the Act, they are no longer subject to those provisions of the Act and related implementing regulations that are specific to section 1814(b)(3) hospitals. Although CMS has waived certain provisions of the Act for Maryland hospitals, as set forth in the agreement between CMS and Maryland and subject to Maryland's compliance with the terms of the agreement, CMS has not waived the POA indicator reporting requirement. In other words, the changes to the status of Maryland hospitals under section 1814(b)(3) of the Act as described above do not in any way change the POA indicator reporting requirement for Maryland hospitals.

There are currently four POA indicator reporting options, ''Y'', ''W'', ''N'', and ''U'', as defined by the *ICD–9–CM Official Guidelines for Coding and Reporting.* We note that prior to January 1, 2011, we also used a POA indicator reporting option ''1''. However, 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 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*.) The POA indicator reporting process will not change when ICD–10–CM and ICD–10–PCS are implemented on October 1, 2014. The current POA indicators and their descriptors are shown in the chart below:

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.

Under the HAC payment 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 and 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 and MCC level. We refer readers to the following rules for a detailed discussion of POA indicator reporting: 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); the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25812 through 25813) and final rule (76 FR 51506 through 51507); the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27893 through 27894) and final rule (77 FR 53284 through 53285); and the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27510 through 27511) and final rule (78 FR 50524 through 50525).

In addition, as discussed previously in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53324), 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 diagnosis and all secondary diagnoses up to 25.

4. HACs and POA Reporting in Preparation for Transition to ICD–10–CM and ICD–10–PCS

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, we indicated that 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 would be discussed in future rulemaking.

At the March 5, 2012 and the September 19, 2012 meetings 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 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 selected HACs available on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. The translations can be found under the link titled ''ICD–10–CM/PCS MS–DRG v30 Definitions Manual Table of Contents—Full Titles—HTML Version in Appendix I—Hospital Acquired Conditions (HACs).'' This CMS Web site regarding the ICD–10–MS–DRG Conversion Project is also available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/icd10_hacs.html*. We encouraged 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 was set up for this purpose under the Related Links section titled ''CMS HAC Feedback.''

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50525), we stated that the final HAC list translation from ICD–9–CM to ICD–10–CM/ICD–10–PCS would be subject to formal rulemaking. We encouraged readers to review the educational materials and draft code sets available for ICD–10–CM/ICD–10–PCS on the CMS Web site at: *http://www.cms.gov/ICD10/*. In addition, we stated that the draft ICD–10–CM/ICD–10–PCS Coding Guidelines could be viewed on the CDC Web site at: *http://www.cdc.gov/nchs/icd/icd10cm.htm*.

The HACs code translation list from ICM–9–CM to ICD–10–CM/ICD–10–PCS is available to the public on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We note that Appendix I of the ICD–10 MS–DRGs Version 31.0–R file posted on the Web site contains the DRA HACs translated to ICD–10.

We note that section 212 of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93), enacted on April 1, 2014, delayed the transition from the ICD–9–CM to the ICD–10 code set.

5. Proposals Regarding Current HACs and Previously Considered Candidate HACs

In this FY 2015 IPPS/LTCH PPS proposed rule, we are not proposing to add or remove categories of the HACs. However, we continue to encourage public dialogue about refinements to the HAC list by written stakeholder comments about both previously selected and potential candidate HACs. We refer readers to section II.F.6. of the FY 2008 IPPS final rule with comment period (72 FR 47202 through 47218) and to section II.F.7. of the FY 2009 IPPS final rule (73 FR 48774 through 48491) for detailed discussion supporting our determination regarding each of these conditions. We also refer readers to section II.F.5. of the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27892 through 27898), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53285 through 53292) for the HAC policy for FY 2013, and the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27509 through 27512) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50523 through 50527) for the HAC policy for FY 2014.

6. RTI Program Evaluation

On September 30, 2009, a contract was awarded to 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 was an intra-agency project with funding and technical support from CMS, OPHS, AHRQ, and CDC. The evaluation also examined the implementation of the program and evaluated additional conditions for future selection. The contract with RTI ended on November 30, 2012. Summary reports of RTI's analysis of the FYs 2009, 2010, and 2011 MedPAR data files for the HAC–POA program evaluation were included in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50085 through 50101), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51512 through 51522), and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53292 through 53302). Summary and detailed data also 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/*.

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

7. Current and Previously Considered Candidate HACs—RTI Report on Evidence-Based Guidelines

The RTI program evaluation includes a report that provides references for all evidence-based guidelines available for

each of the selected and previously considered candidate HACs that provide recommendations for the prevention of the corresponding conditions. Guidelines were primarily identified using the AHRQ National Guidelines Clearing House (NGCH) and the CDC, along with relevant professional societies. Guidelines published in the United States were used, if available. In the absence of U.S. guidelines for a specific condition, international guidelines were included.

Evidence-based guidelines that included specific recommendations for the prevention of the condition were identified for each of the selected conditions. In addition, evidence-based guidelines also were found for the previously considered candidate conditions. RTI prepared a final report to summarize its findings regarding evidence-based guidelines. This report can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Downloads/Evidence-Based-Guidelines.pdf*. Subsequent to this final report, RTI was awarded an FY 2014 Evidence-Based Guidelines Monitoring contract. Under the contract, RTI will provide a summary report of all evidence-based guidelines available for each of the selected and previously considered candidate HACs that provide recommendations for the prevention of the corresponding conditions. This report is usually delivered to CMS annually in a May/June timeframe. Updates to the guidelines will be made available to the public.

G. Proposed Changes to Specific MS–DRG Classifications

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

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

Providers use the code sets under the ICD–9–CM coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system. The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the Official ICD–10–CM and ICD–10–PCS Guidelines for Coding and Reporting. The ICD–10 coding system was initially adopted for transactions conducted on or after October 1, 2013, as described in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification: Modifications to Medical Data Code Set Standards to Adopt ICD–10–CM and ICD–10–PCS Final Rule published in the **Federal Register** on January 16, 2009 (74 FR 3328 through 3362) (hereinafter referred to as the ''ICD–10–CM and ICD–10–PCS final rule''). However, the Secretary of Health and Human Services issued a final rule that delays the compliance date for ICD–10 from October 1, 2013, to October 1, 2014. That final rule, entitled ''Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for ICD–10–CM and ICD–10–PCS Medical Data Code Sets,'' CMS–0040–F, was published in the **Federal Register** on September 5, 2012 (77 FR 54664) and is available for viewing on the Internet at: *http://www.gpo.gov/fdsys/pkg/FR-2012-09-05/pdf/2012-21238.pdf*. On April 1, 2014, the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) was enacted. Section 212 of Public Law 113–93, titled ''Delay in Transition from ICD–9 to ICD–10 Code Sets,'' provides that ''[t]he Secretary of Health and Human Services may not, prior to October 1, 2015, adopt ICD–10 code sets as the standard for code sets under section 1173(c) of the Social Security Act (42 U.S.C. 1320d–2(c)) and section 162.1002 of title 45, Code of Federal Regulations.'' As of now, the Secretary has not implemented this provision under HIPPA.

The anticipated move to ICD–10 necessitated the development of an ICD–10–CM/ICD–10–PCS version of the MS–DRGs. CMS began a project to convert the ICD–9–CM-based MS–DRGs to ICD–10 MS–DRGs. In response to the FY 2011 IPPS/LTCH PPS proposed rule, we received public 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). 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 current MS–DRGs from ICD–9–CM codes to ICD–10 codes and sharing this information through the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee. We undertook this early conversion project to assist other payers and providers in understanding how to implement 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 other payers and providers to follow. Information on the ICD–10 MS–DRG conversion project can be found on the ICD–10 MS–DRG Conversion Project Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. 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–10 (previously ICD–9–CM) Coordination and Maintenance Committee. Information on these committee meetings can be found on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html*.

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.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html*.

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. 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–DRGs Web page. We stated that we believed that, by providing the ICD–10 MS–DRGs 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–DRG Conversion Project 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.

CMS prepared the ICD–10 MS–DRGs Version 30.0 based on the FY 2013 MS–DRGs (Version 30.0) that we finalized in the FY 2013 IPPS/LTCH PPS final rule. We posted a Definitions Manual of the ICD–10 MS–DRGs Version 30.0 on our ICD–10 MS–DRG Conversion Project Web site. We also prepared a document that describes changes made from Version 29.0 to Version 30.0 to facilitate a review. We produced mainframe and computer software for Version 30.0, which was made available to the public in February 2013. Information on ordering the mainframe and computer software through NTIS was posted on the ICD–10 MS–DRG Conversion Project Web site. The ICD–10 MS–DRGs Version 30.0 computer software facilitated additional review of the ICD–10 MS–DRGs conversion.

We provided information on a study conducted on the impact of converting MS–DRGs to ICD–10. Information on this study is summarized in a paper entitled ''Impact of the Transition to ICD–10 on Medicare Inpatient Hospital Payments.'' This paper was posted on the CMS ICD–10 MS–DRGs Conversion Project Web site and was distributed and discussed at the September 15, 2010 ICD–9–CM Coordination and Maintenance Committee meeting. The paper described 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) which was 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 impact of the conversion from ICD–9–CM to ICD–10 on Medicare MS–DRG hospital payments was estimated using FY 2009 Medicare claims data. The study found a hospital payment increase of 0.05 percent using the ICD–10 MS–DRGs Version 27.0.

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.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html*. 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 of the impact study was presented at the March 5, 2013 ICD–9–CM Coordination and Maintenance Committee meeting. The study found that moving from an ICD–9–CM-based system to an ICD–10 MS–DRG replicated system would lead to DRG reassignments on only 1 percent of the 10 million MedPAR sample records used in the study. Ninety-nine percent of the records did not shift to another MS–DRG when using an ICD–10 MS–DRG system. For the 1 percent of the records that shifted, 45 percent of the shifts were to a higher weighted MS–DRG, while 55 percent of the shifts were to lower weighted MS–DRGs. The net impact across all MS–DRGs was a reduction by 4/10000 or minus 4 pennies per $100. The updated paper is posted on the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html* under the ''Downloads'' section. Information on the March 5, 2013 ICD–9–CM Coordination and Maintenance Committee meeting can be found on the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html*. This update of the impact paper and the ICD–10 MS–DRG Version 30.0 software provided additional information to the public who were evaluating the conversion of the MS–DRGs to ICD–10 MS–DRGs.

CMS prepared the ICD–10 MS–DRGs Version 31.0 based on the FY 2014 MS–DRGs (Version 31.0) that we finalized in the FY 2014 IPPS/LTCH PPS final rule. In November 2013, we posted a Definitions Manual of the ICD–10 MS–DRGs Version 31.0 on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We also prepared a document that described changes made from Version 30.0 to Version 31.0 to facilitate a review. We produced mainframe and computer software for Version 31.0, which was made available to the public in December 2013. Information on ordering the mainframe and computer software through NTIS was posted on the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html* under the ''Related Links'' section. This ICD–10 MS–DRGs Version 31.0 computer software facilitated additional review of the ICD–10 MS–DRGs conversion. We encouraged the public to submit to CMS any comments on areas where they believed the ICD–10 MS–DRGs did not accurately reflect grouping logic found in the ICD–9–CM MS–DRGs Version 31.0.

We reviewed comments received and developed an update of ICD–10 MS–DRGs Version 31.0, which we called ICD–10 MS–DRGs Version 31.0–R. We have posted a Definitions Manual of the ICD–10 MS–DRGs Version 31.0–R on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We also prepared a document that describes changes made from Version 31.0 to Version 31.0–R to facilitate a review. We will continue to share ICD–10–MS–DRG conversion activities with the public through this Web site.

b. Basis for FY 2015 MS–DRG Updates

CMS encourages input from our stakeholders concerning the annual IPPS updates when that input is made available to us by December 7 of the year prior to the next annual proposed rule update. For example, to be considered for any updates or changes in FY 2016, comments and suggestions should be submitted by December 7, 2014. The comments that were submitted in a timely manner for FY 2015 are discussed below in this section.

Following are the changes we are proposing to the MS–DRGs. 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 also are 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. For this FY 2015 proposed rule, our MS–DRG analysis is based on claims data from the December

2013 update of the FY 2013 MedPAR file, which contains hospital bills received through September 30, 2013, for discharges occurring through September 30, 2013. In our discussion of the proposed MS–DRG reclassification changes that follows, we refer to our analysis of claims data from the ''December 2013 update of the FY 2013 MedPAR file.'' For the FY 2015 final rule, we intend to calculate the final relative weights on claims data from the March 2014 update of the FY 2013 MedPAR file, which will contain hospital bills received through December 31, 2013, for discharges occurring through December 31, 2013.

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

2. MDC 1 (Diseases and Disorders of the Nervous System)

a. Intracerebral Therapies: Gliadel® Wafer

During the comment period for the FY 2014 IPPS/LTCH PPS proposed rule, we received a public comment that we considered to be outside the scope of that proposed rule. We stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50550) that we would consider this issue in future rulemaking as part of our annual review process. The commenter requested that a new MS–DRG be created for intracerebral therapies, including implantation of chemotherapeutic agents. Specifically, the commenter referred to the Gliadel® Wafer for the treatment of High-Grade Malignant Gliomas (HGGs) defined as aggressive tumors originating in the brain.

The Gliadel® Wafer has been discussed in prior rulemaking, including the FY 2004 IPPS proposed rule (68 FR 27187) and final rule (68 FR 45354 through 45355 and 68 FR 45391 through 45392); the FY 2005 IPPS proposed rule (69 FR 28221 through 28222) and final rule (69 FR 48957 through 48971); and the FY 2008 IPPS/LTCH PPS final rule (72 FR 47252 through 47253). We refer readers to these prior discussions for further background information regarding the Gliadel® Wafer.

Effective October 1, 2002, ICD–9–CM procedure code 00.10 (Implantation of chemotherapeutic agent) was created to identify and describe insertion of the Gliadel® Wafer. This procedure code is assigned to MS–DRG 023 (Craniotomy with Major Device Implant/Acute Complex Central Nervous System (CNS) PDX with MCC or Chemo Implant) in MDC 1. According to the commenter, this current MS–DRG assignment does not compensate providers adequately for the expenses incurred to perform the surgery and implantation of the wafer device. The commenter noted that MS–DRG 023 has a national average payment rate of approximately $28,016. However, the commenter stated, ''the acquisition cost for 1 box of the Gliadel® Wafer alone (typical utilization per procedure is 8 wafers or 1 box) is $29,035.''

We conducted an analysis using claims data from the December 2013 update of the FY 2013 MedPAR file. Our findings are shown in the table below.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 023—All cases	5,383	10.98	$36,982
MS–DRG 023—Cases with procedure code 00.10	158	7.0	34,027

As shown in the table above, there were a total of 5,383 cases in MS–DRG 023 with an average length of stay of 10.98 days and average costs of $36,982. The number of cases reporting procedure code 00.10 in MS–DRG 023 totaled 158, with an average length of stay of 7.0 days and average costs of $34,027.

The data clearly demonstrate that the volume of cases reporting procedure code 00.10 within MS–DRG 023 have a shorter average length of stay and are lower in average costs in comparison to all the cases in the MS–DRG. Given the low volume of cases, shorter average length of stay, and lower average costs, the data do not support the creation of a new MS–DRG for cases utilizing the Gliadel® Wafer. In addition, our clinical advisors determined that cases reporting procedure code 00.10 are appropriately assigned within MS–DRG 023. As discussed in the FY 2005 IPPS final rule (69 FR 48959), Gliadel® Wafer cases were assigned to a new DRG that was clinically coherent and reflected the resources used to treat those cases, which appropriately addressed the concerns of commenters who raised questions regarding DRG assignment for those cases at that time. Subsequently, with the adoption of the MS–DRGs, in the FY 2008 IPPS/LTCH PPS final rule (72 FR 47252 through 47253), we assigned all cases utilizing the Gliadel® Wafer technology to MS–DRG 023, the higher severity level, and revised the title of this MS–DRG in recognition of the complexity and costs associated with the implantation. Our clinical advisors continue to support this assignment for these same reasons. Therefore, we are not proposing to create a new MS–DRG for FY 2015 for cases where ICD–9–CM procedure code 00.10 is reported. We are inviting public comments on our proposal to maintain the current MS–DRG structure.

b. Endovascular Embolization or Occlusion of Head and Neck

We received a request to change the MS–DRG assignment for the following three ICD–9–CM procedure codes representing endovascular embolization or occlusion procedures of the head and neck:

- 39.72 (Endovascular (total) embolization or occlusion of head and neck vessels);
- 39.75 (Endovascular embolization or occlusion of vessel(s) of head or neck using bare coils); and
- 39.76 (Endovascular embolization or occlusion of vessel(s) of head or neck using bioactive coils).

These three procedure codes are currently assigned to the following eight

MS–DRGs under MDC 1. Cases assigned to MS–DRGs 020, 021, and 022 require a principal diagnosis of hemorrhage. Cases assigned to MS–DRGs 023 and 024 require the insertion of a major implant or an acute complex central nervous system (CNS) principal diagnosis. Cases assigned to MS–DRGs 025, 026, and 027 do not have a principal diagnosis of hemorrhage, an acute complex CNS principal diagnosis, or a major device implant.

- MS–DRG 020 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage with MCC)
- MS–DRG 021 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage with CC)
- MS–DRG 022 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage without CC/MCC)
- MS–DRG 023 (Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis with MCC or Chemo Implant)
- MS–DRG 024 (Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis without MCC)
- MS–DRG 025 (Craniotomy & Endovascular Intracranial Procedures with MCC)
- MS–DRG 026 (Craniotomy & Endovascular Intracranial Procedures with CC)
- MS–DRG 027 (Craniotomy & Endovascular Intracranial Procedures without CC/MCC)

The requestor recommended that cases with procedure codes 39.72, 39.75, and 39.76 be moved from MS–DRGs 025, 026, and 027 to MS–DRGs 023 and 024, even when there is no reported acute complex CNS principal diagnosis or a major device implant. The requestor stated that unruptured aneurysms can be treated by a minimally invasive technique utilizing endovascular coiling. The requester noted that a microcatheter is inserted into a groin artery and navigated through the vascular system to the location of the aneurysm. The coils are inserted through the microcatheter into the aneurysm in order to occlude (fill) the aneurysm from inside the blood vessel. Once the coils are implanted, the blood flow pattern within the aneurysm is altered. The requestor stated that these cases do not have a principal diagnosis of hemorrhage because the treatment is for an unruptured aneurysm which has not hemorrhaged. Furthermore, the requestor stated that only a few of these cases without hemorrhage have a complex CNS principal diagnosis. Therefore, the requester believed that most of the cases should be assigned to MS–DRGs 025, 026, and 027.

The requestor stated that the average costs of coil cases captured by procedure codes 39.72, 39.75, and 39.76 are significantly higher than other cases within MS–DRGs 025, 026, and 027 where most of the coil cases are assigned. As stated earlier, the requester recommended that cases with procedure codes 39.72, 39.75, and 39.76 be moved to MS–DRGs 023 and 024, even when there is not an acute complex CNS principal diagnosis or a major device implant reported.

We examined claims data from the December 2013 update of the FY 2013 MedPAR file for cases of endovascular embolization or occlusion of head and neck. The table below shows our findings. For MS–DRGs 025, 026, and 027, the cases identified by procedure code 39.72, 39.75, or 39.76 (endovascular embolization or occlusion of head and neck) have higher average costs and shorter lengths of stay in comparison to all the cases within each of those respective MS–DRGs. The average costs of cases in MS–DRG 024 are $4,049 higher than the average costs of the 1,731 endovascular embolization or occlusion of head and neck procedures cases in MS–DRG 027 ($26,250 versus $22,201). The findings also show that the 524 cases with procedure code 39.72, 39.75, or 39.76 with average costs of $41,030 in MS–DRG 025 are closer to the average costs of $36,982 for cases in MS–DRG 023. Lastly, we found that the 721 endovascular embolization or occlusion of head and neck procedure cases in MS–DRG 026 have average costs of $27,998 compared to average costs of $26,250 for cases in MS–DRG 024.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 23—All cases	5,383	10.98	$36,982
MS–DRG 24—All cases	1,745	6.30	26,250
MS–DRG 25—All cases	15,937	9.68	29,722
MS–DRG 25—Cases with procedure code 39.72, 39.75, or 39.76	524	7.97	41,030
MS–DRG 26—All cases	8,520	6.16	21,194
MS–DRG 26—Cases with procedure code 39.72, 39.75, or 39.76	721	3.14	27,998
MS–DRG 27—All cases	10,326	3.30	16,389
MS–DRG 27—Cases with procedure code 39.72, 39.75, or 39.76	1,731	1.66	22,201

Our clinical advisors reviewed the results of our examination and determined that the endovascular embolization or occlusion of head and neck procedures are appropriately classified within MS–DRGs 025, 026, and 027 because they do not have an acute complex CNS principal diagnosis or a major device implant which would add to their clinical complexity. Cases in MS–DRG 024 have average costs that are $4,049 higher than cases in MS–DRG 027 with procedure code 39.72, 39.75, or 39.76. We acknowledge that the 1,245 cases with procedure code 39.72, 39.75, or 39.76 in MS–DRGs 025 and 026 have average costs that are closer to those in MS–DRGs 024 and 025. However, these cases are 1,245 of the total 2,976 cases that would be involved if we moved all MS–DRGs 025, 026, and 027 cases with procedure code 39.72, 39.75, or 39.76 to MS–DRGs 024 and 025, even if they did not have an acute complex CNS principal diagnosis or a major device implant. Based on these findings and the recommendations from our clinical advisors, we have determined that proposing to move endovascular embolization or occlusion of head and neck procedures from MS–DRGs 025, 026, and 027 to MS–DRGs 023 and 024 is not warranted. Therefore, we are proposing to maintain the current MS–DRG assignments for endovascular embolization or occlusion of head and neck procedures. We are inviting public comments on our proposal.

3. MDC 4 (Diseases and Disorders of the Ear, Nose, Mouth and Throat): Avery Breathing Pacemaker System

We received a request to create a new MS–DRG for the Avery Breathing Pacemaker System. This system is also called a diaphragmatic pacemaker and is captured by ICD–9–CM procedure code 34.85 (Implantation of diaphragmatic pacemaker). The requestor stated that the diaphragmatic pacemaker is indicated for adult and

pediatric patients with chronic respiratory insufficiency that would otherwise be dependent on ventilator support. The procedure consists of surgically implanted receivers and electrodes mated to an external transmitter by antennas worn over the implanted receivers. The external transmitter and antennas send radiofrequency energy to the implanted receivers under the skin. The receivers then convert the radio waves into stimulating pulses sent down the electrodes to the phrenic nerves, causing the diaphragm to contract. The requestor stated that this normal pattern is superior to mechanical ventilators that force air into the chest. The requestor also stated that the system is expensive; the device cost is approximately $57,000. According to the requestor, given the cost of the device, hospitals are reluctant to use it. The requestor did not make a specific MS–DRG reassignment request.

When used for a respiratory failure patient, procedure code 34.85 is assigned to MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively).

We examined claims data from the December 2013 update of the FY 2013 MedPAR file for diaphragmatic pacemaker cases. The following table shows our findings.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 163—All cases	11,766	13.13	$34,308
MS–DRG 163—Cases with procedure code 34.85	13	2.23	29,406
MS–DRG 164—All cases	16,087	6.58	18,352
MS–DRG 164—Cases with procedure code 34.85	34	1.71	23,406
MS–DRG 165—All cases	9,207	3.91	13,081
MS–DRG 165—Cases with procedure code 34.85	1	1.00	22,977

There were only 48 cases of diaphragmatic pacemakers within MS–DRGs 163, 164, and 165. The average costs of these diaphragmatic pacemaker cases ranged from $22,977 for the single case in MS–DRG 165 to $29,406 for the cases in MS–DRG 163, compared to the average costs for all cases in MS–DRGs 163, 164, and 165, which range from $13,081 to $34,308. The average cost for diaphragmatic pacemaker cases in MS–DRG 163 was lower than that for all cases in MS–DRG 163, $29,406 compared to $34,308 for all cases. The average cost for diaphragmatic pacemaker cases was higher for MS–DRG 164, $23,406 compared to $18,352 for all cases. While the average cost for the single diaphragmatic pacemaker case was significantly higher for MS–DRG 165, $22,977 compared to $13,081, we were unable to determine if additional factors might have impacted the higher cost for this single case.

Given the small number of diaphragmatic pacemaker cases that we found, we do not believe that there is justification for creating a new MS–DRG. Basing a new MS–DRG on such a small number of cases could lead to distortions in the relative payment weights for the MS–DRG because several expensive cases could impact the overall relative payment weight. Having larger clinical cohesive groups within an MS–DRG provides greater stability for annual updates to the relative payment weights. We note that, as discussed in section II.G.4.c. of the preamble of this proposed rule, one of the criteria we apply in evaluating whether to create new severity subgroups within an MS–DRG is whether there are at least 500 cases in the CC or MCC subgroup. While this criterion is used to evaluate whether to create a severity subgroup within an MS–DRG, applying it here suggests that creating a new MS–DRG for only 48 cases would not be appropriate. Although the average costs of these diaphragmatic pacemaker cases are higher than the average costs of all cases in MS–DRGs 163 and 164, we believe the current MS–DRG assignment is appropriate and that the data do not support creating an MS–DRG because there are so few cases.

Our clinical advisors reviewed this issue and determined that the diaphragmatic pacemaker cases are appropriately classified within MS–DRGs 163, 164, and 165 because they are clinically similar to other cases of patients with major chest procedures within MS–DRGs 163, 164, and 165. Our clinical advisors did not support creating a new MS–DRG for such a small number of cases.

Based on the results of the examination of the claims data, the recommendations from our clinical advisors, and the small number of diaphragmatic pacemaker cases, we are not proposing to create a new MS–DRG for diaphragmatic pacemaker cases at this time. We are proposing to maintain the current MS–DRG assignments for diaphragmatic pacemaker cases. We are inviting public comments on our proposal.

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

a. Exclusion of Left Atrial Appendage

We received a request to move the exclusion of the left atrial appendage procedure, which is a non-O.R. procedure and captured by ICD–9–CM procedure code 37.36 (Excision, destruction or exclusion of left atrial appendage (LAA)), from MS–DRGs 250 (Percutaneous Cardiovascular without Coronary Artery Stent with MCC) and 251 (Percutaneous Cardiovascular without Coronary Artery Stent without MCC) to MS–DRGs 237 (Major Cardiovascular Procedures with MCC) and 238 (Major Cardiovascular Procedures without MCC). The requestor stated that the exclusion of the left atrial appendage procedure code 37.36 is not clinically coherent with the other procedures in MS–DRGs 250 and 251 and that this current assignment to MS–DRGs 250 and 251 does not compensate providers adequately for the expenses incurred to perform this procedure and placement of the device.

The exclusion of the left atrial appendage procedure involves a percutaneous placement of a snare/suture around the left atrial appendage to close it off. The exclusion of the left atrial appendage procedure takes place in the cardiac catheterization laboratory under general anesthesia and is a catheter based closed-chest procedure instead of an open heart surgical technique to treat the same clinical condition, with the same intended results. The procedure can be performed by either an interventional cardiologist or an electrophysiologist.

We analyzed claims data from the December 2013 update of the FY 2013 MedPAR file for cases assigned to MS–DRGs 250 and 251 and MS–DRGs 237 and 238. Our findings are shown in the table below.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 250—All cases	9,174	6.90	$21,319
MS–DRG 250—Cases with procedure code 37.36	61	7.21	29,637
MS–DRG 251—All cases	26,331	3.01	14,614
MS–DRG 251—Cases with procedure code 37.36	341	3.01	18,298
MS–DRG 237—All cases	17,813	9.66	35,642
MS–DRG 238—All cases	33,644	3.73	24,511

The data in the table above show that, while the average costs of the atrial appendage exclusion procedures are higher ($29,637) than those for all cases ($21,319) within MS–DRG 250 and are higher ($18,298) than for all cases ($14,614) within MS–DRG 251, they are lower than those in MS–DRGs 237 ($35,642) and 238 ($24,511). Our clinical advisors reviewed this issue and recommended not moving these stand-alone percutaneous cases to MS–DRGs 237 and 238 because they do not consider them to be major cardiovascular procedures. Our clinical advisors stated that cases reporting ICD–9–CM procedure code 37.36 are appropriately assigned within MS–DRG 250 and 251 because they are percutaneous cardiovascular procedures and are clinically similar to other procedures within the MS–DRG. Therefore, we are not proposing to reassign exclusion of atrial appendage procedure cases from MS–DRGs 250 and 251 to MS–DRGs 237 and 238 for FY 2015. We are inviting public comments on our proposal to maintain the current MS–DRG structure for the exclusion of the left atrial appendage.

b. Transcatheter Mitral Valve Repair: MitraClip®

The MitraClip® System (hereafter referred to as MitraClip®) for transcatheter mitral valve repair has been discussed in extensive detail in previous rulemaking, including the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25822) and final rule (76 FR 51528 through 51529) and the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27902 through 27903) and final rule (77 FR 53308 through 53310), in response to requests for MS–DRG reclassification, as well as, in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27547 through 27552) under the new technology add-on payment policy. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50575), the application for a new technology add-on payment for MitraClip® was unable to be considered further due to lack of FDA approval by the July 1, 2013 deadline.

Subsequently, on October 24, 2013, MitraClip® received FDA approval. As a result, the manufacturer has submitted new requests for both an MS–DRG reclassification and new technology add-on payment for FY 2015. We refer readers to section II.I. of the preamble of this proposed rule for discussion regarding the application for MitraClip® under the new technology add-on payment policy. Below we discuss the MS–DRG reclassification request.

The manufacturer's request for MS–DRG reclassification involves two components. The first component consists of reassigning cases reporting a transcatheter mitral valve repair using the MitraClip® from MS–DRGs 250 and 251(Percutaneous Cardiovascular Procedure without Coronary Artery Stent with MCC and without MCC, respectively) to MS–DRGs 216 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC), 217 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC), 218 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC), 219 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC), 220 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC), and 221 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC). The second component of the manufacturer's request was for CMS to examine the creation of a new base MS–DRG for transcatheter valve therapies.

Effective October 1, 2010, ICD–9–CM procedure code 35.97 (Percutaneous mitral valve repair with implant) was created to identify and describe the MitraClip® technology.

To address the first component of the manufacturer's request, we conducted an analysis of claims data from the December 2013 update of the FY 2013 MedPAR file for cases reporting procedure code 35.97 in MS–DRGs 250 and 251. The table below shows our findings.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 250—All cases	9,174	6.90	$21,319
MS–DRG 250—Cases with procedure code 35.97	67	8.48	39,103
MS–DRG 251—All cases	26,331	3.01	14,614
MS–DRG 251—Cases with procedure code 35.97	127	3.94	25,635

As displayed in the table above, the data demonstrate that, for MS–DRG 250, there were a total of 9,174 cases with an average length of stay of 6.90 days and average costs of $21,319. The number of cases reporting the ICD–9–CM procedure code 35.97 in MS–DRG 250 totaled 67 with an average length of stay of 8.48 days and average costs of $39,103. For MS–DRG 251, there were a total of 26,331 cases with an average length of stay of 3.01 days and average costs of $14,614. There were 127 cases found in MS–DRG 251 reporting the procedure code 35.97 with an average length of stay of 3.94 days and average costs of $25,635. We recognize that the cases reporting procedure code 35.97 have a longer length of stay and higher average costs in comparison to all the cases within MS–DRGs 250 and 251. However, as stated in prior rulemaking (77 FR 53309), it is a fundamental principle of an averaged payment system that half of the procedures in a group will have above average costs. It is expected that there will be higher cost and lower cost subsets, especially when a subset has low numbers.

We also evaluated the claims data from the December 2013 update of the FY 2013 MedPAR file for MS–DRGs 216

through 221. Our findings are shown in the table below.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 216—All cases	10,131	15.41	$65,478
MS–DRG 217—All cases	5,374	9.51	44,695
MS–DRG 218—All cases	882	6.88	39,470
MS–DRG 219—All cases	17,856	11.63	54,590
MS–DRG 220—All cases	21,059	7.13	38,137
MS–DRG 221—All cases	4,586	5.32	34,310

The data in our findings do not warrant reassignment of cases reporting use of the MitraClip®. If we were to propose reassignment of cases reporting procedure code 35.97 to MS–DRGs 216 through 221, they would be significantly overpaid, as the average costs range from $34,310 to $65,478 for those MS–DRGs. In addition, our clinical advisors do not support reassigning these cases. They noted that the current MS–DRG assignment is appropriate for the reasons stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53309). To reiterate, our clinical advisors note that the current MS–DRG assignment is reasonable because the operating room resource utilizations of percutaneous procedures, such as those found in MS–DRGs 250 and 251, tend to group together, and are generally less costly than open procedures, such as those found in MS–DRGs 216 through 221. Percutaneous procedures by organ system represent groups that are reasonably clinically coherent. More significantly, our clinical advisors state that postoperative resource utilization is significantly higher for open procedures with much greater morbidity and consequent recovery needs. Because the equipment, technique, staff, patient populations, and physician specialty all tend to group by type of procedure (percutaneous or open), separately grouping percutaneous procedures and open procedures is more clinically consistent. Therefore, we are not proposing to modify the current MS–DRG assignment for cases reporting procedure code 35.97 from MS–DRGs 250 and 251 to MS–DRGs 216 through 221 for FY 2015. We are inviting public comments on our proposal to not make any modifications to the current MS–DRG logic for these cases.

As indicated above, the second component of the manufacturer's request involved the creation of a new base MS–DRG for transcatheter valve therapies. We also received a similar request from another manufacturer recommending that we create a new MS–DRG for procedures referred to as endovascular cardiac valve replacement procedures. We reviewed each of these requests using the same data analysis, as set forth below. The discussion for endovascular cardiac valve replacement procedures is included in section II.G.4.c. of the preamble of this proposed rule and includes findings from the analysis and our proposals for each of these similar, but distinct requests.

c. Endovascular Cardiac Valve Replacement Procedures

As noted in the previous section related to the MitraClip® technology, we received two requests to create a new base MS–DRG for what was referred to as ''transcatheter valve therapies'' by one manufacturer and ''endovascular cardiac valve replacement'' procedures by another manufacturer. Below we summarize the details of each request and review results of the data analysis that was performed.

Transcatheter Valve Therapies

The request related to transcatheter valve therapies consisted of creating a new MS–DRG that would include the MitraClip® technology (ICD–9–CM procedure code 35.97 (Percutaneous mitral valve repair with implant)), along with the following list of ICD–9–CM procedure codes that identify the various types of valve replacements performed by an endovascular or transcatheter technique:

- 35.05 (Endovascular replacement of aortic valve);
- 35.06 (Transapical replacement of aortic valve);
- 35.07 (Endovascular replacement of pulmonary valve);
- 35.08 (Transapical replacement of pulmonary valve); and
- 35.09 (Endovascular replacement of unspecified valve).

We performed analysis of claims data from the December 2013 update of the FY 2013 MedPAR file for both the percutaneous mitral valve repair and the transcatheter/endovascular cardiac valve replacement codes in their respective MS–DRGs. The percutaneous mitral valve repair with implant (MitraClip®) procedure code is currently assigned to MS–DRGs 250 and 251, while the transcatheter/endovascular cardiac valve replacement procedure codes are currently assigned to MS–DRGs 216, 217, 218, 219, 220, and 221. As illustrated in the table below, the data demonstrate that, for MS–DRGs 250 and 251, there were a total of 194 cases reporting procedure code 35.97, with an average length of stay of 5.5 days and average costs of $30,286.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 250 through 251—Cases with procedure code 35.97	194	5.5	$30,286

Upon analysis of cases in MS–DRGs 216 through 221 reporting the cardiac valve replacement procedure codes, we found a total of 7,287 cases with an average length of stay of 8.1 days and average costs of $53,802, as shown in the table below.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 216 through 221—Cases with procedure codes 35.05, 35.06, 35.07, 35.08 and 35.09	7,287	8.1	$53,802
MS–DRGs 216 through 221—Cases without procedure codes 35.05, 35.06, 35.07, 35.08 and 35.09	52,601	10.1	47,177

The data clearly demonstrate that the volume of cases for the transcatheter/endovascular cardiac valve replacement procedures are much higher in comparison to the volume of cases for the percutaneous mitral valve repair (MitraClip®) procedure (7,287 compared to 194). In addition, the average costs of the transcatheter/endovascular cardiac valve replacement procedures are significantly higher than the average costs of the percutaneous mitral valve repair with implant ($53,802 compared to $30,286).

Our clinical advisors do not support grouping a percutaneous valve repair procedure with transcatheter/endovascular valve replacement procedures. They do not believe that these procedures are clinically coherent or similar in terms of resource consumption because the MitraClip® technology identified by procedure code 35.97 is utilized for a percutaneous mitral valve *repair,* while the other technologies, identified by procedure codes 35.05 through 35.09, are utilized for transcatheter/endovascular cardiac valve *replacements.* Consequently, the data analysis and our clinical advisors do not support the creation of a new MS–DRG. Therefore, for FY 2015, we are not proposing to create a new MS–DRG to group cases reporting the percutaneous mitral valve repair (MitraClip®) procedure with transcatheter/endovascular cardiac valve replacement procedures. We are inviting public comments on our proposal.

Endovascular Cardiac Valve Replacement

The similar but separate request relating to endovascular cardiac valve replacement procedures consisted of creating a new MS–DRG that would only include the various types of cardiac valve replacements performed by an endovascular or transcatheter technique. In other words, this request specifically did *not* include the MitraClip® technology (ICD–9–CM procedure code 35.97 (Percutaneous mitral valve repair with implant)) and only included the list of ICD–9–CM procedure codes that identify the various types of valve replacements performed by an endovascular or transcatheter technique (ICD–9–CM procedure codes 35.05 through 35.09) as described earlier in this section.

The human heart contains four major valves—the aortic, mitral, pulmonary, and tricuspid valves. These valves function to keep blood flowing through the heart. When conditions such as stenosis or insufficiency/regurgitation occur in one or more of these valves, valvular heart disease may result. Cardiac valve replacement surgery is performed in an effort to correct these diseased or damaged heart valves. The endovascular or transcatheter technique presents a viable option for high-risk patients who are not candidates for the traditional open surgical approach.

We reviewed the claims data from the December 2013 update of the FY 2013 MedPAR file for cases in MS–DRGs 216 through 221. Our findings are shown in the chart below. The data analysis shows that cardiac valve replacements performed by an endovascular or transcatheter technique represent a total of 7,287 of the cases in MS–DRGs 216 through 221, with an average length of stay of 8.1 days and higher average costs ($53,802 compared to $47,177) in comparison to all of the cases in MS–DRGs 216 through 221.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRGs 216 through 221—Cases with procedure codes 35.05, 35.06, 35.07, 35.08 and 35.09	7,287	8.1	$53,802
MS–DRGs 216 through 221—Cases without procedure codes 35.05, 35.06, 35.07, 35.08 and 35.09	52,601	10.1	47,177

As the data appear to indicate support for the creation of a new base MS–DRG, based on our evaluation of resource consumption, patient characteristics, volume, and costs between the cardiac valve replacements performed by an endovascular or transcatheter technique and the open surgical technique, we then applied our established criteria to determine if these cases would meet the requirements to create subgroups. We use five criteria established in the FY 2008 IPPS final rule (72 FR 47169) to review requests involving the creation of a new CC or an MCC subgroup within a base MS–DRG. As outlined in the FY 2012 IPPS proposed rule (76 FR 25819), the original criteria were based on average charges but were later converted to average costs. In order to warrant creation of a CC or an MCC subgroup within a base MS–DRG, this subgroup must meet all of the following five criteria:

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

In applying the five criteria, we found that the data support the creation of a new MS–DRG subdivided into two severity levels. We also consulted with our clinical advisors. Our clinical advisors stated that patients receiving endovascular cardiac valve replacements are significantly different from those patients who undergo an open chest cardiac valve replacement. They noted that patients receiving endovascular cardiac valve replacements are not eligible for open chest cardiac valve procedures because of a variety of health constraints. This highlights the fact that peri-operative complications and post-operative morbidity have significantly different profiles for open chest procedures compared with endovascular interventions. This is also substantiated by the different average lengths of stay

demonstrated by the two cohorts. Our clinical advisors further noted that separately grouping these endovascular valve replacement procedures provides greater clinical cohesion for this subset of high-risk patients.

We are proposing to create the following MS–DRGs for endovascular cardiac valve replacements:

- Proposed new MS–DRG 266 (Endovascular Cardiac Valve Replacement with MCC); and
- Proposed new MS–DRG 267 (Endovascular Cardiac Valve Replacement without MCC).

Proposed new MS–DRGs for endovascular cardiac valve replacement	Number of cases	Average length of stay	Average costs
Proposed New MS–DRG 266 with MCC	3,516	10.6	$61,891
Proposed New MS–DRG 267 without MCC	3,771	5.7	46,259

We are inviting public comments on our proposal to create these new MS–DRGs for FY 2015.

d. Abdominal Aorta Graft

We received a request that we change the MS–DRG assignment for procedure code 39.71 (Endovascular implantation of other graft in abdominal aorta), which is assigned to MS–DRGs 237 and 238 (Major Cardiovascular Procedures with MCC and without MCC, respectively). The requestor asked that we reassign procedure code 39.71 to MS–DRGs 228, 229, and 230 (Other Cardiothoracic Procedures with MCC, with CC, and without CC/MCC, respectively). The requestor stated that the average cost of endovascular abdominal aorta graft implantation cases is significantly higher than other cases in MS–DRGs 237 and 238. The requestor stated that the average cost of endovascular abdominal aorta graft implantation cases is closer to those in MS–DRGs 228, 229, and 230.

The requestor stated that the goal of endovascular repair for abdominal aneurysm is to isolate the diseased, aneurismal portion of the aorta and common iliac arteries from continued exposure to systemic blood pressure. The procedure involves the delivery and deployment of endovascular prostheses, also referred to as a graft, as required to isolate the aneurysm above and below the extent of the disease. The requestor stated that this significantly reduces patient morbidity and death caused by leakage and/or sudden rupture of an untreated aneurysm.

We examined claims data from the December 2013 update of the FY 2013 MedPAR file for cases of endovascular abdominal aorta graft implantations. The following table shows our findings.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 237—All cases	17,813	9.66	$35,642
MS–DRG 237—Cases with procedure code 39.71	2,093	8.30	44,898
MS–DRG 238—All cases	33,644	3.73	24,511
MS–DRG 238—Cases with procedure code 39.71	15,483	2.30	28,484
MS–DRG 228—All cases	1,543	13.48	52,315
MS–DRG 229—All cases	2,003	7.47	32,070
MS–DRG 230—All cases	493	4.95	29,281

As this table shows, endovascular abdominal aorta graft implantation cases have higher average costs and shorter lengths of stay than all cases within MS–DRGs 237 and 238. The average cost for endovascular abdominal aorta graft implantation cases in MS–DRG 237 is $9,256 greater than that for all cases in MS–DRG 237 ($44,898 compared to $35,642). The average cost for endovascular abdominal aorta graft implantation cases in MS–DRG 238 is $3,973 higher than that for all cases in MS–DRG 238 ($28,484 compared to $24,511). Cases in MS–DRG 228 have average costs that are $7,417 higher than the endovascular abdominal aorta graft implantation cases in MS–DRG 237 ($52,315 compared to $44,898). MS–DRG 228 and MS–DRG 237 both contain cases with MCCs. Cases in MS–DRG 229, which contain a CC, have average costs that are $3,586 higher than average costs of the endovascular abdominal aorta graft implantation cases in MS–DRG 238, which do not contain an MCC ($32,070 compared to $28,484). Cases in MS–DRG 230, which have neither an MCC nor a CC, have average costs that are $797 higher than the endovascular abdominal aorta graft implantation cases in MS–DRG 238 ($29,281 compared to $28,484). While the average costs were higher for endovascular abdominal aorta graft implantation cases compared to all cases within MS–DRGs 237 and 238, each MS–DRG has some cases that are higher and some cases that are lower than the average costs for the entire MS–DRG. MS–DRGs were developed to capture cases that are clinically consistent with similar overall average resource requirements. This results in some cases within an MS–DRG having costs that are higher than the overall average and other cases having costs that are lower than the overall average. This may be due to specific types of cases included within the MS–DRGs or to the fact that some cases will simply require additional resources on a specific admission. However, taken as a whole, the hospital will be paid an appropriate amount for the group of cases that are assigned to the MS–DRG. We believe the endovascular abdominal aorta graft implantation cases are appropriately grouped with other procedures within MS–DRGs 237 and 238.

Our clinical advisors reviewed this issue and determined that the endovascular abdominal aorta graft implantation cases are appropriately classified within MS–DRGs 237 and 238 because they are clinically similar to the other procedures in MS–DRGs 237 and 238, which include other procedures on the aorta. While the endovascular abdominal aorta graft implantation cases have higher average costs than the average for all cases within MS–DRGs 237 and 238, our clinical advisors do not believe this justifies moving the cases to MS–DRGs 228, 229 and 230, which involve a different set of cardiothoracic surgeries.

Based on the results of examination of the claims data and the recommendations of our clinical advisors, we do not believe that

proposing to reclassify endovascular abdominal aorta graft implantation cases from MS–DRGs 237 and 238 is warranted. We are proposing to maintain the current MS–DRG assignments for endovascular abdominal aorta graft implantation cases. We are inviting public comments on our proposal.

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

a. Shoulder Replacement Procedures

We received a request to change the MS–DRG assignment for shoulder replacement procedures. This request involved the following two procedure codes:

- 81.88 (Reverse total shoulder replacement); and
- 81.97 (Revision of joint replacement of upper extremity).

With respect to procedure code 81.88, the requestor asked that reverse total shoulder replacements be reassigned from MS–DRGs 483 and 484 (Major Joint/Limb Reattachment Procedure of Upper Extremities with CC/MCC and without CC/MCC, respectively) to MS–DRG 483 only. The reassignment of procedure code 81.88 from MS–DRGs 483 and 484 was discussed previously in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50534 through 50536). The result of reassigning reverse shoulder replacements from MS–DRGs 483 and 484 to MS–DRG 483 only would be that this procedure would be assigned to MS–DRG 483 whether or not the case had a CC or an MCC. The requestor stated that reverse shoulder replacement procedures are more clinically cohesive with higher severity MS–DRGs due to the complexity and resource consumption of these procedures. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50534 through 50536) for a discussion of the reverse total shoulder replacement.

The requestor also recommended that we reassign what it described as another shoulder procedure involving procedure code 81.97, which is assigned to MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively), to MS–DRG 483. We point out that MS–DRG 483 contains upper joint replacements, including shoulder replacements. MS–DRG 483 does not contain any joint revision procedures. Similar to the request for reassignment of procedure code 81.88, this would mean that procedure code 81.97 would be assigned to MS–DRG 483 whether or not the case had a CC or an MCC. If CMS did not support this recommendation for moving procedure code 81.97 to MS–DRG 483, the requestor recommended an alternative reassignment to MS–DRG 515 (Other Musculoskeletal System and Connective Tissue O.R. procedures with MCC) even if the case had no MCC.

We point out that, while the requestor refers to procedure code 81.97 as a shoulder procedure, the code description actually includes revisions of joint replacements of a variety of upper extremity joints, including those in the elbow, hand, shoulder, and wrist.

As stated earlier, reverse shoulder replacements are assigned to MS–DRGs 483 and 484. Revisions of upper joint replacements are assigned to MS–DRGs 515, 516, and 517. We examined claims data from the December 2013 update of the FY 2013 MedPAR file for MS–DRGs 483 and 484. The following table shows our findings of cases of reverse shoulder replacement.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 483—All cases	14,220	3.20	$18,807
MS–DRG 483—Cases with procedure code 81.88	7,086	3.19	20,699
MS–DRG 484—All cases	23,183	1.95	16,354
MS–DRG 484—Cases with procedure code 81.88	9,633	2.03	18,719
Proposed Revised MS–DRG 483 with all severity levels included	37,403	2.4	17,287

As the above table shows, MS–DRG 484 reverse shoulder replacement cases have similar average costs to those in MS–DRG 483 ($18,719 for reverse shoulder replacements in MS–DRG 484 compared to $18,807 for all cases in MS–DRG 483). However, in reviewing the data, we observed that the claims data no longer support two severity levels for MS–DRGs 483 and 484.

We use the five criteria established in FY 2008 (72 FR 47169) to review requests involving the creation of a new CC or MCC subgroup within a base MS–DRG. As outlined in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25819), the original criteria were based on average charges but were later converted to average costs. In order to warrant creation of a CC or an MCC subgroup within a base MS–DRG, the subgroup must meet all of the following five criteria:

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

We found through our examination of the claims data from the December 2013 update of the FY 2013 MedPAR file that the two severity subgroups of MS–DRG 483 and 484 no longer meet the fourth criterion of at least a 20-percent difference in average costs between subgroups. We found that there is a $2,453 difference in average costs between MS–DRG 483 and MS–DRG 484. The difference in average costs would need to be $3,761 to meet the fourth criterion. Therefore, our claims data support collapsing MS–DRGs 483 and 484 into a single MS–DRG. Our clinical advisors reviewed this issue and agree that there is no longer enough difference between the two severity levels to justify separate severity subgroups for MS–DRGs 483 and 484, which include a variety of upper joint replacements. Therefore, our clinical advisors support our recommendation to collapse MS–DRGs 483 and 484 into a single MS–DRG.

Based on the results of examination of the claims data and the advice of our clinical advisors, we are proposing to collapse MS–DRGs 483 and 484 into a single MS–DRG by deleting MS–DRG 484 and revising the title of MS–DRG 483 to read ''Major Joint/Limb Reattachment Procedure of Upper Extremities''.

The following table shows our findings of cases of revisions of upper joint replacement from the December 2013 update of the FY 2013 MedPAR file.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 515—All cases	3,407	9.22	$22,191
MS–DRG 515—Cases with procedure code 81.97	88	5.66	22,085
MS–DRG 516—All cases	8,502	5.34	14,356
MS–DRG 516—Cases with procedure code 81.97	799	2.84	18,214
MS–DRG 517—All cases	5,794	3.28	12,172
MS–DRG 517—Cases with procedure code 81.97	1,256	2.07	15,920
MS–DRG 483—All cases	14,220	3.20	18,807

Cases identified by code 81.97 in MS–DRGs 515, 516, and 517 have lower average costs and shorter lengths of stay than all cases in MS–DRG 515. The average costs of cases in MS–DRG 515 are $3,977 higher than the average costs of the cases with procedure code 81.97 in MS–DRG 516 ($22,191 compared to $18,214). The average costs of cases in MS–DRG 515 are $6,271 higher than cases with procedure code 81.97 in MS–DRG 517 ($22,191 compared to $15,920).

The table above shows that the average costs of cases in MS–DRG 483 are $3,278 lower than the average costs of cases with procedure code 81.97 in MS–DRG 515 ($18,807 compared to $22,085). The average costs of cases in MS–DRG 483 are $593 higher than the average costs of cases with procedure code 81.97 in MS–DRG 516 ($18,807 compared to $18,214). The average costs of cases in MS–DRG 483 are $2,887 higher than the average costs of cases with procedure code 81.97 in MS–DRG 517 ($18,807 compared to $15,920).

The claims data do not support moving all procedure code 81.97 cases to MS–DRG 515 or MS–DRG 483, whether or not there is a CC or an MCC. We also point out once again that procedure code 81.97 is a nonspecific code that captures revisions to not only the shoulder, but also a variety of upper extremity joints including those in the elbow, hand, shoulder, and wrist. Therefore, we have no way of determining how many cases reporting procedure code 81.97 were actually shoulder procedures as opposed to procedures on the elbow, hand, or wrist.

Our clinical advisors reviewed this issue and determined that the revisions of upper joint replacement procedures are appropriately classified within MS–DRGs 515, 516, and 517, which include other joint revision procedures. They do not support moving revisions of upper joint replacement procedures to MS–DRG 515, whether or not there is an MCC. They support the current classification, which bases the severity level on the presence of a CC or an MCC. They also do not support moving revisions of upper joint replacement procedures to MS–DRG 483, whether or not there is a CC or an MCC, because these revisions are not joint replacements. Based on the results of our examination and the advice of our clinical advisors, we are not proposing moving revisions of upper joint replacement procedures to MS–DRG 515 or MS–DRG 483, whether or not there is a CC or an MCC.

In summation, we are proposing to collapse MS–DRGs 483 and 484 into a single MS–DRG by deleting MS–DRG 484 and revising the title of MS–DRG 483 to read ''Major Joint/Limb Reattachment Procedure of Upper Extremities''. We are proposing to maintain the current MS–DRG assignments for revisions of upper joint replacement procedures in MS–DRGs 515, 516, and 517. We are inviting public comments on our proposals.

b. Ankle Replacement Procedures

We received a request to change the MS–DRG assignment for two ankle replacement procedures. The request involved the following two procedure codes:

- 81.56 (Total ankle replacement); and
- 81.59 (Revision of joint replacement of lower extremity, not elsewhere classified).

The reassignment of procedure code 81.56 from MS–DRGs 469 and 470 (Major Joint Replacement or Reattachment of Lower Extremity with CC and without MCC, respectively) to a new MS–DRG or, alternatively, to MS–DRG 469 was discussed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50536 through 50537). We refer readers to this final rule for a discussion of ankle replacement procedures. The requestor asked that we again evaluate reassigning total ankle replacement procedures. The requestor also asked that we reassign what it referred to as another ankle replacement revision procedure captured by procedure code 81.59 (Revision of joint replacement of lower extremity, not elsewhere classified), which is assigned to MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

The requestor asked that we reassign procedure code 81.56 from MS–DRGs 469 and 470 to MS–DRG 483 (Major Joint/Limb Reattachment Procedure of Upper Extremities with CC/MCC) and rename the MS–DRG to better capture the additional lower extremity cases. The requestor stated that the result would be assignment of lower joint procedures to an MS–DRG that currently captures only upper extremity cases and assignment to the highest severity level even if the case did not have a CC or an MCC. If CMS did not find this acceptable, the requestor made an alternative recommendation of assigning procedure code 81.56 to MS–DRG 469 and renaming the MS–DRG to better capture the additional cases. Cases would be assigned to the highest severity level whether or not the case had an MCC.

The requestor also recommended that procedure code 81.59, which is assigned to MS–DRGs 515, 516, and 517 be reassigned to MS–DRG 483 and that the MS–DRG be given a new title to better capture the additional lower extremity cases. The requestor stated that the result would be assignment of lower joint procedures to an MS–DRG that currently captures only upper extremity cases and assignment to the highest severity level even if the patient did not have a CC or an MCC. If CMS did not support this recommendation, the requestor suggested two additional recommendations. One involves moving procedure code 81.59 to MS–DRG 515 even when the case had no MCC. The other recommendation was to move procedure code 81.59 to MS–DRG 469, whether or not the case had a MCC.

We point out that while the requestor refers to procedure code 81.59 as a revision of an ankle replacement, the code actually includes revisions of joint replacements of a variety of lower extremity joints including the ankle, foot, and toe.

The following table shows the number of total ankle replacement cases, average length of stay, and average costs for procedure code 81.56 in MS–DRGs 469 and 470 found in claims data from the December 2013 update of the FY 2013

MedPAR file compared to all cases within MS–DRGs 469, 470, and 483.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 469—All cases	25,916	722	$22,548
MS–DRG 469—Cases with procedure code 81.56	32	6.19	27,419
MS–DRG 470—All cases	406,344	3.25	15,119
MS–DRG 470—Cases with procedure code 81.56	1,379	2.13	19,332
MS–DRG 483	14,220	3.20	18,807

In summary, the requestor asked us to reassign procedure code 81.56 in MS–DRGs 469 and 470 to one of the following two options: MS–DRG 483 (highest severity level); or MS–DRG 469 (highest severity level).

As the table for total ankle replacement above shows, the average cost of cases with procedure code 81.56 in MS–DRG 469 is $27,419 and $19,332 in MS–DRG 470. This compares with the average costs of all cases in MS–DRGs 469 and 470 of $22,548 and $15,119, respectively. While the average cost of cases reporting procedure code 81.56 in MS–DRG 469 is $4,871 higher than the average cost for all cases in MS–DRG 469, we point out that there were only 32 cases. The relatively small number of cases may have been impacted by other factors such as complications or comorbidities. Several expensive cases could impact the average costs for a very small number of patients. The average cost of cases reporting procedure code 81.56 in MS–DRG 470 is $4,213 higher than the average cost for all cases in MS–DRG 470. While the average costs are higher, within all MS–DRGs, some cases have higher and some cases have lower average costs. MS–DRGs are groups of clinically similar cases that have similar overall costs. Within a group of cases, one would expect that some cases have costs that are higher than the overall average and some cases have costs that are lower than the overall average.

MS–DRG 469 ankle replacement cases have average costs that are $8,612 higher than the average costs of all cases in MS–DRG 483 ($27,419 compared to $18,807). Moving these cases (procedure code 81.56) to MS–DRG 483 would result in payment below average costs compared to the current MS–DRG assignment in MS–DRG 469. Furthermore, as noted earlier, moving total ankle replacement cases to MS–DRG 483 would result in a lower extremity procedure being added to what is now an upper extremity MS–DRG. This would significantly disrupt the clinical cohesion of MS–DRG 483.

The average costs of all cases in MS–DRG 469 are $3,216 higher than the average costs of those cases with procedure code 81.56 in MS–DRG 470 ($22,548 compared to $19,332) The data do not support moving procedure code 81.56 cases to MS–DRG 483 or 469 because it would not result in payments that more accurately reflect their current average costs. Our clinical advisors reviewed this issue and determined that the ankle replacement cases are appropriately classified within MS–DRGs 469 and 470 with the severity level leading to the MS–DRG assignment. They do not support moving these cases to MS–DRG 483 because ankle replacements, which are lower joint procedures, are not clinically similar to upper joint replacement procedures. Based on the results of examination of the claims data, the issue of clinical cohesion, and the recommendations from our clinical advisors, we are not proposing to move total ankle procedures to MS–DRG 483 or MS–DRG 469 when there is no MCC. We are proposing to maintain the current MS–DRG assignments for ankle replacement cases. We are inviting public comments on our proposal.

The following table shows our findings from examination of the claims data from the December 2013 update of the FY 2013 MedPAR file for the number of cases reporting procedure code 81.59 in MS–DRGs 515, 516, and 517 (revision of joint replacement of lower extremity) and their average length of stay and average costs as compared to all cases within MS–DRGs 515, 516, and 517 (where procedure code 81.59 is currently assigned), as well as data for MS–DRGs 469 and 483.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 515—All cases	3,407	9.22	$22,191
MS–DRG 515—Cases with procedure code 81.59	5	6.00	16,988
MS–DRG 516—All cases	8,502	5.34	14,356
MS–DRG 516—Cases with procedure code 81.59	16	3.00	16,998
MS–DRG 517—All cases	5,794	3.28	12,172
MS–DRG 517—Cases with procedure code 81.59	40	1.80	13,704
MS–DRG 483—All cases	25,916	722	22,548
MS- DRG 469—All cases	14,220	3.20	18,807

The requestor asked that all cases with procedure code 81.59 in MS–DRGs 515, 516, and 517 be assigned to one of the following three choices:

- MS–DRG 483 (highest severity level);
- MS–DRG 515 (highest severity level) whether or not there is an MCC; or
- MS–DRG 469 (highest severity level).

Our review of data from the above revision of joint replacement of lower extremity table shows that cases in MS–DRG 483 have average costs that are $5,560 higher than the average costs of cases with procedure code 81.59 in MS–DRG 515; $5,550 greater than those in MS–DRG 516; and $8,844 greater than those in MS–DRG 517 ($22,548 compared to $16,988; $22,548 compared to $16,998, and $22,548 compared to $13,704, respectively). As mentioned earlier, MS–DRG 483 is currently composed of only upper extremity procedures. Moving lower extremity procedures into this MS–DRG would disrupt the clinical cohesiveness of MS–DRG 483.

The average costs of all cases in MS–DRG 469 are $18,807, compared to average costs of $16,988, $16,998, and $13,703 for procedure code 81.59 cases in MS–DRGs 515, 516, and 517, respectively. The data do not support moving all procedure code 81.59 cases to MS–DRG 469 even when there is no MCC. We also point out that moving cases with procedure code 81.59 to MS–DRG 469 would disrupt the clinical cohesiveness of MS–DRG 469, which currently captures major joint replacement or reattachment procedures of the lower extremity. Procedure code 81.59 includes revisions of joint replacements of a variety of lower extremity joints including the ankle, foot, and toe. This nonspecific code would not be considered a major joint procedure. The code captures revisions of an ankle replacement as well as a more minor revision of the toe.

Our clinical advisors reviewed this issue and determined that the revision of joint replacement of lower extremity cases are appropriately classified within MS–DRGs 515, 516, and 517 where revisions of other joint replacements are captured. They support the current severity levels in MS–DRGs 515, 516, and 517, which allow the presence of a CC or an MCC to determine the severity level assignment. They do not support moving these cases to MS–DRG 483, which is applied to upper extremity procedures because these procedures are not clinically consistent with revisions of lower joint procedures. They also do not support moving these cases to MS–DRG 469 when there is no MCC because these procedures are not joint replacement procedures. Based on the findings of our examination of the claims data, the issue of clinical cohesion, and the recommendations from our clinical advisors, we are not proposing to move the revision of joint replacement of lower extremity cases to MS–DRGs 483 or 469, whether or not there is an MCC. We are proposing to maintain the current MS–DRG assignments for revision of joint replacement of lower extremity cases.

In summary, we are proposing to maintain the current MS–DRG assignment for total ankle replacements in MS–DRGs 469 and 470 and revision of joint replacement of lower extremity procedures in MS–DRGs 515, 516, and 517. We are inviting public comments on our proposals.

c. Back and Neck Procedures

We received a request to reassign cases identified with a complication or comorbidity (CC) in MS–DRG 490 (Back & Neck Procedures Except Spinal Fusion with CC/MCC or Disc Device/Neurostimulator) to MS–DRG 491 (Back & Neck Procedures Except Spinal Fusion without CC/MCC or Disc Device/Neurostimulator). The requester suggested that we create a new MS–DRG that would be subdivided based solely on the ''with MCC or Disc Device/Neurostimulator'' and the ''without MCC'' (and no device) criteria.

For the FY 2008 rulemaking cycle, we performed a comprehensive analysis of all the spinal DRGs as we proposed (72 FR 24731 through 24735) and finalized (72 FR 47226 through 47232) adoption of the MS–DRGs. With the revised spinal MS–DRGs, we were better able to identify a patient's level of severity, complexity of service, and utilization of resources. This was primarily attributed to the new structure for the severity level designations of ''with MCC,'' ''with CC,'' and ''non-CC'' (or without CC/MCC). Another contributing factor was that we incorporated specific procedures and technologies into the GROUPER logic for some of those spinal MS–DRGs. Specifically, as noted above, in the title of MS–DRG 490, we accounted for disc devices and neurostimulators because the data demonstrated that the procedures utilizing those technologies were more complex and required greater utilization of resources.

According to the requester, since that time, concerns have been expressed in the provider community regarding inadequate payment for MS–DRG 490 when these technologies are utilized. An analysis conducted by the requester alleged that the subset of patients identified in the ''with MCC or disc device/neurostimulator'' group are different with regard to resource use from the ''without CC/MCC'' (and no device) patient group.

We examined claims data from the December 2013 update of the FY 2013 MedPAR file for MS–DRGs 490 and 491. The table below shows our findings.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 490—All cases	16,930	4.53	$13,727
MS–DRG 491—All cases	25,778	2.20	8,151

As shown in the table above, there were a total of 16,930 cases in MS–DRG 490 with an average length of stay of 4.53 days and average costs of $13,727. For MS–DRG 491, there were a total of 25,778 cases with an average length of stay of 2.20 days and average costs of $8,151.

We then analyzed the data for MS–DRGs 490 and 491 by subdividing cases based on the ''with MCC or Disc Device/Neurostimulator'' and the ''without MCC'' (and no device) criteria. We found a total of 3,379 cases with an average length of stay of 6.6 days and average costs of $21,493 in the ''with MCC or Disc Device/Neurostimulator'' group and a total of 39,329 cases with an average length of stay of 2.8 days and average costs of $9,405 in the ''without MCC'' and no device group. Due to the wide range in the volume of cases, length of stay, and average costs between these two subgroups, we concluded that further analysis of the data using a separate ''with CC'' (and no device) subset of patients was warranted.

Therefore, we evaluated the data using a three-way severity level split that consisted of the three subgroups shown in the table below.

ADDITIONAL ANALYSIS FOR BACK & NECK PROCEDURES EXCEPT SPINAL FUSION: DISC DEVICE/NEUROSTIMULATOR

Severity level split	Number of cases	Average length of stay	Average costs
—With MCC or disc device/neurostimulator	3,379	6.6	$21,493
—With CC	13,551	3.9	11,791
—Without CC/MCC	25,778	2.2	8,151

For the first subgroup, ''with MCC or Disc Device/Neurostimulator,'' we found a total of 3,379 cases with an average length of stay of 6.6 days and average costs of $21,493. In the second subgroup, ''with CC'' (no device), we found a total of 13,551 cases with an average length of stay of 3.9 days and average costs of $11,791. In the third subgroup, ''without CC/MCC'' (no device), we found a total of 25,778 cases with an average length of stay of 2.2 days and average costs of $8,151.

The results of this additional data analysis demonstrate a better distribution of cases with regard to length of stay and average costs. Our clinical advisors agree that a patient's severity of illness is captured more appropriately with this subdivision. The data also meet the established criteria for creating subgroups within a base MS–DRG as discussed earlier in this proposed rule.

As the subdivision of the claims data based on these subgroups better captures a patient's severity level and utilization of resources and is supported by our clinical advisors, we are proposing to create three new MS–DRGs and to delete MS–DRGs 490 and 491. These proposed new MS–DRGs would be titled as follows and would be effective as of October 1, 2014:

- Proposed new MS–DRG 518 (Back & Neck Procedures Except Spinal Fusion with MCC or Disc Device/ Neurostimulator);
- Proposed new MS–DRG 519 (Back & Neck Procedures Except Spinal Fusion with CC); and
- Proposed new MS–DRG 520 (Back & Neck Procedures Except Spinal Fusion without CC/MCC).

We are inviting public comments on our proposal to create these proposed new MS–DRGs for FY 2015.

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

We received a comment on the FY 2014 IPPS/LTCH PPS proposed rule that we considered out of scope for the proposed rule. We stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50550) that we would consider this issue in future rulemaking as part of our annual review process. The request was 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. This issue has been discussed previously in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27904 and 27905) and final rule (77 FR 53311 through 53313).

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). In 1984, this pharmaceutical agent became the first approved drug for a rare disease to be designated under the Orphan Drug Act. The requestor stated that 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 claims data from the December 2013 update of the FY 2013 MedPAR file for cases assigned to MS–DRG 642. Our findings are shown in the table below.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 642—All cases	1,486	4.61	$8,151
MS–DRG 642—Cases with principal diagnosis code 277.1	299	5.98	13,303

As shown in the table above, we found a total of 1,486 cases in MS–DRG 642, with an average length of stay of 4.61 days and average costs of $8,151. 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 299 cases, with an average length of stay of 5.98 days and average costs of $13,303.

While the data show that the average costs for the 299 cases reporting a principal diagnosis code of 277.1 were higher than the average costs for all cases in MS–DRG 642 ($13,303 compared to $8,151), the number of cases is small. Given the small number of porphyria cases, we do not believe there is justification for creating a new MS–DRG. Basing a new MS–DRG on such a small number of cases could lead to distortions in the relative payment weights for the MS–DRG because several expensive cases could impact the overall relative payment weight. Having larger clinical cohesive groups within an MS–DRG provides greater stability for annual updates to the relative payment weights. In addition, as discussed earlier, one of the criteria we apply in evaluating whether to create new severity subgroups within an MS–DRG is whether there are at least 500 cases in the CC or MCC subgroup. While this criterion is used to evaluate whether to create a severity subgroup within an MS–DRG, applying it here suggests that creating a new MS–DRG for cases reporting a principal diagnosis of code 277.1 would not be appropriate. Our clinical advisors reviewed this issue and recommended no MS–DRG change for porphyria cases because they fit clinically within MS–DRG 642.

In summary, we are not proposing to create a new MS–DRG for porphyria cases. We are inviting public comments on our proposal to maintain porphyria cases in MS–DRG 642.

7. MDC 15 (Newborns and Other Neonates With Conditions Originating in the Perinatal Period)

We received a request to evaluate the MS–DRG assignment of seven ICD–9–CM diagnosis codes in MS–DRG 794 (Neonate With Other Significant Problems) under MDC 15. The requestor stated that these codes have no bearing on the infant, and are not representative of a neonate with a significant problem. The requestor recommended that we change the MS–DRG logic so that the following seven ICD–9–CM codes would not lead to assignment of MS–DRG 794. The requestor recommended that the diagnoses be added to the ''only secondary diagnosis'' list under MS–DRG 795 (Normal newborn) so that the case would be assigned to MS–DRG 795 (Normal newborn).

- V17.0 (Family history of psychiatric condition)
- V17.2 (Family history of other neurological Diseases)

- V17.49 (Family history of other cardiovascular diseases)
- V18.0 (Family history of diabetes mellitus)
- V18.19 (Family history of other endocrine and metabolic diseases)
- V18.8 (Family history of infectious and parasitic diseases)
- V50.3 (Ear piercing)

In the case of a newborn with one of these diagnosis codes reported as a secondary diagnosis, the case would be assigned to MS–DRG 794. The commenter believed that any of these seven diagnosis codes (noted above), when reported as a secondary diagnosis for a newborn case, should be assigned to MS–DRG 795 instead of MS–DRG 794.

Our clinical advisors reviewed this request and concur with the commenter that the seven ICD–9–CM diagnosis codes noted above should not continue to be assigned to MS–DRG 794, as there is no clinically usable information reported in those codes identifying significant problems. Therefore, for FY 2015, we are proposing to reassign these following seven diagnoses to the ''only secondary diagnosis list'' under MS–DRG 795 so that the case would be assigned to MS–DRG 795.

- V17.0 (Family history of psychiatric condition)
- V17.2 (Family history of other neurological diseases)
- V17.49 (Family history of other cardiovascular diseases)
- V18.0 (Family history of diabetes mellitus)
- V18.19 (Family history of other endocrine and metabolic diseases)
- V18.8 (Family history of infectious and parasitic diseases)
- V50.3 (Ear piercing)

We are inviting public comments on this proposal.

8. 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.

As discussed in section II.G.1.a. of the preamble of this proposed rule, we developed an ICD–10 version of the current MS–DRGs, which are based on ICD–9–CM codes. We refer to this version of the MS–DRGs as the ICD–10 MS–DRGs Version 31.0–R. In November 2013, we also posted a Definitions of Medicare Code Edits Manual of the ICD–10 MCE Version 31.0 on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We produced mainframe and computer software for Version 31.0 of the MS–DRG GROUPER with Medicare Code Editor, which was made available to the public in December 2013. Information on ordering the mainframe and computer software through NTIS was posted on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html* under the ''Related Links'' section. This ICD–10 MS–DRG GROUPER with Medicare Code Editor Version 31.0 computer software facilitated additional review of the ICD–10 MS–DRGs conversion. We encouraged the public to submit to CMS any comments on areas where they believed the ICD–10 MS–DRG GROUPER and MCE did not accurately reflect the logic and edits found in the ICD–9–CM MS–DRG GROUPER and MCE Version 31.0.

We also have posted an ICD–10 version of the current MCE, which is based on ICD–9–CM codes, and refer to that version of the MCE as the ICD–10 MCE Version 31.0–R. Both of these documents are posted on our ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We will continue to share ICD–10 MS–DRG and MCE conversion activities with the public through this Web site.

For FY 2015, we are proposing to remove extracranial-intracranial (EC–IC) bypass surgery from the ''Noncovered Procedure'' edit code list for Version 32.0 of the MCE. This procedure is identified by ICD–9–CM procedure code 39.28 (Extracranial-intracranial (EC–IC) vascular bypass).

Because of the complexity of appropriately classifying the circumstances under which the EC–IC bypass surgery may, or may not, be considered reasonable and necessary for certain conditions, we are proposing to remove the MCE ''Noncovered Procedure'' edit for EC–IC bypass surgery from the ''Noncovered Procedure'' edit code list for Version 32.0 of the MCE. We are inviting public comments on this proposal.

9. Proposed Changes to Surgical Hierarchies

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

Because the relative resource intensity of surgical classes can shift as a function of MS–DRG reclassification and recalibrations, for FY 2015, 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 001 and 002 and surgical class B includes MS–DRGs 003, 004, and 005. Assume also that the average costs of MS–DRG 001 are higher than that of MS–DRG 003, but the average costs of MS–DRGs 004 and 005 are higher than the average costs of MS–DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of ''other O.R. procedures'' as discussed 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 with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

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

Based on the changes that we are proposing to make for FY 2015, as discussed in sections II.G.4.c., II.G.5.a., and II.G.5.c. of the preamble of this FY 2015 IPPS/LTCH PPS proposed rule, we are proposing to revise the surgical hierarchy for MDC 5 (Diseases and Disorders of the Circulatory System) and MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) as follows:

In MDC 5, we are proposing to sequence proposed new MS–DRG 266 (Endovascular Cardiac Valve Replacement with MCC) and proposed new MS–DRG 267 (Endovascular Cardiac Valve Replacement without MCC) above MS–DRG 222 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC).

In MDC 8, we are proposing to delete MS–DRGs 490 (Back & Neck Procedures Except Spinal Fusion with CC/MCC or Disc Device/Neurostimulator) and MS–DRG 491 (Back & Neck Procedures Except Spinal Fusion without CC/MCC or Disc Device/Neurostimulator) from the surgical hierarchy. We are proposing to sequence proposed new MS–DRG 518 (Back & Neck Procedure Except Spinal Fusion with MCC or Disc Device/Neurostimulator), proposed new MS–DRG 519 (Back & Neck Procedure Except Spinal Fusion with CC), and proposed new MS–DRG 520 (Back & Neck Procedure Except Spinal Fusion without CC/MCC) above MS–DRG 492 (Lower Extremity and Humerus Procedure Except Hip, Foot, Femur with MCC).

We are inviting public comments on our proposals.

10. Proposed Changes to the MS–DRG Diagnosis Codes for FY 2015

a. Major Complications or Comorbidities (MCCs) and Complications or Comorbidities (CC) Severity Levels for FY 2015

A complete updated MCC, CC, and Non-CC Exclusion List is available via the Internet on the CMS Web site at: *http://cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as follows:

- Table 6I (Complete MCC list);
- Table 6J (Complete CC list); and
- Table 6K (Complete list of CC Exclusions).

b. Coronary Atherosclerosis Due to Calcified Coronary Lesion

We received a request that we change the severity level for ICD–9–CM diagnosis code 414.4 (Coronary atherosclerosis due to calcified coronary lesion) from a non-CC to an MCC. This issue was previously discussed in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27522) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50541 through 50542).

We examined claims data from the December 2013 update of the FY 2013 MedPAR file for ICD–9–CM diagnosis code 414.4. The following chart shows our findings.

Code	Diagnosis description	CC Level	Cnt 1	Cnt 1 Impact	Cnt 2	Cnt 2 Impact	Cnt 3	Cnt 3 Impact
414.4	Coronary atherosclerosis due to calcified lesion.	Non-CC	1,796	1.16	3,056	2.18	2,835	3.01

We ran the above data as described in the 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 an MCC. The C3 value reflects a patient with at least one other secondary diagnosis that is an MCC.

The chart above shows that the C1 finding is 1.16. A value close to 1.0 in the C1 field suggests that the diagnosis 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 a non-CC. The C2 finding was 2.18. A C2 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 when there is at least one other secondary diagnosis that is a CC but none that is an MCC. While the C1 value of 1.16 is above the 1.0 value for a non-CC, it does not support reclassification to an MCC. As stated earlier, a value close to 3.0 suggests the condition is expected to consume resources more similar to an MCC than a CC or a non-CC. The C2 finding of 2.18 also does not support reclassifying this diagnosis code to an MCC. Our clinical advisors reviewed the data and evaluated this condition. They recommended that we not change the severity level of diagnosis code 414.4 from a non-CC to an MCC. They do not believe that this diagnosis would increase the severity level of patients. They pointed out that a similar code, diagnosis code 414.2 (Chronic total occlusion of coronary artery), is a non-CC. Our clinical advisors believe that diagnosis code 414.4 represents patients who are less severe than diagnosis code 414.2. Considering the C1 and C2 ratings and the input from our clinical advisors, we are not proposing to reclassify diagnosis code 414.4 to an MCC; the diagnosis code would continue to be considered a non-CC.

Therefore, based on the data and clinical analysis, we are proposing to maintain diagnosis code 414.4 as a non-

CC. We are inviting public comments on our proposal.

11. Complications or Comorbidity (CC) Exclusions List

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

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

b. Proposed CC Exclusions List for FY 2015

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; and
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC.[1]

For FY 2015, we are not proposing any changes to the CC Exclusion List. Therefore, we are not developing or publishing Tables 6G (Additions to the CC Exclusion List) or Table 6H (Deletions from the CC Exclusion List). We have developed Table 6K (Complete List of CC Exclusions), which is available only via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Because of the length of Table 6K, we are not publishing it in the Addendum to this proposed rule. Each of these principal diagnosis codes for which there is a CC exclusion is shown 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. Beginning with discharges on or after October 1 of each year, the indented diagnoses are not recognized by the GROUPER as valid CCs for the asterisked principal diagnoses.

A complete updated MCC, CC, and Non-CC Exclusions List is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

Because there are no proposed new, revised, or deleted diagnosis or procedure codes for FY 2015, we are not developing Table 6A (New Diagnosis Codes), Table 6B (New Procedure Codes), Table 6C (Invalid Diagnosis Codes), Table 6D (Invalid Procedure Codes), Table 6E (Revised Diagnosis Code Titles), and Table 6F (Revised Procedure Codes) to this proposed rule and they are not published as part of this proposed rule.

We are proposing no additions or deletions to the MS–DRG MCC List for FY 2015 and no additions or deletions to the MS–DRG CC List for FY 2015. Therefore, we are not developing Tables 6I.1 (Additions to the MCC List), 6I.2 (Deletions to the MCC List), 6J.1 (Additions to the CC List), and 6J.2 (Deletions to the CC List), and they are not published as part of this proposed rule.

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 31.0, is available on a CD for $225.00. This manual 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. Version

[1] We refer readers to 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); the FY 2012 final rule (76 FR 51542); the FY 2013 final rule (77 FR 53315); and the FY 2014 final rule (78 FR 50541). 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.

32.0 of this manual, which will include the final FY 2015 MS–DRG changes, will be available after publication of the FY 2015 final rule on a CD for $225.00. This manual may be obtained by writing 3M/HIS at the address provided above; or by calling (203) 949–0303; or by obtaining an order form at the Web site at: *http://www/3MHIS.com*. Please specify the revision or revisions requested.

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

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

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

- 60.0 (Incision of prostate);
- 60.12 (Open biopsy of prostate);
- 60.15 (Biopsy of periprostatic tissue);
- 60.18 (Other diagnostic procedures on prostate and periprostatic tissue);
- 60.21 (Transurethral prostatectomy);
- 60.29 (Other transurethral prostatectomy);
- 60.61 (Local excision of lesion of prostate);
- 60.69 (Prostatectomy, not elsewhere classified);
- 60.81 (Incision of periprostatic tissue);
- 60.82 (Excision of periprostatic tissue);
- 60.93 (Repair of prostate);
- 60.94 (Control of (postoperative) hemorrhage of prostate);
- 60.95 (Transurethral balloon dilation of the prostatic urethra);
- 60.96 (Transurethral destruction of prostate tissue by microwave thermotherapy);
- 60.97 (Other transurethral destruction of prostate tissue by other thermotherapy); and
- 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.[2]

Our review of MedPAR claims data showed that there were no cases that merited movement or should logically be assigned to any of the other MDCs. Therefore, for FY 2015, we are not proposing to change the procedures assigned among these MS–DRGs.

[2] 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 the FY 2000 (64 FR 41496), in the FY 2001 (65 FR 47064), or in the 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 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, 2010, 2011, 2012, 2013, and 2014, no procedures were moved, as noted in the FY 2008 final rule with comment period (72 FR 46241), in the FY 2009 final rule (73 FR 48513), in the FY 2010 final rule (74 FR 43796), in the FY 2011 final rule (75 FR 50122), in the FY 2012 final rule (76 FR 51549), in the FY 2013 final rule (77 FR 53321), and in the FY 2014 final rule (78 FR 50545).

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 2015, 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 costs and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the MS–DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we

have an adequate number of discharges to analyze the data.

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 2015, 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 II.G.2. through 7. of the preamble of this proposed rule, we are not proposing to add any diagnosis or procedure codes to MDCs for FY 2015.

13. Proposed Changes to the ICD–9–CM System

a. ICD–10 Coordination and Maintenance Committee

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 final update to ICD–9–CM codes was to be made on October 1, 2013. Thereafter, the name of the Committee was changed to the ICD–10 Coordination and Maintenance Committee, effective with the March 19–20, 2014 meeting. The ICD–10 Coordination and Maintenance Committee will address updates to the ICD–10–CM, ICD–10–PCS, and ICD–9–CM coding systems. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the coding systems to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The official list of ICD–9–CM diagnosis and procedure codes by fiscal year can be found on the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.html*. The official list of ICD–10–CM and ICD–10–PCS codes can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html*.

The NCHS has lead responsibility for the ICD–10–CM and ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–10–PCS and ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The Committee encourages participation in the 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 2015 at a public meeting held on September 18–19, 2013, and finalized the coding changes after consideration of comments received at the meetings and in writing by November 15, 2013.

The Committee held its 2014 meeting on March 19–20, 2014. Any new ICD–10–CM/PCS codes for which there was consensus of public support and for which complete tabular and indexing changes will be made by May 2014 will be included in the October 1, 2014 update to ICD–10–CM/ICD–10–PCS. For FY 2015, there are no proposed new, revised, or deleted ICD–9–CM diagnosis or procedure codes.

Copies of the minutes of the procedure codes discussions at the Committee's September 18–19, 2013 meeting and March 19–20, 2014 meeting can be obtained from the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/03_meetings.asp*. The minutes of the diagnosis codes discussions at the September 18–19, 2013 meeting and March 19–20, 2014 meeting are found at: *http://www.cdc.gov/nchs/icd/icd9cm.html*. 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–10 Coordination and Maintenance Committee, NCHS, Room 2402, 3311 Toledo Road, Hyattsville, MD 20782. Comments may be sent by Email to: *dfp4@cdc.gov*.

Questions and comments concerning the procedure codes should be addressed to: Patricia Brooks, Co-Chairperson, ICD–10 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 Email 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–10 (previously the ICD–9–CM) Coordination and Maintenance Committee holds its meetings in the spring and fall in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the Committee meeting if the request is received at least 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 diagnosis and procedure coding changes, 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 Meeting minutes. The public agreed that there was a need to hold the fall meetings earlier, in September or October, in order to meet the new implementation dates. The public provided comment that additional time would be needed to update hospital systems and obtain new code books and coding software. There was considerable concern expressed about the impact this 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–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the 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, 2014 implementation of a code at the September 18–19, 2013 Committee meeting. Therefore, there were no new codes implemented on April 1, 2014.

ICD–9–CM addendum and code title information is published on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/01overview.asp#TopofPage*. ICD–10–CM and ICD–10–PCS addendum and code title information is published on the CMS Web site at *http://www.cms.gov/Medicare/Coding/ICD10/index.html*. Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can also be found on the CDC Web site at: *http://www.cdc.gov/nchs/icd/icd10cm.html*. Information on new, revised, and deleted ICD–10–CM/ICD–10–PCS codes is also provided to the AHA for publication in the *Coding Clinic for ICD–10*. 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.

The code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

b. Code Freeze

In the January 16, 2009 ICD–10–CM and ICD–10–PCS final rule (74 FR 3340), 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.

HHS 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, HHS 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. The Committee also considered the delay in implementation of ICD–10 until October 1, 2014. There was an announcement at the September 19, 2012 ICD–9–CM Coordination and Maintenance Committee meeting 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 and October 1, 2013, 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, 2014, 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 Public Law 108–173. There were to be no updates to ICD–9–CM on October 1, 2014.
- On October 1, 2015, one year after the originally scheduled implementation of ICD–10, regular updates to ICD–10 were to begin.

The ICD–10 (previously 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 one year after the implementation of ICD–10, 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–10 Coordination and Maintenance Committee Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html*. A summary of the September 19, 2012 Committee meeting, along with both written and audio transcripts of this meeting, is posted on the Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials-Items/2012-09-19-MeetingMaterials.html*.

This partial code freeze has dramatically decreased the number of codes created each year as shown by the following information.

TOTAL NUMBER OF CODES AND CHANGES IN TOTAL NUMBER OF CODES PER FISCAL YEAR

ICD–9–CM codes			ICD–10–CM and ICD–10–PCS codes		
Fiscal year	Number	Change	Fiscal year	Number	Change
FY 2009 (October 1, 2008):			FY 2009:		
Diagnoses	14,025	348	ICD–10–CM	68,069	+5
Procedures	3,824	56	ICD–10–PCS	72,589	−14,327
FY 2010 (October 1, 2009):			FY 2010:		
Diagnoses	14,315	290	ICD–10–CM	69,099	+1,030
Procedures	3,838	14	ICD–10–PCS	71,957	−632
FY 2011 (October 1, 2010):					
Diagnoses	14,432	117	ICD–10–CM	69,368	+269
Procedures	3,859	21	ICD–10–PCS	72,081	+124
FY 2012 (October 1, 2011):			FY 2012:		
Diagnoses	14,567	135	ICD–10–CM	69,833	+465
Procedures	3,877	18	ICD–10–PCS	71,918	−163
FY 2013 (October 1, 2012):			FY 2013:		
Diagnoses	14,567	0	ICD–10–CM	69,832	−1
Procedures	3,878	1	ICD–10–PCS	71,920	+2
FY 2014 (October 1, 2013):			FY 2014:		
Diagnoses	14,567	0	ICD–10–CM	69,823	−9
Procedures	3,882	4	ICD–10–PCS	71,924	+4

As mentioned earlier, the public is provided the opportunity to comment on any requests for new diagnosis or procedure codes discussed at the ICD–10 Coordination and Maintenance Committee meeting. The public has supported only a limited number of new codes during the partial code freeze, as can be seen by data shown above. We have gone from creating several hundred new codes each year to creating only a limited number of new ICD–9–CM and ICD–10 codes.

At the September 18–19, 2013 and March 19–20, 2014 Committee meetings, we discussed any requests we had received for new ICD–10–CM diagnosis and ICD–10–PCS procedure codes that were to be implemented on October 1, 2014. We did not discuss ICD–9–CM codes. The public was given the opportunity to comment on whether or not new ICD–10–CM and ICD–10–PCS codes should be created, based on the partial code freeze criteria. The public was to use the criteria as to whether codes were needed to capture new diagnoses or new technologies. If the codes do not meet those criteria for implementation during the partial code freeze, consideration was to be given as to whether the codes should be created after the partial code freeze ends one year after the implementation of ICD–10–CM/PCS. We invited public comments on any code requests discussed at the September 18–19, 2013 and March 19–20, 2014 Committee meetings for implementation as part of the October 1, 2014 update. The deadline for commenting on code proposals discussed at the September 18–19, 2013 Committee meeting was November 15, 2013. The deadline for commenting on code proposals discussed at the March 19–20, 2014 Committee meeting was April 18, 2014.

H. Recalibration of the Proposed FY 2015 MS–DRG Relative Weights

1. Data Sources for Developing the Proposed Relative Weights

In developing the proposed FY 2015 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 2013 MedPAR data used in this proposed rule include discharges occurring on October 1, 2012, through September 30, 2013, based on bills received by CMS through December 31, 2013, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS under section 1814(b)(3) of the Act). The FY 2013 MedPAR file used in calculating the proposed relative weights includes data for approximately 10,050,984 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, 2013 update of the FY 2013 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 2015 also excludes claims with claim type values not equal to ''60.'' The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. We note that the FY 2015 proposed relative weights are based on the ICD–

9–CM diagnoses and procedures codes from the MedPAR claims data, grouped through the ICD–9–CM version of the FY 2015 GROUPER (Version 32). The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. Normally, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. Specifically, we used cost report data from the December 31, 2013 update of the FY 2012 HCRIS for calculating the proposed FY 2015 cost-based relative weights.

2. Methodology for Calculation of the Proposed Relative Weights

As we explain in section II.E.2. of the preamble of this proposed rule, we are calculating the proposed FY 2015 relative weights based on 19 CCRs, as we did for FY 2014. The methodology we used to calculate the proposed FY 2015 MS–DRG cost-based relative weights based on claims data in the FY 2013 MedPAR file and data from the FY 2012 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2015 MS–DRG classifications discussed in sections II.B. and II.G. of the preamble of this proposed rule.
- The transplant cases that were used to establish the proposed relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2012 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 92.2 percent of the providers in the MedPAR file had charges for 14 of the 19 cost centers. All claims of providers that did not have charges greater than zero for at least 14 of the 19 cost centers were deleted. In other words, a provider must have no more than five blank cost centers. If a provider did not have charges greater than zero in more than five cost centers, the claims for the provider were deleted. (We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50551) for the edit threshold related to FY 2014 and prior fiscal years).
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.
- Effective October 1, 2008, because hospital inpatient claims include a POA indicator field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to ''Y'' for ''Yes'' for all claims that otherwise have an ''N'' (No) or a ''U'' (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

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

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

Once the MedPAR data were trimmed and the statistical outliers were removed, the charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals located 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 19 cost groups so that each MS–DRG had 19 standardized charge totals. These charges were then adjusted to cost by applying the national average CCRs developed from the FY 2012 cost report data.

The 19 cost centers that we used in the proposed relative weight calculation are shown in the following table. The table shows the lines on the cost report and the corresponding revenue codes that we used to create the 19 national cost center CCRs.

Cost center group name (19 total)	MedPAR charge field	Revenue codes contained in MedPAR charge field	Cost report line description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS–2552–10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS–2552–10	Medicare charges from HCRIS (Worksheet D–3, Column & line number) Form CMS–2552–10
Routine Days	Private Room Charges.	011X and 014X	Adults & Pediatrics (General Routine Care).	C_1_C5_30	C_1_C6_30	D3_HOS_C2_30
	Semi-Private Room Charges.	012X, 013X and 016X–019X				
	Ward Charges	015X				
Intensive Days	Intensive Care Charges.	020X	Intensive Care Unit	C_1_C5_31	C_1_C6_31	D3_HOS_C2_31
	Coronary Care Charges.	021X	Coronary Care Unit	C_1_C5_32	C_1_C6_32	D3_HOS_C2_32
			Burn Intensive Care Unit.	C_1_C5_33	C_1_C6_33	D3_HOS_C2_33
			Surgical Intensive Care Unit.	C_1_C5_34	C_1_C6_34	D3_HOS_C2_34
			Other Special Care Unit.	C_1_C5_35	C_1_C6_35	D3_HOS_C2_35
Drugs	Pharmacy Charges	025X, 026X and 063X.	Intravenous Therapy.	C_1_C5_64	C_1_C6_64 C_1_C7_64	D3_HOS_C2_64
			Drugs Charged To Patient.	C_1_C5_73	C_1_C6_73 C_1_C7_73	D3_HOS_C2_73
Supplies and Equipment.	Medical/Surgical Supply Charges.	0270, 0271, 0272, 0273, 0274, 0277, 0279, and 0621, 0622, 0623.	Medical Supplies Charged to Patients.	C_1_C5_71	C_1_C6_71 C_1_C7_71	D3_HOS_C2_71
	Durable Medical Equipment Charges.	0290, 0291, 0292 and 0294–0299.	DME-Rented	C_1_C5_96	C_1_C6_96 C_1_C7_96	D3_HOS_C2_96
	Used Durable Medical Charges.	0293	DME-Sold	C_1_C5_67	C_1_C6_97 C_1_C7_97	D3_HOS_C2_97
Implantable Devices		0275, 0276, 0278, 0624.	Implantable Devices Charged to Patients.	C_1_C5_72	C_1_C6_72 C_1_C7_72	D3_HOS_C2_72
Therapy Services	Physical Therapy Charges.	042X	Physical Therapy	C_1_C5_66	C_1_C6_66 C_1_C7_66	D3_HOS_C2_66
	Occupational Therapy Charges.	043X	Occupational Therapy.	C_1_C5_67	C_1_C6_67 C_1_C7_67	D3_HOS_C2_67
	Speech Pathology Charges.	044X and 047X	Speech Pathology	C_1_C5_68	C_1_C6_68 C_1_C7_68	D3_HOS_C2_68
Inhalation Therapy	Inhalation Therapy Charges.	041X and 046X	Respiratory Therapy.	C_1_C5_65	C_1_C6_65 C_1_C7_65	D3_HOS_C2_65
Operating Room	Operating Room Charges.	036X	Operating Room	C_1_C5_50	C_1_C6_50 C_1_C7_50	D3_HOS_C2_50
		071X	Recovery Room	C_1_C5_51	C_1_C6_51 C_1_C7_51	D3_HOS_C2_51
Labor & Delivery	Operating Room Charges.	072X	Delivery Room and Labor Room.	C_1_C5_52	C_1_C6_52 C_1_C7_52	D3_HOS_C2_52
Anesthesia	Anesthesia Charges	037X	Anesthesiology	C_1_C5_53	C_1_C6_53 C_1_C7_53	D3_HOS_C2_53
Cardiology	Cardiology Charges	048X and 073X	Electrocardiology	C_1_C5_69	C_1_C6_69 C_1_C7_69	D3_HOS_C2_69
Cardiac Catheterization.		0481	Cardiac Catheterization.	C_1_C5_59	C_1_C6_59 C_1_C7_59	D3_HOS_C2_59
Laboratory	Laboratory Charges	030X, 031X, and 075X.	Laboratory	C_1_C5_60	C_1_C6_60 C_1_C7_60	D3_HOS_C2_60
			PBP Clinic Laboratory Services.	C_1_C5_61	C_1_C6_61 C_1_C7_61	D3_HOS_C2_61
		074X, 086X	Electro-Encephalography.	C_1_C5_70	C_1_C6_70 C_1_C7_70	D3_HOS_C2_70
Radiology	Radiology Charges	032X, 040X	Radiology—Diagnostic.	C_1_C5_54	C_1_C6_54 C_1_C7_54	D3_HOS_C2_54
		028x, 0331, 0332, 0333, 0335, 0339, 0342.	Radiology—Therapeutic.	C_1_C5_55	C_1_C6_55	D3_HOS_C2_55
		0343 and 344	Radioisotope	C_1_C5_56	C_1_C6_56 C_1_C7_56	D3_HOS_C2_56
Computed Tomography (CT) Scan.	CT Scan Charges	035X	Computed Tomography (CT) Scan.	C_1_C5_57	C_1_C6_57 C_1_C7_57	D3_HOS_C2_57

Cost center group name (19 total)	MedPAR charge field	Revenue codes contained in MedPAR charge field	Cost report line description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS–2552–10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS–2552–10	Medicare charges from HCRIS (Worksheet D–3, Column & line number) Form CMS–2552–10
Magnetic Resonance Imaging (MRI).	MRI Charges	061X	Magnetic Resonance Imaging (MRI).	C_1_C5_58	C_1_C6_58 C_1_C7_58	D3_HOS_C2_58
Emergency Room	Emergency Room Charges.	045x	Emergency	C_1_C5_91	C_1_C6_91 C_1_C7_91	D3_HOS_C2_91
Blood and Blood Products.	Blood Charges	038x	Whole Blood & Packed Red Blood Cells.	C_1_C5_62	C_1_C6_62 C_1_C7_62	D3_HOS_C2_62
	Blood Storage/Processing.	039x	Blood Storing, Processing, & Transfusing.	C_1_C5_63	C_1_C6_63 C_1_C7_63	D3_HOS_C2_63
Other Services	Other Service Charge.	0002–0099, 022X, 023X, 024X, 052X, 053X. 055X–060X, 064X–070X, 076X–078X, 090X–095X and 099X.				
	Renal Dialysis	0800X	Renal Dialysis	C_1_C5_74	C_1_C6_74	D3_HOS_C2_74
	ESRD Revenue Setting Charges.	080X and 082X–088X.			C_1_C7_74	
			Home Program Dialysis.	C_1_C5_94	C_1_C6_94 C_1_C7_94	D3_HOS_C2_94
	Outpatient Service Charges.	049X	ASC (Non Distinct Part).	C_1_C5_75	C_1_C6_75	D3_HOS_C2_75
	Lithotripsy Charge	079X			C_1_C7_75	
			Other Ancillary	C_1_C5_76	C_1_C6_76 C_1_C7_76	D3_HOS_C2_76
	Clinic Visit Charges	051X	Clinic	C_1_C5_90	C_1_C6_90 C_1_C7_90	D3_HOS_C2_90
			Observation beds	C_1_C5_92.01	C_1_C6_92.01 C_1_C7_92.01	D3_HOS_C2_92.01
	Professional Fees Charges.	096X, 097X, and 098X.	Other Outpatient Services.	C_1_C5_93	C_1_C6_93 C_1_C7_93	D3_HOS_C2_93
	Ambulance Charges.	054X	Ambulance	C_1_C5_95	C_1_C6_95 C_1_C7_95	D3_HOS_C2_95
			Rural Health Clinic	C_1_C5_88	C_1_C6_88 C_1_C7_88	D3_HOS_C2_88
			FQHC	C_1_C5_89	C_1_C6_89 C_1_C7_89	D3_HOS_C2_89

We refer readers to the FY 2009 IPPS/LTCH PPS final rule (73 FR 48462) for a discussion on the revenue codes included in the Supplies and Equipment and Implantable Devices CCRs, respectively.

3. Development of National Average CCRs

We developed the national average CCRs as follows:

Using the FY 2012 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. We then created CCRs for each provider for each cost center (see prior table for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. We then took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–3 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–3. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the 19 cost centers by the corresponding national average CCR, we summed the 19 ''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 2015 cost-based relative weights were then normalized by an adjustment factor of 1.642112 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 proposed 19 national average CCRs for FY 2015 are as follows:

Group	CCR
Routine Days	0.483
Intensive Days	0.405
Drugs	0.191
Supplies & Equipment	0.293
Implantable Devices	0.355
Therapy Services	0.345
Laboratory	0.128
Operating Room	0.212
Cardiology	0.124
Cardiac Catheterization	0.131
Radiology	0.164
MRIs	0.086
CT Scans	0.043
Emergency Room	0.197
Blood and Blood Products	0.360
Other Services	0.398
Labor & Delivery	0.393
Inhalation Therapy	0.182
Anesthesia	0.115

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 2015 IPPS/LTCH PPS proposed rule, we are proposing to use that same case threshold in recalibrating the proposed MS–DRG relative weights for FY 2015. Using data from the FY 2013 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 2015, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for these low-volume MS–DRGs, we are proposing to compute relative weights for the low-volume MS–DRGs by adjusting their final FY 2014 relative 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.	Final FY 2014 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
789	Neonates, Died or Transferred to Another Acute Care Facility.	Final FY 2014 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate.	Final FY 2014 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
791	Prematurity with Major Problems	Final FY 2014 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
792	Prematurity without Major Problems	Final FY 2014 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
793	Full-Term Neonate with Major Problems	Final FY 2014 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
794	Neonate with Other Significant Problems	Final FY 2014 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
795	Normal Newborn	Final FY 2014 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).

4. Bundled Payments for Care Improvement (BPCI) Initiative

The Bundled Payments for Care Improvement (BPCI) initiative, developed under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of four broadly defined models of care, which link payments for multiple services beneficiaries receive during an episode of care. Under the BPCI initiative, organizations enter into payment arrangements that include financial and performance accountability for episodes of care. On January 31, 2013, CMS announced the health care organizations selected to participate in the BPCI initiative. For additional information on the BPCI initiative, we refer readers to the CMS' Center for Medicare and Medicaid Innovation's Web site at *http://innovation.cms.gov/initiatives/Bundled-Payments/index.html* and to section IV.H.4. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343) for a discussion on the BPCI initiative.

In the FY 2013 IPPS/LTCH PPS final rule, for FY 2013 and subsequent fiscal years, we finalized a policy to treat hospitals that participate in the BPCI initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process without regard to a hospital's participation within these bundled payment models (that is, as if a hospital were not participating in those models under the BPCI initiative). Therefore, for FY 2015, we are proposing to continue 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. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals participating in

the BPCI initiative in our ratesetting process.

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 § 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 the 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 2014 IPPS/LTCH PPS final rule contains the final thresholds that we use to evaluate applications for new technology add-on payments for FY 2015. We refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2014-IPPS-Final-Rule-Home-Page.html* for a complete viewing of Table 10 from the FY 2014 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 more detailed 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, the additional 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 criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We 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 Center for Clinical Standards and Quality (CCSQ) and the Director of the Center for Medicare (CM), who is also designated as the CTI's Executive Coordinator.

The specific processes for coverage, coding, and payment are implemented by CM, CCSQ, and the local 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 2016 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.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html*. To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2016, the CMS 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 2015 prior to publication of the FY 2015 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on November 29, 2013 (78 FR 71555 through 71557), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on February 12, 2014. 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 2015 new medical service and technology add-on payment applications before the publication of the FY 2015 proposed rule.

Approximately 91 individuals registered to attend the town hall meeting in person, while additional individuals listened over an open telephone line. We also live-streamed the town hall meeting and posted the town hall on the CMS YouTube Web page at: *http://www.youtube.com/watch?v=WXyR_TILfKo&list=TLiu1B_AxXsinTW6EEn4BVUdR4iEM61eV4.* 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 January 21, 2014, in our evaluation of the new technology add-on payment applications for FY 2015 in this proposed rule.

In response to the published notice and the New Technology Town Hall meeting, we received written comments regarding the applications for FY 2015 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.

A number of attendees at the New Technology Town Hall meeting provided comments that were unrelated to the ''substantial clinical improvement'' criterion. As explained above and in the **Federal Register** notice

announcing the New Technology Town Hall meeting (78 FR 71555 through 71557), the purpose of the meeting was specifically to discuss the substantial clinical improvement criterion in regard to pending new technology add-on payment applications for FY 2015. 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 2015 Status of Technologies Approved for FY 2014 Add-On Payments

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 of result of renal impairment. The administration of Glucarpidase causes a rapid and sustained reduction of toxic MTX concentrations.

Voraxaze® 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 the FY 2013 IPPS/LTCH PPS final rule (77 FR 53346 through 53350). Voraxaze® was available on the market in the United States as a commercial product to the larger population as of April 30, 2012. In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27936 through 27939), we expressed concerns about whether Voraxaze® could be considered new for FY 2013. After consideration of all of the public comments received, in the FY 2013 IPPS/LTCH PPS final rule, we stated that we considered Voraxaze® to be ''new'' as of April 30, 2012, which is the date of market availability.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for Voraxaze® and consideration of the public comments we received in response to the FY 2013 IPPS/LTCH PPS proposed rule, we approved Voraxaze® for new technology add-on payments for FY 2013. Cases of Voraxaze® are identified with ICD–9–CM procedure code 00.95 (Injection or infusion of glucarpidase). The cost of Voraxaze® is $22,500 per vial. The applicant stated that an average of four vials is used per Medicare beneficiary. Therefore, the average cost per case for Voraxaze® is $90,000 ($22,500 × 4). Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for Voraxaze® is $45,000 per case.

As stated above, 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 service or technology'' (§ 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 Voraxaze®, as stated above, we consider the beginning of the newness period to commence when Voraxaze® was first available on the market on April 30, 2012. Because the 3-year anniversary date for Voraxaze® will occur in the latter half of FY 2015 (April 30, 2015), we are proposing to continue new technology add-on payments for this technology for FY 2015. We are inviting public comments on this proposal.

b. DIFICID™ (Fidaxomicin) Tablets

Optimer Pharmaceuticals, Inc. submitted an application for new technology add-on payments for FY 2013 for the use of DIFICID™ tablets. 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 asserted 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 asserted 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 asserted that Fidaxomicin does not alter this native intestinal microflora.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27939 through 27941), we expressed concern that DIFICID™ may not be eligible for new technology add-on payments because eligibility is limited to new technologies associated with procedures described by ICD–9–CM codes. We further stated that drugs that are only taken orally (such as DIFICID™) may not 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). In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53350 through 53358), after consideration of the public comments received, we revised our policy to allow the use of National Drug Codes (NDCs) to identify oral medications that have no inpatient procedure for the purposes of new technology add-on payments. The revised policy is effective for payments for discharges occurring on or after October 1, 2012. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on this issue.

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. In the FY 2013 IPPS/LTCH PPS final rule, we established that the beginning of the newness period for this technology is its FDA approval date of May 27, 2011.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for DIFICID™ and consideration of the public comments we received in response to the FY 2013 IPPS/LTCH PPS proposed rule, we approved DIFICID™ for new technology add-on payments for FY 2013. Cases of DIFICID™ are identified with ICD–9–CM diagnosis code 008.45 (Intestinal infection due to *Clostridium difficile*) in combination with NDC code 52015–0080–01. Providers must report the NDC on the 837i Health Care Claim Institutional form (in combination with ICD–9–CM diagnosis code 008.45) in order to receive the new technology add-on payment. According to the applicant, the cost of DIFICID™ is

$2,800 for a 10-day dosage. The average cost per day for DIFICID™ is $280 ($2,800/10). Cases of DIFICID™ within the inpatient setting typically incur an average dosage of 6.2 days, which results in an average cost per case for DIFICID™ of $1,736 ($280 × 6.2). Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for DIFICID™ is $868.

As stated above, 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 service or technology'' (§ 412.87(b)(2)).

The manufacturer commented through a letter to CMS, prior to the publication of this proposed rule, requesting that CMS extend the eligibility for a third year of new technology add-on payments for DIFICID™ in FY 2015. The manufacturer maintained that the technology still meets all three criteria for new technology add-on payments. Regarding the substantial clinical improvement criterion, the applicant stated that DIFICID™ continues to remain the only FDA-approved treatment to demonstrate substantial clinical improvement over existing therapies. No new treatments for CDAD have been approved by the FDA since DIFICID™. The applicant further stated that a third year of new technology add-on payments for DIFICID™ would continue to reduce access barriers in the acute care hospital inpatient setting, which would support the appropriate use of DIFICID™, a treatment that offers a substantial clinical improvement over existing therapies.

With respect to the cost criterion, the applicant stated that DIFICID™ continues to meet the cost criterion. Using claims data from the FY 2012 MedPAR file, the applicant provided updated data from the two analyses described in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53350 through 53358), and demonstrated that the average case-weighted standardized charge per case exceeded the average case-weighted thresholds under both analyses. The applicant stated that the new technology add-on payment is intended to offer additional payments to support patient access and appropriate use of new technologies for a period of time until the MS–DRGs are adjusted to reflect the cost of the new technology. The applicant believed that the analyses conducted with the most recent MedPAR claims data available demonstrate that the MS–DRG recalibrations are insufficient to accommodate the cost associated with CDAD and new technologies to treat CDAD under the IPPS within the allotted timeframe of 2 years. According to the applicant, these payment amounts remain an obstacle for the appropriate use of new technologies for CDAD that demonstrate substantial clinical improvement over existing treatments, such as DIFICID™. The applicant concluded that a third year of new technology add-on payments for DIFICID™ is needed to allow sufficient data for future MS–DRG recalibration analyses.

With regard to newness criterion, the manufacturer commented that it believed that the technology still meets the newness criterion for the following reason: § 412.87(b)(2) states 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 International Classification of Diseases, Ninth Revision, Clinical Modification (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.'' The manufacturer noted that DIFICID™ was not assigned an ICD–9–CM procedure code and DIFICID™ is the first product for which no inpatient procedure is associated to receive a new technology add-on payment since the implementation of the new technology add-on payment policy.

The manufacturer also cited the FY 2013 IPPS/LTCH PPS final rule (77 FR 53352), which indicated that ''Hospitals currently code and report procedures and more invasive services such as surgeries, infusion of drugs, and specialized procedures such as cardiac catheterizations. Hospitals neither code nor report self-administered drugs.'' Therefore, the manufacturer contended that, as an oral therapy, neither DIFICID™ nor its administration was assigned an ICD–9–CM procedure code and, therefore, the technology should still be eligible for the new technology add-on payments.

The manufacturer further noted that, in the FY 2013 IPPS/LTCH PPS final rule, because an ICD–9–CM procedure code for the administration of an oral medication did not exist and hospitals had no other mechanism to report the use of DIFICID™, for FY 2013, CMS instructed hospitals to report the DIFICID™ NDC on hospital inpatient claims to receive the new technology add-on payment for DIFICID™. Prior to October 1, 2012, hospitals did not use NDCs on hospital inpatient claims, which prevented CMS from isolating DIFICID™ cases and their associated costs. The manufacturer further stated that the NDC methodology was a bold change in policy and inpatient billing processes, and it stands to reason that, because of hospitals unfamiliarity with reporting NDCs on inpatient claims, hospitals' use of the DIFICID™ NDC would greatly lag behind the traditional use of ICD–9–CM procedure codes. As such, the manufacturer reasoned that any lag in hospital reporting would directly impact CMS' ability to track and analyze the cost data associated with DIFICID™ cases.

The manufacturer also noted that on August 31, 2012, CMS issued Transmittal 2539, which is a change request for Medicare Administrative Contractors concerning updates for the upcoming fiscal year. The manufacturer stated that because the new technology add-on heading was omitted in the transmittal, this change request did not highlight the NDC billing approach to ensure that hospitals recognized the important change, which may have caused hospitals to overlook the claim reporting instructions for DIFICID™.

The manufacturer added that Transmittal 2539 and a Medicare Learning Network® Matters (MLN) article were rescinded and replaced by Transmittal 2627 on January 4, 2013. The manufacturer noted that among CMS' reasons for replacing the transmittal was to insert the omitted new technology add-on section heading. The manufacturer stated that, although the original transmittal further supports that collection of DIFICID™-specific data did not begin until at least October 1, 2012, CMS' reissuance of the claims processing instructions, and the missing header in the initial instructions, effectively delayed implementation of the new technology add-on payments for 3 months past the October 2012 beginning date. The manufacturer also believed that the need to replace the transmittal underlies hospitals' difficulties instituting claims' reporting instructions to receive new technology add-on payments for DIFICID™ at the hospital level.

The manufacturer noted that anecdotal feedback from hospitals, which was shared with CMS during a

meeting in June 2013, suggests that some hospitals faced challenges implementing the appropriate billing and coding processes. The manufacturer was concerned that that these challenges were, in part, caused by the missing header, and that these challenges may have impacted whether eligible cases were properly billed and coded to receive the new technology add-on payment for DIFICID™. The manufacturer was further concerned that the effects of any lag or delay caused by unfamiliarity with reporting NDCs and the missing header would also impact the data available to CMS to recalibrate the MS–DRGs and, separately, to evaluate the impact of the new technology add-on payment for DIFICID™. The manufacturer further explained that, while DIFICID™ was available to hospitals after its launch in July 2011, hospitals had no experience reporting NDCs until October 2012, and may not have recognized the opportunity to, or understood the mechanism for doing so, until after January 2013. For the purposes of inpatient data collection and ratesetting, the manufacturer believed that this meant that 2 complete years of DIFICID™ costs would not be fully reflected in the Medicare claims data for the FY 2015 MS–DRG recalibrations.

The manufacturer also analyzed the 100 percent sample of the Standard Analytical File (SAF) for calendar year 2012, which contained first quarter claims data for FY 2013, the first 3 months that DIFICID™ was eligible for the new technology add-on payments. The manufacturer found a total of 43,608 cases with a diagnosis of CDI. Of these 43,608 cases, the manufacturer found 38 cases across 26 hospitals that reported new technology add-on payments for DIFICID™ on submitted claims. The manufacturer stated that this preliminary data suggests that the number of cases available for MS–DRG recalibrations for FY 2015 is limited. The manufacturer stated that it is currently attempting to secure FY 2013 MedPAR claims data and that it will likely provide further insights on these issues.

In addition, the manufacturer noted that prior new technology add-on payment application approvals have involved technologies with much narrower patient populations compared to DIFICID™, allowing the costs of those technologies to influence the MS–DRG relative payment weights for the small number of MS–DRGs with which they are associated. The manufacturer explained that, unlike other technologies approved for new technology add-on payments, the DIFICID™ therapeutic value, while limited to patients with CDAD, is used in patients across a wide range of MS–DRGs due to it being reported as a secondary diagnosis in two-thirds of the cases compared to other technologies, which are assigned to a relatively small number of MS–DRGs. For example, cases involving the Spiration IBV® Valve System, which was granted approval for new technology add-on payments in FY 2010, primarily mapped to three MS–DRGs: 163 (Major Chest Procedures with MCC), 164 (Major Chest Procedures with CC), and 165 (Major Chest Procedures without CC/MCC). In its analysis of the FY 2012 MedPAR data for the cost criterion, the manufacturer found cases using DIFICID™ mapped to 544 unique MS–DRGs. Under the 100 percent sample of the SAF for calendar year 2012, the 38 cases mentioned above mapped to 20 different MS–DRGs. The manufacturer maintained that because of the diffuse nature of the DIFICID™ cases mapping to many MS–DRGs, it believed an extension of the newness period is required for the costs to be adequately reflected in the MS–DRG relative payment weights. In the unique case of DIFICID™ for the treatment of CDAD, the manufacturer stated that 2 years of new technology add-on payments is insufficient to allow the 544 MS–DRGs to be recalibrated to sufficiently reflect the cost of the use of DIFICID™, a treatment that offers significant clinical improvement over existing therapies.

With regard to the technology's newness, as discussed in the FY 2005 IPPS final rule (69 FR 49003), the timeframe that a new technology can be eligible to receive new technology add-on payments begins when data become available. Section 412.87(b)(2) clearly states 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).'' Section 412.87(b)(2) also states, ''[a]fter 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.'' Therefore, regardless of whether a technology can be individually identified by a separate ICD–9–CM code or whether it can only be identified using a NDC code, if the costs of the technology are included in the charge data, and the MS–DRGs have been recalibrated using that data, then the technology can no longer be considered ''new'' for the purposes of this provision. We further stated in that final rule that the period of newness does not necessarily start with the approval date for the medical service or technology, and does not necessarily start with the issuance of a distinct code. Instead, it begins with availability of the product on the U.S. market, which is when data become available. We have consistently applied this standard, and believe that it is most consistent with the purpose of new technology add-on payments.

In addition, similar to our discussion in the FY 2006 IPPS final rule (70 FR 47349), we do not believe that case volume is a relevant consideration for making the determination as to whether a product is ''new.'' Consistent with the statute, a technology no longer qualifies as ''new'' once it is more than 2 to 3 years old, irrespective of how frequently it has been used in the Medicare population. Similarly, this same determination is applicable no matter how many MS–DRGs the technology is spread across. Therefore, if a product is more than 2 to 3 years old, we consider its costs to be included in the MS–DRG relative weights whether its use in the Medicare population has been frequent or infrequent. We recognize that using an NDC was a novel billing practice under the IPPS. Nevertheless, even though hospitals may not have coded all uses of DIFICID™ with the NDC, hospital bills would still include charges for all items and services furnished to a Medicare patient, including use of DIFICID™. Therefore, even though we may be not be able to identify all uses of DIFICID™ in the Medicare charge data, hospital charges for the MS–DRGs would continue to reflect use of this technology.

With respect to the Transmittal 2539 omitting the header referenced above, as noted above, CMS corrected this issue as soon as possible by rescinding and reissuing this transmittal. Additionally, as noted by the manufacturer, this transmittal was meant for MACs and not hospitals. We believe the guidance issued in Transmittal 2539 clearly described to MACs how hospitals were to report the NDC on the inpatient claim in order to identify cases using DIFICID™ for purposes of new technology add-on payments. Additionally, the MLN article that the manufacturer referred to above (MLN articles are typically a summary of transmittals for the general public) clearly indicated that DIFICID™ was new for FY 2013 new technology add-

on payments and clearly described how to properly code DIFICID™ on the inpatient bill in order to receive the new technology add-on payment for FY 2013. The MLN article can be downloaded from the CMS Web site at: *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8041.pdf*.

After considering the manufacturer's comments above, we still consider the beginning of the newness period to commence when DIFICID™ was first approved by the FDA on May 27, 2011. Because the 3-year anniversary date of the product's entry on the U.S. market occurred in the second half of the fiscal year (after April 1, 2014), we continued new technology add-on payments for DIFICID™ for FY 2014. However, for FY 2015, the 3-year anniversary date of the product's entry on the U.S. market would occur on May 27, 2014, which is prior to the beginning of FY 2015. Therefore, we are proposing to discontinue new technology add-on payments for DIFICID™ for FY 2015. We are inviting public comments on this proposal.

c. 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.

With respect to newness, the applicant stated that FDA approval for the use of the Zenith® F. Graft was granted on April 4, 2012. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53360 through 53365), we stated that because the Zenith® F. Graft was approved by the FDA on April 4, 2012, we believed that the Zenith® F. Graft met the newness criterion as of that date.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the Zenith® F. Graft and consideration of the public comments we received in response to the FY 2013 IPPS/LTCH PPS proposed rule, we approved the Zenith® F. Graft for new technology add-on payments for FY 2013. Cases involving the Zenith® F. Graft that are eligible for new technology add-on payments are identified by ICD–9–CM procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta). In the application, the applicant provided a breakdown of the costs of the Zenith® F. Graft. The total cost of the Zenith® F. Graft utilizing bare metal (renal) alignment stents was $17,264. Of the $17,264 in costs for the Zenith® F. Graft, $921 are for components that are used in a standard Zenith AAA Endovascular Graft procedure. Because the costs for these components are already reflected within the MS–DRGs (and are no longer ''new''), in the FY 2013 IPPS/LTCH PPS final rule, we stated that we do not believe it is appropriate to include these costs in our calculation of the maximum cost to determine the maximum add-on payment for the Zenith® F. Graft. Therefore, the total maximum cost for the Zenith® F. Graft is $16,343 ($17,264 − $921). Under § 412.88(a)(2), 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 Zenith® F. Graft is $8,171.50.

As stated above, 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 service or technology'' (§ 412.87(b)(2)). With regard to the newness criterion for the Zenith® F. Graft, as stated above, we consider the beginning of the newness period to commence when the Zenith® F. Graft was approved by the FDA on April 4, 2012. Because the 3-year anniversary date of the entry of the Zenith® F. Graft on the U.S. market will occur in the second half of the fiscal year (April 4, 2015), we are proposing to continue new technology add-on payments for this technology for FY 2015. We are inviting public comments on this proposal.

d. Kcentra™

CSL Behring submitted an application for new technology add-on payments for Kcentra™ for FY 2014. Kcentra™ is a replacement therapy for fresh frozen plasma (FFP) for patients with an acquired coagulation factor deficiency due to warfarin and who are experiencing a severe bleed. Kcentra™ contains the Vitamin K dependent coagulation factors II, VII, IX and X, together known as the prothrombin complex, and antithrombotic proteins C and S. Factor IX is the lead factor for the potency of the preparation. The product is a heat-treated, non-activated, virus filtered and lyophilized plasma protein concentrate made from pooled human plasma. Kcentra™ is available as a lyophilized powder that needs to be reconstituted with sterile water prior to administration via intravenous infusion. The product is dosed based on Factor IX units. Concurrent Vitamin K treatment is recommended to maintain blood clotting factor levels once the effects of Kcentra™ have diminished.

Kcentra™ was approved by the FDA on April 29, 2013. In the FY 2014 IPPS/LTCH PPS final rule, we approved new ICD–9–CM procedure code 00.96 (Infusion of 4-Factor Prothrombrin Complex Concentrate) which uniquely identifies Kcentra™.

In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27538), we noted that we were concerned that Kcentra™ may be substantially similar to FFP and/or Vitamin K therapy. In the FY 2014 IPPS/LTCH PPS final rule, in response to comments submitted by the manufacturer, we stated that we agree that Kcentra™ may be used in a patient population that is experiencing an acquired coagulation factor deficiency due to Warfarin and who are experiencing a severe bleed currently but are ineligible for FFP, particularly for use by IgA deficient patients and other patient populations that have no other treatment option to resolve severe bleeding in the context of an acquired Vitamin K deficiency. In addition, FFP is limited because it requires special storage conditions while Kcentra™ is stable for up to 36 months at room temperature thus allowing hospitals that otherwise would not have access to FFP (for example, small rural hospitals as discussed by the applicant in its comments) to keep a supply of Kcentra™ and treat patients who would possibly have no access to FFP. We noted that FFP is considered perishable and can be scarce by nature (due to production and other market limitations) thus making some hospitals unable to store FFP, which limits access to certain patient populations in certain locations. Therefore, we stated that we believe that Kcentra™ provides a therapeutic option for a new patient population and is not substantially similar to FFP. Also, we gave credence to the information presented by the

manufacturer that Kcentra™ provides a simple and rapid repletion relative to FFP and reduces the risk of a transfusion reaction relative to FFP because it does not contain ABO antibodies and does not require ABO typing. As a result, we concluded that Kcentra™ is not substantially similar to FFP, and that it meets the newness criterion.

After evaluation of the newness, cost, and substantial clinical improvement criteria for new technology add-on payments for Kcentra™ and consideration of the public comments we received in response to the FY 2014 IPPS/LTCH PPS proposed rule, we approved Kcentra™ for new technology add-on payments for FY 2014 (78 FR 50575 through 50580). Cases involving Kcentra™ that are eligible for new technology add-on payments are identified by ICD–9–CM procedure code 00.96. In the application, the applicant estimated that the average Medicare beneficiary would require an average dosage of 2500 International Units (IU). Vials contain 500 IU at a cost of $635 per vial. Therefore, cases of Kcentra™ would incur an average cost per case of $3,175 ($635 × 5). Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum add-on payment for a case of Kcentra™ is $1,587.50 for FY 2014.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50579), we stated that new technology add-on payments for Kcentra™ would not be available with respect to discharges for which the hospital received an add-on payment for a blood clotting factor administered to a Medicare beneficiary with hemophilia who is a hospital inpatient. Under section 1886(d)(1)(A)(iii) of the Act, the national adjusted DRG prospective payment rate is ''the amount of the payment with respect to the operating costs of inpatient hospital services (as defined in subsection (a)(4) of this section)'' for discharges on or after April 1, 1988. Section 1886(a)(4) of the Act excludes from the term ''operating costs of inpatient hospital services'' the costs with respect to administering blood clotting factors to individuals with hemophilia. The costs of administering a blood clotting factor to a Medicare beneficiary who has hemophilia and is a hospital inpatient are paid separately from the IPPS. (For information on how the blood clotting factor add-on payment is made, we refer readers to Section 20.7.3 of Chapter Three of the Medicare Claims Processing Manual, which can be downloaded from the CMS Web site at: *http://cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*.) In addition, we stated that if Kcentra™ is approved by the FDA as a blood clotting factor, we believed that it may be eligible for blood clotting factor add-on payments when administered to Medicare beneficiaries with hemophilia. We make an add-on payment for Kcentra™ for such discharges in accordance with our policy for payment of a blood clotting factor, and the costs would be excluded from the operating costs of inpatient hospital services as set forth in section 1886(a)(4) of the Act.

Section 1886(d)(5)(K)(i) of the Act requires the Secretary to ''establish a mechanism to recognize the costs of new medical services and technologies under the payment system established under this subsection'' beginning with discharges on or after October 1, 2001. We believe that it is reasonable to interpret this requirement to mean that the payment mechanism established by the Secretary recognizes only costs for those items that would otherwise be paid based on the prospective payment system (that is, ''the payment system established under this subsection''). As noted above, under section 1886(d)(1)(A)(iii) of the Act, the national adjusted DRG prospective payment rate is the amount of payment for the operating costs of inpatient hospital services, as defined in section 1886(a)(4) of the Act, for discharges on or after April 1, 1988. We understand this to mean that a new medical service or technology must be an operating cost of inpatient hospital services paid based on the prospective payment system, and not excluded from such costs, in order to be eligible for the new technology add-on payment. We pointed out that new technology add-on payments are based on the operating costs per case relative to the prospective payment rate as described in § 412.88. Therefore, we believe that new technology add-on payments are appropriate only when the new technology is an operating cost of inpatient hospital services and are not appropriate when the new technology is excluded from such costs.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50579), we stated that we believe that hospitals may only receive new technology add-on payments for discharges where Kcentra™ is an operating cost of inpatient hospital services. In other words, a hospital would not be eligible to receive the new technology add-on payment when it is administering Kcentra™ in treating a Medicare beneficiary who has hemophilia. In those instances, Kcentra™ is specifically excluded from the operating costs of inpatient hospital services in accordance with section 1886(a)(4) of the Act and paid separately from the IPPS. However, when a hospital administers Kcentra™ to a Medicare beneficiary who does not have hemophilia, the hospital would be eligible for a new technology add-on payment because Kcentra™ would not be excluded from the operating costs of inpatient hospital services. Therefore, discharges where the hospital receives a blood clotting factor add-on payment are not eligible for a new technology add-on payment for the blood clotting factor. We refer readers to Chapter Three, Section 20.7.3 of the Medicare Claims Processing Manual for a complete discussion on when a blood clotting factor add-on payment is made. The manual can be downloaded from the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*.

As stated above, 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 service or technology'' (§ 412.87(b)(2)). With regard to the newness criterion for Kcentra™, as stated above, we consider the beginning of the newness period to commence when Kcentra™ was approved by the FDA on April 29, 2013. Because Kcentra™ is still within the 3-year newness period, we are proposing to continue new technology add-on payments for this technology for FY 2015. We are inviting public comments on this proposal.

e. Argus® II Retinal Prosthesis System

Second Sight Medical Products, Inc. submitted an application for new technology add-on payments for the Argus® II Retinal Prosthesis System (Argus® II System) for FY 2014. The Argus® II System is an active implantable medical device that is intended to provide electrical stimulation of the retina to induce visual perception in patients who are profoundly blind due to retinitis pigmentosa (RP). These patients have bare or no light perception in both eyes. The system employs electrical signals to bypass dead photo-receptor cells and stimulate the overlying neurons according to a real-time video signal that is wirelessly transmitted from an externally worn video camera. The Argus® II implant is intended to be implanted in a single eye, typically the worse-seeing eye. Currently, bilateral

implants are not intended for this technology. According to the applicant, the surgical implant procedure takes approximately 4 hours and is performed under general anesthesia.

The Argus® II System consists of three primary components: (1) An implant which is an epiretinal prosthesis that is fully implanted on and in the eye (that is, there are no percutaneous leads); (2) external components worn by the user; and (3) a ''fitting'' system for the clinician that is periodically used to perform diagnostic tests with the system and to custom-program the external unit for use by the patient. We describe these components more fully below.

- *Implant:* The retinal prosthesis implant is responsible for receiving information from the external components of the system and electrically stimulating the retina to induce visual perception. The retinal implant consists of: (a) A receiving coil for receiving information and power from the external components of the Argus® II System; (b) electronics to drive stimulation of the electrodes; and (c) an electrode array. The receiving coil and electronics are secured to the outside of the eye using a standard scleral band and sutures, while the electrode array is secured to the surface of the retina inside the eye by a retinal tack. A cable, which passes through the eye wall, connects the electronics to the electrode array. A pericardial graft is placed over the extra-ocular portion on the outside of the eye.
- *External Components:* The implant receives power and data commands wirelessly from an external unit of components, which include the Argus II Glasses and Video Processing Unit (VPU). A small lightweight video camera and transmitting coil are mounted on the glasses. The telemetry coils and radio-frequency system are mounted on the temple arm of the glasses for transmitting data from the VPU to the implant. The glasses are connected to the VPU by a cable. This VPU is worn by the patient, typically on a belt or a strap, and is used to process the images from the video camera and convert the images into electrical stimulation commands, which are transmitted wirelessly to the implant.
- *''Fitting System'':* To be able to use the Argus® II System, a patient's VPU needs to be custom-programmed. This process, which the applicant called ''fitting'', occurs in the hospital/clinic shortly after the implant surgery and then periodically thereafter as needed. The clinician/physician also uses the ''Fitting System'' to run diagnostic tests (for example, to obtain electrode and impedance waveform measurements or to check the radio-frequency link between the implant and external unit). This ''Fitting System'' can also be connected to a ''Psychophysical Test System'' to evaluate patients' performance with the Argus® II System on an ongoing basis.

These three components work together to stimulate the retina and allow a patient to perceive phosphenes (spots of light), which they then need to learn to interpret. While using the Argus® II System, the video camera on the patient-worn glasses captures a video image. The video camera signal is sent to the VPU, which processes the video camera image and transforms it into electrical stimulation patterns. The electrical stimulation data are then sent to a transmitter coil mounted on the glasses. The transmitter coil sends both data and power via radio-frequency (RF) telemetry to the implanted retinal prosthesis. The implant receives the RF commands and delivers stimulation to the retina via an array of electrodes that is secured to the retina with a retinal tack.

In patients with RP, the photoreceptor cells in the retina, which normally transduce incoming light into an electro-chemical signal, have lost most of their function. The stimulation pulses delivered to the retina via the electrode array of the Argus® II Retinal Prosthesis System are intended to mimic the function of these degenerated photoreceptors cells. These pulses induce cellular responses in the remaining, viable retinal nerve cells that travel through the optic nerve to the visual cortex where they are perceived as phosphenes (spots of light). Patients learn to interpret the visual patterns produced by these phosphenes.

With respect to the newness criterion, according to the applicant, the FDA designated the Argus® II System a Humanitarian Use Device in May 2009 (HUD designation #09–0216). The applicant submitted a Humanitarian Device Exemption (HDE) application (#H110002) to the FDA in May 2011 to obtain market approval for the Argus® II System. The HDE was referred to the Ophthalmic Devices Panel of the FDA's Medical Devices Advisory Committee for review and recommendation. At the Panel's meeting held on September 28, 2012, the Panel voted 19 to 0 that the probable benefits of the Argus® II System outweigh the risks of the system for the proposed indication for use. The applicant received the HDE approval from the FDA on February 14, 2013. Currently there are no other approved treatments for patients with severe to profound RP. The Argus® II System has an IDE number of G050001 and is a Class III device. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50580 through 50583), we approved new ICD–9–CM procedure code 14.81 (Implantation of Epiretinal Visual Prosthesis), which uniquely identifies the Argus® II System. The other two codes approved by CMS are for removal, revision, or replacement of the device. More information on these codes can be found on the CMS Web site at: *http://cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials-Items/2013-03-05-MeetingMaterials.html*.

After evaluation of the new technology add-on payment application and consideration of public comments received, we concluded that the Argus® II System met all of the new technology add-on payment policy criteria. Therefore, we approved the Argus® II System for new technology add-on payments in FY 2014 (78 FR 50580 through 50583). Cases involving the Argus® II System that are eligible for new technology add-on payments are identified by ICD–9–CM procedure code 14.81. We note that section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services. The system of payment for capital costs is established under section 1886(g) of the Act, which makes no mention of any add-on payments for a new medical service or technology. Therefore, it is not appropriate to include capital costs in the add-on payments for a new medical service or technology. In the application, the applicant provided a breakdown of the costs of the Argus® II System. The total operating cost of the Argus® II System is $144,057.50. Under § 412.88(a)(2), 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 Argus® II System for FY 2014 is $72,028.75.

As stated above, 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 service or technology'' (§ 412.87(b)(2)). With regard to the newness criterion for the Argus® II System, as stated above, we consider the beginning of the newness period to commence when the Argus® II

System was approved by the FDA on February 14, 2013. Because the Argus® II System is still within the 3-year newness period, we are proposing to continue new technology add-on payments for this technology for FY 2015. We are inviting public comments on this proposal.

f. Zilver® PTX® Drug Eluting Peripheral Stent

Cook® Medical submitted an application for new technology add-on payments for the Zilver® PTX® Drug Eluting Peripheral Stent (Zilver® PTX®) for FY 2014. 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 stated 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 indicated 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 applicant received FDA approval on November 15, 2012, for the Zilver® PTX®. The applicant maintains that the Zilver® PTX® is the first drug-eluting stent used for superficial femoral arteries. The technology is currently described by ICD–9–CM procedure code 00.60 (Insertion of drug-eluting stent(s) of the superficial femoral artery).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50583 through 50585), after evaluation of the new technology add-on payment application and consideration of the public comments received, we approved the Zilver® PTX® for new technology add-on payments in FY 2014. Cases involving the Zilver® PTX® that are eligible for new technology add-on payments are identified by ICD–9–CM procedure code 00.60. As explained in the FY 2014 IPPS/LTCH PPS final rule, 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, the applicant used an average of 1.9 stents per case based on the Zilver® PTX® Global Registry Clinical Study. The applicant stated in its application that the anticipated cost per stent is approximately $1,795. Therefore, cases of the Zilver® PTX® would incur an average cost per case of $3,410.50 ($1,795 × 1.9). Under § 412.88(a)(2), 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 of the Zilver® PTX® is $1,705.25 for FY 2014.

As stated above, 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 service or technology'' (§ 412.87(b)(2)). With regard to the newness criterion for the Zilver® PTX®, as stated above, we consider the beginning of the newness period to commence when the Zilver® PTX® was approved by the FDA on November 15, 2012. Because the Zilver® PTX® is still within the 3-year newness period, we are proposing to continue new technology add-on payments for this technology for FY 2015. We are inviting public comments on this proposal.

4. FY 2015 Applications for New Technology Add-On Payments

We received seven applications for new technology add-on payments for FY 2015, three of which were applications resubmitted from FY 2014. However, one applicant withdrew its application prior to the publication of this proposed rule. In accordance with the regulations under § 412.87(c), applicants for new technology add-on payments must have FDA approval by July 1 of each year prior to the beginning of the fiscal year that the application is being considered. A discussion of the six remaining applications is presented below.

a. Dalbavancin (Durata Therapeutics, Inc.)

Durata Therapeutics, Inc. submitted an application for new technology add-on payments for FY 2015 for the use of Dalbavancin. Dalbavancin is an intravenous (IV) lipoglycopeptide antibiotic administered as a once-weekly 30-minute infusion via a peripheral line for the treatment of patients with acute bacterial skin and skin structure infections, or ABSSSI. According to the applicant, Dalbavancin's unique pharmacokinetic profile demonstrates rapid bactericidal activity that is potent and sustained against serious gram-positive bacteria, including methicillin-resistant Staphylococcus aureus (MRSA).

With respect to the newness criterion, the applicant stated that Dalbavancin's once-weekly dosing, a simpler regimen than the current standard of care (Vancomycin) of daily or multiple-times daily intravenous dosing, allows for the discontinuation of IV access with its attendant risks of line-related thrombosis and infection. The applicant submitted a New Drug Approval Application (NDA) on September 26, 2013, and anticipates FDA approval of Dalbavancin sometime in May of 2014. To date, no ICD–10–PCS code specifically describes the administration of Dalbavancin. The applicant applied for a new ICD–10–PCS code to describe the administration of Dalbavancin, which was presented at the March 19–20, 2014 ICD–10 Coordination and Maintenance Committee meeting. If approved, the code will be effective on October 1, 2014. We are inviting public comments on whether the technology meets the newness criterion.

We note that in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically: (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS–DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of the criteria above, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

In evaluating the first criterion, the applicant stated that Dalbavancin's mechanism of action is unique compared to other antibiotics as it involves the interruption of cell wall synthesis resulting in bacterial cell death. Furthermore, the applicant cited Dalbavancin's long half-life as the factor that differentiates itself from existing antibacterial agents active against MRSA. With respect to the second criterion, we believe that cases of ABSSSI that use Dalbavancin or other antibiotics for treatment would be assigned to the same MS–DRGs. Finally, with respect to the third criterion, we believe that Dalbavancin and other antibiotics used to treat cases of ABSSSI treat the same disease and patient population. Based on evaluation of the substantially similarity criteria, it appears that Dalbavancin is not substantially similar to other antibiotics for the treatment of ABSSSI because it

does not use the same or a similar mechanism of action to achieve a therapeutic outcome. We are inviting public comments regarding whether Dalbavancin is substantially similar to existing antibiotics and whether Dalbavancin meets the newness criterion.

According to the applicant, Dalbavancin is indicated to treat gram-positive ABSSSIs, such as cellulitis or erysipelas, and MRSA. These conditions may be a primary diagnosis, but are often secondary to an underlying condition such as diabetes, heart failure, pressure ulcers, etc. Therefore, the technology is eligible to be used across all MS–DRGs. To demonstrate that it meets the cost criterion, the applicant searched the FY 2012 MedPAR file (across all MS–DRGs) for cases where at least one ABSSSI ICD–9–CM code was present on the claim, including those where MRSA was present on a claim with an ABSSSI diagnosis. Specifically, the applicant searched for cases with one of the following diagnosis codes: 035 (Erysipelas); 681.00 (Cellulitis and abscess of finger, unspecified); 681.01 (Felon); 681.02 (Onychia and paronychia of finger); 681.10 (Cellulitis and abscess of toe, unspecified); 681.11 (Onychia and paronychia of toe); 681.9 (Cellulitis and abscess of unspecified digit); 682.0–682.9 (Other cellulitis and abscess of face, neck, trunk, upper arm and forearm, hand except fingers and thumb, buttock, leg except foot, foot except toes, specified sites, unspecified sites); 686.00 (Pyoderma, unspecified); 686.01 (Pyoderma gangrenosum); 686.09 (Other pyoderma); 686.1 (Pyogenic granuloma of skin and subcutaneous tissue); 686.8 (Other specified local infections of skin and subcutaneous tissue); 686.9 (Unspecified local infection of skin and subcutaneous tissue); 958.3 (Posttraumatic wound infection not elsewhere classified); 998.51 (Infected postoperative seroma); and 998.59 (Other postoperative infection). The applicant believed that these cases represent potential cases eligible for the administration of Dalbavancin.

The applicant found 570,698 cases across 682 MS–DRGs and noted that almost 25 percent of the total number of cases would map to MS–DRGs 603 (Cellulitis without MCC), while the top 10 MS–DRGs accounted for almost half (or 49 percent) of the total number of cases. Of the 682 MS–DRGs, only 90 of these MS–DRGs accounted for 1,000 cases or more. The applicant standardized the charges for all 570,698 cases, which equated to an average case-weighted standardized charge per case of $46,138. We note that the applicant did not inflate the charges nor did it include charges for Dalbavancin in the average case-weighted standardized charge per case. The applicant calculated an average case-weighted threshold of $44,255 across all MS–DRGs. Therefore, the applicant asserted the average case-weighted standardized charge per case (without inflating and including charges for Dalbavancin) exceeds the average case-weighted threshold of $44,255 (as indicated in Table 10 of the FY 2014 IPPS/LTCH PPS final rule). Therefore, the applicant maintained that Dalbavancin meets the cost criterion. We are inviting public comments regarding whether Dalbavancin meets the cost criterion, particularly with regard to the assumptions and methodology used in the applicant's analysis.

With regard to substantial clinical improvement, as previously stated by the applicant, Dalbavancin is a new intravenous (IV) lipoglycopeptide antibiotic administered as a once-weekly 30 minute infusion via a peripheral line for the treatment of patients with acute bacterial skin and skin structure infections, or ABSSSI. The applicant noted that, in the setting of continuing emergence of resistance among gram-positive pathogens worldwide, there is an increasing medical need for new antibacterial agents with enhanced gram-positive activity. The applicant cited the Infectious Diseases Society of America (IDSA),[3] stating the need for a multi-pronged approach to address the impact of antibiotic resistance. In addition, the applicant stated the FDA has also designated MRSA as a pathogen of special interest which allows an antibiotic effective against this organism to be designated as a ''Qualified Infectious Disease Product,'' recognizing the medical need for drugs to treat infections caused by this pathogen. The applicant believed that having a medicinal agent with clinical efficacy against gram-positive pathogens, including MRSA and CA–MRSA, a favorable benefit/risk ratio, and a favorable pharmacokinetics profile allowing convenient dosing in inpatients and outpatients with the potential for minimizing patient noncompliance would be a valuable addition to the antibacterial armamentarium for the treatment of ABSSSI. The applicant also noted that, when taking Dalbavancin, there is no need for oral step-down therapy.

The applicant suggested that Dalbavancin offers treatment advantages over other available options for therapy for skin infections as a result of the following:

- Improved potency against key bacterial pathogens with the concentration of Dalbavancin required to kill key target pathogens lower relative to other antibiotics commonly used to treat such pathogens;
- Retained activity against staphylococcus aureus resistant to other antibiotics;
- Improved safety profile as Dalbavancin exhibits more favorable tolerability and safety than alternative approved antibacterial drugs in areas such as no evidence of thrombocytopenia as seen with linezolid and tedezolid, superior infusion related tolerability relative to other antiobiotics, an absence or reduction of drug specific toxicities, and once a week dosing of IV Dalbavancin avoids pitfalls of patient noncompliance with an oral medication;
- Lack of drug interactions due to metabolic profile which minimizes risk of unexpected adverse events when co-administered with other compounds as seen with linezolid and quinupristin/dalfopristin;
- Decreased requirement for therapeutic interventions, specifically the need for an intravenous catheter as Dalbavancin is administered once a week, thus reducing catheter related infection as well;
- Reduced time to patient defined recovery;
- Reduced mortality rate as demonstrated in the combined phase of the Discover 1 and Discover 2 clinical trials;
- The potential for avoidance of admission to the hospital as Dalbavancin allows the utilization of a weekly treatment regimen, thus potentially increasing the convenience of outpatient therapy for patients.

The applicant conducted three phase three randomized, controlled, double blinded clinical trials. The first was the pivotal VER001–9 study with a total of 873 patients with cSSSIs, which compared the safety and efficacy of IV Dalbavancin with possible switch to oral placebo to IV Linezolid with possible switch to oral Linezolid. According to the applicant, the primary efficacy endpoint of clinical response at test of 14 days with a plus or minus of 2 days after completion of therapy demonstrated comparable clinical efficacy to linezolid and met the requirement of statistical demonstration of noninferiority. In the clinically evaluable population, 88.9 percent of patients who received Dalbavancin compared to 91.2 percent of patients who received vancomycin/linezolid

[3] ''Bad Bugs, No Drugs,'' July 2004.

were clinical successes. The applicant also noted that Dalbavancin had an improved safety profile compared to Linezolid as the overall incidence and percentage of adverse events and deaths were lower in the Dalbavancin group, which was statistically significant.

The second and third clinical trials were the Discover 1 and Discover 2 trials, which enrolled a total of 1,312 patients with ABSSSI and compared IV Dalbavancin with IV placebo every 12 hours to match Vancomycin with possible switch to oral Vancomycin to IV Vancomycin with IV placebo to match IV Dalbavancin with possible switch to oral Linezolid. The applicant reported that in both studies, the primary efficacy outcome measure was clinical response in 48 to 72 hours post-study drug initiation and a secondary outcome measure was clinical status at the end of treatment visit (day 14) in the Intent to Treat (ITT) and clinically evaluable at End of Treatment populations. Clinical status was also determined at the short-term follow-up and long-term follow-up visits.

According to the applicant, the Discover 1 trial demonstrated that 83.3 percent of patients in the ITT population who received Dalbavancin were responders at 48 to 72 hours after the start of therapy compared to 81.8 percent of patients who received Vancomycin/Linezolid. The applicant also noted that Dalbavancin was noninferior to Vancomycin/Linezolid (Absolute Difference in Success Rates (95 percent confidence interval): −4.6 percent; 7.9 percent).

The applicant further noted that the Discover 2 trial showed similar results to the Discover 1 trial. Specifically, the trial demonstrated that 76.8 percent of patients in the ITT population who received Dalbavancin were responders at 48 to 72 hours after the start of therapy compared to 78.3 percent of patients who received Vancomycin/Linezolid. The applicant again noted that Dalbavancin was noninferior to Vancomycin/Linezolid (Absolute Difference in Success Rates (95 percent confidence interval): −7.4 percent; 4.6 percent).

The applicant found Dalbavancin to be effective against MRSA and other gram-positive bacteria associated with ABSSSI. The applicant stated that 25 percent of patients in the study were treated without an inpatient admission.

We are concerned with the details of the trial design and the primary efficacy endpoints used within those trials that were used to provide the clinical data supplied by the applicant. All of the trials were noninferiority studies, which prevent any determination as to substantial clinical improvement from the trial data. The primary efficacy endpoint was defined as having no increase in lesion size, and no fever 48 to 72 hours after drug initiation. The secondary endpoint was a >20 percent reduction in infection area at defined points in time. At neither endpoint is the patient oriented endpoint of resolution of infection increased. With these limitations in using efficacy data to establish substantial clinical improvement, the applicant suggested that the outpatient treatment, elimination of central lines and avoidance of hospitalization all *may* improve safety, avoid treatment-associated infections and improve patient satisfaction, and that these factors demonstrate substantial clinical improvement. While the factors mentioned may be true, the applicant did not present any evidence to support its assertions. We are inviting public comments on whether Dalbavancin meets the substantial clinical improvement criterion, including public comments in response to our concern that the applicant has only provided efficacy data of noninferiority, and no data for the other suggested benefits.

We did not receive any public comments in response to the New Technology Town Hall meeting held on February 12, 2014 regarding this technology.

b. Heli-FX™ EndoAnchor System (Aptus Endosystems, Inc.)

The Heli-FX™ EndoAnchor System is indicated for use in the treatment of patients whose endovascular grafts during treatment of aortic aneurysms have exhibited migrations or endoleaks, or in the treatment of patients who are at risk of such complications, and in whom augmented radial fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion.

The Heli-FX™ EndoAnchor System is comprised of the following three components: (1) The EndoAnchor Implant; (2) the Heli-FX™ Applier; and (3) the Heli-FX™ Guide with Obturator. The Heli-FX™ EndoAnchor System is a mechanical fastening device that is designed to enhance the long-term durability and reduce the risk of repeat interventions in endovascular aneurysm repair (EVAR) and thoracic endovascular aneurysm repair (TEVAR). By deploying a small helical screw (the Heli-FX™ EndoAnchors) to connect the endograft to the aorta, the Heli-FX™ System seeks to provide a permanent seal and fixation, similar to the stability achieved with an open surgical anastomosis.

The original Heli-FX™ EndoAnchor System, designed for treating abdominal aortic aneurysms (AAA), was cleared by the FDA through the ''de novo'' 510(k) process on November 21, 2011 (reference K102333). The Heli-FX™ Thoracic System, which allows the expanded use of the Heli-FX™ EndoAnchor System technology to the treatment of thoracic aortic aneurysms (TAA), was cleared by the FDA on August 14, 2012 (reference K121168).

The applicant submitted two applications for approval for new technology add-on payment in FY 2015: one for the treatment of AAAs and the other for the treatment of TAA repair. We note that, as stated in the Inpatient New Technology Add-on Payment Final Rule (66 FR 46915), two applications are necessary in this instance, because patients that may be eligible for use of the technology under the first indication are not expected to be assigned to the same MS–DRGs as patients receiving treatment using the new technology under the second indication. Specifically, patients who have endovascular grafts implanted for the treatment of AAA map to MS–DRGs 237 (Major Cardiovascular Procedures with MCC) and 238 (Major Cardiovascular Procedures without MCC), while patients who have endovascular grafts implanted for the treatment of TAA map to MS–DRGs 219 (Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheter with MCC), 220 (Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheter with CC), and 221 (Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheter without CC/MCC). Each indication/application must also meet the cost criterion and the substantial clinical improvement criterion in order to be eligible for new technology add-on payments beginning in FY 2015. We discuss both of these applications below.

(1) Heli-FX™ EndoAnchor System for the Treatment of AAA

As mentioned above, the original Heli-FX™ EndoAnchor System, designed for treating patients diagnosed with AAA, was cleared by the FDA through the ''de novo'' 510(k) process on November 21, 2011 (reference K102333). According to the applicant, the device became available to Medicare beneficiaries following the product launch at the Society of Vascular Surgery (SVS) Annual Meeting held on June 7–9, 2012. Therefore, the applicant maintained that the Heli-FX™ EndoAnchor System meets the ''newness'' criterion because the

technology was not available on the U.S. market until June 2012. The applicant explained that the delay in the general market availability of the original Heli-FX™ EndoAnchor System, following initial FDA clearance, was mainly because of the regulatory uncertainty inherent in the ''de novo'' 510(k) process. This uncertainty prevented the manufacturer from being able to secure the venture capital funding that was necessary to prepare for commercialization before obtaining market clearance. The ability to secure venture capital through the fundraising process was dependent upon the FDA clearance. According to the applicant, funding to commercially market the technology was not obtained until June 2012. In subsequent discussions with the applicant, the applicant confirmed that the Heli-FX™ EndoAnchor System was available on the U.S. market as of November 2011. Further, the applicant acknowledged that four implantations were performed on Medicare beneficiaries between November 2011 and June 2012. Therefore, the Heli-FX™ EndoAnchor System is considered ''new'' as of November 2011 when the technology was cleared by the FDA and became available on the U.S. market.

Section 412.87(b)(2) of the regulations 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.'' Our past practice has been to begin and end the eligibility for new technology add-on payments on a fiscal year basis. We have generally followed a guideline that uses a 6-month window, before and after the beginning of the fiscal year, to determine whether to still consider a technology ''new'' and extend approved new technology add-on payments for an additional fiscal year. In general, a technology is still considered ''new'' (and eligible to receive new technology add-on payments) only if the 3-year anniversary date of the product's entry on the market occurs in the latter half of the fiscal year. (We refer readers to 70 FR 47362.) With regard to the newness criterion for the Heli-FX™ EndoAnchor System, as stated above, we consider the beginning of the newness period for the device to begin when the technology first became available on the U.S. market in November 2011. As previously stated, the applicant acknowledged that four implantations were performed on Medicare beneficiaries between November 2011 and June 2012. Therefore, the costs of the Heli-FX™ EndoAnchor System are currently reflected in the MS–DRGs, and the 3-year anniversary date under the newness criterion for the product's entry on the U.S. market will occur during November 2014 (the first half of FY 2015). As such, we do not believe that the Heli-FX™ EndoAnchor System meets the newness criterion. We are inviting public comments on whether the Heli-FX™ EndoAnchor System meets the newness criterion.

The applicant requested an ICD–10–PCS code, and presented comments at the March 2014 ICD–10 Coordination & Maintenance Committee meeting.

To demonstrate that the technology meets the cost criterion, the applicant researched claims data from the 100 percent sample of the 2012 Inpatient Hospital Standard Analytical File (SAF) for cases reporting either procedure code 39.71 (Endovascular implantation of other graft in abdominal aorta), or procedure code 39.79 (Other endovascular procedures on other vessels) in the first or second procedure position on the claim, in combination with one of the following primary diagnosis codes: 441.4 (Abdominal aneurysm without mention of rupture); 996.1 (Mechanical complication of other vascular device, implant, and graft); or 996.74 (Other complications due to other vascular device, implant, and graft). The applicant believed that this combination of ICD–9–CM codes identifies cases treated for AAA. We note that the 2012 SAF dataset includes all claims submitted from hospitals paid under the IPPS for calendar year 2012.

The applicant focused its analysis on MS–DRGs 237 and 238 because these are the MS–DRGs that cases treated with the implantation of endovascular grafts for AAAs would most likely map to. The applicant found a total of 8,142 cases, and noted that 9.35 percent of the total number of cases would map to MS–DRG 237, and 90.65 percent of the total number of cases would map to MS–DRG 238. The applicant standardized the charges for all 8,142 cases. Using the inflation factor of 1.47329 published in the FY 2014 IPPS/LTCH final rule (78 FR 50982), the applicant inflated the standardized charges by 14.88 percent (the applicant multiplied $1.47329 \times 1.47329 \times 1.47329$ in order to inflate the charges from 2012 to 2015). The applicant then added the charges for the Heli-FX™ EndoAnchor System to the standardized charges by dividing the cost of the Heli-FX™ EndoAnchor System device by each individual hospital specific CCR from the FY 2012 impact file. This equated to an average case-weighted inflated standardized charge per case of $111,613. The applicant noted that the average case-weighted inflated standardized charge per case did not contain additional operating room charges that relate to the Heli-FX™ EndoAnchor System. Therefore, the applicant determined that it was necessary to add an additional $1,440 for operating room charges, which was based on an additional half hour of operating room time from one hospital, to the average case-weighted standardized charge per case. This resulted in an average case-weighted standardized charge per case of $113,053. The applicant calculated an average case-weighted threshold of $86,278 across both MS–DRGs 237 and 238. The applicant noted that the average case-weighted standardized charge per case, computed without including the additional operating room charges that relate to the Heli-FX™ EndoAnchor System, exceeded the average case-weighted threshold of $86,278. Therefore, the applicant maintained that the technology meets the cost criterion.

The applicant also submitted claims data from the ANCHOR (Aneurysm Treatment Using the Heli-FX Aortic Securement System Global Registry) study to demonstrate that the technology meets the cost criterion. A total of 51 cases were submitted with 11.76 percent of all the cases mapping to MS–DRG 237, and 88.24 percent of all the cases mapping to MS–DRG 238. The applicant standardized the charges for all 51 cases, and determined an average case-weighted standardized charge per case of $128,196. The applicant calculated an average case-weighted threshold of $87,118 across MS–DRGs 237 and 238. Therefore, because the average case-weighted standardized charge per case exceeds the average case-weighted threshold, the applicant maintained that the technology meets the cost criterion. We are inviting public comments on whether the Heli-FX™ EndoAnchor System meets the cost criterion, particularly with regard to the assumptions and methodology used in the applicant's analyses. We discuss whether the Heli-FX™ EndoAnchor System represents a substantial clinical improvement over other treatments used for the repair of both abdominal and thoracic aortic aneurysms in one discussion below.

(2) Heli-FX™ EndoAnchor System for the Treatment of Thoracic Aortic Aneurysms

The Heli-FX™ Thoracic System, which allows the expanded use of the Heli-FX™ EndoAnchor System technology to TAA repair, was cleared

by the FDA on August 14, 2012 (reference K121168). The new system consists of a longer delivery device with additional tip configurations to allow the helical EndoAnchor technology to treat TAA. A line extension to the original Heli-FX™ EndoAnchor System, allowing improved treatment of AAA patients with larger aortic neck diameters, was cleared by the FDA on April 12, 2013 (reference K130677).

With regard to the newness criterion for the Heli-FX™ Thoracic System, we consider the beginning of the newness period for the device to begin when the technology was approved by the FDA on August 14, 2012. Because the 3-year anniversary date of the product's entry on the U.S. market would occur in the second half of FY 2015 (August 14, 2015), we believe that the Heli-FX™ Thoracic System meets the newness criterion. We are inviting public comments on whether the Heli-FX™ Thoracic System meets the newness criterion. As stated above, the applicant requested an ICD–10–PCS code, and presented comments at the March 2014 ICD–10 Coordination & Maintenance Committee meeting.

To demonstrate that the Heli-FX™ Thoracic System meets the cost criterion, similar to the analysis performed for the Heli-FX™ EndoAnchor System for the treatment of AAA, the applicant researched claims data from the 100 percent sample of the 2012 SAF for cases reporting procedure code 39.73 (Endovascular implantation of graft in thoracic aorta) in the first or second procedure position on the claim, in combination with one of the following primary diagnosis codes: 404.93 (Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end-stage renal disease); 441.01 (Dissection of aorta, thoracic); 441.03 (Dissection of aorta, thoracoabdominal); 441.2 (Thoracic aneurysm without mention of rupture); 441.4 (Abdominal aneurysm without mention of rupture); 441.7 (Thoracoabdominal aneurysm, without mention of rupture); 996.1 (Mechanical complication of other vascular device, implant, and graft); or 996.74 (Other complications due to other vascular device, implant, and graft). The applicant believed that this combination of ICD–9–CM codes identifies cases treated for TAA. We note that the 2012 SAF dataset includes all claims submitted from hospitals paid under the IPPS for CY 2012.

The applicant focused its analysis on MS–DRGs 219, 220, and 221 because these are the MS–DRGs to which cases treated with the implantation of endovascular grafts for TAA repair would most likely map. The applicant found a total of 642 cases, and noted that 27.88 percent of the total number of cases would map to MS–DRG 219, 40.50 percent of the total number of cases would map to MS–DRG 220, and 31.62 percent of the total number of cases would map to MS–DRG 221. The applicant standardized the charges for all 642 cases. Using the inflation factor of 1.47329 published in the FY 2014 IPPS/LTCH final rule (78 FR 50982), the applicant inflated the standardized charges by 14.88 percent (the applicant multiplied $1.47329 \times 1.47329 \times 1.47329$ in order to inflate the charges from 2012 to 2015). The applicant then added the charges for the Heli-FX™ EndoAnchor System to the standardized charges by dividing the cost of the Heli-FX™ EndoAnchor System device by each individual hospital specific CCR from the FY 2012 impact file. This equated to an average case-weighted inflated standardized charge per case of $156,625. The applicant noted that the average case-weighted inflated standardized charge per case did not contain additional operating room charges related to the use of this technology. Therefore, the applicant determined that it was necessary to add an additional $2,160 for operating room charges, which was based on an additional 45 minutes of operating room time from one hospital, to the average case-weighted standardized charge per case. This resulted in an average case-weighted standardized charge per case of $158,785. The applicant calculated an average case-weighted threshold of $141,194 across MS–DRGs 219, 220, and 221. The applicant noted that the average case-weighted standardized charge per case, without including charges for additional operating room time, exceeded the average case-weighted threshold of $141,194. Therefore, the applicant maintained that the technology meets the cost criterion. We are inviting public comments on whether the Heli-FX™ Thoracic System meets the cost criterion, particularly with regard to the assumptions and methodology used in the applicant's analysis.

(3) Evaluation of the Substantial Clinical Improvement Criterion for the Heli-FX™ EndoAnchor System for the Treatment of Abdominal and Thoracic Aortic Aneurysms

The applicant stated that the Heli-FX™ EndoAnchor System represents a substantial clinical improvement for the following reasons: The technology improves overall rates of aneurysm exclusion and long-term success after EVAR by increasing the integrity and long-term durability of the proximal seal and fixation; the technology reduces the risk and rate of secondary interventions and readmissions due to aneurysm-related complications (for example, endoleaks, migration, aneurysm enlargement) caused by failure of the proximal seal; the technology improves the general applicability of EVAR to patients with a broader spectrum of aortoiliac anatomy, including those with hostile proximal neck anatomy; and the technology reduces the rigor of life-long imaging follow-up for EVAR patients by reducing the rate of late failure and increasing the post-EVAR rates of aneurysm sac regression due to complete, endoleak-free durable aneurysm exclusion.

While current devices and capabilities are greatly improved over the first generation of devices, the applicant noted that EVAR treatments using the first generation of devices has not proven to be as durable, anatomically applicable, or complication-free as open surgery.[4][5][6][7] Several critical and life-threatening limitations continue to require improvement to these devices and procedures, including the need to reduce serious early and late device and procedure-related complications, such as loss of stability, and integrity and robustness of the clinical proximal aortic landing zone, and to offer an alternative method of EVAR to a broader segment of the patient population.

The applicant provided literature, analyses of data from the ''STAPLE–2'' clinical trial and the ANCHOR Registry, and a meta-analysis of EVAR trials to demonstrate that the Heli-FX™ EndoAnchor System represents a substantial clinical improvement above current treatments available. We summarize the information provided by the applicant that supports the clinically beneficial results of using the Heli-FX™ EndoAnchor System.

The ''STAPLE–2'' clinical trial enrolled 155 patients at 25 U.S. centers between September 2007 and January

[4] Abbruzzese, T.A., Kwolek, C.J., Brewster, D.C., et al, ''Outcomes following endovascular abdominal aortic aneurysm repair (EVAR): An anatomic and device-specific analysis,'' Journal of Vascular Surgery, 2008, Vol. 48, pp. 19–28.

[5] Dangas, G., O'Connor, D., Firwana, B., et al, ''Open Versus Endovascular Stent Graft Repair of Abdominal Aortic Aneurysms: A Meta-Analysis of Randomized Trials,'' JACC, 2012, Vol. 5 (10), pp. 1072–1080.

[6] De Bruin, J.L., Baas, A.F., Buth, J., et al, ''Long-Term Outcome of Open or Endovascular Repair of Abdominal Aortic Aneurysm,'' New England Journal of Medicine, May 2010, Vol. 362(20), pp. 1881–1889.

[7] Greenhalgh, R.M., Brown, L.C., Powell, J.T., et al, ''Endovascular versus open repair of abdominal aortic aneurysm,'' New England Journal of Medicine, May 2010, Vol. 362(20), pp. 1863–1871.

2009. Clinical (and imaging) data are available for 147, 139 and 125 patients at 1-year, 2-year, and 3-year follow-up, respectively, representing the complete data sets at these time points. Patients enrolled in the clinical trial and observed under the study will continue to be followed per protocol for 5 years following aneurysm repair. According to the applicant, the results of the trial and study demonstrate that the Heli-FX™ EndoAnchor System is associated with an extremely low rate of proximal neck-related issues in long-term follow-up. The applicant maintained that this determination results in improved outcomes for aortic aneurysm patients, and reduced rate of re-interventions, which are associated with hospital admissions, procedural risks, and reversions to increased follow-up frequency requiring more physician visits and radiographic imaging studies.

The data used for this analysis was extracted from the clinical database on February 1, 2013, and are identical to those used to generate the most recent Annual Progress Report (APR) submitted to the FDA, as required under the U.S. IDE regulations.

While the ''STAPLE–2'' clinical trial was conducted exclusively with the Aptus AAA endograft (which remains investigational), the applicant believed that the use of the Heli-FX™ EndoAnchor System-related data is applicable to the use of the anchor with the compatible Cook, Gore, and Medtronic manufactured endografts in treatment anatomies for AAA and TAA cases.

Through 3-year follow-up, the applicant noted that there have been no anchor fractures as observed by the core lab. Further, there have been no relative migrations of the Heli-FX™ EndoAnchor System as compared to other endografts reported by the core laboratory.

In the analysis of the ''STAPLE–2'' clinical trial data at 1-year follow-up, the applicant noted that the core lab observed no proximal migrations, and a single case of Type I endoleak. A single secondary intervention was required to address the Type I endoleak in a patient with a circumferentially incomplete proximal neck within the 1-year follow-up period.

The applicant further noted that no additional Type I endoleaks have been observed beyond the 1-year follow-up in any patient enrolled in the trial. In addition, there were no reported instances of aneurysm rupture, vessel perforation, vessel dissection, catheter embolization, enteric fistula, infection, Type III endoleak, conversion, allergic reactions, renal emboli, or patient death associated with the use of the Heli-FX™ EndoAnchor System. Further, there have been no reports of bleeding or hematoma at the EndoAnchor penetration locations in the aortic neck.

Beyond the 1-year follow-up, three patients have demonstrated proximal migrations less than 1 cm. None of these cases were associated with Type I endoleaks or aneurysm sac expansions.

The applicant then compared migrations and Type I endoleaks data from the ''STAPLE–2'' clinical trial to analogous data from five compatible AAA endografts that were not anchored (data taken from published SSE data obtained from the FDA's Web site). One year of data was compared because this timeframe is what is reported in a standard fashion from IDE trials of endografts. The applicant noted that the Heli-FX™ EndoAnchor System data compares favorably against the data obtained in U.S. pivotal trials of devices that did not employ discrete independent fixation means, particularly when viewed in light of the shorter average neck lengths treated in the ''STAPLE–2'' clinical trial versus those involving the Cook, Gore, and Medtronic manufactured endografts. According to the applicant, the number of proximal migrations were low across devices as reported in the SSE data, and an analysis using the Fisher's exact method demonstrated no statistically significant differences when compared to the anchored endografts used in the ''STAPLE–2'' clinical trial (all $p = NS$). The incidence of Type I endoleaks and the need for secondary interventions to address them was significantly lower for the Heli-FX™ EndoAnchor System endografts analyzed under the ''STAPLE–2'' clinical trial versus the Medtronic, AneuRx, and Talent manufactured endografts ($p = 0.026$ versus AneuRx and $p = 0.015$ versus Talent). The applicant stated that the applicability of post-hoc statistical analyses is limited. However, the applicant believed that because the data being compared under the analyses were collected through similar protocols and with the same endpoint definitions, post-hoc comparisons were deemed appropriate. The applicant further believed that the comparison of this data demonstrates that the Heli-FX™ EndoAnchor System is associated with very low rates of Type I endoleaks and migrations.

The applicant also provided data from the ANCHOR Registry, which is a post-market, prospective, observational, multi-center, international, dual-arm study designed to capture real-world data on the usage patterns and clinical results associated with the use of the Heli-FX™ EndoAnchor System as a method of treatment for patients in need of EVAR. The applicant explained that the ANCHOR Registry represents a growing body of data on the application of the Heli-FX™ EndoAnchor System used as a method of endovascular aortic aneurysm repair. The applicant noted that to its knowledge, the anatomical challenges present in the registry are greater than those in any large scale published series. The applicant further noted that, although long-term results are limited, the acute results demonstrate a high level of device safety, technical feasibility and acute success in a patient population with few viable options.

Primary safety for the ANCHOR Registry is being measured as a composite of freedom from device or procedure-related serious adverse events through 1-year follow-up following the Heli-FX™ EndoAnchor System implantation. Primary effectiveness is being measured as a composite of acute technical success and freedom from Type Ia endoleaks and endograft migrations through 1-year follow-up. Inclusion and exclusion criteria are minimal, essentially following the IFU requirements. Patients are being followed in the registry by their physician's standard of care for 5 years.

Enrollment in the ANCHOR Registry began in March 2012. Through August 2013, a total of 258 patients were enrolled at 40 participating centers (29 located in the United States and 11 located in the European Union), and data are available in the registry's database. Of these, 195 patients (76 percent) were enrolled in the primary arm, having the Heli-FX™ EndoAnchor System implanted at the time of their initial aneurysm treatment, either as a prophylactic measure, or to address an acute leak seen on completion arteriography. The remaining patients (63 or 24 percent) were enrolled in the revision arm, having the Heli-FX™ EndoAnchor Systems implanted at a secondary procedure to arrest migration, or address endoleaks discovered on follow-up in previously implanted endografts.

The applicant noted that physicians are choosing to apply the Heli-FX™ EndoAnchor System in a subset of patients that are at a higher risk for proximal neck-related complications during follow-up. The large average sac diameter in the revision arm suggested that these patients' initial treatments were unsuccessful and, as such, they have experienced continued sac expansion post-EVAR. These patients

also represent a high-risk subset of patients.

Acute results are measured in terms of technical success. In the primary arm, 193 of 194 procedures were successful, and in the revision arm, 57 of 63 procedures were successful. All technical failures were persistence of Type Ia endoleaks. There has been a single re-intervention at 69 days post-Endoanchor implantation for a persistent Type Ia endoleak in one patient in the revision arm, in which the Heli-FX™ EndoAnchor System combined with a proximal cuff were unable to completely resolve the endoleak. There have been no device-related serious adverse events.

As mentioned above, because the ''STAPLE–1,'' [8] and ''STAPLE–2'' clinical trials were single-arm studies, no data are available from them to assess the impact of the Heli-FX™ EndoAnchor System on endograft performance. To make this assessment, a meta-analysis was conducted. The meta-analysis combined long-term AAA endograft performance from endografts marketed in the United States, and compared these measures to those from long-term follow-up in the ''STAPLE–2'' trial.

According to the applicant, the key findings from the meta-analysis are as follows:

- Heli-FX™ EndoAnchors reduced the proportion of treated aneurysms with enlargement greater than 5 mm at 3 years from 12.7 percent to 3.9 percent ($p = .002$).
- Heli-FX EndoAnchor System reduced the proportion of leaks requiring treatment at 3 years from 12 percent to 1.3 percent ($p < .001$).
- Heli-FX™ EndoAnchor System reduced (all-cause) mortality at 3 years from 18.8 percent to 8.4 percent ($p = .002$). However, this does not appear to have been totally mediated by AAA-related mortality, which was reduced by the Heli-FX™ EndoAnchor System from 2.5 percent to 0.7 percent at 3 years (but was not statistically significant, $p = .372$).

According to the applicant, in general, patients in the ANCHOR Registry were similar to the patients in the AAA endograft studies. The applicant noted that the results of the analysis using the Fisher's Exact Tests were consistent between the All-Studies' comparisons and the IDE-Studies' comparisons: All-Cause Mortality, Leaks requiring Treatment, and Enlargement were all significantly lower at 3 years in the endografts implanted with the Heli-FX™ EndoAnchor System than in standard endografts.

The applicant asserted that the meta-analysis shows that there is objective evidence that the Heli-FX™ EndoAnchor System effectively reduces well-documented problems with endografts. By providing the endograft with better apposition to the native artery, the applicant noted that the Heli-FX™ EndoAnchor System reduces the rates of enlargement and endoleaks requiring treatment. The applicant further noted that these results were consistent in the All-Studies' and IDE Studies' meta-analyses. The applicant believed that lower rates of leaks requiring intervention would save payers money over the long term.

The applicant observed that, while there was no significant improvement in the rate of ruptures with the Heli-FX™ EndoAnchor System, this may be due to the fact that leaks were treated and, thereby, prevented any ruptures. The applicant believed that the higher rate of treated endoleaks in endografts implanted without the Heli-FX™ EndoAnchor System provides for this hypothesis. Also, migration did not appear to be significantly reduced by the Heli-FX™ EndoAnchor System (3.5 percent at 3 years in both groups; $p = 1.0$).

Finally, the applicant concluded that, overall, the lower complication rates seen with the Heli-FX™ EndoAnchor System in the meta-analysis provide evidence of the clinical benefits and likely economic benefits associated with the use of the Heli-FX™ EndoAnchor System. The applicant believed that the technology may be especially helpful in patients with difficult anatomy, and that it may be reasonable to consider using the Heli-FX™ EndoAnchor System prophylactically in the treatment of all such patients.

In addition to the formal study data from the ''STAPLE–2'' trial, the Global ANCHOR Registry, and the meta-analysis based on these, the applicant provided published peer-reviewed literature that represent an early state of scientific data dissemination outside of non-company sponsored clinical studies, which is commensurate with the recent market approvals of the Heli-FX™ EndoAnchor System technology. The applicant believed that this data demonstrates strong initial physician enthusiasm and resulting favorable clinical results in their experience to date. The applicant noted that the general body of scientific literature is considered meaningful and growing for this early stage of market introduction. However, the applicant asserted that the literature supports the study and meta-analysis data above that documents that improved clinical outcomes were observed, including outcomes in a broader range of patients that are often ineligible for, or at greatest risk with, EVAR.

We are concerned that the three sources of data, the ''STAPLE–2'' clinical trial, the Anchor registry, and the literature review that the applicant submitted to support their application are not high quality evidence. The ''STAPLE–2'' study was a single-arm study and only used one endograft, the registry is an observational study, and the literature review does not provide clinical data. Also, the meta-analysis of all the submitted data is only as good as the data used. While the clinical data submitted suggests that some outcomes such as EVAR failure are improved, we are concerned that there is not enough clinical evidence to support the substantial clinical improvement criterion. We are inviting public comments on whether the submitted data demonstrate that the Heli-FX™ EndoAnchor System represents a substantial clinical improvement in the treatment of Medicare beneficiaries, particularly in regard to the concerns we have identified.

We received public comments in response to the New Technology Town Hall meeting held on February 12, 2014. We summarize these comments below.

Comment: Several commenters supporting new technology add-on payments for the Heli-FX™ EndoAnchor System. In addition, one commenter believed that EndoAnchors would broaden the applicability of endovascular aneurysm repair. The commenter noted that use of EndoAnchors increases the force needed to dislodge the proximal neck of the graft by several times, and in some cases even stronger than a hand-sewn anastomosis. This commenter further noted that this would allow patients with short, or otherwise difficult aortic necks to be treated more safely with endovascular aneurysm repair. The commenter stated that the technology is beneficial for patients who have medical problems or advanced age as contraindications to open surgery because endovascular repair can be made possible with the Heli-FX™ EndoAnchor System.

The commenter further stated that patients with endoleaks identified during follow-up are frequently not candidates for extension prostheses and would otherwise require open explantation of the graft and aneurysm

[8] Deaton, D.H., Mehla, M., Kasirajan, K., et al., ''The Phase I Multi-center Trial (Staple-1) of the Aptus Endovascular Repair System: Results at 6 Months and 1 Year,'' Journal of Vascular Surgery, 2009, Vol. 49, pp. 851–857 (discussion on pp. 857–858.)

repair. The commenter explained that these are far more challenging and risky operations than primary open aneurysm repairs, and are routinely associated with blood loss of several liters as well as prolonged lower extremity, renal, and visceral ischemia. The commenter noted that many of these often elderly patients can be successfully treated in a minimally invasive manner using the Heli-FX™ EndoAnchor System, reestablishing proximal fixation and seal while avoiding the morbidity and mortality associated with graft explantation and open repair. The commenter concluded that if new technology add-on payments are approved for the Heli-FX™ EndoAnchor System, many patients would realize the advantages of this unique and necessary device, improving their care and reducing overall cost.

Another commenter stated that the Heli-FX™ EndoAnchor System provides an opportunity to extend a less mortal procedure (EVAR) to patients whose anatomy may predispose them to late failure, including patients with large proximal neck diameters, increased iliac diameters, or abnormal neck anatomy. In primary repair, the applicant stated that endoanchors have been demonstrated to mimic a surgical anastomosis. The commenter believed that this would lead to less reinterventions and less aneurysm related mortality. Given the cost of reintervention or treating a ruptured AAA, the commenter believed that this technology should have a real impact in the overall cost of EVAR in this patient population.

Response: We appreciate the commenters' support. We considered these comments in our evaluation of the Heli-FX™ EndoAnchor System application for new technology add-on payments for FY 2015 and in the development of this proposed rule. As stated above, we are inviting additional public comments on whether the Heli-FX™ EndoAnchor System represents a substantial clinical improvement in the treatment of Medicare beneficiaries, particularly in regard to the concerns we have identified.

c. WATCHMAN® Left Atrial Appendage Closure Technology

Boston Scientific Corporation submitted an application for new technology add-on payments for the WATCHMAN® Left Atrial Appendage Closure Technology (Watchman® System) for FY 2015. When a patient has an arrhythmia known as atrial fibrillation (AF), the left atrium does not expand and contract normally. As a result, the left atrium is not capable of completely emptying itself of blood. Blood may pool, particularly in the part of the left atrium called the left atrial appendage. This pooled blood is prone to clotting, causing formation of a thrombus (that is, a blood clot). When a thrombus breaks off, it is called an embolism (or thromboembolism). An embolism can cause a stroke or other peripheral arterial blockage.

The WATCHMAN® Left Atrial Appendage (LAA) Closure Device is an implant that acts as a physical barrier, sealing the LAA to prevent thromboemboli from entering into the arterial circulation from the LAA, thereby reducing the risk of stroke and potentially eliminating the need for Warfarin therapy in those patients diagnosed with nonvalvular AF and who are eligible for Warfarin therapy.

The applicant anticipates FDA premarket approval of the WATCHMAN® System in the first half of 2014. According to the applicant, the WATCHMAN® System is the first LAA closure device that would be approved by the FDA. Therefore, the applicant believes that the technology meets the newness criterion. The device is currently identified by ICD–9–CM procedure code 37.90 (Insertion of Left Atrial Appendage Device), which was issued on October 1, 2004. We are inviting public comments on if, and how, the WATCHMAN® System meets the newness criterion.

With regard to the cost criterion, the applicant used the FY 2012 MedPAR file and searched the claims data for cases reporting with ICD–9–CM procedure code 37.90. The applicant provided two analyses. The first analysis includes all claims that contained ICD–9–CM procedure code 37.90 regardless of whether it was the principle procedure that determined the MS–DRG assignment of the case. This returned 243 cases spread across 21 MS–DRGs. The applicant noted that the MedPAR file contained claims that were returned to the provider reporting charges for actual cases from clinical trials that used the WATCHMAN® System that were well below post-FDA approval pricing. Therefore, the applicant removed the premarket device related charges. The applicant then standardized the charges, applied an inflation factor of 1.096898 based on the 2-year charge inflation factor listed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50982) and then added post-FDA approval charges for the WATCHMAN® System. This resulted in an average case-weighted standardized charge per case of $176,943. The applicant calculated an average case-weighted threshold of $107,345 across all MS–DRGs. Therefore, the applicant asserted that the average case-weighted standardized charge per case exceeds the average case-weighted threshold and maintained that the technology meets the cost criterion.

The second analysis focused on cases reporting ICD–9–CM procedure code 37.90, and assigned to MS–DRGs 250 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent with MCC) and 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent without MCC). According to the applicant, these are the MS–DRGs to which cases using the WATCHMAN® System in the delivery of treatment as the principal procedure performed during the inpatient stay are assigned. The applicant found a total of 122 cases, and noted that 9.02 percent of the total number of cases would map to MS–DRG 250, and 90.98 percent of the total number of cases would map to MS–DRG 252. Similar to above, the applicant noted that the MedPAR file contained claims that were returned to the provider reporting charges for actual cases from clinical trials that used the WATCHMAN® System that were well below post-FDA approval pricing. Therefore, the applicant removed the premarket device-related charges. The applicant then standardized the charges, applied an inflation factor of 1.096898 based on the 2-year charge inflation factor listed in the FY 2014 IPPS/LTCH final rule (78 FR 50982), and then added post FDA-approval charges for the WATCHMAN® System. This resulted in an average case-weighted standardized charge per case of $113,210. The applicant calculated an average case-weighted threshold of $68,093. The applicant asserted that the average case-weighted standardized charge per case exceeds the average case-weighted threshold. Therefore, the applicant maintained that the technology meets the cost criterion. We are inviting public comments on whether the WATCHMAN® System meets the cost criterion, particularly with regard to the assumptions and methodology used in the applicant's analysis.

The applicant asserted in its application that the WATCHMAN® System meets the substantial clinical improvement criterion. The applicant believed that the WATCHMAN® System provides a permanent solution proven to reduce the risk of thromboembolic stroke in patients diagnosed with high-risk, nonvalvular AF, and who are eligible for Warfarin therapy. Therefore, the applicant believed that the WATCHMAN® System fulfills a major unmet clinical need. According to the applicant, clinical trial data

demonstrated non-inferiority of the WATCHMAN® System compared to Warfarin therapy. Further, long-term follow-up data suggested superiority compared to Warfarin therapy by demonstrating 40 percent relative reduction of primary efficacy events, and 60 percent relative reduction for CV mortality. The applicant also stated that, procedure complication rate is low, with the majority of events occurring soon before, during, or soon after the procedure.

The applicant submitted multiple clinical trial studies to demonstrate that the technology represents a substantial clinical improvement. Specifically, the WATCHMAN® System United States clinical program included five studies with approximately 2000 patients. There were two prospective, randomized-controlled trials (PROTECT AF [9] [10] [11] [12] and PREVAIL [13] [14]), two continued access registries for patients who completed PROTECT AF and PREVAIL (CAP and CAP2, respectively), and the ASAP feasibility study.

According to the applicant, PROTECT AF was a prospective, randomized-controlled trial comparing the outcomes of patients who received care for LAA closure using the WATCHMAN® System (463 patients) with those of patients who were anticoagulated with Warfarin therapy (244 patients). The trial was designed to show that the WATCHMAN® System was noninferior to Warfarin therapy. The primary outcome was anticipated to occur at a rate of 6.15 per 100 patient-years in the control group, and the sample size was chosen using a ''two-fold non-inferiority margin.'' Because patients could be randomized to Warfarin therapy, all patients were eligible to continue Warfarin, and did not have an excessive risk of bleeding. By design, all patients in PROTECT AF continued Warfarin therapy for 45 days after the device implantation procedure.

Outcome data from PROTECT AF have been reported after mean follow-ups of 1.5 years, 2.3 years, and 3.7 years. The primary efficacy endpoint was the composite of stroke, systemic embolism, cardiovascular death, or unexplained death. This primary endpoint occurred in the control group at a lower rate than was assumed in the sample size calculations: The observed rate was between 3.8 and 4.9 per 100 patient-years compared with the design estimate of 6.15 per 100 patient-years. According to the applicant, patients randomly assigned to receive the WATCHMAN® System device in the PROTECT AF trial had numerically lower rates of the primary endpoint than the patients randomly assigned to Warfarin (also known as Coumadin) at all time points. We note that, although the point estimates favor the device for the primary endpoint, the differences were not statistically significant because the upper 95 percent confidence intervals are all above 1.0. However, the secondary endpoint of cardiovascular death was reduced significantly, as was all-cause mortality with a rate ratio of 0.66 (CL 0.45–0.98).

The criteria for noninferiority of the primary endpoint were met over all follow-up intervals. According to the applicant, the probability is >99 percent that device-treated patients have no more than twice the rate of stroke, embolism, or death than Warfarin-treated patients.

Also, the incidence of procedural-related complications in this trial was 8.7 percent. The applicant noted that complications early in the trial were related to procedures performed by new users. As a result, changes were made to the procedure and physician training, and the complication rate subsequently decreased.

The applicant stated in its application that the Circulatory System Devices Advisory Panel to the Division of Cardiovascular Devices (DCD) within the Center for Devices and Radiological Health (CDRH) of the FDA reviewed the 1-year PROTECT AF data on April 23, 2009. The panel voted 7:5 in favor of the device, resulting in a positive recommendation for ''approval with conditions.'' However, noting the complication rate, the FDA required additional data collection on procedural safety to confirm the lower rates observed in the second half of the trial. As a result of this requirement, the PREVAIL trial study was designed in a similar fashion to PROTECT AF, but with modifications to trial entry criteria and a minimum number of new operators.

According to the applicant, in the interim, FDA also recognized the effectiveness of the WATCHMAN® System and the need for a new therapeutic option for patients receiving Warfarin therapy, and a continued access program (CAP) was authorized. With 460 patients enrolled, according to the applicant, efficacy rates in the CAP trial study were similar to those seen in the PROTECT AF trial study, and procedural complications were reduced by over 50 percent compared to the PROTECT AF trial study, from 8.7 percent to 4.1 percent.

From November 2010 to June 2012, the PREVAIL trial enrolled a total of 407 patients, 269 of whom received treatment for LAA closure with the WATCHMAN® System, and 138 who received Warfarin therapy. The applicant noted that the procedural complication rate was 4.4 percent, confirming the rate seen in the second half of the PROTECT AF trial study and the CAP trial study. After the PREVAIL trial closed, the FDA authorized a second CAP (specifically, CAP2), which has enrolled 336 patients as of the date the applicant submitted its application.

The applicant also submitted data concerning patients diagnosed with AF who are not on an oral anticoagulant. These patients are not protected from stroke by an oral anticoagulant. There may be increased periprocedural risk of device implantation because thrombus might form on the device surface more readily in patients with no anticoagulation (patients in the PROTECT AF trial were treated with Warfarin for 45 days after the device implantation procedure). Specifically, the ASAP Registry (5) enrolled 150 patients, at one of four centers, that had a contraindication to even short-term anticoagulation, mostly a history of prior bleeding. There was no control group. Device implantation led to a serious adverse event in 13 patients (8.7 percent), including one case of device thrombus leading to ischemic stroke. Five other patients had a device-related thrombus that did not lead to stroke (four of these patients were treated with low molecular weight heparin), resulting in an overall 4.0 percent incidence (6 out of 150) of device-associated thrombus. In the PROTECT AF trail study, 20 of the 473 patients (4.2 percent) had device-associated thrombus, 3 of which led to an ischemic stroke. The rates of device-related thrombus are similar in the two studies

[9] Wrigley, B., Lip, G., ''Can the WATCHMAN device truly PROTECT from stroke in atrial fibrillation?'', Lancet Neurology, 2009.

[10] Reddy, V., Holmes, D., Doshi, S., et al. ''Safety of percutaneous left atrial appendage closure: Results from the WATCHMAN left atrial appendage system for embolic protection in patients With AF (PROTECT AF) clinical trial and the Continued Access Registry. Circulation.'' Vol. 123, 2011.

[11] Reddy, V., Doshi, S., Sievert, H., et. al., ''Percutaneous left atrial appendage closure for stroke prophylaxis in patients with atrial fibrillation: 2.3-year follow up of the PROTECT AF (Watchman Left Atrial Appendage System for embolic protection in patients with atrial fibrillation) trial,'' Circulation., 2013, Vol. 127, pp. 720–729.

[12] Alli, O., Doshi, S., Kar, S., et al., ''Quality of Life Assessment in the Randomized PROTECT AF Trial of Patients at Risk for Stroke With Non-Valvular Atrial Fibrillation,'' Journal of American College of Cardiology, Vol. 61, No 17, 2013, pp. 1790–1798.

[13] Landmesser, U., Holmes, D., ''Left atrial appendage closure: A percutaneous transcatheter approach for stroke prevention in atrial fibrillation,'' European Heart Journal, Vol. 33, 2012.

[14] Homes, D.R. *PREVAIL Results CIT,* 2013.

(4.0 percent versus 4.2 percent), but the number of patient studied is smaller in the ASAP Registry (5) study compared to the PROTECT AF clinical trial study.

In the 14-month follow-up data for the ASAP Registry (5) study, the rate of stroke or systemic embolism was 2.3 percent per year, which was said to be ''lower than expected'' based on prior data for patients diagnosed with AF who were not treated with Warfarin (there was no concurrent control group). The data provided suggested efficacy in this patient population. However, we are concerned that there is not strong evidence that the device prevents stroke.

All trials in the U.S. clinical program allowed for continued follow-up of patients out to 5 years post-randomization. According to the applicant, the patients enrolled in the PROTECT AF clinical trial now have an average of 3.8 years of follow-up. The applicant asserted that an analysis of this long-term data demonstrates superior primary efficacy outcomes of the WATCHMAN® System over Warfarin therapy.

The applicant concluded that the WATCHMAN® System provides a permanent solution to reduce the risk of ischemic strokes caused by thromboemboli originating in the LAA in patients diagnosed with nonvalvular AF. The applicant further stated that, the data demonstrate that LAA closure using the WATCHMAN® System is a substantial improvement in care as compared to currently available pharmacologic therapy, such as Warfarin therapy.

The WATCHMAN® System may be used in two populations: (1) Patients who could take Warfarin (or other oral anticoagulant), but would prefer to avoid the risk of bleeding from anticoagulant therapy; (2) patients who are not eligible for oral anticoagulation therapy because of an unacceptable risk of bleeding. Most of the clinical evidence presented by the applicant is from the former group, and the applicant has requested from the FDA that the label indication be for ''high risk patients with nonvalvular atrial fibrillation who are eligible for warfarin therapy, but, for whom the risks posed by long-term warfarin therapy outweigh the benefits.''

We are concerned that the evidence presented by the applicant demonstrating the superiority of the WATCHMAN® System compared to Warfarin therapy is insufficient. The clinical study discussed above was designed to demonstrate that the WATCHMAN® is noninferior to Warfarin therapy. Specifically, in the PREVAIL AF trial study, the primary endpoint was not significantly improved in the conventional hypothesis testing statistical analysis at any time point. The longer term data has improved efficacy and safety data, but still remain sparse. Even for the secondary patient population ineligible for anticoagulation therapy, the evidence remains weak as the only data comes from the ASAP Registry (5) observational study of 150 patients without a concurrent control group.

A recent article in the *Journal of the American College of Cardiology* echoes these concerns: ''Current issues compromising the implementation of procedural approaches for stroke prevention in AF are discussed herein and include: (1) Lack of multiple randomized clinical trials; (2) lack of consensus regarding the appropriate target population to study; and (3) ability to obtain approval of devices for outcome measures of unconfirmed clinical importance, such as, the use of complete closure of the LAA at the time of the index procedure as a surrogate for clinical efficacy.'' [15]

We are inviting public comments on whether this technology meets the substantial clinical improvement criterion, particularly regarding our concerns discussed above.

We did not receive any public comments in response to the New Technology Town Hall meeting held on February 12, 2014 in regard to this technology.

d. CardioMEMS™ HF (Heart Failure) System

CardioMEMS, Inc. submitted an application for new technology add-on payment for FY 2015 for the CardioMEMS™ HF (Heart Failure) System, which is an implantable hemodynamic monitoring system comprised of an implantable sensor/monitor placed in the distal pulmonary artery. Pulmonary artery hemodynamic monitoring is used in the management of heart failure. The CardioMEMS™ HF System measures multiple pulmonary artery pressure parameters for an ambulatory patient to measure and transmit data via a wireless sensor to a secure Web site.

The CardioMEMS™ HF System utilizes radiofrequency (RF) energy to power the sensor and to measure pulmonary artery (PA) pressure and consists of three components: An Implantable Sensor with Delivery Catheter, an External Electronics Unit, and a Pulmonary Artery Pressure Database. The system provides the physician with the patient's PA pressure waveform (including systolic, diastolic, and mean pressures) as well as heart rate. The sensor is permanently implanted in the distal pulmonary artery using transcatheter techniques in the catheterization laboratory where it is calibrated using a Swan-Ganz catheter. PA pressures are transmitted by the patient at home in a supine position on a padded antenna, pushing one button which records an 18-second continuous waveform. The data also can be recorded from the hospital, physician's office or clinic.

The hemodynamic data, including a detailed waveform, are transmitted to a secure Web site that serves as the Pulmonary Artery Pressure Database, so that information regarding PA pressure is available to the physician or nurse at any time via the Internet. Interpretation of trend data allows the clinician to make adjustments to therapy and can be used along with heart failure signs and symptoms to adjust medications.

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

The applicant anticipates FDA approval and commercial launch in the second quarter of 2014. The CardioMEMS™ HF System is currently described by ICD–9–CM procedure code 38.26 (Insertion of implantable pressure sensor without lead for intracardiac or great vessel hemodynamic monitoring). We are inviting public comments regarding how the CardioMEMS™ HF System meets the newness criterion.

With respect to cost criterion, the applicant submitted actual claims from

[15] Holmes, D.R., et. al., ''Left Atrial Occlusion,'' *Journal of American College of Cardiology,* 2014, Vol. 63, pp. 291–8.

the CHAMPION [16] clinical trial. Of the 550 patients enrolled in the trial, the applicant received 310 hospital bills. The applicant excluded the following claims: Incomplete or missing procedure codes, incomplete charge information and bills that were statistical outliers (three standard deviations away from the geometric mean). This resulted in a final cohort of 138 claims. The applicant noted that cases treated with the CardioMEMS™ HF System would typically map to MS–DRG 264 (Other Circulatory System Operating Room Procedures). Using the 138 clinical trial claims, the applicant standardized the charges and added charges for the CardioMEMS™ HF System (because the clinical trial claims did not contain charges for the CardioMEMS™ HF System). This resulted in an average case-weighted standardized charge per case of $79,218.

Using the FY 2014 Table 10 thresholds, the threshold for MS–DRG 264 is $60,172. Because the average case-weighted standardized charge per case exceeded the threshold amount, the applicant maintained that the CardioMEMS™ HF System would meet the cost criterion. We are inviting public comments on whether or not the CardioMEMS™ HF System meets the cost criterion.

With regard to substantial clinical improvement, the applicant asserted that elevated PA pressures occur prior to signs and symptoms of heart failure and changes in PA pressures provide a sound physiologic basis for its management. The applicant also contended that, until the creation of the CardioMEMS wireless PA implant, knowledge of PA pressure was only feasible in the hospital with the performance of a right heart catheterization. According to the applicant, the CardioMEMS™ HF System provides physicians knowledge of PA pressure while the patient is at home, allowing proactive management to prevent heart failure decompensation and hospitalization.

The applicant cited clinical data from the CHAMPION trial. The trial is a prospective, multicenter, randomized, single-blinded clinical trial conducted in the United States, designed to evaluate the safety and efficacy of the CardioMEMS™ HF System in reducing heart failure-related hospitalizations in a subset of subjects suffering from heart failure. The applicant shared several major findings from the CHAMPION trial as described below.

The primary efficacy endpoint of the CHAMPION trial was the rate of HF hospitalizations during the first 6 months of randomized access. There were 84 heart failure hospitalizations in the treatment group compared with 120 heart failure hospitalizations in the control group. This difference between the groups represented a 28-percent reduction in the rate of hospitalization for heart failure in the treatment group (0.32 hospitalizations per patient in the treatment group versus 0.44 hospitalizations per patient in the control group, $p = 0.0002$). Although not a primary end point, the rate of HF hospitalizations after 18 months was 33 percent lower in the treatment group than in the control group.

According to the applicant, secondary endpoints of the CHAMPION trial are changes in pulmonary artery pressures, proportion of subjects hospitalized, days alive outside of the hospital, quality of life (QOL), and heart failure management which demonstrated the following results:

- Pulmonary Artery Pressures: At baseline, both treatment and control patients had similar PA mean pressures. The change in pressure over the first 6 months was evaluated by integrating the area under the pressure curve (AUC). At 6 months of follow-up, the treatment group had a significantly greater reduction in AUC of -155.7 mmHg days compared to the control group which had an increase in AUC of +33.1 mmHg-days; $p = 0.0077$.
- Proportion of Subjects Hospitalized: During the 6-month follow-up period, the proportion of subjects hospitalized for 1 or more HF hospitalizations was significantly lower in the treatment group (55 out of 270 patients) than in the control group (80 out of 280 patients) (20.4 percent versus 28.6 percent; $p = 0.0292$).
- Days Alive Outside of the Hospital: At 6 months, treatment patients had a nonsignificant and clinically not meaningful increase in days alive outside of the hospital (174.4 versus 172.1; $p = 0.0280$) and fewer average days in the hospital (2.2 versus 3.8; $p = 0.0246$) compared to control patients.
- Quality of Life: The heart failure specific quality of life was assessed with the MLHFQ total score at 6 months. The average total score in the treatment group was 45.2 ± 26.4 which was significantly better than the average total score in the control group 50.6 ± 24.8 ($p = 0.0236$). The difference in total quality of life was primarily due to the physical domain. The average physical score for the treatment group (19.8 ± 11.2) was significantly better than the control group (22.4 ± 10.9) ($p = 0.0096$). There was also a significant difference in the emotional domain with an average score of 9.5 ± 8.1 for the treatment group and 11.0 ± 7.7 for the control group ($p = 0.0398$).
- Heart Failure Management: Physicians responded to treatment of patients' elevated PA pressures by making medication changes to lower PA pressures and reduce the risk for HF hospitalization. Physicians documented all medication changes for all patients and indicated whether the change was made in response to PA pressures or standard of care information. During the 6-month follow-up period, physicians made approximately one additional HF medication change per patient per month in the treatment group when compared to the control group. Specifically, treatment patients had 1.55 medication changes per month on average compared to control patients having 0.65 medication changes per month ($p < 0.0001$). The difference in HF management between the treatment and control group was due to HF medication changes made in response to PA pressures.

The study met the two primary safety endpoints: (1) Freedom from device/system related complications (DSRC); and (2) freedom from sensor failure. The protocol pre-specified objective performance criterion (OPC) were that at least 80 percent of patients were to be free from DSRC and at least 90 percent were to be free from pressure sensor failure. Of the 575 patients in the safety population, 567 (98.6 percent) were free from DSRC at 6 months (lower confidence limit 97.3 percent, $p < 0.0001$). This lower limit of 97.3 percent is greater than the pre-specified OPC of 80 percent. There were no sensor explants or repeat implants and all sensors were operational at 6 months for a freedom from sensor failure of 100 percent (lower confidence limit 99.3 percent, $p < 0.0001$). This lower limit of 99.3 percent is greater than the pre-specified OPC of 90 percent.

The applicant also noted that the CardioMEMS™ HF System reduces the occurrence of HF hospitalizations in NYHA Class III heart failure patients. According to the applicant, the device had very few device and system related complications occurring over the course of the clinical trial. All primary and secondary study endpoints were successfully achieved. In addition, the CHAMPION trial suggests the safety and effectiveness of the device was

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

maintained during longer term follow-up.

After reviewing the information provided by the applicant, we have the following concerns. The applicant did not discuss long-term outcomes, specifically death. We believe additional long-term outcome information and how the technology changes long-term outcomes would further assist in our determination of whether the technology represents a substantial clinical improvement. With regard to the clinical trial, information from the randomized access period and the open access period did not include the total number of deaths in each group. While the data support a reduction in total hospitalizations, the rate of hospitalization in each group (0.32 versus 0.44) does not appear to be clinically meaningful. This is supported by total days alive out of the hospital being virtually identical in both groups. Finally, we are concerned about the cause of the significant dropouts in the Kaplan Meier curves which further demonstrates lack of impact on survival. We are inviting public comments on whether or not the CardioMEMS™ HF Monitoring System technology represents a substantial clinical improvement in the Medicare population.

We received public comments via email in response to the February 12, 2014 New Technology Town Hall meeting in regard to this technology. We summarize these comments below.

Comment: Commenters supported the approval of new technology add-on payments for the CardioMEMS™ HF System. One commenter stated that it had personal experience with the CardioMEMS™ HF System. The commenter explained that having access to a patient's daily pressures provides trend data. The commenter further explained that if there is a variation or increase in a patient's pressure, the physician can contact the patient over the phone and conduct an evaluation to look for increased symptoms or to learn if the patient has skipped their diuretics. The device prompts the clinician to ask questions such as what is different today than yesterday and if the patient is feeling okay, especially if the patient has not taken a pressure rate in a few days. Based on the answer to these questions or if the clinician has concerns, the primary investigator or the patient's primary cardiologist can assess the pressures and symptoms and decide the next course of treatment for the patient. The commenter believed that this structured and consistent monitoring has kept many patients out of the hospital.

The commenter noted that the monitoring of pressures to assess clinical status before the patient recognizes symptoms for chronic CHF patients with significant left ventricular dysfunction can be very useful. The commenter explained that these patients are accustomed to being sick and tend to ignore the first symptoms and do not seek treatment until they are unable to breathe. The commenter noted that often a clinician can increase the patient's home medications before pressures get too high.

The commenter also noted that, for patients who go to a CHF clinic on a regular basis, typically patient information of pressure trends, along with symptoms and laboratory results, can help determine if medications should be given that day. The commenter stated that extra information from the CardioMEMS™ HF System can change the way physicians treat the patient and has, in many instances, at its site. The commenter concluded the CardioMEMS™ HF System provides a substantial clinical benefit versus current methods for managing heart failure.

Another commenter stated that the implant procedure was very simple and straightforward for patients, especially compared to having a pacemaker or defibrillator implanted. The commenter further stated that the device is compatible with defibrillators and cardiac resynchronization therapy, which are present in many advanced heart failure patients. The commenter added that the CardioMEMS™ HF System is a wireless device and does not involve addition of another intracardiac lead. Aside from regular pressure readings, the commenter noted that it found unexpected intake issues for some patients who were unknowingly consuming certain high-sodium foods. The commenter noted that they were able to reduce sodium intake further to help reduce pressures. The commenter also noted that it presented a case report of increasing pressures in a patient in whom the primary investigator adjusted diuretic therapy and later the patient's ACE-Inhibitor and nitrates. The commenter stated that it successfully lowered pressures and avoided a probable heart failure hospitalization. The commenter added that the CardioMEMS™ HF System allows hospitals to easily obtain pressures at home for transmission and the ability to check pressures rather than perform right heart catheterization if a patient was admitted to the hospital.

The commenter also stated that patients found transmission of their data easy and were surprised how quickly the data was sent to the clinic. The commenter added that it had patients that liked the portability of the home electronic equipment, which allowed them to take it with them on long weekends or vacations. The commenter added that this information was advantageous as it further allowed clinicians to implement changes in a timely manner.

The commenter noted the following trial results in its clinic, which the commenter believed confirm the benefit of hemodynamic monitoring: A 28-percent reduction in heart failure hospitalization at 6 months and a 15-percent reduction at 15 months. The commenter noted that there were no sensor failures and 98.6 percent of patients remained free from device or system complications. The commenter further noted that it did not experience any complications in patients who were implanted with the device. The commenter did explain that inevitably, due to the nature of heart failure, several patients eventually required advanced therapies with transplantation or ventricular assist device support without any issue from the sensor. The commenter also noted some additional key points such as: A reduction in hospitalization for patients with preserved ejection fraction; in addition to diuretic adjustment, the study found nitrates were also adjusted, which further supports use of the device to optimize vasodilator therapy for pulmonary hypertension and afterload reduction in this patient population. The commenter concluded that, for the reasons stated above, the CardioMEMS™ HF System provides a substantial clinical benefit versus current methods for managing heart failure.

One commenter stated that the CardioMEMS™ HF System provides clinicians with daily remotely monitored pulmonary artery pressure and has been proven clinically and dramatically to reduce heart failure hospitalizations. The commenter cited the CHAMPION IDE trial, which was a prospective, multicenter, single-blind, clinical study that enrolled 550 patients randomized to treatment guided by the CardioMEMS™ HF System verses optimal medical therapy. The commenter stated that the trial met all of its primary safety and efficacy endpoints; reducing heart failure hospitalizations by 28 percent 6 months after implant ($p = 0.0002$). The commenter further stated that the reduction in heart failure hospitalizations increased over time reaching 33 percent ($p < 0.0001$) at 17 months after implant. In addition, the

commenter asserted that the system was shown to be extremely safe, with almost 99 percent of patients free from device or system complications.

The commenter also stated that one criterion CMS uses to evaluate substantial clinical improvement is that the device offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. The commenter believed that there is evidence that use of the CardioMEMS™ HF System to make a diagnosis affects the management of the patient. The commenter added that the CHAMPION trial demonstrated that therapy guided by CardioMEMS™ HF System allows physicians to titrate medications earlier and more effectively reduce heart failure hospitalizations. The commenter noted that this information is not available with any other device or treatment alternative.

The commenter further stated that another of CMS' criteria is that use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments, such as a decreased number of future hospitalizations. The commenter stated that evidence provided in the CHAMPION trial at 6 months showed a 28-percent reduction in heart failure hospitalizations and even a larger reduction of 33 percent during long-term follow-up at 17 months. Based on the criteria outlined by CMS and the evidence supporting the CardioMEMS™ HF System, the commenter believed that the CardioMEMS™ HF System meets the criteria for substantial clinical improvement.

Another commenter, the applicant, reiterated the statements set forth above in the substantial clinical improvement discussion.

Response: We appreciate the commenters' support. We considered these comments in our evaluation of the CardioMEMS™ HF System for new technology add-on payments for FY 2015 and in the development of this proposed rule. As stated above, we are inviting additional public comments on whether or not the CardioMEMS™ HF System represents a substantial clinical improvement in the Medicare population.

e. MitraClip® System

Abbott Vascular submitted an application for new technology add-on payments for the MitraClip® System for FY 2015. (We note that the applicant submitted an application for new technology add-on payments for FY 2014 but failed to receive FDA approval by the July 1 deadline.) The MitraClip® System is a transcatheter mitral valve repair system that includes a MitraClip® device implant, a Steerable Guide Catheter, and a Clip Delivery System. It is designed to perform reconstruction of the insufficient mitral valve for high-risk patients who are not candidates for conventional open mitral valve repair surgery.

Mitral regurgitation (MR), also referred to as mitral insufficiency or mitral incompetence, occurs when the mitral valve fails to close completely causing the blood to leak or flow backwards (regurgitate) into the left ventricle. If the amount of blood that leaks backwards into the left ventricle is minimal, then intervention is usually not necessary. However, if the amount of blood that is regurgitated becomes significant, this can cause the left ventricle to work harder to meet the body's need for oxygenated blood. Severity levels of MR can range from grade 1+ through grade 4+. If left untreated, severe MR can lead to heart failure and death. The American College of Cardiology (ACC) and the American Heart Association (AHA) issued practice guidelines in 2006 that recommended intervention for moderate/severe or severe MR (grade 3+ to 4+). The applicant stated that the MitraClip® System is ''indicated for percutaneous reduction of significant mitral regurgitation . . . in patients who have been determined to be at prohibitive risk for mitral value surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease and in whom existing comorbidities would not preclude the expected benefit from correction of the mitral regurgitation.''

The MitraClip ® System mitral valve repair procedure is based on the double-orifice surgical repair technique that has been used as a surgical technique in open chest, arrested-heart surgery for the treatment of MR since the early 1990s. According to the applicant, in utilizing ''the double-orifice technique, a portion of the anterior leaflet is sutured to the corresponding portion of the posterior leaflet using standard techniques and forceps and suture, creating a point of permanent coaptation (''approximation'') of the two leaflets. When the suture is placed in the middle of the valve, the valve will have a functional double orifice during diastole.''

With regard to the newness criterion, the MitraClip® System received a premarket approval from the FDA on October 24, 2013. The MitraClip® System is indicated ''for the percutaneous reduction of significant symptomatic mitral regurgitation (MR >= 3+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.'' The MitraClip® System became immediately available on the U.S. market following FDA approval. The MitraClip® System is a Class III device, and has an investigational device exemption (IDE) for the EVEREST study (Endovascular Valve Edge-to-Edge Repair Study)—IDE G030061, and for the COAPT study (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Health Failure Patients with Functional Mitral Regurgitation)—IDE G120024. Effective October 1, 2010, ICD–9–CM procedure code 35.97 (Percutaneous mitral valve repair with implant) was created to identify and describe the MitraClip® System technology.

Abbott Vascular has also submitted an application for a National Coverage Decision (NCD) for the MitraClip® System device. We refer readers to the CMS Web site at: *http://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=273&NcaName=Transcatheter+Mitral+Valve+(TMV)+Procedures&TimeFrame=90&DocType=All&bc=AAAAIAAACAAAAA%3d%3d&* for information related to this ongoing NCD. The tracking sheet for this National Coverage Analysis (NCA) indicates an expected NCA completion date of August 16, 2014, which is after the FY 2015 IPPS/LTCH PPS final rule is scheduled to be published. The processes for evaluation and determination of an NCD, and the processes for evaluation and approval of an application for new technology add-on payments are made independent of each other. However, any payment made under the Medicare program for services provided to a beneficiary would be contingent on CMS' coverage of the item, and any restrictions on the coverage would apply. We are inviting public comments on how the MitraClip® System meets the newness criterion for purposes of new technology add-on payments and the issues that may arise from concurrent NCD requests and new technology add-on payment application review and approval processes.

With regard to the cost criterion, the applicant conducted two analyses. The applicant noted that, while ICD–9–CM procedure code 35.97 maps to MS–DRGs 246 (Percutaneous Cardiovascular Procedure with Drug- Eluting Stent with Major Complication or Comorbidity (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), clinical experience with the MitraClip® System device has demonstrated that it is extremely rare for a patient to receive stents concurrently during procedures using the MitraClip® System device. The applicant further cited the FY 2013 IPPS/LTCH PPS final rule (77 FR 53308) which stated, ''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 a result, the applicant stated that it conducted its analyses solely for MS–DRGs 250 and 251 to demonstrate that the cases involving the MitraClip® System device meet the incremental cost thresholds provided in Table 10 for those MS–DRGs.

The applicant researched the FY 2012 MedPAR file for claims for cases reporting ICD–9–CM procedure code 35.97. Under the first analysis and methodology, the applicant noted that this search yielded actual claims for cases in which the MitraClip® System device was used in procedures performed in an IDE study type setting, and hospitals obtained the MitraClip® System device at a reduced investigational price. The applicant further stated that it is likely that hospitals did not report the charges for the investigational device, or submitted claims for charges that were significantly less than the actual device acquisition costs (we refer readers to the explanation below). The applicant found 57 cases in MS–DRG 250 (29.38 percent of the total number of cases), and 137 cases in MS–DRG 251 (70.61 percent of the total number of cases), which resulted in an average case-weighted standardized charge per case of $232,670.

The applicant standardized the charges using the FY 2014 IPPS final rule impact file, and inflated the result using three different inflation factors. We note that, since the applicant used FY 2012 MedPAR data, we believe it is appropriate to use comparable data for standardization. Therefore, we believe use of the FY 2012 final rule impact file is more appropriate rather than the FY 2014 final rule impact file. The first analysis and methodology used an inflation factor of 4.57 percent, which was based on data from the BLS' non-seasonally adjusted CPI for all urban consumers between January 2011 and January 2013. This resulted in an average case-weighted standardized charge per case of $94,517. The second methodology under the first analysis used an inflation factor of 9.92 percent, which was based on the 2-year charge inflation factor listed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50982). This resulted in an average case-weighted standardized charge per case of $96,199. The third methodology used under the first analysis used an inflation factor of 4.63 percent, which was based on the Medicare Economic Index (MEI) from the IPPS market basket update between the third quarter of 2012 projected through the third quarter of 2014. This resulted in an average case-weighted standardized charge per case of $91,570. The applicant noted that all three methodologies used under the first analysis to determine each respective average case-weighted standardized charge per case were calculated without any adjustments to reflect the reduced investigational price, or inadequate hospital claim reporting and billing.

Using the FY 2014 IPPS Table 10 thresholds, the average case-weighted threshold for MS–DRGs 250 and 251 is $71,467 (all calculations above were performed using unrounded numbers). Because the average case-weighted standardized charge per case for the applicable MS–DRGs calculated under each methodology under the first analysis discussed above exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

Under the second analysis, which used the same premise as the first analysis, the applicant researched the FY 2012 MedPAR file for claims for cases reporting procedure code 35.97 that mapped to MS–DRGs 250 and 251, except that the applicant excluded charges related to the MitraClip® System by removing all charges from the claim that would map to the implantable cost center on the cost report. The applicant then standardized the charges, inflated the result using the three inflation factors above, and added a fixed amount of commercial charges based on post-FDA approval pricing. This resulted in an average case weighted standardized charge per case of $139,536 under the first inflation factor (4.57 percent), $142,364 under the second inflation factor (9.2 percent), and $139,568 under the third inflation factor (4.63 percent).

Using the FY 2014 IPPS Table 10 thresholds, the average case-weighted threshold for MS–DRGs 250 and 251 is $71,467 (all calculations above were performed using unrounded numbers). Because the average case-weighted standardized charge per case for the applicable MS–DRGs calculated under all three methodologies discussed above exceeds the average case-weighted threshold amount, the applicant maintained that the MitraClip® System meets the cost criterion.

We are inviting public comments on whether or not the MitraClip® System meets the cost criterion. In addition, we are inviting public comments on the methodologies used by the applicant in its two analyses.

The applicant asserted that the MitraClip® System meets the substantial clinical improvement criterion. Severe MR is associated with significant morbidity and mortality rates, and is a progressive condition. For symptomatic patients diagnosed with significant MR, surgical repair or replacement is considered the gold standard—offering improvements in symptoms and longer survival rates. However, the applicant explained that studies have indicated that a significant proportion of patients are not eligible for mitral valve repair and/or replacement surgery because of risk factors, including reduced left ventricular function, significant comorbidities, and advanced age. As a result, the applicant stated that there is a significant unmet clinical need for patients diagnosed with severe MR who are too high-risk for surgery, who are receiving palliative medical management.

The applicant also stated that the MitraClip® System meets the substantial clinical improvement criterion based on clinical studies [17,18,19,20,21,22,23,24,25]

[17] Feldman, et al., ''Percutaneous Repair or Surgery for Mitral Regurgitation,'' New England Journal of Medicine, 2011, Vol. 364, pp. 1395–1406.

[18] Foster, et al., ''Percutaneous Mitral Valve Repair in the Initial EVEREST Cohort: Evidence of Reverse Left Ventricular Remodeling,'' Circulation

Continued

that have consistently shown that procedures performed using the MitraClip ® System device lead to a significant reduction of MR; improvements in left ventricular (LV) function including LV volumes and dimensions; improved patient outcomes as measured by improvements in New York Heart Association (NYHA) functional class, improvement in health-related quality of life measures, and reductions in heart-failure related hospitalizations; and significantly lower mortality rates than predicted surgical mortality rates.

The applicant cited clinical data from the EVEREST II High-Risk Study and the EVEREST II (REALISM) Continued Access Study/Registry. The applicant also cited clinical data from a high-risk cohort of patients (the EVEREST II High-Risk Cohort), which is an integrated analysis of the following: (1) Patients within the EVEREST II High-Risk Study who met eligibility criteria for being too high-risk to undergo mitral valve repair surgery; and (2) patients within the EVEREST II (REALISM) Continued Access Study/Registry who were too high-risk for surgery using identical eligibility inclusion criteria. The applicant also cited data from the Prohibitive Risk Degenerative Mitral Regurgitation (DMR) Cohort, which is an analysis of retrospectively evaluated high-risk patients diagnosed with DMR enrolled in the EVEREST II studies that had 1-year follow-up available.

In addition to the published clinical experience from the EVEREST studies, the applicant cited data on the use of the MitraClip® System device in a ''real-world'' setting published recently by a select number of European centers as part of their individual and/or multi-center commercial experience or enrollment in the MitraClip® System device group of the ACCESS–EU post-approval clinical trial in Europe. The European use of the MitraClip® System device is focused on patients who are too high-risk for surgery, and patients who are selected for therapy using a multi-disciplinary ''heart team'' approach.

The applicant stated that published reports on the MitraClip® System device and the procedures in which the device was used have consistently demonstrated a significant reduction in MR incidents that have been durable out to 1, 2, 3, and 4 years. The applicant cited the EVEREST II High-Risk Study (an analysis of 78 patients diagnosed with degenerative or functional MR enrolled in the trial), which stated that ''objective measures of MR grade improved in the MitraClip™ group, including MR grade of <=2+ in 78 percent of surviving patients at 1 year. These patients also experienced clinically significant improvements in left ventricular volume measurements. The clinical significance of these improvements is reflected in the NYHA class improvements. At baseline, 89 percent of patients were NYHA III/IV, improving to Class I/II in 74 percent of surviving patients at 12 months. Quality of life scores also improved significantly. Finally, the number of admissions for heart failure was significantly reduced compared to the year prior to MitraClip™ therapy.''

The applicant cited clinical outcomes from the Prohibitive Risk DMR cohort. These results are the basis of the FDA premarket approval. Major effectiveness endpoints evaluated at 12 months demonstrated clinically important improvements in MR severity, with MR severity grades of 3+/4+ decreasing from 90.4 percent at baseline to 16.7 percent at 1 year; NYHA Class III/IV decreasing from 86.6 percent at baseline to 13.1 percent at 1 year; and the SF–36 Physical/Mental scale measuring 33.4/46.6 at baseline increasing to 39.4/52.2 at 1 year.

The applicant stated in its new technology add-on payment application that, ''Heart failure hospitalizations were reduced by 73 percent in the 12 months post MitraClip™ procedure from the 12 month pre-MitraClip™ procedure . . .,'' and ''the primary safety analysis indicated low procedural (30-day) mortality (6.3 percent) after MitraClip™ in comparison with the STS predicted surgical mortality risk score for these patients (13.2 percent).''

The applicant discussed published results [26] ''assessing the relationship between the magnitude of reduction in MR and left ventricular (LV) and left atrial (LA) remodeling after the MitraClip™ therapy.'' In this study of patients diagnosed with significant (grade 3+ or 4+) DMR or functional MR (FMR), the authors found that, ''even reduction of MR severity to moderate (2+) is associated with LV and LA reverse remodeling. In both DMR and FMR, reduction in left ventricular end-diastolic volume (LVEDV) and LA volumes were improved proportionally to the degree of MR reduction at one year.''

In conclusion, the applicant cited data from the ACCESS–EU study, which noted improvement in disease-specific quality of life measures, including the Minnesota Living with Heart Failure Questionnaire and Six-Minute Walk Test. The applicant also provided data supporting the overall safety and effectiveness of the MitraClip® System device in European ''real-world'' outcome studies.

As noted in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27547 through 27552), we are concerned that the applicant revised its initial FDA request for the use of the MitraClip® System device in all patients diagnosed with significant MR, after learning that the FDA expressed concern that the initial study, EVEREST II, demonstrated that, while the MitraClip® System device had clinically meaningful improvements in LV volume and QOL, the surgical option had better outcomes than the MitraClip® System device in surgical candidates. The FDA then required a second trial focused on high surgical risk patients. We note that the data evaluated by the FDA and presented by the applicant in its application for new technology add-on payments included information from the following:

- EVEREST I feasibility trial; enrollment 2003–2006; 55 patients.
- EVEREST II RCT; enrollment 2005–2008; 279 patients.

in Cardivascular Imaging, July 2013, Vol. 6(4), pp. 522–530.

[19] Grayburn, et al., ''The Relationship between the Magnitude of Reduction in Mitral Regurgitation Severity and Left Ventricular and Left Atrial Reverse Remodeling after MitraClip Therapy,'' Circulation in Cardiovascular Imaging, September 2013, epub, September 6, 2013.

[20] Lim, et al., ''Improved Functional Status and Quality of Life in Prohibitive Surgical Risk Patients With Degenerative Mitral Regurgitation Following Transcatheter Mitral Valve Repair With the MitraClip® System,'' Journal of American College of Cardiology, 2013, In Press, Accepted Manuscript, Available online, October 31, 2013.

[21] Maisano, F., et al., ''Percutaneous Mitral Valve Interventions in the Real World: Early and One Year Results From the ACCESS–EU, a Prospective, Multicenter, Non-Randomized Post-Approval Study of the MitraClip Therapy in Europ,'' Journal of American College of Cardiology, 2013, doi: 10.1016/j.jacc.2013.02.094.

[22] Mauri, et al., ''4-Year Results of a Randomized Controlled Trial of Percutaneous Repair Versus Surgery for Mitral Regurgitation,'' Journal of American College of Cardiology, Volume 62, Issue 4, 2013, pp. 317–328.

[23] Munkholm, et al., ''Asystemic Review on the Safety and Efficacy of Percutaneousedge-to-edge Mitral Valve Repair with the MitraClip System for high surgical risk candidates,'' Heart, June 27, 2013.

[24] Reichenspurner, H., et al., ''Clinical Outcomes Through 12 Months in Patients With Degenerative Mitral Regurgitation Treated With the MitraClip Device in the ACCESS–EUrope Phase I Trial,'' European Journal of Cardiology-and Thoracic Surgy, 2013, Vol. 15, pp. 919–927.

[25] Whitlow, et al,. ''Acute and 12-Month Results With Catheter-Based Mitral Valve Leaflet Repair: The EVEREST II (Endovascular Valve Edge-to-Edge Repair) High Risk Study,'' Journal of American College of Cardiology, 2012, Vol. 59, pp. 130–139.

[26] Grayburn, et al., ''The Relationship between the Magnitude of Reduction in Mitral Regurgitation Severity and Left Ventricular and Left Atrial Reverse Remodeling after MitraClip Therapy,'' Circulation in Cardiovascular Imaging, September 2013, epub, September 6, 2013.

▪ EVEREST II High-Risk Study; enrollment 2007–2008; 78 patients. (A comparator group of 36 patients was identified from patients who were screened for the study, but did not meet the mitral valve anatomic criteria for placement of the device.)

▪ EVEREST (REALISM) Continued Access Study and compassionate use; enrollment 2009–2013; 49 patients.

The applicant provided comparisons of various outcomes prior to the procedure using the MitraClip® System device and outcomes 12 months later. MR severity, LV end diastolic volume, NYHA Class, SF36 Physical/Mental scale, and heart failure hospitalization rates all had clinically meaningful improvements. For the EVEREST II HRS, the applicant provided analysis demonstrating a significant survival benefit (76 percent versus 55 percent/p <0.047) over the comparator group.

In our review of the clinical trials' data, we have the following key points of concern:

• Post-hoc analyses of pooled data sets retain all of the individual shortcomings of the individual data sets;

• Pooling does not enhance the utility and scientific value of uncontrolled single-arm registries with no comparators; and

• Inappropriate pooling introduces additional confounders.

It is also unclear if the appropriate target population for the MitraClip® System device has been identified because the clinical trials conducted by the applicant included patients diagnosed with both DMR and FMR. This makes it difficult to determine which group of patients may benefit more, or less, from the new technology. For example, in a subgroup analysis of the EVEREST II RCT, the authors concluded that, older patients and those patients diagnosed with FMR or abnormal left ventricular function had results more comparable to surgical repair. Data results from 2 years of the EVEREST II RCT also demonstrated that surgery reduced incidents of MR more than the procedures performed using the percutaneous MitraClip® System device. However, both the surgical patients and the patients who were treated using the MitraClip® System device showed comparable results for improved left ventricular function, NYHA functional class, and quality of life.

We are inviting public comments on whether this technology meets the substantial clinical improvement criterion, particularly in comparison to other surgical therapies, such as mitral valve repair or replacement, and the appropriate target population for this technology.

We did not receive any public comments in response to the New Technology Town Hall meeting held on February 12, 2014 in regard to this technology.

f. Responsive Neurostimulator (RNS®) System

NeuroPace, Inc. submitted an application for new technology add-on payments for FY 2015 for the use of the RNS® System. (We note that the applicant submitted an application for new technology add-on payments for FY 2014, but failed to receive FDA approval prior to the July 1 deadline.) Seizures occur when brain function is disrupted by abnormal electrical activity. Epilepsy is a brain disorder characterized by recurrent, unprovoked seizures. According to the applicant, the RNS® System is the first implantable medical device (developed by NeuroPace, Inc.) for treating persons diagnosed with epilepsy whose partial onset seizures have not been adequately controlled with antiepileptic medications. The applicant further stated that, the RNS® System is the first closed-loop, responsive system to treat partial onset seizures. Responsive electrical stimulation is delivered directly to the seizure focus in the brain when abnormal brain activity is detected. A cranially implanted programmable neurostimulator senses and records brain activity through one or two electrode-containing leads that are placed at the patient's seizure focus/foci. The neurostimulator detects electrographic patterns previously identified by the physician as abnormal, and then provides brief pulses of electrical stimulation through the leads to interrupt those patterns. Stimulation is delivered only when abnormal electrocorticographic activity is detected. The typical patient is treated with a total of 5 minutes of stimulation a day. The RNS® System incorporates remote monitoring, which allows patients to share information with their physicians remotely.

With respect to the newness criterion, the applicant stated that some patients diagnosed with partial onset seizures that cannot be controlled with antiepileptic medications may be candidates for the vagus nerve stimulator (VNS) or for surgical removal of the seizure focus. According to the applicant, these treatments are not appropriate for, or helpful to, all patients. Therefore, the applicant believed that there is an unmet clinical need for additional therapies for partial onset seizures. The applicant further stated that the RNS® System addresses this unmet clinical need by providing a novel treatment option for treating persons diagnosed with medically intractable partial onset seizures. The applicant received FDA premarket approval in November 2013. The following ICD–9–CM procedure codes are used to identify this technology: 01.20 (Cranial implantation or replacement of neurostimulator pulse generator); 01.29 (Removal of cranial neurostimulator pulse generator); and 02.93 (Implantation or replacement of intracranial neurostimulator lead(s)). We are inviting public comments on whether the technology meets the newness criterion.

With regard to the cost criterion, the applicant stated that substantially all cases eligible for the RNS® System would map to MS–DRG 024 (Craniotomy with Major Device Implant/Acute Complex Central Nervous System Principal Diagnosis without MCC). The applicant further stated that, while it is possible for some cases to occur in MS–DRG 023 (Craniotomy with Major Device Implant/Acute Complex Central Nervous System Principal Diagnosis with MCC or Chemotherapy Implant), it would be extremely rare because the applicant believed that these major complications and/or comorbidities would probably preclude a patient from receiving treatment using the RNS® System because the technology is an elective procedure.

The applicant submitted two analyses to demonstrate that the technology meets the cost criterion. For the first analysis, the applicant used clinical trial claims data collected in the RNS® System Pivotal Clinical Investigation to calculate the anticipated average case-weighted standardized charge per case. The applicant maintained that this analysis best represents the anticipated charges for the technology because it is based on actual cases treated using this technology. The applicant analyzed 163 claims from 28 hospitals participating in the clinical trial. Five claims from one hospital were excluded because no hospital-specific information regarding standardization was available. The resulting 158 claims included dates of service ranging from May 2006 through May 2009. The average case-weighted standardized charge per case for these 158 claims was $54,691.

The applicant then standardized the charges for each claim. The applicant noted that it was not necessary to remove any charges from these claims because the technology was provided at no charge in the trial. After standardizing the charges for each

claim, the applicant inflated the charges reported on each claim using the BLS' CPI–IP data covering the same period. Specifically, because the publicly available FY 2012 MedPAR data do not identify the month of the discharge on inpatient claims, but do identify the calendar quarter, the applicant used a mid-month convention to determine the relevant monthly CPI–IP for each calendar quarter. The applicant then calculated the percentage change from the relevant quarter to the quarter of the most recently available CPI–IP, which was the August 2013 CPI–IP. Specifically, the applicant used the following assumptions:

FY 2012 calendar quarter	Midpoint of quarter	CPI IP	Percent change to August 2013
Q4 2011	Nov–11	242.672	7.93
Q1 2012	Feb–11	245.721	6.59
Q2 2012	May–11	247.646	5.76
Q3 2012	Aug–11	248.856	5.25
Most recent as of application	Aug–13	261.915	

Source as cited by applicant: Bureau of Labor Statistics' Web site, accessed October 13, 2013; Base Period: December 1996 = 100.

After inflating the charges, the applicant estimated charges for the RNS® System by multiplying the device cost to the hospital by an anticipated hospital markup of 100 percent, or conversely by dividing the device cost by a CCR of 0.50. The applicant based its estimated CCR on four analyses. First, the applicant reviewed the 2007 and 2008 reports prepared by RTI for CMS on charge compression, which found that the national aggregate CCR for devices and implants was 0.43 and 0.467, as presented in the respective reports. Second, the applicant queried hospitals participating in the RNS® System Pivotal trial, and these queries yielded a mean and median CCR for implantable devices of 0.37 and 0.36, respectively. Third, the applicant reviewed data from the (All Payor) Premier database for cases performed during 2000 through 2010 that reported ICD–9 CM procedure codes 02.93 and/or 86.95 on a claim, and calculated a mean and median CCR for implanted leads and neurostimulators of 0.50 and 0.44, respectively. The applicant then reviewed other discussions of past new technology add-on payment applications published in the **Federal Register**, and noted that other applicants used lower CCRs (higher markups) for implanted devices than the CCR of 0.50 used in the applicant's analyses.

Using this approach, the applicant added the anticipated hospital charge for the implantable RNS® System to the average case-weighted standardized charge per case, and determined a final average case-weighted standardized charge per case of $128,723. The anticipated hospital charge for the implantable RNS® System is $73,900. Using the FY 2014 IPPS Table 10 thresholds, the threshold for MS–DRG 024 is $91,197. Because the final average case-weighted standardized charge per case of $128,723 for MS–DRG 024 exceeds the average case-weighted threshold amount, the applicant maintained that the RNS® System meets the cost criterion.

In the second analysis, which the applicant characterizes as supplementary, the applicant researched the FY 2012 MedPAR file for cases reporting the following combinations of ICD–9–CM procedures codes: 02.93 and 86.95, or procedures codes 02.93 and 01.20 that mapped to MS–DRG 024. The applicant found 383 claims for cases reporting the combination of ICD–9–CM procedures codes 02.93 and 01.20, and pointed out that these cases were coded with procedure code 01.20 in error because no new RNS® System implantations occurred after May 2009. The applicant analyzed these 383 claims, and found that more than 90 percent of these cases had a primary or secondary diagnosis of Parkinson's disease, essential tremor, or dystonia. These diagnoses are FDA-approved indications for deep brain stimulation (DBS). In addition, the applicant noted that the total covered charges for these cases were less than the estimated charges for a full DBS system, and hypothesized that these cases did not represent implantation of a full DBS system, but did represent the implantation of leads only. The applicant contacted two hospitals that reported claims for cases where total covered charges were less than the charges for a full DBS system, and the hospitals confirmed that their claims represented lead implantations only. Therefore, for the second analysis, the applicant included all of the cases assigned to MS–DRG 024 reporting a combination of ICD–9–CM procedures codes 02.93 and 86.95, and all of the cases assigned to MS–DRG 024 reporting a combination of ICD–9–CM procedures codes 02.93 and 01.20 where the covered charges were greater than, or equal to, the estimated charges of a full DBS system. The applicant maintained that 374 claims from 106 providers met this criterion, and data represented claims from the fourth calendar quarter of 2011 through the third calendar quarter of 2012. Based on this assumption, the applicant calculated an average case-weighted standardized charge per case of $65,555.

The applicant then removed DBS charges from the average case-weighted standardized charge per case. The applicant estimated charges for a full DBS system, and maintained that the average cost for a full DBS system is $25,979. Similar to its first analysis, the applicant assumed a CCR of 0.50, or 100 percent markup, which resulted in estimated charges for a full DBS system of $51,958. After removing the DBS system charges, the applicant inflated the charges to the current period using the same methodology in the first analysis, added charges for the RNS® System, and determined a final average case-weighted standardized charge per case of $130,233. As noted above, the anticipated hospital charge for the implantable RNS® System is $73,900. Using the FY 2014 IPPS Table 10 thresholds, the average case-weighted threshold for MS–DRG 024 is $91,197. Because the final average standardized charge per case of $130,233 for MS–DRG 024 exceeds the threshold amount, the applicant maintained that the RNS® System meets the cost criterion.

Under either analysis, the applicant maintained that the final average case-weighted standardized charge per case would exceed the average case-weighted threshold. We are inviting public comments on whether the RNS® System meets the cost criterion, particularly based on the assumptions and methodology used in the applicant's analyses.

With regard to substantial clinical improvement, as previously stated, some patients diagnosed with partial

onset seizures may not be able to control their seizures with antiepileptic medications, VNS, or with surgical removal of the seizure focus. The applicant stated that the RNS® System provides treatment for those patients diagnosed with partial onset seizures who fail treatment with antiepileptic medications, or VNS therapy, and who are ineligible for resective surgery because of the extent and/or location of the seizure focus, or patients who do not elect surgery. According to the applicant, the RNS® System clinical trials provide Class I evidence that treatment using the RNS® System substantially reduces disabling seizures in patients diagnosed with severe epilepsy, who have tried and failed treatment with antiepileptic medications, and in many cases, VNS or epilepsy surgery. The applicant maintained that the results from their clinical trials demonstrate significant and sustained improvements in health outcomes over the controlled period and over the long term. The applicant conducted a feasibility trial, which was designed to demonstrate adequate safety of its treatment, and provide evidence of effectiveness to support commencement of a randomized double-blinded pivotal trail. In addition, the applicant has an ongoing long-term treatment clinical investigation trial (LTT trial) to assess the long-term safety and effectiveness of the treatment on patients who have completed either the Feasibility trial, or the RNS® System Pivotal trial for an additional seven years. The LTT trial started in April 2006, and the final patient is expected to complete the trial in 2018. The applicant noted that patients enrolled in the LTT trial continued to experience a reduction in seizures over several years of follow-up, further demonstrating the positive effect of responsive stimulation from the RNS® System is durable.

The applicant stated that their pivotal trial met its primary effectiveness endpoint by proving that there was a statistically significant greater reduction in seizures in the treatment group&fnl; compared to the control group (p = 0.012). Significant improvements at 1 and 2 years post-implant included:

- A significant reduction in disabling seizures of 44 percent and 53 percent at 1 and 2 years, respectively;
- Fifty-five percent of patients who reached 2 years post-implant experienced a 50 percent or greater reduction in seizures; and
- Significant improvements in overall quality of life, as well as individual quality of life measures including memory, language, attention, concentration and medication effects.

The applicant asserted that there was no negative effect of treatment using the RNS® System on neuropsychological function (including verbal functioning, visual spatial processing, and memory) or mood. The applicant concluded that the RNS® System Pivotal trial provides Class I evidence that responsive cortical stimulation is effective in significantly reducing seizure frequency in adults with one or two seizure foci who have failed two or more antiepileptic medication trials. The applicant stated that experience across all of the RNS® System trials demonstrates the reduction in seizure frequency of disabling partial onset seizures improves over time. In addition, the applicant noted that sustained improvements were also seen in quality of life. Finally, the applicant noted that safety and tolerability measures compare favorably to alternative treatments, such as antiepileptic medications, VNS, and epilepsy surgery.

With regard to the substantial clinical improvement criterion, we are concerned that the average age of the patients enrolled in the applicant's trials was 35 years. Although the applicant maintained that 31 percent of the patients enrolled in the pivotal trial were Medicare beneficiaries, we are unsure of the extent to which this technology would be used by Medicare beneficiaries because of the relatively young age of the majority of the patients enrolled in the pivotal trial. We also are concerned that further clarification on how the RNS® System compares to other neurostimulation treatments was not provided by the applicant.

Because the applicant included claims with DBS charges in one of its cost analyses, we believe that the similarities and differences between DBS and the RNS® System may also be relevant under the substantial clinical improvement criterion. In addition, we are concerned that the time period in the clinical trial may not be sufficient to confirm durability. In the RNS® System Pivotal Clinical Investigation, the primary effectiveness endpoint considered seizure frequency over the last 3 months of the blinded period of the trial. We note that the applicant is currently conducting a 5-year study. We are inviting public comments on whether the RNS® System meets the substantial clinical improvement criterion, particularly in regard to the degree in which the technology would be used by Medicare beneficiaries, the comparison to other neurostimulation treatments, and its durability.

We received public comments in response to the New Technology Town Hall meeting held on February 12, 2014, regarding this technology and the application for new technology add-on payments. We summarize these comments below.

Comment: One commenter, a physician, stated that even with the release of multiple new antiepileptic medications in the past 20 years, over one-third of people diagnosed with epilepsy cannot obtain adequate seizure control. The commenter noted that seizures lead to loss of employment and driving licenses and are socially disabling. The commenter further noted that uncontrolled seizures can cause physical injury and even significantly increased risk of death. The commenter stated that only a fraction of these patients are candidates for potentially curative resective brain surgery and antiepileptic medications can have disabling or severe adverse effects, such as lethargy, ataxia, organ or blood cell damage, Stevens-Johnson syndrome, and psychiatric changes including suicidal ideation. For this reason, the commenter believed that new treatments are still needed.

The commenter asserted that the RNS® System represents a much needed new therapy for patients who are desperate to get seizures under control and lead a productive life. The commenter stated that of its patients that participated in the clinical trials, these patients have demonstrated significant and sustained benefits from treatment with the RNS® System. The commenter noted that two patients had a significant reduction in the amount of seizures per month, and are now able to obtain driver licenses and both show improved quality of life.

The commenter also noted that the RNS® System is a unique therapy for the following reasons: (1) While medications are chemicals that circulate to every organ, the RNS® System delivers therapy directly to the epileptic focus; (2) RNS® therapy is delivered automatically, avoiding compliance problems that occur with medications; and (3) the RNS® System constantly records data on seizure occurrences that is available to the clinician at any time which can track a patient's progress without depending on the patient's memory or willingness to report seizures. The commenter asserted that no other therapy offers this capability.

The commenter urged CMS to approve the new technology add-on payment application for the RNS® System, which the commenter believed would help ensure access to this novel therapy for Medicare beneficiaries for whom there are otherwise no good treatment options available.

Another commenter, also a physician, stated that some of the benefits of the RNS® System therapy include a significant reduction in the seizure frequency and severity, and for some patients, extended periods of seizure freedom. The commenter explained that this reduction in the seizure frequency improves over time, is sustained over several years of follow-up, and can result in improved cognition and a better quality of life. The commenter further stated that some patients have been able to live independently for the first time in their life, take care of children, resume driving, go back to school and/or obtain employment. The commenter concluded the following comparisons between the RNS® System and the vagus nerve stimulator (VNS):

- In clinical trials, the RNS® System subjects experienced a greater reduction in seizures than VNS subjects. The median percent reduction in seizures was: 1 year: RNS—44 percent and VNS—31 percent; 2 years: RNS—53 percent and VNS—41 percent.
- VNS therapy results in stimulation-related side effects, including coughing, difficulties with speech and throat pain. RNS® therapy does not result in chronic side effects.
- About one-third of patients in RNS® System pivotal trial had previously failed therapy with a VNS. These subjects achieved the same positive improvements in health outcomes from the RNS® System as patients that had not previously tried a VNS.
- In the commenter's experience, not only is the frequency of the seizure activity improved but also the severity of the seizures can improve with the RNS® System.

The commenter further noted the ''positive long-term results of RNS therapy.'' The commenter stated that therapy is being evaluated in the ongoing LTT trial, in which patients are enrolled for an additional 7 years after completing the initial 2-year clinical trial with some patients having the implant for over 9 years. The commenter asserted that the long-term data clearly show that the therapy is durable. Specifically, the commenter noted that seizure reductions are maintained at 50 percent or greater through 7 years (that is, the median percent reduction in seizures is about 60 percent at 7 years). The commenter added that the vast majority of its patients have elected to continue treatment with the device given their response to the RNS® therapy. The commenter encouraged CMS to approve new technology add-on payments for the RNS® System.

Response: We appreciate the commenters' support. We considered these comments in our evaluation of the RNS® System new technology add-on payment application for FY 2015 and in the development of this proposed rule. As stated above, we are inviting additional public comments on whether the RNS® System meets the substantial clinical improvement criterion, particularly in regard to the degree in which the technology would be used by Medicare beneficiaries, the comparison to other neurostimulation treatments, and its durability.

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 adjust the standardized amounts ''for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.'' We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the proposed FY 2015 hospital wage index based on the statistical areas appears under section III.B. of the preamble of this proposed rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. This provision also requires that any updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The proposed adjustment for FY 2015 is discussed in section II.B. of the Addendum to this proposed rule.

As discussed in section III.H. of the preamble of this proposed rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The proposed budget neutrality adjustment for FY 2015 is discussed in section II.A.4.b. of the Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are proposing to apply to the FY 2015 wage index appears under section III.F. of the preamble of this proposed rule.

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

1. Background

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core-Based Statistical Areas (CBSAs) established by the Office of Management and Budget (OMB). The current statistical areas used in FY 2014 are based on OMB standards published on December 27, 2000 (65 FR 82228) and Census 2000 data and Census Bureau population estimates for 2007 and 2008 (OMB Bulletin No. 10–02). 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) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53365) that, in 2013, OMB planned to announce new labor market area delineations based on new standards adopted in 2010 (75 FR 37246) and the 2010 Census of Population and Housing data. As stated in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27552) and final rule (78 FR 50586), on February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of this bulletin may be obtained at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf.* According to OMB, ''[t]his bulletin provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical

Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246–37252) and Census Bureau data.'' In this FY 2015 IPPS/LTCH PPS proposed rule, when referencing the new OMB geographic boundaries of statistical areas, we are using the term ''delineations'' rather than the term '' definitions'' that we have used in the past, consistent with OMB's use of the terms (75 FR 37249).

In order to implement these changes for the IPPS, it is necessary to identify the new labor market area delineation for each county and hospital in the country. While the revisions OMB published on February 28, 2013 are not as sweeping as the changes OMB announced in 2003, the February 28, 2013 bulletin does contain a number of significant changes. For example, under the new OMB delineations, there would be new CBSAs, urban counties that would become rural, rural counties that would become urban, and existing CBSAs would be split apart. In addition, the effect of the new OMB delineations on various hospital reclassifications, the out-migration adjustment (established by section 505 of Pub. L. 108–173), and treatment of hospitals located in certain rural counties (that is, ''Lugar'' hospitals) provided for under section 1886(d)(8)(B) of the Act must be considered. These are just a few of the many issues that need to be reviewed regarding the effects of the new OMB labor market area delineations prior to proposing and establishing policies.

However, because the bulletin was not issued until February 28, 2013, with supporting data not available until later, and because the changes made by the bulletin and their ramifications needed to be extensively reviewed and verified, we were unable to undertake such a lengthy process before publication of the FY 2014 IPPS/LTCH PPS proposed rule and, thus, did not implement changes to the wage index for FY 2014 based on these new OMB delineations. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50586), we stated that we intended to propose changes to the wage index based on the new OMB delineations in this FY 2015 proposed rule. As discussed below, in this proposed rule, we are proposing to implement the new OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13–01, effective for the FY 2015 IPPS wage index.

2. Proposed Implementation of New Labor Market Area Delineations

As discussed previously, CMS delayed implementing the new OMB labor market area delineations to allow for sufficient time to assess the new changes. We believe it is important for the IPPS to use the latest labor market area delineations available as soon as is reasonably possible in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. While CMS and other stakeholders have explored potential alternatives to the current CBSA-based labor market system (we refer readers to the CMS Web site at: *www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html*), no consensus has been achieved regarding how best to implement a replacement system. As discussed in the FY 2005 IPPS final rule (69 FR 49027), ''While we recognize that MSAs are not designed specifically to define labor market areas, we believe they do represent a useful proxy for this purpose.'' We further believe that using the most current delineations will increase the integrity of the IPPS wage index system by creating a more accurate representation of geographic variations in wage levels. We have reviewed our findings and impacts relating to the new OMB delineations, and find no compelling reason to further delay implementation. Therefore, we are proposing to implement the new OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13–01, effective for the FY 2015 IPPS wage index. We are proposing to use these new delineations to calculate area wage indexes in a manner that is generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule, and refined in subsequent rulemaking. We also are proposing a wage index transition period applicable to all hospitals that experience negative impacts due to the proposed implementation of the new OMB delineations. This transition is discussed in more detail below.

a. Micropolitan Statistical Areas

As discussed in the FY 2005 IPPS final rule (69 FR 49029 through 49032), CMS considered whether to use Micropolitan Statistical Areas to define the labor market areas for the purpose of the IPPS wage index. OMB defines a ''Micropolitan Statistical Area'' as a CBSA ''associated with at least one urban cluster that has a population of at least 10,000, but less than 50,000'' (75 FR 37252). We refer to these areas as Micropolitan Areas. After extensive impact analysis, CMS determined the best course of action would be to treat all hospitals located in Micropolitan Areas as ''rural'' and include them in the calculation of each State's rural wage index. Because Micropolitan areas tend to encompass smaller population centers and contain fewer hospitals than MSAs, we determined that if Micropolitan Areas were to be treated as separate labor market areas, the IPPS wage index would have included drastically more single-provider labor market areas. This larger number of labor market areas with fewer hospitals could create instability in year-to-year wage index values for a large number of hospitals; could reduce the averaging effect of the wage index, thus lessening some of the efficiency incentive inherent in a system based on the average hourly wages for a large number of hospitals; and could arguably create an inequitable system when so many hospitals have wage indexes based solely on their own wage data while other hospitals' wage indexes are based on an average hourly wage across many hospitals. For these reasons, we adopted a policy to include Micropolitan Areas in the State's rural wage area, and have continued this policy through the present.

Based upon the new 2010 Decennial Census data, a number of urban counties have switched status and have joined or became Micropolitan Areas, and some counties that once were part of a Micropolitan Area, under current OMB delineations, have become urban. Overall, there are fewer Micropolitan Areas (541) under the new OMB delineations based on the 2010 Census than existed under the latest data from the 2000 Census (581). We believe that the best course of action would be to continue the policy established in the FY 2005 IPPS final rule and include hospitals located in Micropolitan Areas in each State's rural wage index. These areas continue to be defined as having relatively small urban cores (populations of 10,000–49,999). We do not believe it would be appropriate to calculate a separate wage index for areas that typically may include only a few hospitals for the reasons set forth in the FY 2005 IPPS/LTCH PPS final rule, as discussed above. Therefore, in conjunction with our proposal to implement the new OMB labor market area delineations beginning in FY 2015, we are proposing to continue to treat Micropolitan Areas as ''rural'' and to include the Micropolitan Areas in the calculation of each State's rural wage index.

b. Urban Counties That Would Become Rural Under the New OMB Delineations

As previously discussed, we are proposing to implement the new OMB labor market area delineations (based

upon the 2010 Decennial Census data) beginning in FY 2015. Our analysis shows that a total of 37 counties (and county equivalents) and 12 hospitals that were once considered part of an urban CBSA would be considered to be located in a rural area, beginning in FY 2015, under these new OMB delineations. The following chart lists the 37 urban counties that would be rural if we finalize our proposal to implement the new OMB delineations.

COUNTIES THAT WOULD LOSE URBAN STATUS

County	State	Previous CBSA number	CBSA
Greene County	IN	14020	Bloomington, IN.
Anson County	NC	16740	Charlotte-Gastonia-Rock Hill, NC-SC.
Franklin County	IN	17140	Cincinnati-Middletown, OH-KY-IN.
Stewart County	TN	17300	Clarksville, TN-KY.
Howard County	MO	17860	Columbia, MO.
Delta County	TX	19124	Dallas-Fort Worth-Arlington, TX.
Pittsylvania County	VA	19260	Danville, VA.
Danville City	VA	19260	Danville, VA.
Preble County	OH	19380	Dayton, OH.
Gibson County	IN	21780	Evansville, IN-KY.
Webster County	KY	21780	Evansville, IN-KY.
Franklin County	AR	22900	Fort Smith, AR-OK.
Ionia County	MI	24340	Grand Rapids-Wyoming, MI.
Newaygo County	MI	24340	Grand Rapids-Wyoming, MI.
Greene County	NC	24780	Greenville, NC.
Stone County	MS	25060	Gulfport-Biloxi, MS.
Morgan County	WV	25180	Hagerstown-Martinsburg, MD-WV.
San Jacinto County	TX	26420	Houston-Sugar Land-Baytown, TX.
Franklin County	KS	28140	Kansas City, MO-KS.
Tipton County	IN	29020	Kokomo, IN.
Nelson County	KY	31140	Louisville/Jefferson County, KY-IN.
Geary County	KS	31740	Manhattan, KS.
Washington County	OH	37620	Parkersburg-Marietta-Vienna, WV-OH.
Pleasants County	WV	37620	Parkersburg-Marietta-Vienna, WV-OH.
George County	MS	37700	Pascagoula, MS.
Power County	ID	38540	Pocatello, ID.
Cumberland County	VA	40060	Richmond, VA.
King and Queen County	VA	40060	Richmond, VA.
Louisa County	VA	40060	Richmond, VA.
Washington County	MO	41180	St. Louis, MO-IL.
Summit County	UT	41620	Salt Lake City, UT.
Erie County	OH	41780	Sandusky, OH.
Franklin County	MA	44140	Springfield, MA.
Ottawa County	OH	45780	Toledo, OH.
Greene County	AL	46220	Tuscaloosa, AL.
Calhoun County	TX	47020	Victoria, TX.
Surry County	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC.

We are proposing that the wage data for all hospitals located in the counties listed above would now be considered rural when calculating their respective State's rural wage index. We recognize that rural areas typically have lower area wage index values than urban areas, and hospitals located in these counties may experience a negative impact in their IPPS payment due to the proposed adoption of the new OMB delineations. We refer readers to section III.B.2.e. of the preamble of this proposed rule for a discussion of the proposed wage index transition period, in particular, the discussion regarding the 3-year transition for hospitals located in these specific counties.

c. Rural Counties That Would Become Urban Under the New OMB Delineations

As previously discussed, we are proposing to implement the new OMB labor market area delineations (based upon the 2010 Decennial Census data) beginning in FY 2015. Analysis of these OMB labor market area delineations shows that a total of 105 counties (and county equivalents) and 81 hospitals that were located in rural areas would be located in urban areas under the new OMB delineations. The following chart lists the 105 rural counties that would be urban if we finalize our proposal to implement the new OMB delineations.

COUNTIES THAT WOULD GAIN URBAN STATUS

County	State	New CBSA number	CBSA.
Utuado Municipio	PR	10380	Aguadilla-Isabela, PR.
Linn County	OR	10540	Albany, OR.
Oldham County	TX	11100	Amarillo, TX.
Morgan County	GA	12060	Atlanta-Sandy Springs-Roswell, GA.
Lincoln County	GA	12260	Augusta-Richmond County, GA-SC.

COUNTIES THAT WOULD GAIN URBAN STATUS—Continued

County	State	New CBSA number	CBSA.
Newton County	TX	13140	Beaumont-Port Arthur, TX.
Fayette County	WV	13220	Beckley, WV.
Raleigh County	WV	13220	Beckley, WV.
Golden Valley County	MT	13740	Billings, MT.
Oliver County	ND	13900	Bismarck, ND.
Sioux County	ND	13900	Bismarck, ND.
Floyd County	VI	13980	Blacksburg-Christiansburg-Radford, VA.
De Witt County	IL	14010	Bloomington, IL.
Columbia County	PA	14100	Bloomsburg-Berwick, PA.
Montour County	PA	14100	Bloomsburg-Berwick, PA.
Allen County	KY	14540	Bowling Green, KY.
Butler County	KY	14540	Bowling Green, KY.
St. Mary's County	MD	15680	California-Lexington Park, MD.
Jackson County	IL	16060	Carbondale-Marion, IL.
Williamson County	IL	16060	Carbondale-Marion, IL.
Franklin County	PA	16540	Chambersburg-Waynesboro, PA.
Iredell County	NC	16740	Charlotte-Concord-Gastonia, NC-SC.
Lincoln County	NC	16740	Charlotte-Concord-Gastonia, NC-SC.
Rowan County	NC	16740	Charlotte-Concord-Gastonia, NC-SC.
Chester County	SC	16740	Charlotte-Concord-Gastonia, NC-SC.
Lancaster County	SC	16740	Charlotte-Concord-Gastonia, NC-SC.
Buckingham County	VA	16820	Charlottesville, VA.
Union County	IN	17140	Cincinnati, OH-KY-IN.
Hocking County	OH	18140	Columbus, OH.
Perry County	OH	18140	Columbus, OH.
Walton County	FL	18880	Crestview-Fort Walton Beach-Destin, FL.
Hood County	TX	23104	Dallas-Fort Worth-Arlington, TX.
Somervell County	TX	23104	Dallas-Fort Worth-Arlington, TX.
Baldwin County	AL	19300	Daphne-Fairhope-Foley, AL.
Monroe County	PA	20700	East Stroudsburg, PA.
Hudspeth County	TX	21340	El Paso, TX.
Adams County	PA	23900	Gettysburg, PA.
Hall County	NE	24260	Grand Island, NE.
Hamilton County	NE	24260	Grand Island, NE.
Howard County	NE	24260	Grand Island, NE.
Merrick County	NE	24260	Grand Island, NE.
Montcalm County	MI	24340	Grand Rapids-Wyoming, MI.
Josephine County	OR	24420	Grants Pass, OR.
Tangipahoa Parish	LA	25220	Hammond, LA.
Beaufort County	SC	25940	Hilton Head Island-Bluffton-Beaufort, SC.
Jasper County	SC	25940	Hilton Head Island-Bluffton-Beaufort, SC.
Citrus County	FL	26140	Homosassa Springs, FL.
Butte County	ID	26820	Idaho Falls, ID.
Yazoo County	MS	27140	Jackson, MS.
Crockett County	TN	27180	Jackson, TN.
Kalawao County	HI	27980	Kahului-Wailuku-Lahaina, HI.
Maui County	HI	27980	Kahului-Wailuku-Lahaina, HI.
Campbell County	TN	28940	Knoxville, TN.
Morgan County	TN	28940	Knoxville, TN.
Roane County	TN	28940	Knoxville, TN.
Acadia Parish	LA	29180	Lafayette, LA.
Iberia Parish	LA	29180	Lafayette, LA.
Vermilion Parish	LA	29180	Lafayette, LA.
Cotton County	OK	30020	Lawton, OK.
Scott County	IN	31140	Louisville/Jefferson County, KY-IN.
Lynn County	TX	31180	Lubbock, TX.
Green County	WI	31540	Madison, WI.
Benton County	MS	32820	Memphis, TN-MS-AR.
Midland County	MI	33220	Midland, MI.
Martin County	TX	33260	Midland, TX.
Le Sueur County	MN	33460	Minneapolis-St. Paul-Bloomington, MN-WI.
Mille Lacs County	MN	33460	Minneapolis-St. Paul-Bloomington, MN-WI.
Sibley County	MN	33460	Minneapolis-St. Paul-Bloomington, MN-WI.
Maury County	TN	34980	Nashville-Davidson-Murfreesboro-Franklin, TN.
Craven County	NC	35100	New Bern, NC.
Jones County	NC	35100	New Bern, NC.
Pamlico County	NC	35100	New Bern, NC.
St. James Parish	LA	35380	New Orleans-Metairie, LA.
Box Elder County	UT	36260	Ogden-Clearfield, UT.
Gulf County	FL	37460	Panama City, FL.
Custer County	SD	39660	Rapid City, SD.

COUNTIES THAT WOULD GAIN URBAN STATUS—Continued

County	State	New CBSA number	CBSA.
Fillmore County	MN	40340	Rochester, MN.
Yates County	NY	40380	Rochester, NY.
Sussex County	DE	41540	Salisbury, MD-DE.
Worcester County	MA	41540	Salisbury, MD-DE.
Highlands County	FL	42700	Sebring, FL.
Webster Parish	LA	43340	Shreveport-Bossier City, LA.
Cochise County	AZ	43420	Sierra Vista-Douglas, AZ.
Plymouth County	IA	43580	Sioux City, IA-NE-SD.
Union County	SC	43900	Spartanburg, SC.
Pend Oreille County	WA	44060	Spokane-Spokane Valley, WA.
Stevens County	WA	44060	Spokane-Spokane Valley, WA.
Augusta County	VA	44420	Staunton-Waynesboro, VA.
Staunton City	VA	44420	Staunton-Waynesboro, VA.
Waynesboro City	VA	44420	Staunton-Waynesboro, VA.
Little River County	AR	45500	Texarkana, TX-AR.
Sumter County	FL	45540	The Villages, FL.
Pickens County	AL	46220	Tuscaloosa, AL.
Gates County	NC	47260	Virginia Beach-Norfolk-Newport News, VA-NC.
Falls County	TX	47380	Waco, TX.
Columbia County	WA	47460	Walla Walla, WA.
Walla Walla County	WA	47460	Walla Walla, WA.
Peach County	GA	47580	Warner Robins, GA.
Pulaski County	GA	47580	Warner Robins, GA.
Culpeper County	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV.
Rappahannock County	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV.
Jefferson County	NY	48060	Watertown-Fort Drum, NY.
Kingman County	KS	48620	Wichita, KS.
Davidson County	NC	49180	Winston-Salem, NC.
Windham County	CT	49340	Worcester, MA-CT.

We are proposing that when calculating the area wage index, the wage data for hospitals located in these counties would be included in their new respective urban CBSAs. Typically, hospitals located in an urban area would receive a higher wage index value than hospitals located in their State's rural area. However, with regard to the wage index applicable to individual hospitals, we are proposing to implement a transitional wage index adjustment for any hospital that would receive a lower wage index under the new OMB delineations than it would have received under the current CBSA definitions. We refer readers to section III.B.2.e. of the preamble of this proposed rule for further discussion of this proposed transition.

d. Urban Counties That Would Move to a Different Urban CBSA Under the New OMB Delineations

In addition to rural counties becoming urban and urban counties becoming rural, several urban counties would shift from one urban CBSA to another urban CBSA under our proposal to adopt the new OMB delineations. In certain cases, adopting the new OMB delineations would involve a change only in CBSA name or number, while the CBSA continues to encompass the same constituent counties. For example, CBSA 29140 (Lafayette, IN) would experience both a change to its number and its name, and become CBSA 29200 (Lafayette-West Lafayette, IN), while all of its three constituent counties would remain the same. We have identified 19 counties that would remain in a CBSA that experienced a change in name or number under the new delineations, but would retain the same constituent counties, as shown in the following table.

COUNTIES THAT WOULD REMAIN IN CBSA THAT CHANGED NUMBER

Prior CBSA No.	New CBSA No.	County	State
14484	14454	Norfolk County	MA.
14484	14454	Plymouth County	MA.
14484	14454	Suffolk County	MA.
47644	47664	Lapeer County	MI.
47644	47664	Livingston County	MI.
47644	47664	Macomb County	MI.
47644	47664	Oakland County	MI.
47644	47664	St. Clair County	MI.
26180	46520	Honolulu County	HI.
29140	29200	Benton County	IN.
29140	29200	Carroll County	IN.
29140	29200	Tippecanoe County	IN.
42044	11244	Orange County	CA.
42060	42200	Santa Barbara County	CA.
44600	48260	Jefferson County	OH.
44600	48260	Brooke County	WV.

COUNTIES THAT WOULD REMAIN IN CBSA THAT CHANGED NUMBER—Continued

Prior CBSA No.	New CBSA No.	County	State
44600	48260	Hancock County	WV.
13644	43524	Frederick County	MD.
13644	43524	Montgomery County	MD.

We are not discussing further in this section these proposed changes because they are inconsequential changes with respect to the IPPS wage index. However, in other cases, if we adopt the new OMB delineations, counties would shift between existing and new CBSAs, changing the constituent makeup of the CBSAs.

In one type of change, an entire CBSA would be subsumed by another CBSA. For example, CBSA 37380 (Palm Coast, FL) currently is a single county (Flagler, FL) CBSA. Flagler County would become a part of CBSA 19660 (Deltona-Daytona Beach-Ormond Beach, FL) under the new OMB delineations.

In another type of change, some CBSAs have counties that would split off to become part of or to form entirely new labor market areas. For example, CBSA 37964 (Philadelphia Metropolitan Division) currently is comprised of five Pennsylvania counties (Bucks, Chester, Delaware, Montgomery, and Philadelphia). If we adopt the new OMB delineations, Montgomery, Bucks, and Chester counties would split off and form the new CBSA 33874 (Montgomery County-Bucks County-Chester County, PA Metropolitan Division), while Delaware and Philadelphia counties would remain in CBSA 37964.

Finally, in some cases, a CBSA would lose counties to another existing CBSA if we adopt the new OMB delineations. For example, Lincoln County and Putnam County, WV would move from CBSA 16620 (Charleston, WV) to CBSA 26580 (Huntington-Ashland, WV–KY–OH). CBSA 16620 still would exist in the new labor market delineations with fewer constituent counties.

The following chart lists the urban counties that would move from one urban CBSA to another urban CBSA if we adopted the new OMB delineations.

COUNTIES THAT WOULD CHANGE TO ANOTHER CBSA

Prior CBSA	New CBSA	County	State
11300	26900	Madison County	IN.
11340	24860	Anderson County	SC.
14060	14010	McLean County	IL.
37764	15764	Essex County	MA.
16620	26580	Lincoln County	WV.
16620	26580	Putnam County	WV.
16974	20994	DeKalb County	IL.
16974	20994	Kane County	IL.
21940	41980	Ceiba Municipio	PR.
21940	41980	Fajardo Municipio	PR.
21940	41980	Luquillo Municipio	PR.
26100	24340	Ottawa County	MI.
31140	21060	Meade County	KY.
34100	28940	Grainger County	TN.
35644	35614	Bergen County	NJ.
35644	35614	Hudson County	NJ.
20764	35614	Middlesex County	NJ.
20764	35614	Monmouth County	NJ.
20764	35614	Ocean County	NJ.
35644	35614	Passaic County	NJ.
20764	35084	Somerset County	NJ.
35644	35614	Bronx County	NY.
35644	35614	Kings County	NY.
35644	35614	New York County	NY.
35644	20524	Putnam County	NY.
35644	35614	Queens County	NY.
35644	35614	Richmond County	NY.
35644	35614	Rockland County	NY.
35644	35614	Westchester County	NY.
37380	19660	Flagler County	FL.
37700	25060	Jackson County	MS.
37964	33874	Bucks County	PA.
37964	33874	Chester County	PA.
37964	33874	Montgomery County	PA.
39100	20524	Dutchess County	NY.
39100	35614	Orange County	NY.
41884	42034	Marin County	CA.
41980	11640	Arecibo Municipio	PR.
41980	11640	Camuy Municipio	PR.
41980	11640	Hatillo Municipio	PR.
41980	11640	Quebradillas Municipio	PR.
48900	34820	Brunswick County	NC.
49500	38660	Guánica Municipio	PR.
49500	38660	Guayanilla Municipio	PR.

COUNTIES THAT WOULD CHANGE TO ANOTHER CBSA—Continued

Prior CBSA	New CBSA	County	State
49500	38660	Peñuelas Municipio	PR.
49500	38660	Yauco Municipio	PR.

If hospitals located in these counties move from one CBSA to another under the new OMB delineations, there may be impacts, both negative and positive, upon their specific wage index values. We refer readers to section III.B.2.e. of the preamble of this proposed rule for a discussion of our proposals to moderate the impact of our proposed adoption of the new OMB delineations.

e. Proposed Transition Period

(1) Background

Overall, we believe implementing the new OMB labor market area delineations would result in wage index values being more representative of the actual costs of labor in a given area. However, we recognize that some hospitals would experience decreases in wage index values as a result of our proposed implementation of the new labor market area delineations. We also realize that some hospitals would have higher wage index values due to our proposed implementation of the new labor market area delineations.

In the past, we have provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts. As discussed in the FY 2005 IPPS final rule (69 FR 49032 through 49034), we evaluated several options to ease the transition to the new CBSA system, which we implemented starting in FY 2005 and which is the system currently in use.

As discussed in that rule, we determined that the transition to the current wage index system would have the largest negative impacts upon hospitals that were originally considered urban, but would be considered rural under the new definitions. To alleviate the decreased payments associated with having a rural wage index, in calculating the area wage index, in the FY 2005 IPPS final rule, we allowed urban hospitals that became rural under new definitions to maintain their assignment to the labor market area where they were located for FY 2004. This adjustment was granted for a period of 3 fiscal years.

In the FY 2005 IPPS final rule, for all hospitals that experienced negative payment impacts due to new definitions (for example, they were moved to an urban CBSA with a lower wage index value than their previous rural or urban labor market area), we implemented a 1-year blended adjustment. We calculated wage indexes for all hospitals using both old and new labor market definitions. Hospitals received 50 percent of their wage index based on the new OMB delineations, and 50 percent of their wage index based on their current labor market area. This adjustment only applied to hospitals that would have experienced a drop in wage index values due to a change in labor market definitions. Hospitals that benefitted from the labor market area transition received their new wage index at the time the new labor market definitions became effective.

We continue to have the same concerns expressed in the FY 2005 IPPS final rulemaking. Therefore, we are proposing a similar transition methodology to mitigate any negative financial impacts experienced by hospitals due to our proposal to implement the new OMB labor market area delineations for FY 2015.

(2) Proposed Transition for Hospitals in Urban Areas That Would Become Rural

For hospitals that are currently located in an urban county that would become rural under the new OMB delineations, and would have no form of wage index reclassification or redesignation in place for FY 2015 (that is, MGCRB reclassifications under section 1886(d)(10) of the Act, redesignations under section 1886(d)(8)(B) of the Act, or rural reclassifications under section 1886(d)(8)(E) of the Act), we are proposing a policy to assign them the urban wage index value of the CBSA in which they are physically located for FY 2014 for a period of 3 fiscal years (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied to the area wage index). As stated in the FY 2005 IPPS proposed rule (69 FR 28252), we have in the past provided transitions when adopting changes that have significant payment implications, particularly large negative impacts. We believe it is appropriate to apply a 3-year transition period for hospitals located in urban counties that would become rural under the new OMB delineations, given the potentially significant payment impacts for these hospitals. This is consistent with the transition policy adopted in FY 2005 (69 FR 49032 through 49034). We continue to believe, as we stated in the FY 2005 IPPS final rule (69 FR 49033), that the longer transition period is appropriate because, as a group, we expect these hospitals would experience a steeper and more abrupt reduction in their wage index due to the labor market revisions compared to other hospitals. Assigning these hospitals the urban wage index value of the CBSA in which they are physically located for FY 2014 for a period of 3 fiscal years (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied to the area wage index) would be the most similar to the actual payment wage index that these hospitals received in FY 2014, thereby minimizing the negative impact of adopting the new OMB delineations for these hospitals. Accordingly, for FYs 2015, 2016, and 2017, assuming no other form of wage index reclassification or redesignation is granted, we are proposing to assign these hospitals the area wage index value of the urban CBSA to which they geographically were located in FY 2014 (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied to the area wage index). For example, if urban CBSA 12345 consisted of three counties in FY 2014, and, under the new OMB delineations, one of those counties, County X, would no longer be part of CBSA 12345 and would become rural for FY 2015, we are proposing that hospitals in County X would be assigned the FY 2015 wage index of CBSA 12345, computed using the remaining two counties, with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied to the area wage index. We believe that assigning the wage index of the hospitals' current area is the simplest and most effective method for mitigating negative payment impacts due to the proposed adoption of the new OMB delineations. We have identified relatively few hospitals that are located in urban counties that would become rural, and fewer yet that do not have a reclassification or redesignation in effect for FY 2015. Because we believe that these urban to rural transitions would

be the most likely to cause significant negative payment impacts, we believe that these hospitals should be granted a longer transition period than hospitals that may be switching between urban labor market areas, which as discussed later, we are proposing may receive 1-year blended wage index.

We note that there are situations where a hospital cannot be assigned the wage index value of the CBSA to which it geographically belonged in FY 2014 because that CBSA would be split and no longer exist and some or all of the constituent counties would be added to another urban labor market area under the new OMB delineations. If the hospital cannot be assigned the wage index value of the CBSA to which it is geographically located in FY 2014 because that CBSA would be split apart and no longer exist, and some or all of its constituent counties would be added to another urban labor market area under the new OMB delineations, we are proposing that hospitals located in such counties that would become rural under the new OMB delineations would be assigned the wage index of the FY 2015 urban labor market area that contains the urban county in their FY 2014 CBSA to which they are closest (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied) for a period of 3 fiscal years. We believe this approach of assigning the wage index of the FY 2015 urban labor market area that contains the urban county in their FY 2014 CBSA to which they are closest (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied) would most closely approximate the hospitals' FY 2014 actual payment wage index, thereby minimizing the negative effects of the proposed change in the OMB delineations. For example, George County, MS and Jackson County, MS, together, in FY 2014, comprise the urban CBSA 37700 (Pascagoula, MS). Under the new OMB delineations, George County would be considered rural and Jackson County, MS would become part of the urban labor market area of Gulfport-Biloxi-Pascagoula, MS (CBSA 25060). In this instance, we are proposing that hospitals in George County, MS would be assigned the FY 2015 wage index for CBSA 25060 (Gulfport-Biloxi-Pascagoula, MS), with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied.

Furthermore, we are proposing that any hospital that is currently located in an urban county that would become rural for FY 2015 under the new OMB delineations, but also has a reclassification or redesignation in effect for FY 2015 (from a pre-existing reclassification or redesignation granted prior to FY 2015), would not be eligible for the 3-year transition wage index. This is because if the hospital is reclassified or redesignated in some manner, it would instead receive a wage index that reflects its own choice to obtain its reclassified or redesignated status. Accordingly, if a hospital is currently located in an urban county that would become rural for FY 2015 under the new OMB delineations and such hospital sought and was granted reclassification or redesignation for FY 2015 or such hospital seeks and is granted any reclassification or redesignation for FY 2016 or FY 2017, we are proposing that the hospital would permanently lose its 3-year transitional assigned wage index status, and would not be eligible to reinstate it. For example, if a hospital that is currently urban but would become rural under the new OMB delineations received a 3-year transition wage index in FY 2015 based on the wage index of the urban CBSA to which it was geographically located in FY 2014 and then by its own choice, reclassifies to obtain a different area wage index in FY 2016, the hospital would not be eligible to reinstate the transition wage index, even if it opts to cancel its reclassification for FY 2017. We are proposing the transition adjustment to assist hospitals if they experience a negative payment impact specifically due to the proposed adoption of the new OMB delineations in FY 2015. If a hospital chooses in a future fiscal year to forego this transition adjustment by obtaining some form of reclassification or redesignation, we do not believe reinstatement of this transition adjustment would be appropriate. The purpose of the adjustment is to assist hospitals that may be negatively impacted by the new OMB delineations in transitioning to a wage index based on these delineations. By obtaining a reclassification or redesignation, we believe that the hospital has made the determination that the transition adjustment is not necessary because it has other viable options for mitigating the impact of the transition to the new OMB delineations.

With respect to the wage index computation, we are proposing to follow our existing policy regarding the inclusion of a hospital's wage index data in the CBSA in which it is geographically located (we refer readers to Step 6 of the method for computing the unadjusted wage index in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592)). Accordingly, beginning with FY 2015, we are proposing that the wage data of all hospitals receiving this type of 3-year transition adjustment would be included in the statewide rural area in which they are geographically located under the new OMB labor market area delineations of FY 2015. After the 3-year transition period, beginning in FY 2018, we are proposing that these formerly urban hospitals discussed above would receive their statewide rural wage index, absent any reclassification or redesignation.

In addition, we are proposing that the hospitals receiving this 3-year transition because they are in counties that were urban under the current CBSA definitions, but would be rural under the new OMB delineations, would not be considered urban hospitals. Rather, they would maintain their status as rural hospitals for other payment considerations. This is because our proposal to apply a 3-year transitional wage index for these newly rural hospitals only applies for the purpose of calculating the wage index under our proposal to adopt the new CBSA delineations. We are not proposing transitions for other IPPS payment policies that may be impacted by the proposed adoption of the new CBSA delineations. However, we will continue to apply the existing regulations at § 412.102 with respect to determining DSH payments in the first year after a hospital loses urban status (we refer readers to section II.B.2.e.(7) of the preamble of this proposed rule).

(3) Proposed Transition for Hospitals Deemed Urban Under Section 1886(d)(8)(B) of the Act Where the Urban Area Would Become Rural Under the New OMB Delineations

As discussed in section II.H.3. of the preamble of this proposed rule, there are some hospitals that currently are geographically located in rural areas but are deemed to be urban under section 1886(d)(8)(B) of the Act. For FY 2015, some of these hospitals currently redesignated under section 1886(d)(8)(B) of the Act would no longer be eligible for deemed urban status under the new OMB delineations, as discussed in detail in section III.H.3. of the preamble of this proposed rule. Similar to the policy implemented in the FY 2005 IPPS final rule (69 FR 49059), and consistent with the policy we are proposing for other hospitals in counties that were urban and would become rural under the new OMB delineations, we are proposing to apply the 3-year transition to these hospitals currently redesignated to urban areas under section 1886(d)(8)(B) of the Act

that would no longer be deemed urban under the new OMB delineations and would revert to being rural. That is, for FYs 2015, 2016, and 2017, assuming no other form of wage index reclassification or redesignation is granted, we are proposing to assign these hospitals the FY 2015 area wage index value of hospitals reclassified to the urban CBSA (that is, the attaching wage index) to which they were redesignated in FY 2014 (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied). If the hospital cannot be assigned the reclassified wage index value of the CBSA to which it was redesignated in FY 2014 because that CBSA would split apart and no longer exist, and some or all of its constituent counties would be added to another urban labor market area under the new OMB delineations, we are proposing that such hospitals would be assigned the wage index of the hospitals reclassified to the FY 2015 urban labor market area that contains the urban county in their FY 2014 redesignated CBSA to which they are closest for a period of 3 fiscal years. We are proposing to assign these hospitals the area wage index of hospitals reclassified to a CBSA because hospitals deemed urban under section 1886(d)(8)(B) of the Act are treated as reclassified under current policy, under which such hospitals receive an area wage index that includes wage data of all hospitals reclassified to the area.

(4) Proposed Transition for Hospitals That Would Experience a Decrease in Wage Index Under the New OMB Delineations

While we believe that instituting the latest OMB labor market area delineations would create a more accurate wage index system, we also recognize that implementing the new OMB delineations may cause some short-term instability in hospital payments. Therefore, in addition to the 3-year transition adjustment for hospitals being transitioned from urban to rural status as discussed above, we are proposing a 1-year blended wage index for all hospitals that would experience any decrease in their actual payment wage index (that is, a hospital's actual wage index used for payment, which accounts for all applicable effects of reclassification and redesignation) exclusively due to the proposed implementation of the new OMB delineations. Similar to the policy adopted in the FY 2005 IPPS final rule (69 FR 49033), we are proposing that a post-reclassified wage index with the rural and imputed floor applied would be computed based on the hospital's FY 2014 CBSA (that is, using all of its FY 2014 constituent county/ies), and another post-reclassified wage index with the rural and imputed floor applied would be computed based on the hospital's new FY 2015 CBSA (that is, the FY 2015 constituent county/ies). We are proposing to compare these two wage indexes. If the proposed FY 2015 wage index with FY 2015 CBSAs would be lower than the proposed FY 2015 wage index with FY 2014 CBSAs, we are proposing that a blended wage index would be computed, consisting of 50 percent of each of the two wage indexes added together. We are proposing that this blended wage index would be the hospital's wage index for FY 2015. We believe a 1-year, 50/50 blend would mitigate the short-term instability and negative payment impacts due to the proposed implementation of the new OMB delineations, providing hospitals with a transition period during which they may adjust to their new geographic CBSA or may assess any reclassification options that would be available to them starting in FY 2016. We are proposing a longer 3-year transition adjustment for hospitals losing urban status because there are significantly fewer affected urban-to-rural hospitals, and we believe the negative impacts to a hospital shifting from urban to rural status would typically be greater than other types of transitions. We believe that a transition period longer than 1 year to address other impacts of the proposed adoption of new OMB delineations would reduce the accuracy of the overall labor market area wage index system because far more hospitals would be affected.

In addition, for FY 2015, for hospitals that would receive the proposed 3-year transition, it is possible that receiving the FY 2015 wage index (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied) of the CBSA where the hospital is geographically located for FY 2014 might still be less than the FY 2015 wage index that the hospital would have received in the absence of the adoption of the new OMB delineations (particularly in States where the rural floor is historically very high). Therefore, such a hospital may additionally benefit from application of the 50/50 blended wage indexes. Accordingly, we are proposing to include the assignment of the 3-year transitional wage index in our calculation of the FY 2015 portion of the 50/50 blended wage index for that hospital. After FY 2015, such a hospital may revert to the second year of the 3-year transition. For example, if Hospital X (formerly part of CBSA 12345, now rural) is assigned CBSA 12345's FY 2015 wage index value of 1.0000 as part of the 3-year transition, but that FY 2015 wage index value would have been 1.1000 under the previous OMB delineations, that hospital would receive a 50/50 blended wage index of 1.0500 for FY 2015. In FY 2016 and FY 2017, Hospital X would still be eligible to receive the remaining 2 years of the 3-year transition wage index of CBSA 12345 (that is, in FY 2016, Hospital X would receive the FY 2016 wage index of CBSA 12345 (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied)), and in FY 2017, Hospital X would receive the FY 2017 wage index of CBSA 12345 (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied).

(5) Impact of Proposed Adoption of New OMB Labor Market Area Delineations

To illustrate how the proposed adoption of the new OMB labor market area delineations would impact hospitals' proposed FY 2015 wage indexes, we compared the proposed FY 2015 occupational mix adjusted post-reclassified wage indexes with rural floor budget neutrality applied under the FY 2014 CBSAs and under the proposed FY 2015 CBSAs using the new OMB delineations. (This analysis does *not* include the effects of the out-migration adjustment, the frontier floor, the proposed 3-year hold harmless transition wage indexes, or the proposed 1-year transition blended wage indexes). As a result of applying the proposed new OMB delineations to the wage data, the proposed wage index values for 2,362 urban hospitals (83.8 percent) and 396 (64.0 percent) rural hospitals would increase. The wage index values of 2,337 (82.9 percent) urban hospitals would increase by less than 5 percent, and the wage index values of 13 (0.5 percent) urban hospitals would increase by at least 5 percent but less than 10 percent. The wage index values of 12 (0.4 percent) urban hospitals would increase by greater than or equal to 10 percent. The wage index values of 369 (59.6 percent) rural hospitals would increase by less than 5 percent, 18 rural hospitals (2.9 percent) would increase by at least 5 percent but less than 10 percent, and 9 rural hospitals (1.5 percent) would increase by greater than or equal to 10 percent. However, the wage index values for 451 urban hospitals (16.0 percent) and 223 (36.0 percent) rural hospitals would decrease. The wage index values of 396 (14.0

percent) urban hospitals would decrease by less than 5 percent, 40 urban hospitals (1.4 percent) would decrease by at least 5 percent but less than 10 percent, and 15 urban hospitals (0.5 percent) would decrease by greater than or equal to 10 percent. The wage index values of 198 (32.0 percent) rural hospitals would decrease by less than 5 percent, 24 rural hospitals (3.9 percent) would decrease by 5 percent and less than 10 percent, and 1 rural hospital (0.2 percent) would decrease by greater than or equal to 10 percent. The wage index values of 6 (0.2 percent) urban hospitals and zero rural hospitals would remain unchanged by the adoption of the new OMB CBSA delineations. The largest positive impacts would be for 8 hospitals in 5 States (Texas, Minnesota, Louisiana, Alabama, and Michigan) that would be moving from a rural to an urban area (ranging from a 16.57 percent to a 22.91 percent increase in wage index), and for 10 hospitals that would be moving from one urban CBSA (FY 2014 CBSA 20764, Edison-New Brunswick, NJ) to new urban CBSA 35614 (New York-Jersey City-White Plains, NY-NJ), representing a 15.12 percent increase in wage index. The largest negative impacts would be for 5 hospitals in 4 States (New York, Alabama, Idaho, and North Carolina) that would be moving from an urban to a rural area (ranging from a 13.08 percent to a 27.25 percent decrease in wage index), and for 8 hospitals that would be moving from one urban CBSA (FY 2014 CBSA 35644, New York-White Plains-Wayne, NY-NJ) to new urban CBSA 20524 (Dutchess County-Putnam County, NY), representing a 11.42 percent decrease in wage index. These results illustrate that hospitals that would move from rural CBSAs to urban CBSAs generally would benefit significantly, while hospitals that would move from urban to rural CBSAs generally would have larger negative impacts. For all hospitals combined, the wage index values of 2,758 (80.2 percent) overall would be increasing, and 674 (19.6 percent) overall would be decreasing, indicating that most hospitals would be positively affected by the adoption of the new OMB delineations. Furthermore, the magnitude of the changes would be relatively small overall, with only 132 hospitals (3.8 percent) experiencing either an increase or decrease of at least 5 percent.

The following table shows the impact of the proposed adoption of the new OMB delineations on hospitals' proposed FY 2015 wage indexes, comparing the proposed FY 2015 occupational mix adjusted post-reclassified wage indexes with rural floor budget neutrality applied under the FY 2014 CBSAs and the proposed FY 2015 CBSAs using the new OMB delineations. (This analysis does *not* include the effects of the out-migration adjustment, the frontier floor, the proposed 3-year hold harmless transition wage indexes, or the proposed 1-year transition blended wage indexes).

Percent change in FY 2015 wage index	Number of post-reclassified rural hospitals based on FY 2014 CBSA	Number of post-reclassified urban hospitals based on FY 2014 CBSA	Total number of hospitals
Decrease greater than or equal to 10.0	1	15	16
Decrease greater than or equal to 5.0 but less than 10.0	24	40	64
Decrease greater than or equal to 2.0 but less than 5.0	36	94	130
Decrease greater than 0.0 but less than 2.0	162	302	464
No change	0	6	6
Increase greater than 0.0 but less than 2.0	365	2,304	2,669
Increase greater than or equal to 2.0 but less than 5.0	4	33	37
Increase greater than or equal to 5.0 but less than 10.0	18	13	31
Increase greater than or equal to 10.0	9	12	21
Total	619	2,819	3,438

(6) Proposed Budget Neutrality

For FY 2015, we are proposing to apply both the 3-year transition and 50/50 blended wage index adjustments in a budget neutral manner. We are proposing to make an adjustment to the standardized amount to ensure that the total payments, including the effect of the transition provisions, would equal what payments would have been if we would not be providing for any transitional wage indexes under the new OMB delineations. For a complete discussion on this proposed budget neutrality adjustment for FY 2015, we refer the reader to section II.A.4.b. of the Addendum to this proposed rule.

We note that, consistent with past practice (69 FR 49034), we are not adopting the new OMB delineations themselves in a budget neutral manner. We do not believe that the revision to the labor market areas in and of itself constitutes an ''adjustment or update'' to the adjustment for area wage differences, as provided under section 1886(d)(3)(E) of the Act.

(7) Proposals With Respect To Determining Disproportionate Share Hospital (DSH) Payments

As noted in the FY 2005 IPPS final rule (69 FR 49033), the provisions of § 412.102 of the regulations would continue to apply with respect to determining DSH payments. Specifically, in the first year after a hospital loses urban status, the hospital would receive an additional payment that equals two-thirds of the difference between the urban DSH payments applicable to the hospital before its redesignation from urban to rural and the rural DSH payments applicable to the hospital subsequent to its redesignation from urban to rural. In the second year after a hospital loses urban status, the hospital would receive an additional payment that equals one-third of the difference between the urban DSH payments applicable to the hospital before its redesignation from urban to rural and the rural DSH payments applicable to the hospital subsequent to its redesignation from urban to rural.

We also are proposing to make changes to the regulations to delete § 412.64(b)(1)(ii)(D). In this regulation section, we currently define a ''hospital reclassified as rural'' as a hospital located in a county that, in FY 2004, was urban but was redesignated as rural after September 30, 2004, as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003. Because this term is not used in § 412.64, but is used in § 412.102, we

are proposing to delete § 412.64(b)(1)(ii)(D) and revise the language at § 412.102 to address the circumstances set forth in § 412.64(b)(1)(ii)(D). The regulation at § 412.102, which addresses special treatment of hospitals located in areas that are changing from urban to rural as a result of a geographic redesignation, is the only location that currently references a ''hospital reclassified as rural'', as defined at § 412.64(b)(1)(ii)(D). To avoid confusion with urban hospitals that choose to reclassify as rural under § 412.103, we are proposing to revise the regulation text at § 412.102 so that it no longer refers to the defined term ''hospital reclassified as rural,'' and instead specifically states the circumstances in which § 412.102 applies. In addition, we are proposing to modify the regulation text so that it would apply to all transitions from urban to rural status that occur as a result of any future adoption of new or revised OMB standards for delineating statistical areas adopted by CMS. Specifically, we are proposing to revise the regulations at § 412.102 to state that ''An urban hospital that was part of an MSA, but was redesignated as rural as a result of the most recent OMB standards for delineating statistical areas adopted by CMS, may receive an adjustment to its rural Federal payment amount for operating costs for 2 successive fiscal years as provided in paragraphs (a) and (b) of this section. . . .''

C. Worksheet S–3 Wage Data for the Proposed FY 2015 Wage Index

The proposed FY 2015 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2011 (the FY 2014 wage indexes were based on data from cost reporting periods beginning during FY 2010).

1. Included Categories of Costs

The proposed FY 2015 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 through 47318)); and
- Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590)) and other deferred compensation costs.

2. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2014, the proposed wage index for FY 2015 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The proposed FY 2015 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally qualified health centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the wage index, for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397 through 45398).

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 indexes 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 indexes 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 proposed FY 2015 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, 2010, and before October 1, 2011. For wage index purposes, we refer to cost reports during this period as the ''FY 2011 cost report,'' the ''FY 2011 wage data,'' or the ''FY 2011 data.'' Instructions for completing the wage index sections of Worksheet S–3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. No. 15–2), Chapter 40, Sections 4005.2 through 4005.4 for Form CMS–2552–10. The data file used to construct the proposed FY 2015 wage index includes FY 2011 data submitted to us as of February 27, 2014. As in past years, we performed an extensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our MACs to revise or verify data elements that result in specific edit failures. For the proposed FY 2015 wage index, we identified and excluded 50 providers with data that were 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 final FY 2015 wage index. We instructed MACs to complete their data verification of questionable data elements and to transmit any changes to the wage data no later than April 9, 2014. We intend that all unresolved data elements will be resolved by the date the FY 2015 final rule is issued. The revised data will be reflected in the FY 2015 IPPS final rule.

In constructing the proposed FY 2015 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2011, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believe that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398). For this proposed rule, we removed 6 hospitals that converted to CAH status on or after February 14, 2013, the cut-off date for CAH exclusion from the FY 2014 wage index, and through and including February 13, 2014, the cut-off date for CAH exclusion from the FY 2015 wage index. After removing hospitals with aberrant data and hospitals that converted to CAH status, the proposed FY 2015 wage index is calculated based on 3,400 hospitals.

For the proposed FY 2015 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located in the same manner that we allotted such hospitals' data in the FY 2014 wage index (78 FR 50587). Table 2 containing the proposed

FY 2015 wage index associated with this proposed rule (available via the Internet on the CMS Web site) includes separate wage data for the campuses of 6 multicampus hospitals.

Questions have been raised recently regarding the reporting of contract housekeeping and dietary services on Worksheet S–3, Part II, lines 33 and 35 of the Medicare cost report. CMS finalized its proposal to begin collecting contract labor costs and hours for housekeeping, and dietary (along with management services and the overhead services of administrative and general) in the FY 2003 IPPS final rule (67 FR 50022 through 50023). At that time, we stated, ''We continue to consider whether to expand our contract labor definition to include more types of contract services in the wage index. In particular, we have examined whether to include the costs for acquired dietary and housekeeping services, as many hospitals now provide these services through contracts. Costs for these services tend to be below the average wages for all hospital employees. Therefore, excluding the costs and hours for these services if they are provided under contract, while including them if the services are provided directly by the hospital, creates an incentive for hospitals to contract for these services in order to increase their average hourly wage for wage index purposes'' (67 FR 50022). In the FY 2003 IPPS proposed rule, we explained that we selected the three overhead services of administrative and general, housekeeping, and dietary because they are provided at all hospitals, either directly or through contracts, and together they comprise about 60 percent of a hospital's overhead hours (67 FR 31433). In the FY 2003 IPPS final rule, we stated that we ''will monitor the hospital industry for information regarding the hospitals' ability to provide the data. Further, we will work with hospitals and intermediaries [MACs] to develop acceptable methods for tracking the costs and hours. Finally, before including these additional costs in the wage index, we will provide a detailed analysis of the impact of including these additional costs in the wage index values in the **Federal Register** and provide for public comment. Our final decision on whether to include contract indirect patient care labor costs in our calculation of the wage index will depend on the outcome of our analyses and public comments'' (67 FR 50023).

Subsequent to the issuance of the FY 2003 IPPS final rule, we revised Worksheet S–3, Part II of the Medicare cost report (CMS Form 2552–96) to add four lines for the reporting of contract labor salaries, wages, and hours. The lines added for contract housekeeping and dietary services were lines 26.01 and 27.01, respectively. (Line 9.03 for contract management and line 22.01 for contract administrative and general (A&G) services were also added at that time). These lines were effective with cost reporting periods beginning on or after October 1, 2003 (that is, FY 2004). Because the cost report data used for the wage index are on a 4-year lag, data from these new contract labor lines would first be available for the FY 2008 wage index.

In the FY 2008 rulemaking process, we provided an analysis of the effect on the inclusion in the wage index of the wages and hours related to the new contract labor lines. At that time, 56 hospitals (1.6 percent) failed edits for contract housekeeping line 26.01; and 99 hospitals (2.8 percent) failed edits for contract dietary line 27.01 (72 FR 24680 and 24782). We also noted that ''many of these edit failures are for wage data that are not to be included in the wage index and will be excluded through the wage index calculation. . . . In addition, some of the aberrant data will be resolved by the final rule through the correction process'' (72 FR 24680 and 24782). The small percentage of hospitals that failed edits for these contract labor lines indicates that the vast majority of hospitals completing these contract labor lines were able to obtain and report reasonable salaries, wages, and hours associated with contract housekeeping and dietary services. In the FY 2008 IPPS final rule, we stated that we believe that ''the impact of this policy is generally very minor, and we do not believe the additional complexity of a transition wage index is warranted for an impact this small. Further, we continue to believe it is prudent policy to include in the wage index the costs for these contract indirect patient care services'' (72 FR 47316). Therefore, we adopted the policy to include the new contract labor lines in the wage index, beginning with the FY 2008 wage index.

The questions that have recently come to our attention involve hospitals that consistently do not provide documentable salaries, wages, and hours for their contracted housekeeping and/or dietary services. (On the Medicare cost report (CMS Form 2552–10), contract housekeeping is on Worksheet S–3, Part II, line 33 and contract dietary is on line 35). When this situation occurs, CMS has instructed the Medicare contractors to use reasonable estimates, such as regional average hourly rates, as a substitute for actual wages and hours, and to report the estimates on the hospital's Worksheet S–3, Part II, line 33 or line 35, respectively. Our policy has been to use reasonable estimates for these housekeeping and dietary lines, rather than report zeroes for wages and hours, because, as discussed above and as stated in the FY 2003 IPPS final rule, ''[c]osts for these services tend to be below the average wages for all hospital employees. Therefore, excluding the costs and hours for these services if they are provided under contract, while including them if the services are provided directly by the hospital, creates an incentive for hospitals to contract for these services in order to increase their average hourly wage for wage index purposes'' (57 FR 50022). We understand that the reason many hospitals provide for failing to report such contract wages and hours is that their contracts do not clearly specify this information, often because they use a single vendor to provide several different contract labor services. We believe that allowing hospitals to routinely use contracts that do not clearly break out the salaries, wages, and hours associated with these services as a reason for not being able to report proper salaries, wages, and hours for these cost report lines undermines the purpose of instituting these lines in the first place. Furthermore, because every hospital must provide housekeeping and dietary services, and because the wage index is a relative measure of the value of the labor provided to a hospital in a particular labor market area, to report zeroes for salaries, wages, and hours for housekeeping and dietary services is not only unrealistic (in that every hospital provides for these services), but also misrepresents the labor costs in that area and undermines our policy. Consequently, CMS has instructed the Medicare contractors not to zero out these line items when a hospital cannot document the housekeeping or dietary salaries, wages, and hours, but instead to use a reasonable estimation of these wages and hours.

In this proposed rule, we are reiterating our requirement that all hospitals must document salaries, wages, and hours for the purpose of reporting this information on Worksheet S–3, Part II, lines 32, 33, 34, and/or 35 (for either directly employed housekeeping and dietary employees on lines 32 and 34, and contract labor on lines 33 and 35). It is not acceptable for a hospital to request that the Medicare contractor zero out these line items if the hospital's contract does not

specifically break out the actual wages and hours. As indicated above, and stated in the FY 2008 IPPS proposed rule (72 FR 24680 and 24782), a small percentage of hospitals failed edits associated with the contract housekeeping and dietary lines, showing that the vast majority of hospitals reporting data on these lines were able to obtain and report reasonable salaries, wages, and hours associated with contract housekeeping and dietary services. We encourage hospitals to ensure that their contracts clearly specify the salaries, wages, and hours related to all of their contract labor. Because these line items have been included in the cost report since FY 2004, we believe that hospitals have had adequate notice and time to structure their contracts so that the wages and hours of contract employees can be determined and included in the cost reports. We expect hospitals to provide accurate data on their cost reports.

We understand that there may be rare situations where a hospital would not have documentable salaries, wages, and hours for contract housekeeping and dietary services. In these situations, we believe that it is appropriate and necessary to use reasonable estimates for these numbers in order to determinate the best, most realistic, wage index that we can. As discussed previously, housekeeping and dietary services are unique in that the costs for housekeeping and dietary services tend to be below the average wages for all hospital employees. Thus, an incentive is created for hospitals to avoid reporting these contract labor salaries, wages, and hours on the cost report in order to increase their average hourly wage for wage index purposes. To deter hospitals from not reporting this information and to ensure that the wage index more accurately reflects the labor costs in an area, we believe that it is both necessary and appropriate for the Medicare contractors to estimate such salaries, wages, and hours in the rare instance where a hospital cannot provide such information. Therefore, in the absence of documentable wages and hours for contract housekeeping and dietary services, Medicare contractors would continue to use reasonable estimates for these services. Examples of reasonable estimates are regional average hourly rates, including an average of the wages and hours for dietary and housekeeping services of other hospitals in the same CBSA as the hospital in question. Hospitals also may conduct time studies to determine hours worked. If, for whatever reason, regional averages or time studies cannot be used, Medicare contractors may use data from the Bureau of Labor Statistics to obtain average wages and hours for housekeeping and dietary services. Commenters may also suggest alternatives for imputing reasonable estimates for possible consideration by CMS. In all cases, Medicare contractors must determine that the data used are reasonable.

E. Method for Computing the Proposed FY 2015 Unadjusted Wage Index

The method used to compute the proposed FY 2015 wage index without an occupational mix adjustment follows the same methodology that we used to compute the FY 2012, FY 2013, and FY 2014 final wage indexes without an occupational mix adjustment (76 FR 51591 through 51593, 77 FR 53366 through 53367, and 78 FR 50587 through 50588, respectively).

As discussed in the FY 2012 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, 2010, through April 15, 2012, 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 2015. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated in the following table.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment factor
10/14/2010	11/15/2010	1.02230
11/14/2010	12/15/2010	1.02078
12/14/2010	01/15/2011	1.01929
01/14/2011	02/15/2011	1.01782
02/14/2011	03/15/2011	1.01637
03/14/2011	04/15/2011	1.01494
04/14/2011	05/15/2011	1.01355
05/14/2011	06/15/2011	1.01219
06/14/2011	07/15/2011	1.01084
07/14/2011	08/15/2011	1.00948
08/14/2011	09/15/2011	1.00811
09/14/2011	10/15/2011	1.00674
10/14/2011	11/15/2011	1.00538
11/14/2011	12/15/2011	1.00403
12/14/2011	01/15/2012	1.00269
01/14/2012	02/15/2012	1.00134
02/14/2012	03/15/2012	1.00000

MIDPOINT OF COST REPORTING PERIOD—Continued

After	Before	Adjustment factor
03/14/2012	04/15/2012	0.99866

For example, the midpoint of a cost reporting period beginning January 1, 2011, and ending December 31, 2011, is June 30, 2011. An adjustment factor of 1.01084 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 2014 IPPS/LTCH PPS final rule (78 FR 50587 through 50588), the proposed FY 2015 national average hourly wage (unadjusted for occupational mix) is $39.1525. The proposed FY 2015 Puerto Rico overall average hourly wage (unadjusted for occupational mix) is $17.0010.

F. Proposed Occupational Mix Adjustment to the Proposed FY 2015 Wage Index

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

1. Development of Data for the Proposed FY 2015 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 2014 IPPS/LTCH PPS final rule (78 FR 50588), the occupational mix adjustment to the FY 2014 wage index was based on data collected on the 2010 Medicare Wage Index Occupational Mix Survey (Form CMS–10079 (2010)). For the FY 2015

wage index, we are proposing to again use occupational mix data collected on the 2010 survey to compute the occupational mix adjustment for FY 2015. We are including data for 3,165 hospitals that also have wage data included in the proposed FY 2015 wage index.

2. New 2013 Occupational Mix Survey for the FY 2016 Wage Index

As stated earlier, section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. We used occupational mix data collected on the 2010 survey to compute the occupational mix adjustment for FY 2013, FY 2014, and the proposed FY 2015 wage index associated with this proposed rule. Therefore, a new measurement of occupational mix will be required for FY 2016.

On December 7, 2012, we published in the **Federal Register** a notice soliciting comments on the proposed 2013 Medicare Wage Index Occupational Mix Survey (77 FR 73032 through 73033). The new 2013 survey, which will be applied to the FY 2016 wage index, includes the same data elements and definitions as the 2010 survey and provides for the collection of hospital-specific wages and hours data for nursing employees for calendar year 2013 (that is, payroll periods ending between January 1, 2013 and December 31, 2013). The comment period for the notice ended on February 5, 2013. After considering the public comments that we received on the December 2012 notice, we made a few minor editorial changes and published the 2013 survey in the **Federal Register** on February 28, 2013 (78 FR 13679). This survey was approved by OMB on May 14, 2013, and is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/WAGE-INDEX-OCCUPATIONAL-MIX-SURVEY2013.pdf*.

The 2013 Occupational Mix Survey Hospital Reporting Form CMS–10079 for the Wage Index Beginning FY 2016 (in excel format) is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2016-Wage-Index-OccupationalMix.html*. Hospitals are required to submit their completed 2013 surveys to their MACs by July 1, 2014. The preliminary, unaudited 2013 survey data will be released afterward, along with the FY 2012 Worksheet S–3 wage data, for the FY 2016 wage index review and correction process.

3. Calculation of the Proposed Occupational Mix Adjustment for FY 2015

For FY 2015, we are proposing to calculate the occupational mix adjustment factor using the same methodology that we used for the FY 2012, FY 2013, and FY 2014 wage indexes (76 FR 51582 through 51586, 77 FR 53367 through 53368, and 78 FR 50588 through 50589, respectively). As a result of applying this methodology, the proposed FY 2015 occupational mix adjusted national average hourly wage (based on the proposed new OMB delineations) is $39.1177. The proposed FY 2015 occupational mix adjusted Puerto Rico-specific average hourly wage (based on the proposed new OMB delineations) is $17.0526.

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 2015 wage index. For the FY 2015 proposed wage index, because we are using the Worksheet S–3, Parts II and III wage data of 3,400 hospitals, and we are using the occupational mix surveys of 3,165 hospitals for which we also have Worksheet S–3 wage data, that represents a ''response'' rate of 93.1 percent (3,165/3,400). In the proposed FY 2015 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 rule and final rule (75 FR 23943 and 75 FR 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 2010 occupational mix survey. We instructed fiscal intermediaries/MACs to continue gathering this information as part of the FY 2014 and FY 2015 wage index desk review process. We stated that we would 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 2015 Occupational Mix Adjusted Wage Index

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

As discussed in section III.F. of the preamble of this proposed rule, for FY 2015, we are proposing to apply the proposed occupational mix adjustment to 100 percent of the proposed FY 2015 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 proposed FY 2015 wage index results in a proposed national average hourly wage (based on the new OMB delineations) of $39.1177 and a proposed Puerto-Rico specific average hourly wage of $17.0526. After excluding data of hospitals that either submitted aberrant data that failed critical edits, or that do not have FY 2011 Worksheet S–3, Parts II and III, cost report data for use in calculating the proposed FY 2015 wage index, we calculated the proposed FY 2015 wage index using the occupational mix survey data from 3,165 hospitals. For the FY 2015 proposed wage index, because we are using the Worksheet S–3, Parts II and III wage data of 3,400 hospitals, and we are using the occupational mix survey data of 3,165 hospitals for which we also have Worksheet S–3 wage data, those data represent a ''response'' rate of 93.1 percent (3,165/3,400). The proposed FY 2015 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	Proposed average hourly wage
National RN	37.388291241
National LPN and Surgical Technician	21.767178303
National Nurse Aide, Orderly, and Attendant	15.31155016
National Medical Assistant	17.246724132
National Nurse Category	31.744397958

The proposed national average hourly wage for the entire nurse category as computed in Step 5 of the occupational mix calculation is $31.744397958. 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 43.43 percent, and the national percentage of hospital employees in the all other occupations category is 56.57 percent. At the CBSA level, using the new OMB delineations proposed for FY 2015, the percentage of hospital employees in the nurse category ranged from a low of 21.88 percent in one CBSA to a high of 73.27 percent in another CBSA.

We compared the proposed FY 2015 occupational mix adjusted wage indexes for each CBSA to the proposed unadjusted wage indexes for each CBSA. We used the proposed FY 2015 new OMB delineations for this analysis. As a result of applying the proposed occupational mix adjustment to the wage data, the proposed wage index values for 215 (52.8 percent) urban areas and 29 (61.7 percent) rural areas would increase. One hundred and sixteen (28.5 percent) urban areas would increase by 1 percent but less than 5 percent, and 4 (1.0 percent) urban areas would increase by 5 percent or more. Fourteen (29.8 percent) rural areas would increase by 1 percent but less than 5 percent, and no rural areas would increase by 5 percent or more. However, the wage index values for 190 (46.7 percent) urban areas and 18 (38.3 percent) rural areas would decrease. Eighty (19.7 percent) urban areas would decrease by 1 percent but less than 5 percent, and 1 (0.2 percent) urban area would decrease by 5 percent or more. Seven (14.9 percent) rural areas would decrease by 1 percent and less than 5 percent, and no rural areas would decrease by 5 percent or more. The largest positive impacts would be 6.56 percent for an urban area and 3.35 percent for a rural area. The largest negative impacts would be 5.32 percent for an urban area and 1.71 percent for a rural area. Two urban areas' wage indexes, but no rural area wage indexes, would remain unchanged by application of the occupational mix adjustment. These results indicate that a larger percentage of rural areas (61.7 percent) would benefit from the occupational mix adjustment than would urban areas (52.8 percent). However, approximately one-third (38.3 percent) of rural CBSAs would still experience a decrease in their wage indexes as a result of the occupational mix adjustment.

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

a. Proposed Rural Floor

Section 4410(a) of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the ''rural floor.'' Section 3141 of Public Law 111–148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor. In the proposed FY 2015 wage index associated with this proposed rule and available on the CMS Web site, based on the proposed implementation of the new OMB delineations discussed in section III.B. of the preamble of this proposed rule, we estimated that 441 hospitals would receive an increase in their FY 2015 proposed wage index due to the application of the rural floor.

b. Proposed Imputed Floor for FY 2015

In the FY 2005 IPPS final rule (69 FR 49109 through 49111), 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 four times, the last of which was adopted in the FY 2014 IPPS/LTCH PPS final rule and is set to expire on September 30, 2014. (We refer readers to further discussion of the imputed floor in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50589 through 50590) and to our regulations at 42 CFR 412.64(h)(4).) There were previously two all-urban States, New Jersey and Rhode Island, that have a range of wage indexes 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 the preamble of this proposed rule). However, as we explain below, the method as of FY 2012 for computing the imputed floor (the original methodology) benefitted only New Jersey, and not Rhode Island.

In computing the imputed floor for an all-urban State under the original methodology, we calculated the ratio of the lowest-to-highest CBSA wage index for each all-urban State as well as the average of the ratios of lowest-to-highest CBSA wage indexes of those all-urban States. We then compared the State's own ratio to the average ratio for all-urban States and whichever is higher is multiplied by the highest CBSA wage index value in the State—the product of which established the imputed floor for the State. Under the current OMB labor market area delineations that we used for the FY 2014 wage index, Rhode Island has only one CBSA (Providence-New Bedford-Fall River, RI–MA) and New Jersey has 10 CBSAs. Therefore, under the original methodology, Rhode Island's own ratio equaled 1.0, and its imputed floor was equal to its original CBSA wage index value. However, because the average ratio of New Jersey and Rhode Island was higher than New Jersey's own ratio, this methodology provided a benefit for New Jersey, but not for Rhode Island.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53368 through 53369), we retained the imputed floor calculated under the original methodology as discussed above, and established an alternative methodology for computing the imputed floor wage index to address the concern that the original imputed floor methodology guaranteed a benefit

for one all-urban State with multiple wage indexes (New Jersey) but could not benefit the other all-urban State (Rhode Island). The alternative methodology for calculating the imputed floor was established using data from the application of the rural floor policy for FY 2013. Under the alternative methodology, we first determined 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 the FY 2013 IPPS/LTCH PPS final rule (which is available on the CMS Web site) included 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 then is increased by this factor, the result of which establishes the State's alternative imputed floor. We amended § 412.64(h)(4) of the regulations to add new paragraphs to incorporate the finalized alternative methodology, and to make reference and date changes.

In summary, for the FY 2013 wage index, we did not make any changes to the original imputed floor methodology at § 412.64(h)(4) and, therefore, made no changes to the New Jersey imputed floor computation for FY 2013. Instead, for FY 2013, we adopted a second, alternative methodology for use in cases where an all-urban State has a range of wage indexes assigned to its hospitals, but the State cannot benefit from the methodology in existing § 412.64(h)(4).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50589 through 50590), we extended the imputed floor policy (both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2014, while we continued to explore potential wage index reforms.

For FY 2015, we are proposing to continue the extension of the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2015, as we continue to explore potential wage index reforms. As discussed in section III.B. of the preamble of this proposed rule, we are proposing to adopt the new OMB labor market area delineations beginning in FY 2015. Under OMB's new labor market area delineations based on Census 2010 data, Delaware would become an all-urban State, along with New Jersey and Rhode Island. Under the new OMB delineations, Delaware would have three CBSAs, New Jersey would have seven CBSAs, and Rhode Island would continue to have only one CBSA (Providence-Warwick, RI–MA). We refer readers to a detailed discussion of our proposal to adopt the new OMB labor market area delineations in section III.B. of the preamble of this proposed rule. We are proposing to revise the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect the proposed 1-year extension of the imputed floor. We are inviting public comments on our proposal regarding the 1-year extension of the imputed floor.

The wage index and impact tables associated with this FY 2015 IPPS/LTCH PPS proposed rule that are available on the CMS Web site reflect the proposed continued application of the imputed floor policy at § 412.64(h)(4) and a national budget neutrality adjustment for the imputed floor for FY 2015. There are 12 providers in New Jersey, and 1 provider in Delaware that would receive an increase in their FY 2015 wage index due to the proposed continued application of the imputed floor policy under the original methodology. The wage index and impact tables for this FY 2015 proposed rule also reflect the proposed application of the second alternative methodology for computing the imputed floor, which would benefit four hospitals in Rhode Island.

c. Proposed State 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 regulations at 42 CFR 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161)). Based on the proposed implementation of the new OMB delineations discussed in section III.B. of the preamble of this proposed rule, 46 hospitals would receive the frontier floor value of 1.0000 for their proposed FY 2015 wage index in this proposed rule. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming. Although Nevada is also defined as a frontier State, its proposed FY 2015 rural floor value of 1.1373 is greater than 1.0000, and therefore, no Nevada hospitals would receive a frontier floor value for their proposed FY 2015 wage index.

The areas affected by the proposed rural, imputed, and frontier floor policies for the proposed FY 2015 wage index are identified in Table 4D associated with this proposed rule, which is available on the CMS Web site.

3. Proposed FY 2015 Wage Index Tables

The proposed wage index values for FY 2015 (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 the preamble of this proposed rule, and the application of the rural, imputed, and frontier State floors as discussed in section III.G.2. of the preamble of this proposed rule. We note that because we are proposing to adopt the new OMB labor market area delineations for FY 2015, these tables have additional tabulations to account for wage index calculations computed under the previous and the new OMB delineations.

Tables 3A and 3B, available on the CMS Web site, list the proposed 3-year average hourly wage for each labor market area before the redesignation or reclassification of hospitals based on FYs 2009, 2010, and 2011 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 proposed adjusted average hourly wage for each hospital from the FY 2009 and FY 2010 cost reporting periods, as well as the FY 2011 period used to calculate the proposed FY 2015 wage index. The proposed 3-year averages are calculated by dividing the sum of the dollars (adjusted to a common reporting period using the method described in Step 5 in section III.G. of the preamble of this proposed rule) across all 3 years, by the sum of the hours. If a hospital is missing data for any of the previous years, its proposed 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 floor budget neutrality adjustment (which includes the proposed imputed floor). The proposed wage index values in Table 2 also include the proposed out-migration adjustment for eligible hospitals. As stated above, because we are proposing to adopt the new OMB labor market area delineations for FY 2015, these tables have additional tabulations to account for wage index calculations computed under the current labor market definitions and the

new OMB labor market area delineations. In addition, for certain applicable hospitals, the proposed wage index values included in Table 2 are computed to reflect the proposed transitional wage index or the 50/50 blended wage index discussed in detail in section III.B.2.e. of the preamble of this proposed rule.

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 not later than 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 in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies for reclassifications and redesignations that we are proposing for FY 2015, 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 in accordance with the provisions of 42 CFR 412.103. While our general policies on geographic reclassification, redesignations under section 1886(d)(8)(B) of the Act, and urban hospitals reclassifying to rural under 42 CFR 412.103 will remain unchanged for FY 2015, we note that, due to our proposed adoption of the new OMB labor market area delineations for FY 2015, there are numerous unique classification considerations for FY 2015 that are discussed in more detail in section III.H. of the preamble of this proposed rule. For a discussion of the new CBSA changes based on the new OMB labor market area delineations and our proposed implementation of those changes, we refer readers to sections III.B. and VI.C. of the preamble of this proposed rule.

2. FY 2015 MGCRB Reclassifications

a. FY 2015 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.

In February 2014, the MGCRB completed its review of FY 2015 reclassification requests. Based on such reviews, there were 379 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2015. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2015, hospitals reclassified beginning during FY 2013 or FY 2014 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 172 hospitals approved for wage index reclassifications in FY 2013, and 287 hospitals approved for wage index reclassifications in FY 2014. Of all the hospitals approved for reclassification for FY 2013, FY 2014, and FY 2015, as of February 2014, 838 hospitals are in a reclassification status for FY 2015.

Under the regulations at 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 through 39888) and the FY 2003 IPPS final rule (67 FR 50065 through 50066). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and ''fallback'' reclassifications, were included in the FY 2008 IPPS final rule (72 FR 47333).

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 2015 will be incorporated into the wage index values published in the FY 2015 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. Effects of Implementation of New OMB Labor Market Area Delineations on Reclassified Hospitals

Because hospitals that have been reclassified beginning in FY 2013, 2014, or 2015 were reclassified based on the current labor market delineations, if we adopt the new OMB labor market area delineations beginning in FY 2015, the areas to which they have been reclassified, or the areas where they are located, may change. Under the new OMB delineations, many existing CBSAs would be reconfigured. Hospitals with current reclassifications are encouraged to verify area wage indexes on Tables 4A–2 and 4B–2 associated with this proposed rule (which are available via the Internet on the CMS Web site), and confirm that the areas to which they have been reclassified for FY 2015 would continue to provide a higher wage index than their geographic area wage index. Hospitals may withdraw their FY 2015 reclassifications by contacting the MGCRB within 45 days from the publication of this proposed rule.

In some cases, adopting the new OMB delineations would result in counties splitting apart from CBSAs to form new CBSAs, or counties shifting from one CBSA designation to another CBSA. Reclassifications granted under section 1886(d)(10) of the Act are effective for 3 fiscal years so that a hospital or county group of hospitals would be assigned a wage index based upon the wage data of hospitals in a nearby labor market area for a 3-year period. If CBSAs are split apart, or if counties shift from one CBSA to another under the new OMB delineations, it raises the question of how to continue a hospital's reclassification for the remainder of its 3-year reclassification period, if that area to which the hospital reclassified no longer exists, in whole or in part. We dealt with this question in FY 2005 as well when CMS adopted the current OMB labor market area definitions.

Consistent with the policy CMS implemented in the FY 2005 IPPS final rule (69 FR 49054 through 49056), if a CBSA would be reconfigured due to the new OMB delineations and it would not be possible for the reclassification to continue seamlessly to the reconfigured CBSA, we believe it is appropriate for us to determine the best alternative location to reassign current reclassifications for the remaining 3 years. Therefore, to maintain the integrity of a hospital's 3-year reclassification period, we are proposing a policy to assure that current geographic reclassifications (applications approved in FY 2013, FY 2014, or FY 2015) that would be affected by CBSAs that are split apart or counties that shift to another CBSA under the new OMB delineations, would ultimately be assigned to a CBSA under the new OMB delineations that contains at least one county from the reclassified CBSA under the current FY 2014 OMB definitions, and would be generally consistent with rules that govern geographic reclassification. That is, consistent with policy finalized in FY 2005 (69 FR 49054 and 49055), we are proposing a general policy that affected reclassified hospitals would be assigned to a CBSA that (1) would contain the most proximate county that is located outside of the hospital's proposed FY 2015 geographic labor market area, and (2) is part of the original FY 2014 CBSA to which the hospital is reclassified. We believe that by assigning reclassifications to the CBSA that contains the nearest eligible county (as described above) satisfies the statutory requirement at section 1886(d)(10)(v) of the Act by maintaining reclassification status for a period of 3 fiscal years, while generally respecting the longstanding principle of geographic proximity in the labor market reclassification process. The hospitals that we are proposing to reassign to a different CBSA based on our proposed policy above are listed in a special Table 9A–2 for this proposed rule, which is available via the Internet on the CMS Web site. In addition, we are proposing to allow a hospital, or county group of hospitals, to request reassignment to another CBSA that would contain a county that is part of the current FY 2014 CBSA to which they are reclassified, if the hospital or county group of hospitals can demonstrate compliance with applicable reclassification proximity rules, as described later in this section.

We recognize that this proposed reclassification reassignment described for hospitals that are reclassified to CBSAs that would split apart or to counties that would shift to another CBSA under the new OMB delineations may result in the reassignment of the hospital for the remainder of its 3-year reclassification period to a CBSA having a lower wage index than the wage index that would have been assigned for the reclassified hospital in the absence of the proposed adoption of the new OMB delineations. Therefore, as discussed in section III.B.2.e.(4) of the preamble of this proposed rule, we are proposing that all hospitals that would experience a decrease in their FY 2015 wage index value due to the proposed implementation of the new OMB delineations would receive a 50/50 blended wage index adjustment in FY 2015. For FY 2015, using FY 2015 wage data, we are proposing to calculate a wage index value based on the current FY 2014 OMB definitions, and a wage index value based upon the proposed new OMB delineations (including reclassification assignments discussed in this section). If the wage index under the proposed new OMB delineations would be lower than the wage index calculated with the current (FY 2014) OMB definitions, the hospital would be assigned a blended wage index (50 percent of the current; 50 percent of the proposed). We believe that this proposed transitional adjustment would mitigate negative payment impacts for FY 2015, and would afford hospitals additional time to fully assess any additional reclassification options available to them under the new OMB delineations.

We are including the following descriptions of specific situations where we have determined that reassignment of reclassification areas would be appropriate.

(1) Reclassifications to CBSAs That Would Be Subsumed by Other CBSAs

We identified 66 counties that are currently located in CBSAs that would be subsumed by another CBSA under the new OMB labor market area delineations. As a result, hospitals reclassifying to those CBSAs would now find that their reclassifications are to a CBSA that no longer exists. For these hospitals, we are proposing to reassign reclassifications to the newly configured CBSA to which all of the original constituent counties in the FY 2014 CBSA are transferred. For example, CBSA 11300 (Anderson, IN) would no longer exist under the proposed FY 2015 delineations. The only constituent county in CBSA 11300, Madison County, IN, would be moving to CBSA 26900 (Indianapolis-Carmel-Anderson, IN). Because the original Anderson, IN labor market area no longer exists, we are proposing to reassign reclassifications from the original Anderson, IN labor market area to a newly configured CBSA where the original constituent county or counties are transferred, which is Indianapolis-Carmel-Anderson, IN. For hospitals reclassified to a CBSA that would be subsumed by another CBSA, the following table reflects the hospitals' current reclassified CBSA, and the CBSA to which CMS is proposing to assign them for FY 2015.

PROPOSED HOSPITAL RECLASSIFICATION REASSIGNMENTS FOR HOSPITALS RECLASSIFIED TO A CBSA THAT WOULD BE SUBSUMED BY ANOTHER CBSA

CMS certification No. (CCN)	Current reclassified CBSA	Proposed CBSA
050022	42044	11244
050054	42044	11244
050102	42044	11244
050243	42044	11244
050292	42044	11244
050329	42044	11244
050390	42044	11244
050423	42044	11244
050534	42044	11244
050573	42044	11244
050684	42044	11244
050686	42044	11244
050701	42044	11244
050765	42044	11244
050770	42044	11244
140067	14060	14010
150089	11300	26900
220001	14484	14454
220002	14484	14454
220008	14484	14454
220011	14484	14454
220019	14484	14454
220020	14484	14454
220049	14484	14454
220058	14484	14454
220062	14484	14454
220063	14484	14454
220070	14484	14454
220073	14484	14454
220074	14484	14454
220082	14484	14454
220084	14484	14454
220090	14484	14454
220095	14484	14454
220098	14484	14454
220101	14484	14454
220105	14484	14454
220163	14484	14454
220171	14484	14454
220175	14484	14454
220176	14484	14454
230002	47644	47664
230020	47644	47664
230024	47644	47664
230053	47644	47664
230089	47644	47664
230104	47644	47664
230142	47644	47664
230146	47644	47664

PROPOSED HOSPITAL RECLASSIFICATION REASSIGNMENTS FOR HOSPITALS RECLASSIFIED TO A CBSA THAT WOULD BE SUBSUMED BY ANOTHER CBSA—Continued

CMS certification No. (CCN)	Current reclassified CBSA	Proposed CBSA
230165	47644	47664
230176	47644	47664
230244	47644	47664
230270	47644	47664
230273	47644	47664
230297	47644	47664
300017	37764	15764
300023	37764	15764
300029	37764	15764
390151	13644	43524
410001	14484	14454
410004	14484	14454
410005	14484	14454
410007	14484	14454
410010	14484	14454
410011	14484	14454
410012	14484	14454

(2) Reclassification to CBSAs Where the CBSA Number or Name Has Changed or to CBSAs Containing Counties That Would Be Moving to Another CBSA

We identified six CBSAs with current reclassifications that would maintain the same constituent counties, but the CBSA number or name would change if we adopted the new OMB delineations. For example, CBSA 29140 (Lafayette, IN) currently contains three counties (Benton, Carroll, and Tippecanoe Counties). The CBSA name and number for these counties would change to CBSA 29200 (Lafayette-West Lafayette, IN) under the new OMB delineations. Because the constituent counties in these CBSAs would not change under the new delineations, we would consider these CBSAs to be unchanged, and we are not proposing any reassignment for hospitals reclassified to those labor market areas. Table 9A–2 for this proposed rule (which is available via the Internet on the CMS Web site) reflects the proposed revised CBSA number effective in FY 2015.

We identified eight CBSAs with current reclassifications that have one or more counties that would split off and move to a new CBSA or to a different existing CBSA under the new OMB delineations. These CBSAs are shown in the following table.

Current FY 2014 CBSA	Current FY 2014 CBSA name
16620 ...	Charleston, WV.
16974 ...	Chicago-Joliet-Naperville, IL.
20764 ...	Edison-New Brunswick, NJ.
31140 ...	Louisville/Jefferson County, KY-IN.
35644 ...	New York-White Plains-Wayne, NY-NJ.
37964 ...	Philadelphia, PA.
39100 ...	Poughkeepsie-Newburgh-Middletown, NY.
48900 ...	Wilmington, NC.

We have determined that 69 hospitals have current reclassifications to one of these CBSAs. Similar to the methodology finalized in the FY 2005 IPPS final rule (69 FR 49054 through 49055), we are proposing to follow the general policy discussed in section III.H.2.b. of the preamble of this proposed rule. Specifically, we are proposing that affected reclassified hospitals would be assigned to a CBSA (under the new OMB delineations) that would contain the most proximate county that is (1) located outside of the hospital's proposed FY 2015 geographic labor market area; and (2) is included in the current CBSA to which they are reclassified. For each of the 69 hospitals, we conducted a mapping analysis and determined driving distances from their geographic location to the borders of each county (that is in the reclassified CBSA under the FY 2014 delineations) and is also included in a CBSA under the new OMB delineations, excluding any counties that would be located in the hospital's proposed FY 2015 geographic labor market area. Following the general reassignment principle that we are proposing, we are proposing to reassign those reclassified hospitals to the CBSA which contains the geographically closest county. For example, there are hospitals that currently are reclassified to CBSA 39100 (Poughkeepsie-Newburgh-Middletown, NY) under the FY 2014 delineations, which is comprised of Dutchess County and Orange County, NY. Under the new OMB delineations, Dutchess County would become part of new CBSA 20524 (Dutchess County-Putnam County, NY), while Orange County would join CBSA 35614 (New York-Jersey City-White Plains, NY-NJ Metropolitan Division). Therefore, we mapped the distances from one reclassified hospital to the border of Dutchess County and Orange County, NY (the two counties that were part of CBSA 39100 under the FY 2014 delineations). Our analysis showed that the hospital is 2.2 miles from Dutchess County, and 25.9 miles from Orange County. Therefore, we are proposing to reassign this hospital's reclassification from the FY 2014 CBSA 39100 to the new CBSA 20524.

We also identified affected county group reclassifications. For these reclassifications, we would follow our proposed policy discussed above, except that, for county group reclassifications, we are proposing to reassign hospitals in a county group reclassification to the CBSA under the new OMB delineations to which the majority of hospitals in the group reclassification are geographically closest. Because hospitals in a county group applied as a group, we believe the reassignment should also be applied to the whole group. For example, the hospitals of Fairfield County, CT are reclassified as a group to CBSA 35644 under the FY 2014 delineations. Under the new OMB delineations, CBSA 35644 would no longer exist and would be split into the following two new CBSAs: 20524 (Dutchess County-Putnam County, NY) and 35614 (New York-Jersey City-White Plains, NY-NJ). Of the six hospitals in the group reclassification, all but one would be closer to an eligible county (Westchester, NY) in CBSA 35614 than to an eligible county (Putnam, NY) in CBSA 20524. Because these hospitals in Fairfield, CT applied as a group, we believe the reassignment should also be applied to the whole group. Therefore, we are proposing to assign the hospitals in this group reclassification to CBSA 35614, the reconfigured CBSA to which the majority of the hospitals in the group reclassification are geographically closest.

To summarize, of the 69 hospitals reclassified to one of the 8 CBSAs in the preceding table that have counties that would split off and move to a new CBSA or a different existing CBSA under the new OMB delineations, there are 27 hospitals that would maintain the same reclassified CBSA number under our proposals. Another 28 hospitals would be reassigned to a reconfigured CBSA that would contain a similar number of counties from their current reclassified CBSA. For example, the new CBSA 35614 (New York-Jersey City-White Plains, NY-NJ Metropolitan Division) would contain 10 out of 11 counties from current (FY 2014) CBSA 35644 (New York-White Plains-Wayne, NY-NJ Metropolitan Division).

For the remaining 14 reclassified hospitals, we are proposing to assign them to a CBSA (under the new OMB delineations) that would have a different CBSA number from the labor market area to which they are currently reclassified (under the current FY 2014 delineations). This is because if the original CBSA to which the hospitals are reclassified is losing counties to another urban CBSA, it may be that the

original reclassification determination would not be reflective of the new delineations. In addition, because proximity to a CBSA is a requirement of reclassifications approved under section 1886(d)(10) of the Act, we believe it is appropriate to propose to reassign reclassification status to an urban CBSA that contains the county (from the hospital's current CBSA reclassification) that is closest to the hospital. We believe this would more accurately reflect the geographic labor market area of the reclassified hospital. For example, under the FY 2014 delineations, CBSA 37964 (Philadelphia, PA Metropolitan Division) is comprised of five counties (Bucks, Chester, Delaware, Montgomery, and Philadelphia Counties, PA). Under the new OMB delineations, CBSA 37964 would retain the same CBSA name and number, but three counties (Bucks, Chester, and Montgomery) would split off to form the new CBSA 33874 (Montgomery County-Bucks County-Chester County, PA Metropolitan Division). While CBSA 37964 exists under the FY 2014 and proposed new labor market area delineations, the fact that three counties would be moved to another CBSA means that current reclassifications to CBSA 37964 (Philadelphia) may be more proximate to new CBSA 33874. Therefore, if reclassified hospitals, or the majority of hospitals in a county group, are geographically closer to a county in CBSA 33874 than to a county in CBSA 37964, we are proposing to reassign the reclassification to that area, new CBSA 33874 (Montgomery County-Bucks County-Chester County, PA Metropolitan Division).

Consistent with refinements implemented in the FY 2005 IPPS final rule (69 FR 49055), we are proposing to allow hospitals that reclassified under section 1886(d)(10) of the Act to one of the eight CBSAs that split (that is, current FY 2014 CBSAs 16620, 16974, 20764, 31140, 35644, 37964, 39100, 48900) to be reclassified to any CBSA containing a county from their original reclassification labor market area, provided that the hospital demonstrates that it meets the applicable proximity requirements under 42 CFR 412.230(b) and (c) (for individual hospitals), 42 CFR 412.232(a)(1) (for a rural group), and 42 CFR 412.234(a)(2) and (a)(3) (for an urban group) to that CBSA. Hospitals that wish to be reassigned to an alternate CBSA (other than the CBSA to which their reclassification would be reassigned in this proposed rule) for which they meet the applicable proximity criteria may request reassignment within 45 days from the publication of this proposed rule. Hospitals must send a request to *WageIndex@cms.hhs.gov* and provide documentation certifying that they meet the requisite proximity criteria for reassignment to an alternate CBSA, as described above. We believe this option of allowing hospitals to submit a request to CMS would provide hospitals with greater flexibility with respect to their reclassification reassignment, while ensuring that the proximity requirements are met. We believe that where the proximity requirements are met, the reclassified wage index would be consistent with the labor market area to which the hospitals were originally approved for reclassification. Under this proposed policy, a hospital may request to be assigned a reclassification to any CBSA that contains any county from the CBSA to which it is currently reclassified. However, to be reassigned to an area that is not the most proximate to the hospital (or the majority of hospitals in a county group), we believe it is necessary that the hospital demonstrates that it complies with the applicable proximity criteria. If a hospital cannot demonstrate proximity to an alternate CBSA, the hospital would not be considered for reclassification to that labor market area, and reassignment would remain with the closest eligible (new) CBSA.

As discussed previously in this section, under the new OMB delineations, we identified CBSA 35644 (New York-White Plains-Wayne, NY-NJ Metropolitan Division) as one of the examples of the eight CBSAs that would have at least one county that would split off and join another new CBSA (Putnam County joined Dutchess County, NY to form new CBSA 20524), while also having multiple counties assigned to a reconfigured CBSA 35614 (New York-Jersey City-White Plains, NY-NJ Metropolitan Division). CBSA 35614 would also add Orange County, NY under the new OMB delineations. The hospitals that are currently located in CBSA 39100 (Poughkeepsie-Newburgh-Middletown, NY) are currently part of a group reclassification of Orange County, NY to CBSA 35644 (New York-White Plains-Wayne, NY-NJ Metropolitan Division). As discussed above, we are proposing to reassign current reclassifications to the CBSA that contains the most proximate county that is located *outside of the reclassified hospital's proposed geographic labor market area,* and is currently part of the original CBSA to which the hospital is reclassified. In the case of the Orange County, NY group reclassification, the closest (and only) county from the original reclassified area (CBSA 35644), that would not be located in Orange County's proposed home labor market area (CBSA 35614) is Putnam County, NY. Therefore, we are proposing to reassign the Orange County group reclassification to CBSA 20524 (Putnam County-Dutchess County, NY). If the hospitals from the Orange County, NY group reclassification do not wish to maintain this assignment, we encourage them to formally terminate the current group reclassification within 45 days from the publication of this proposed rule, as discussed earlier in this section.

The following table shows proposed hospital reclassification assignments for hospitals reclassified to CBSAs from which counties would be split off and moved to a different CBSA under the new OMB delineations. The following table shows the current reclassified CBSA and the CBSA to which CMS is proposing reassignment.

PROPOSED HOSPITAL RECLASSIFICATION REASSIGNMENTS FOR HOSPITALS THAT ARE RECLASSIFIED TO CBSAS FROM WHICH COUNTIES WOULD BE SPLIT OFF AND MOVED TO A DIFFERENT CBSA

CMS Certification number (CCN)	Current reclassified CBSA	Proposed reassigned CBSA
070006	35644	35614
070010	35644	35614
070018	35644	35614
070028	35644	35614
070033	35644	35614
070034	35644	35614
140B10	16974	16974
140012	16974	20994
140033	16974	16974
140084	16974	16974
140100	16974	16974
140110	16974	16974
140130	16974	16974
140155	16974	16974
140161	16974	16974
140186	16974	16974
140202	16974	16974
140291	16974	16974
150002	16974	16974
150004	16974	16974
150008	16974	16974
150034	16974	16974
150090	16974	16974
150125	16974	16974
150126	16974	16974
150165	16974	16974
150166	16974	16974
180012	31140	31140
180048	31140	31140
310002	35644	35614
310009	35644	35614
310014	37964	37964
310015	35644	35614
310017	35644	35614
310031	20764	35614
310038	35644	20524

PROPOSED HOSPITAL RECLASSIFICATION REASSIGNMENTS FOR HOSPITALS THAT ARE RECLASSIFIED TO CBSAS FROM WHICH COUNTIES WOULD BE SPLIT OFF AND MOVED TO A DIFFERENT CBSA—Continued

CMS Certification number (CCN)	Current reclassified CBSA	Proposed reassigned CBSA
310039	35644	20524
310050	35644	35614
310054	35644	35614
310070	35644	20524
310076	35644	35614
310083	35644	35614
310096	35644	35614
310108	35644	20524
310119	35644	35614
330027	35644	35614
330106	35644	35614
330126	35644	20524
330135	35644	20524
330167	35644	35614
330181	35644	35614
330182	35644	35614
330198	35644	35614
330205	35644	20524
330224	39100	20524
330225	35644	35614
330259	35644	35614
330264	35644	20524
330331	35644	35614
330332	35644	35614
330372	35644	35614
340042	48900	48900
340068	48900	34820
390044	37964	33874
390096	37964	33874
390316	37964	33874
420085	48900	48900
510062	16620	16620
510070	16620	16620

Table 9A–2 for this proposed rule (which is available via the Internet on the CMS Web site) reflects all proposed reassignments of hospital reclassifications. We are proposing that hospitals that disagree with our determination of the most proximate county must provide an alternative method for determining proximity to CMS within 45 days from the publication of this proposed rule.

The hospital's request for reassignment should contain the hospital's name, address, CCN, and point of contact information. All requests must be sent to *WageIndex@cms.hhs.gov*. Changes to a hospital's CBSA assignment on the basis of a hospital's disagreement with our determination of closest county, or on the basis of being granted a reassignment due to meeting applicable proximity criteria to an eligible CBSA will be announced in the FY 2015 IPPS final rule.

(3) Reclassifications to CBSAs That Would Contain Hospital's Geographic County

We identified 14 reclassified hospitals that would be geographically located in their reclassified labor market area under the new OMB delineations. For example, hospital 34–0015 is located in Rowan County, NC. Rowan County is currently a Micropolitan Statistical Area in NC, and treated as rural. The hospital is reclassified to CBSA 16740 (Charlotte-Concord-Rock Hill, NC–SC). Under the new OMB delineations, CBSA 16740 (Charlotte-Concord-Gastonia, NC–SC) would include Rowan County. Therefore, the current reclassification would become redundant. CBSA 16740 did not lose any counties to another labor market area; therefore, assignment to another alternate CBSA would not be an option under our proposed methodology. Because, by definition, a hospital would not be ''reclassified'' to its own geographic labor market area, and maintaining that ''reclassified'' status to its own geographic labor market area would serve no beneficial purpose for a hospital, we expect that all such affected hospitals would wish to terminate their reclassification status. Therefore, we are assuming for purposes of this proposed rule that the affected hospitals would be terminating their reclassification status for the remaining years of their 3-year reclassification period, and for FY 2015, we are proposing to assign them the wage index of the CBSA in which they are geographically located. Affected hospitals should inform CMS if they wish to retain their current reclassification by sending notice to *WageIndex@cms.hhs.gov* within 45 days from the publication of this proposed rule. If an affected hospital does not inform us that they wish to retain their current reclassification, we will assume that the hospital has elected to terminate the reclassification. For purposes of this proposed rule, we are presenting tables under the presumption that all 14 hospitals will opt to cancel their reclassification status. We are proposing to assign these hospitals the wage index value of their home area from Table 4A–2 for this proposed rule (which is available via the Internet on the CMS Web site), and not include them as reclassified hospitals in Table 9A–2 for this proposed rule (which is available via the Internet on the CMS Web site).

HOSPITALS RECLASSIFIED TO PROPOSED HOME LABOR MARKET AREA

CMS certification No. (CCN)	Current geographic CBSA	Proposed geographic CBSA
340015	34	16740
340129	34	16740
340144	34	16740
420036	42	16740
450596	45	23104
420027	11340	24860
150088	11300	26900
150113	11300	26900
190003	19	29180
440073	44	34980
460017	46	36260
460039	46	36260
190144	19	43340
490019	49	47894

We have included a footnote for Table 9A–2 for this proposed rule indicating that these hospitals have been removed from this table, pending notification by the hospitals.

c. Applications for Reclassifications for FY 2016

Applications for FY 2016 reclassifications are due to the MGCRB by September 2, 2014 (the first working day of September 2014). We note that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under 42 CFR 412.273(d). As discussed in section III.B. of the preamble of this proposed rule, we are proposing to adopt the new OMB labor market area delineations announced on February 28, 2013. Therefore, hospitals would apply for reclassifications based on the new OMB delineations we are proposing to use for FY 2015. Applications and other information about MGCRB reclassifications may be obtained via the Internet on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/index.html*, 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.

We also are proposing changes to the regulations at § 412.232(b)(2) and § 412.234(a)(3)(iv) to include reference to the most recent OMB standards for delineating statistical areas (using the most recent Census Bureau data and estimates) that were adopted by CMS. For rural groups, the group of hospitals must demonstrate that the county in which the hospitals are located meets the standards for redesignation to an MSA as an ''outlying county.'' For urban groups, hospitals located in counties that are in the same combined statistical area or CBSA as the urban area to which

they seek redesignation qualify as meeting the proximity requirements for reclassification to the urban area to which they seek redesignation. We are not proposing any changes to the reclassification policy, but would include language to reflect use of the most recent OMB standards for delineating statistical areas (using the most recent Census Bureau data and estimates) that were adopted by CMS in consideration of group reclassification applications submitted for review in FY 2015 (that is submitted by September 30, 2014, reviewed by the MGCRB in FY 2015, to be effective in FY 2016) and future years.

3. Redesignation of Hospitals Under Section 1886(d)(8)(B) of the Act

Section 1886(d)(8)(B)(i) of the Act requires the Secretary to ''treat a hospital located in a rural county adjacent to one or more urban areas as being located in the urban metropolitan statistical area to which the greatest number of workers in the county commute'' if certain adjacency and commuting criteria are met. The criteria utilize standards for designating Metropolitan Statistical Areas published in the **Federal Register** by the Director of the Office of Management and Budget (OMB) based on the most recently available decennial population data. Effective beginning FY 2005, we used OMB's CBSA standards based on the 2000 Census and the 2000 Census 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.

As discussed in section III.B. of the preamble to this proposed rule, we are proposing to implement OMB's revised labor market area delineations based on the Census 2010 data for purposes of determining applicable wage indexes for acute care hospitals beginning in FY 2015. As we have done in the past, we also are proposing to use the new OMB delineations to identify rural counties that would qualify as ''Lugar'' under section 1886(d)(8)(B) of the Act and therefore would be redesignated to urban areas for FY 2015. We are proposing to revise the regulations at § 412.64(b)(3)(i) to reflect the most recent OMB standards for delineating statistical areas adopted by CMS. By applying the new OMB delineations, the number of qualifying counties, shown in the following chart, would increase from 98 to 127. After evaluating and analyzing the 2010 Census commuting data, we are proposing that, effective for discharges on or after October 1, 2014, in accordance with section 1886(d)(8)(B) of the Act, hospitals located in the rural counties listed in the first column of the following table would be designated as part of the urban area listed in the second column based on the criteria discussed above. We note that rural counties that no longer meet the qualifying criteria to be Lugar are discussed below in section III.H.3.c. of the preamble of this proposed rule.

RURAL COUNTIES CONTAINING HOSPITALS REDESIGNATED AS URBAN UNDER SECTION 1886(d)(8)(B) OF THE ACT (BASED ON NEW OMB DELINEATIONS AND CENSUS 2010 DATA)

Rural county		Lugar designated CBSA		*NEW*
County name	State	CBSA	CBSA name	
Chambers County	AL	12220	Auburn-Opelika, AL	*New.*
Cherokee County	AL	40660	Rome, GA	
Cleburne County	AL	11500	Anniston-Oxford-Jacksonville, AL	*New.*
Macon County	AL	12220	Auburn-Opelika, AL	
Talladega County	AL	11500	Anniston-Oxford-Jacksonville, AL	
Denali Borough	AK	21820	Fairbanks, AK	*New.*
Hot Spring County	AR	26300	Hot Springs, AR	
Litchfield County	CT	35300	New Haven-Milford, CT	
Bradford County	FL	27260	Jacksonville, FL	
Levy County	FL	23540	Gainesville, FL	
Washington County	FL	37460	Panama City, FL	*New.*
Chattooga County	GA	40660	Rome, GA	
Jackson County	GA	12060	Atlanta-Sandy Springs-Roswell, GA	
Lumpkin County	GA	12060	Atlanta-Sandy Springs-Roswell, GA	
Polk County	GA	40660	Rome, GA	
Talbot County	GA	17980	Columbus, GA-AL	
Oneida County	ID	36260	Ogden-Clearfield, UT	*New.*
Christian County	IL	44100	Springfield, IL	
Iroquois County	IL	28100	Kankakee, IL	
Logan County	IL	44100	Springfield, IL	
Mason County	IL	37900	Peoria, IL	
Ogle County	IL	40420	Rockford, IL	
Union County	IL	16060	Carbondale-Marion, IL	
Clinton County	IN	29200	Lafayette-West Lafayette, IN	
Greene County	IN	14020	Bloomington, IN	*New.*
Henry County	IN	26900	Indianapolis-Carmel-Anderson, IN	
Marshall County	IN	43780	South Bend-Mishawaka, IN-MI	*New.*
Parke County	IN	45460	Terre Haute, IN	*New.*
Spencer County	IN	21780	Evansville, IN-KY	
Starke County	IN	16980	Chicago-Naperville-Elgin, IL-IN-WI	
Tipton County	IN	26900	Indianapolis-Carmel-Anderson, IN	*New.*
Warren County	IN	29200	Lafayette-West Lafayette, IN	
Boone County	IA	11180	Ames, IA	
Buchanan County	IA	47940	Waterloo-Cedar Falls, IA	
Cedar County	IA	26980	Iowa City, IA	
Delaware County	IA	20220	Dubuque, IA	*New.*
Iowa County	IA	26980	Iowa City, IA	*New.*

RURAL COUNTIES CONTAINING HOSPITALS REDESIGNATED AS URBAN UNDER SECTION 1886(d)(8)(B) OF THE ACT (BASED ON NEW OMB DELINEATIONS AND CENSUS 2010 DATA)—Continued

Rural county		Lugar designated CBSA		*NEW*
County name	State	CBSA	CBSA name	
Jasper County	IA	19780	Des Moines-West Des Moines, IA	*New.*
Franklin County	KS	28140	Kansas City, MO-KS	*New.*
Nelson County	KY	31140	Louisville/Jefferson County, KY-IN	*New.*
Assumption Parish	LA	12940	Baton Rouge, LA	
Jefferson Davis Parish	LA	29340	Lake Charles, LA	*New.*
St. Landry Parish	LA	29180	Lafayette, LA	*New.*
Oxford County	ME	30340	Lewiston-Auburn, ME	*New.*
Caroline County	MD	12580	Baltimore-Columbia-Towson, MD	*New.*
Franklin County	MA	44140	Springfield, MA	*New.*
Allegan County	MI	24340	Grand Rapids-Wyoming, MI	
Ionia County	MI	24340	Grand Rapids-Wyoming, MI	*New.*
Lenawee County	MI	11460	Ann Arbor, MI	*New.*
Newaygo County	MI	24340	Grand Rapids-Wyoming, MI	*New.*
Shiawassee County	MI	29620	Lansing-East Lansing, MI	
Tuscola County	MI	40980	Saginaw, MI	
Goodhue County	MN	33460	Minneapolis-St. Paul-Bloomington, MN-WI	*New.*
Meeker County	MN	33460	Minneapolis-St. Paul-Bloomington, MN-WI	*New.*
Rice County	MN	33460	Minneapolis-St. Paul-Bloomington, MN-WI	*New.*
Pearl River County	MS	25060	Gulfport-Biloxi-Pascagoula, MS	
Stone County	MS	25060	Gulfport-Biloxi-Pascagoula, MS	*New.*
Dade County	MO	44180	Springfield, MO	
Otoe County	NE	30700	Lincoln, NE	*New.*
Douglas County	NV	16180	Carson City, NV	*New.*
Lyon County	NV	16180	Carson City, NV	
Los Alamos County	NM	42140	Santa Fe, NM	
Cayuga County	NY	45060	Syracuse, NY	
Cortland County	NY	27060	Ithaca, NY	*New.*
Genesee County	NY	40380	Rochester, NY	
Greene County	NY	10580	Albany-Schenectady-Troy, NY	
Lewis County	NY	48060	Watertown-Fort Drum, NY	*New.*
Montgomery County	NY	10580	Albany-Schenectady-Troy, NY	*New.*
Schuyler County	NY	27060	Ithaca, NY	
Seneca County	NY	40380	Rochester, NY	*New.*
Camden County	NC	47260	Virginia Beach-Norfolk-Newport News, VA-NC	*New.*
Caswell County	NC	15500	Burlington, NC	
Granville County	NC	20500	Durham-Chapel Hill, NC	
Greene County	NC	24780	Greenville, NC	*New.*
Harnett County	NC	39580	Raleigh, NC	
Polk County	NC	43900	Spartanburg, SC	
Wilson County	NC	40580	Rocky Mount, NC	*New.*
Traill County	ND	24220	Grand Forks, ND-MN	*New.*
Ashtabula County	OH	17460	Cleveland-Elyria, OH	
Champaign County	OH	44220	Springfield, OH	
Columbiana County	OH	49660	Youngstown-Warren-Boardman, OH-PA	
Harrison County	OH	48260	Weirton-Steubenville, WV-OH	*New.*
Preble County	OH	19380	Dayton, OH	*New.*
Clinton County	PA	48700	Williamsport, PA	
Fulton County	PA	25180	Hagerstown-Martinsburg, MD-WV	*New.*
Greene County	PA	38300	Pittsburgh, PA	
Lawrence County	PA	38300	Pittsburgh, PA	*New.*
Schuylkill County	PA	39740	Reading, PA	
Susquehanna County	PA	13780	Binghamton, NY	
Adjuntas Municipio	PR	38660	Ponce, PR	*New.*
Coamo Municipio	PR	41980	San Juan-Carolina-Caguas, PR	*New.*
Las Marías Municipio	PR	32420	Mayagüez, PR	*New.*
Maricao Municipio	PR	32420	Mayagüez, PR	*New.*
Salinas Municipio	PR	25020	Guayama, PR	*New.*
Clarendon County	SC	44940	Sumter, SC	
Colleton County	SC	16700	Charleston-North Charleston, SC	*New.*
Lee County	SC	44940	Sumter, SC	
Marion County	SC	22500	Florence, SC	*New.*
Newberry County	SC	17900	Columbia, SC	*New.*
Meigs County	TN	17420	Cleveland, TN	
Blanco County	TX	12420	Austin-Round Rock, TX	*New.*
Bosque County	TX	47380	Waco, TX	
Calhoun County	TX	47020	Victoria, TX	*New.*
Fannin County	TX	19100	Dallas-Fort Worth-Arlington, TX	
Grimes County	TX	17780	College Station-Bryan, TX	
Harrison County	TX	30980	Longview, TX	

RURAL COUNTIES CONTAINING HOSPITALS REDESIGNATED AS URBAN UNDER SECTION 1886(d)(8)(B) OF THE ACT (BASED ON NEW OMB DELINEATIONS AND CENSUS 2010 DATA)—Continued

Rural county		Lugar designated CBSA		NEW
County name	State	CBSA	CBSA name	
Henderson County	TX	46340	Tyler, TX	
Hill County	TX	19100	Dallas-Fort Worth-Arlington, TX	*New.*
Milam County	TX	12420	Austin-Round Rock, TX	
Van Zandt County	TX	19100	Dallas-Fort Worth-Arlington, TX	
Willacy County	TX	15180	Brownsville-Harlingen, TX	
King and Queen County	VA	40060	Richmond, VA	*New.*
Louisa County	VA	40060	Richmond, VA	*New.*
Madison County	VA	16820	Charlottesville, VA	*New.*
Orange County	VA	47900	Washington-Arlington-Alexandria, DC-VA-MD-WV	*New.*
Page County	VA	25500	Harrisonburg, VA	
Shenandoah County	VA	49020	Winchester, VA-WV	
Southampton County	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC	*New.*
Surry County	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC	*New.*
Island County	WA	42660	Seattle-Tacoma-Bellevue, WA	
Mason County	WA	36500	Olympia-Tumwater, WA	
Jackson County	WV	16620	Charleston, WV	
Morgan County	WV	25180	Hagerstown-Martinsburg, MD-WV	*New.*
Roane County	WV	16620	Charleston, WV	
Green Lake County	WI	22540	Fond du Lac, WI	
Jefferson County	WI	33340	Milwaukee-Waukesha-West Allis, WI	
Walworth County	WI	33340	Milwaukee-Waukesha-West Allis, WI	

a. Proposed New Lugar Areas for FY 2015

Of the 127 qualifying counties identified as Lugar counties based on the new OMB delineations, 58 counties would be newly designated as Lugar for FY 2015 if we finalize our proposed adoption of the new OMB delineations. Hospitals in these counties, with at least 25 percent of their workers commuting to a higher wage area, effective October 1, 2014, will be deemed to be located in the CBSA to which the highest number of their workers commute (which is identified in the column titled ''Lugar Designated CBSA'' in the table above). Hospitals in these counties would receive the reclassified urban wage index of the corresponding Lugar Designated CBSA, unless they choose to waive their Lugar status, as discussed later in this section.

Some areas that are currently urban counties would be geographically rural if we adopted the new OMB delineations and would meet the requirements for redesignation as Lugar areas. As described in section III.B.2.e.(2) of the preamble of this proposed rule, we are proposing a 3-year hold harmless transitional wage index adjustment for hospitals located in urban counties that become rural under the new OMB delineations. Because Lugar status is a form of redesignation, hospitals that currently are located in urban counties that would become rural under the new OMB delineations and are also considered Lugar areas under the new OMB delineations would not be eligible for the 3-year transition wage index adjustment unless they choose to waive Lugar status for FY 2015 (as discussed later in this section) and seek no other form of wage index reclassification.

b. Hospitals Redesignated Under Section 1886(d)(8)(B) of the Act Seeking Reclassification by the MGCRB

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. Using Table 4C associated with this proposed rule (which is available via the Internet on the CMS Web site), affected hospitals may compare the reclassified wage index for the labor market area into which they would be reclassified by the MGCRB to the reclassified 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 2015 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 the FY 2008 IPPS final rule with comment period (72 FR 47337 through 47338) for a discussion of this policy.)

c. Rural Counties No Longer Meeting the Criteria To Be Redesignated as Lugar

If we adopt the new OMB delineations, 29 rural counties would no longer meet the qualifying criteria to be redesignated as Lugar effective October 1, 2014, either because they would be geographically located in an urban area, or they would fail to meet the 25-percent cumulative out-migration threshold with application of the new 2010 Census commuting data.

Counties that were deemed urban under section 1886(d)(8)(B) of the Act in FY 2014, but would be geographically located in an urban area under the new OMB delineations for FY 2015 are:

Windham County, CT
Flagler County, FL
Walton County, FL
Morgan County, GA
Peach County, GA
De Witt County, IL
Allen County, KY
St. James Parrish, LA
Montcalm County, MI
Fillmore County, MN
Lincoln County, NC
Cotton County, OK
Linn County, OR
Adams County, PA
Monroe County, PA
Falls County, TX
Buckingham County, VA
Floyd County, VA
Green County, WI

Counties that would fail to meet the 25-percent threshold in FY 2015 are:

Banks County, GA
Hendry County, FL
Bingham County, ID
Oceana County, MI
Columbia County, NY
Sullivan County, NY
Wyoming County, NY
Oconee County, SC
Middlesex County, VA
Wahkiakum County, WA

In section III.B.2.e.(2) of the preamble of this proposed rule, to help ease dramatic negative impacts in payment for hospitals designated as urban under the current FY 2014 OMB delineations, but would be classified as rural under the new OMB delineations, for FYs 2015, 2016, and 2017, assuming no other form of wage index reclassification or redesignation is granted, we are proposing to assign these hospitals the FY 2015 area wage index value of the urban CBSA to which they geographically belonged in FY 2014 (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied to the area wage index). (For purposes of the wage index computation, the wage data of these hospitals would remain assigned to the statewide rural area in which they are located.) Similarly, we are proposing that the same 3-year transition apply to hospitals located in those counties that would lose their deemed urban designation under section 1886(d)(8)(B) of the Act and would become rural if we adopt the new OMB delineations. Because these hospitals would, in fact, lose their designated urban status, we are proposing to extend the 3-year hold harmless transitional wage index adjustment to these hospitals located in counties formerly designated as urban under section 1886(d)(8)(B) of the Act. That is, for FYs 2015, 2016, and 2017, assuming no other form of wage index reclassification or redesignation is granted, we are proposing to assign these hospitals the FY 2015 area wage index value of the urban CBSA to which they were designated as urban in FY 2014 (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied). We are proposing to use the wage data from these hospitals as part of computing the rural wage index. In addition, during this 3-year transition period, these hospitals would be eligible to apply for reclassification by the MGCRB. As discussed in section III.B.2.e.(3) of the preamble of this proposed rule, we are proposing that if a hospital is currently located in an urban county that would become rural for FY 2015 under the new OMB delineations, and such hospital seeks and is granted any reclassification or redesignation during FYs 2015, 2016, or 2017, the hospital would permanently lose its 3-year transitional assigned wage index, and would not be able to reinstate it. Similarly, we are proposing that this policy also apply to hospitals located in those counties that would lose their deemed urban designation under section 1886(d)(8)(B) of the Act and would become rural if we adopt the new OMB delineations. In FY 2018, we are proposing that these hospitals would receive their statewide rural wage index.

4. 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.F. of the preamble of this proposed rule.)

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 45 days from the publication of the proposed rule) to waive its urban status for the full 3-year period for which its out-migration adjustment is effective. By doing so, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. Therefore, 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. If the hospital does notify CMS that it is electing to return to its deemed urban status, it would again be treated as urban for all IPPS payment purposes.

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.

5. Update of Application of Urban to Rural Reclassification Criteria

Section 401(a) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), which amended section 1886(d)(8) of the Act by adding a new paragraph (E), directed the Secretary to treat any subsection (d) hospital located in an urban area as being located in the rural area of the State in which the hospital is located, providing that the hospital applied for reclassification in a manner determined by the Secretary and met certain criteria. As discussed in the FY 2001 interim final rule (65 FR 47029 through 47031), we codified in regulation at § 412.103 the application process and the qualifying criteria for any hospital seeking rural reclassification.

In order to be approved for a rural reclassification, a hospital must meet one of three criteria. The first criterion, located at § 412.103(a)(1), qualifies a hospital located in a rural census tract of an MSA area, as determined under the most recent version of the Goldsmith Modification, the Rural-Urban Commuting Area (RUCA) codes. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. These delineations are based on 2010 decennial Census data. Several modifications of RUCA codes were necessary to take into account updated commuting data and revised OMB delineations. We refer readers to the U.S. Department of Agriculture's Economic Research Service Web site for a detailed listing of updated RUCA codes found at: *http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx*. The updated RUCA code definitions were introduced in late 2013. As discussed at § 412.103(f), the duration of an approved rural reclassification remains in effect without need for reapproval unless there is a change in the circumstances under which the

classification was approved. If a hospital located in an urban area was approved for a rural reclassification under § 412.103(a)(1), that reclassification would no longer be valid if the hospital is no longer located within a rural census tract of an MSA defined as an RUCA. Therefore, we encourage all hospitals with active rural reclassifications under section 1886(d)(8)(E) of the Act to review their original reclassification application and determine whether the reclassification status would still apply. As discussed in section VI.C.2. of the preamble of this proposed rule, we are proposing a 2-year grace period allowing affected CAHs additional time to seek a new rural reclassification without the threat of losing its CAH status. As discussed in section VI.C.2. of the preamble of this proposed rule, we are not proposing a grace period for other types of hospitals to seek a new rural reclassification. We note that rural reclassification status under § 412.103 is effective as of the filing date of the application. Therefore, if the change in RUCA codes invalidates any hospital's rural reclassification status, we believe hospitals will have adequate time to apply for a new reclassification using an alternative qualification criterion specified at either § 412.103(a)(2) or § 412.103(a)(3). A rural referral center (RRC) or a sole community hospital (SCH) that continues to meet the appropriate qualification criteria would, in itself, qualify for a rural reclassification. If a complete application is received before October 1, 2014, and is approved by the CMS Regional Office, the hospital would experience no interruption in its rural status.

I. Proposed FY 2015 Wage Index Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the ''out-migration'' adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index.

When this provision was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau which was derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the ''long-form'' survey, which the Census Bureau used at the time, and it contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was ''short form'' only; therefore, this information was not collected as part of the 2010 Census. The Census Bureau is working with CMS to provide an alternative dataset based on the latest available data that is expected to meet our needs for developing a new out-migration adjustment. We believe we will have the necessary time to obtain, review and analyze the data in order to propose new out-migration adjustments based on new commuting patterns developed from the 2010 Census data beginning with FY 2016. Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. The data used for the FY 2014 out-migration adjustment are the most recent data that have been analyzed, and we believe that these data are appropriate to establish the qualifying counties. Therefore, we are proposing that the FY 2015 out-migration adjustments continue to be based on the 2000 Census data. We also are proposing that the FY 2015 out-migration adjustments continue to be based on the policies, procedures, and computation that were used for the FY 2014 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) of the Act to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602)). Table 4J, which is available via the Internet on the CMS Web site, lists the proposed out-migration adjustments for the proposed FY 2015 wage index.

Section 1886(d)(13)(F) of the Act states that ''[a] wage index increase under this paragraph shall be effective for a period of 3 fiscal years, except that the Secretary shall establish procedures under which a subsection (d) hospital may elect to waive the application of such wage index increase.'' Therefore, for FY 2015, because we are proposing to continue to use the out-migration adjustment data used for FY 2014, consistent with the statute, we also are proposing to allow hospitals that qualified in FY 2013 or FY 2014 to receive the out-migration adjustment based on the commuting data and the CBSA delineations used for FY 2014 to continue to receive the same out-migration adjustment for the remainder of their 3-year qualification period. Similarly, if a hospital qualifies for and opts to receive the out-migration adjustment for the first time in FY 2015, we also are proposing to allow that hospital to receive the out-migration adjustment based on the data used for FY 2014 for FYs 2015, 2016, and 2017. Accordingly, even if we propose to adopt new out-migration adjustment data for FY 2016, as we believe we will be able to do, hospitals that are already receiving an out-migration adjustment beginning with a fiscal year prior to FY 2016 would still receive their out-migration adjustment based on the data used for FY 2014 for the years that remain of their 3-year qualification period in FY 2016 and after.

We intend to address application of the FY 2016 out-migration adjustment in greater detail in the FY 2016 proposed rule. However, in this FY 2015 proposed rule, we are soliciting comments on how to implement the new out-migration adjustment data for FY 2016, given the statutory requirement at section 1886(d)(13)(F) of the Act that an out-migration adjustment be effective for 3 fiscal years.

As discussed in section III.B. of the preamble of this proposed rule, we are proposing to use OMB's new labor market area delineations based on the 2010 Census data to identify counties qualifying as Lugar counties for FY 2015. In section III.H.3 of the preamble of this proposed rule, we discuss hospitals located in rural counties that are deemed to be urban under section 1886(d)(8)(B) of the Act. These rural counties are known as ''Lugar'' counties. Under the new OMB delineations, there would be counties newly qualifying as Lugar as well as counties that were previously Lugar counties that would no longer meet the criteria to be redesignated as Lugar. As discussed in section III.H.4. of the preamble of this proposed rule, if a Lugar hospital qualifies for and accepts the out-migration adjustment, it must waive its deemed urban status and can do so for the 3-year period for which the out-migration adjustment is effective. Therefore, hospitals located in counties newly designated as Lugar due to the new OMB delineations would have the choice to either maintain their Lugar status or waive it in order to receive the out-migration adjustment in FY 2015 based on the out-migration adjustment data used for FY 2014.

On the other hand, there are hospitals in counties deemed to be Lugar under

the previous CBSA delineations that waived their Lugar status for the out-migration adjustment, but are not Lugar under the new OMB delineations. These hospitals would continue to receive the out-migration adjustment for the 3-year eligibility period through FY 2015 or FY 2016. However, these hospitals that are located in urban counties under the new OMB delineations, and wish to continue to maintain their rural status effective October 1, 2014, must do so by reclassifying from urban to rural under § 412.103. Section 1886(d)(13)(G) of the Act states that a hospital cannot simultaneously receive the out-migration adjustment and be subject to a reclassification under section 1886(d)(8) or 1886(d)(10) of the Act. Therefore, if such hospital is not located in a geographically rural area under the new OMB delineations, and reclassifies under § 412.103 of the regulations in order to be treated as rural for IPPS purposes, the hospital would be ineligible to receive an out-migration adjustment, even if the 3-year eligibility period has not expired.

As discussed in section III.B.5. of the preamble of this proposed rule, we are proposing a 1-year blended wage index for any provider that experiences a decrease in wage index value due to the proposed implementation of the new OMB labor market area delineations. This proposal would create a wage index that is 50 percent of the wage index derived using the current FY 2014 OMB delineations, and 50 percent of the wage index based on the proposed new OMB delineations. As discussed in section III.B.2.e.(4) of the preamble of this proposed rule, we are proposing to apply this blended wage index value to any affected hospital in a budget neutral manner. However, we are proposing that hospitals receiving the out-migration adjustment would have it added to the result of the 50/50 blended wage index, after budget neutrality is applied. We are proposing the blended wage index transition adjustment specifically to address any negative impact that may be caused by the proposed adoption of the new OMB delineations in FY 2015. To specifically identify and address any such negative payment impact, we are proposing to apply the out-migration adjustment independent of the blended wage index and other wage index adjustments (for example, the rural floor) and related budget neutrality adjustments. This is consistent with our current policy to apply the out-migration adjustment after all other wage index adjustments and related budget neutrality adjustments have been applied. Therefore, we believe the out-migration adjustment would be properly applied as a supplemental addition to a hospital's final wage index value, similar to our treatment of hospitals receiving the frontier State floor value of 1.00, as described under 42 CFR 412.64(m), that also qualify for an out-migration adjustment and would receive that adjustment.

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 2015 wage index were made available on September 13, 2013, through the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY-2015-Wage-Index-Home-Page.html*.

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 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.gov/Outreach-and-Education/Outreach/OpenDoorForums/index.html*.

In a memorandum dated September 16, 2013, we instructed all 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 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 September 13, 2013 wage and occupational mix data files, the hospital was to submit corrections along with complete, detailed supporting documentation to its MAC by November 21, 2013. Hospitals were notified of this deadline and of all other deadlines and requirements, including the requirement to review and verify their data as posted in the preliminary wage index data files on the Internet, through the September 16, 2013 memorandum referenced above.

In the September 16, 2013 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 September, highlight the revised cells on its spreadsheet, and submit its spreadsheet(s) and complete documentation to its MAC no later than November 21, 2013.

The MACs notified the hospitals by early-February 2014 of any changes to the wage index data as a result of the desk reviews and the resolution of the hospitals' late-November revision requests. The MACs also submitted the revised data to CMS by late January 2014. CMS published the proposed wage index public use files that included hospitals' revised wage index data on February 20, 2014. Hospitals had until March 3, 2014, to submit requests to the MACs for reconsideration of adjustments made by the MACs as a result of the desk review, and to correct errors due to CMS' or 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, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by April 9, 2014. The deadline for a hospital to request CMS intervention in cases where the hospital disagreed with the MAC's policy interpretations was April 16, 2014. We note that, beginning with the FY 2015 wage index, per the FY 2015 wage index timeline posted on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2015-WI-Timeline.pdf*, the April appeals must be sent via mail and email. We refer readers to the wage index timeline for complete details.

Upon release of this proposed rule, hospitals should examine Table 2, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY-2015-Wage-Index-Home-Page.html*. Table 2 contains each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2011 data used to construct the proposed FY 2015 wage index. We note that the proposed hospital average hourly wages shown in

Table 2 only reflect changes made to a hospital's data that were transmitted to CMS by February 26, 2014.

The final wage index data public use files are posted on May 2, 2014 on the Internet at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY-2015-Wage-Index-Home-Page.html*. The May 2014 public use files are made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process described above (revisions submitted to CMS by the MACs by April 9, 2014).

After the release of the May 2014 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 MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before April 9, 2014.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the February 20, 2014 wage index public use files.
- Requests to revisit factual determinations or policy interpretations made by the MAC or CMS during the wage index data correction process.

If, after reviewing the May 2014 final public use files, a hospital believes that its wage or occupational mix data are incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital should notify both its MAC and CMS regarding why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital is required to send its request to CMS and to the MAC no later than June 2, 2014. Similar to the April appeals, beginning with the FY 2015 wage index, in accordance with the FY 2015 wage index timeline posted on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2015-WI-Timeline.pdf*, the June appeals must be sent via mail and email to CMS and the MACs. We refer readers to the wage index timeline for complete details. (We refer readers to section II.K. of the preamble to this proposed rule where we are proposing revisions to the wage index timetable.)

Verified corrections to the wage index data received timely by CMS and the MACs (that is, by June 2, 2014) will be incorporated into the final wage index in the FY 2015 IPPS/LTCH PPS final rule, which will be effective October 1, 2014.

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 2015 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 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 PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections.

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 MAC's attention. Moreover, because hospitals have access to the final wage index data by early May 2014, they have the opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 2015 wage index by August 2014, and the implementation of the FY 2015 wage index on October 1, 2014. 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 2, 2014, 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 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 deadline for making corrections to the wage data for the following fiscal year's wage index (for example, June 2, 2014 for the FY 2015 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 MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) The MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the June 2, 2014 deadline for the FY 2015 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the June 2, 2014 deadline for the FY 2015 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; and it can only be used for the current Federal fiscal year. In situations where our policies would allow midyear

corrections other than those specified in 42 CFR 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

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

K. Notice of Change to Wage Index Development Timetable

As explained in section III.J. the preamble of this proposed rule, the preliminary, unaudited Worksheet S–3 wage data and occupational mix survey data files for the proposed FY 2015 wage index were made available on September 13, 2013, through the Internet on the CMS Web site. The posting of these preliminary files initiate what is virtually a year-long cycle for developing the wage index associated with the following IPPS fiscal year. This lengthy, almost year-long cycle is unique to the development of the IPPS wage index, and occurs independently from the development of the IPPS proposed and final rules, which typically are published in the spring and summer each year. In addition, the wage index, which is based on hospitals' wage data reported on Worksheets S–3, Parts II and III of the Form CMS–2552–10 of the Medicare cost report and occupational mix data, is the only portion of the IPPS that historically has been subject to its own annual review process, first by the MACs, and then by CMS, followed by distinct opportunities for hospitals to appeal decisions made by the MACs or CMS. This process is separate and independent from the standard cost report settlement and appeals processes established under the regulations at 42 CFR 405.1800 through 405.1889.

Although this unique wage index development timetable has been in place since the early days of the IPPS, the current timetable is rooted in changes adopted in the FY 1998 IPPS final rule with comment period (62 FR 45990 through 45993). However, with numerous legislative and regulatory changes made to the IPPS since FY 1998, the demands on hospitals, MACs, and CMS have increased substantially. As a result, it has become increasingly challenging for wage index stakeholders to manage the wage index timetable with competing priorities. For the FY 2015 wage index, CMS made slight changes to the wage index development timetable, by posting the preliminary public use file (PUF) in September 2013 rather than in October 2013, which, in turn, moved back the deadline for hospitals to request revisions to the data displayed in that preliminary PUF to November 2013, instead of December 2013. In addition, the date for the MACs to complete desk reviews on that data was similarly moved to a slightly earlier deadline in early CY 2014. The FY 2015 Wage Index Development Timetable, which is posted on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2015-WI-Timeline.pdf*, shows that hospitals have a little more than 2 months to request revisions to their data displayed in the September 13, 2013 preliminary PUF, until the commencement of the desk review process by the MACs on November 21, 2013. The MACs also have a little more than 2 months to complete the desk reviews and submit revised cost report data to CMS by January 29, 2014. Less than a month later, on February 20, 2014, the revised FY 2015 wage index and occupational mix PUFs were posted on the CMS Web site. Ensuring the accuracy of the February PUF is extremely important and beneficial to hospitals because, as the timetable shows, it is the basis for hospitals to appeal data that are incorrect, with March 3, 2014 being the last date that hospitals can request revisions to errors in the February 20, 2014 PUF.

Therefore, we have concluded that steps should be taken to improve the accuracy of the February PUF, most importantly by proposing changes to the wage index timetables for future IPPS fiscal years that are much more significant and fundamental than the slight revisions to the timetable implemented for FY 2015. We believe that the changes we are proposing below would not only improve the accuracy of the February PUF, but also would reduce the number of hospital appeals based on the February PUF. For example, as specified below, instead of the current timetable which only provides CMS with less than a month to review the MACs' desk reviews and prepare the February PUF, we are proposing approximately 3 months between the date that the MACs' desk reviews would end and the date that CMS would post the subsequent PUF. To allow hospitals and MACs adequate time to prepare for the changes to the wage index development timetable, we are proposing to make the following significant changes beginning with the FY 2017 wage index cycle. We are listing the proposed changes for FY 2017 below in a table side by side with the existing timetable, so that commenters may read the proposed changes in the context of the existing timetable. Under the proposed changes for FY 2017, although we are not providing exact dates for the FY 2017 wage index timetable, we note that, with every change listed below, we intend to provide hospitals and MACs with the same or somewhat *more* time than under the current timetable to complete reviews and request revisions. The proposed revisions would not reduce the amount of time that either hospitals or MACs have to review wage data. Therefore, these proposed changes would not result in additional work on the part of the hospitals or MACs; in fact, in shifting the various dates, we expect that more time would be provided to hospitals, MACs, and CMS to ensure an even more accurate wage index.

Deadlines	FY 2015 Timetable	Proposed FY 2017 timetable
Posting of Preliminary PUF on CMS Web site	September 13, 2013	Mid May 2015.
Deadline for Hospitals to Request Revisions to Preliminary PUF	November 21, 2013	Early August 2015.
Deadline for MACs to Complete Desk Reviews	January 29, 2014	Mid-October 2015.
Posting of February PUF on CMS Web site	February 20, 2014	Late January 2016.
Deadline Following Posting of February PUF for Hospitals to Request Revisions	March 3, 2014	Mid-February 2016.
Completion of Appeals by MACs and Transmission of Final Wage Data to CMS	April 9, 2014	Mid- to Late March 2016.
Deadline for Hospitals to Appeal in April	April 16, 2014	Early April 2016.
Posting of Final Rule PUF	May 2, 2014	Late April 2016.
Deadline for Hospitals to Appeal in June	June 2, 2014	Late May 2016.
Expected Issuance of IPPS final rule	August 1, 2014	August 1, 2016.

With regard to the FY 2016 wage index cycle, we believe it can serve as a transition to the more significant changes we are proposing for the FY 2017 wage index cycle. We believe that there are steps we can take to improve the accuracy of the February 2016 PUF by building in more time to the FY 2016 wage index review process as well. Specifically, we are notifying hospitals of changes to the deadlines only in the beginning of the FY 2016 wage index timetable, as a transition to the more significant proposed changes for the entire FY 2017 wage index timetable. That is, for FY 2016, we are only changing the following four dates: the posting of the preliminary wage index PUF; the posting of the CY 2013 occupational mix survey data preliminary PUF; the deadline for hospitals to request revisions to the wage data and occupational mix data preliminary PUFs; and the deadline for MACs to complete the desk reviews. We are not changing the remainder of the FY 2016 timetable at this time. We expect that making these changes for the FY 2016 timetable would improve the accuracy of the February 2016 PUF, and also mitigate the number of hospital appeals based on the February 2016 PUF. In addition, we believe these changes would help hospitals, MACs, and CMS adjust to the more significant timeline changes proposed for FY 2017. We are listing only the changes for FY 2016 in the following table side by side with the existing FY 2015 timetable, so that commenters may read the FY 2016 changes in the context of the existing timetable. We are not listing dates that would remain unchanged for FY 2016.

Deadlines	FY 2015 Timetable	Adjusted FY 2016 timetable
Posting of Preliminary Wage Data PUF on CMS Web site	September 13, 2013	Late May 2014.
Posting of Preliminary CY 2013 Occupational Mix Data PUF on CMS Web site	September 13, 2013	Early to Mid-July 2014.
Deadline for Hospitals to Request Revisions to Preliminary PUF	November 21, 2013	Early October 2014.
Deadline for MACs to Complete Desk Reviews	January 29, 2014	Mid-December 2014.

Typically, the preliminary PUF initiating the start of an IPPS wage index fiscal year contains one spreadsheet with the Worksheet S–3 wage data for the applicable fiscal year on one tab, and another tab with the preliminary occupational mix data for that fiscal year. For the FY 2016 wage index, new occupational mix survey data will be available for use, based on the CY 2013 occupational mix survey. Hospitals are required to submit their CY 2013 occupational mix surveys to their MACs no later than July 1, 2014. Therefore, we will not have the preliminary CY 2013 occupational mix survey data in time to post it simultaneously in late May 2014 with the preliminary FY 2016 wage data. Accordingly, as the table above indicates, we would post the preliminary FY 2016 wage data by itself first in late May 2014, to be followed by a separate posting of the preliminary CY 2013 occupational mix survey data when the data are available, in early to mid-July 2014.

We are inviting public comments on our proposals set forth above to make revisions to the wage index timetables for FY 2017.

L. Labor-Related Share for the FY 2015 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 2014 IPPS/LTCH PPS final rule (78 FR 50596 through 50607), we rebased and revised the hospital market basket. We established a FY 2010-based IPPS hospital market basket to replace the FY 2006-based IPPS hospital market basket, effective October 1, 2013. In that final rule, we presented our analysis and conclusions regarding the frequency and methodology for updating the labor-related share for FY 2014. Using the FY 2010-based IPPS market basket, we finalized a labor-related share for FY 2014 of 69.6 percent. 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 2015 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, employee benefits, contract labor, the labor-related portion of professional fees, administrative and facilities support services, and all other labor-related services.

Therefore, for FY 2015, we are proposing to continue to use a labor-related share of 69.6 percent for discharges occurring on or after October 1, 2014. Tables 1A and 1B, which are published in section VI. of the Addendum to this proposed rule and available via the Internet, reflect this proposed labor-related share. For FY 2015, for all IPPS hospitals whose wage indexes are less than or equal to 1.0000, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals whose wage indexes are greater than 1.0000, for FY 2015, we are proposing to apply the wage index to a proposed labor-

related share of 69.6 percent of the national standardized amount. We note that, for Puerto Rico hospitals, the national labor-related share is 62 percent because the national wage index for all Puerto Rico hospitals is less than 1.0.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50601 through 50603), we also rebased and revised the labor-related share for the Puerto Rico-specific standardized amounts using FY 2010 as a base year. We finalized a labor-related share for the Puerto Rico-specific standardized amounts for FY 2014 of 63.2 percent. In this FY 2015 proposed rule, we are not proposing to make any further changes to the Puerto Rico specific average proportion of operating costs that are attributable to wages and salaries, employee benefits, contract labor, the labor-related portion of professional fees, administrative and facilities support services, and all other labor-related services. Therefore, for FY 2015, we are proposing to continue to use a labor-related share for the Puerto Rico-specific standardized amounts of 63.2 percent for discharges occurring on or after October 1, 2014. Puerto Rico hospitals are paid based on 75 percent of the national standardized amounts and 25 percent of the Puerto Rico-specific standardized amounts. For FY 2015, we are proposing to adopt that the labor-related share of a hospital's Puerto Rico-specific rate would be either the Puerto Rico-specific labor-related share of 63.2 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 for FY 2015, we are proposing to set the hospital's rates using a labor-related share of 63.2 percent for the 25 percent portion of the hospital's payment determined by the Puerto Rico standardized amounts because this amount would result in higher payments. Conversely, a hospital with a Puerto Rico-specific wage index of less than or equal to 1.0 for FY 2015 would 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 would result in higher payments. The proposed Puerto Rico labor-related share of 63.2 percent for FY 2015 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. Proposed Changes to MS–DRGs Subject to the Postacute Care Transfer Policy (§ 412.4)

1. Background

Existing regulations at § 412.4(a) define discharges under the IPPS as situations in which a patient is formally released from an acute care hospital or dies in the hospital. Section 412.4(b) defines acute care transfers, and § 412.4(c) defines postacute care transfers. Our policy, set forth in § 412(f), provides that when a patient is transferred and his or her length of stay is less than the geometric mean length of stay for the MS–DRG to which the case is assigned, the transferring hospital is generally paid based on a graduated per diem rate for each day of stay, not to exceed the full MS–DRG payment that would have been made if the patient had been discharged without being transferred.

The per diem rate paid to a transferring hospital is calculated by dividing the full DRG payment by the geometric mean length of stay for the MS–DRG. Based on an analysis that showed that the first day of hospitalization is the most expensive (60 FR 45804), our policy generally provides for payment that is twice the per diem amount for the first day, with each subsequent day paid at the per diem amount up to the full MS–DRG payment (§ 412.4(f)(1)). Transfer cases are also eligible for outlier payments. In general, the outlier threshold for transfer cases, as described in § 412.80(b), is equal to the fixed-loss outlier threshold for nontransfer cases (adjusted for geographic variations in costs), divided by the geometric mean length of stay for the MS–DRG, and multiplied by the length of stay for the case, plus one day.

We established the criteria set forth in § 412.4(d) for determining which DRGs qualify for postacute care transfer payments in the FY 2006 IPPS final rule (70 FR 47419 through 47420). The determination of whether a DRG is subject to the postacute care transfer policy was initially based on the Medicare Version 23.0 GROUPER (FY 2006) and data from the FY 2004 MedPAR file. However, if a DRG did not exist in Version 23.0 or a DRG included in Version 23.0 is revised, we use the current version of the Medicare GROUPER and the most recent complete year of MedPAR data to determine if the DRG is subject to the postacute care transfer policy. Specifically, if the MS–DRG's total number of discharges to postacute care equals or exceeds the 55th percentile for all MS–DRGs and the proportion of short-stay discharges to postacute care to total discharges in the MS–DRG exceeds the 55th percentile for all MS–DRGs, CMS will apply the postacute care transfer policy to that MS–DRG and to any other MS–DRG that shares the same base MS–DRG. In the preamble to the FY 2006 IPPS final rule (70 FR 47419), we stated that ''we will not revise the list of DRGs subject to the postacute care transfer policy annually unless we are making a change to a specific DRG.''

To account for MS–DRGs subject to the postacute care transfer policy that exhibit exceptionally higher shares of costs very early in the hospital stay, § 412.4(f) also includes a special payment methodology. For these MS–DRGs, hospitals receive 50 percent of the full MS–DRG payment, plus the single per diem payment, for the first day of the stay, as well as a per diem payment for subsequent days (up to the full MS–DRG payment (§ 412.4(f)(6)). For an MS–DRG to qualify for the special payment methodology, the geometric mean length of stay must be greater than 4 days, and the average charges of 1-day discharge cases in the MS–DRG must be at least 50 percent of the average charges for all cases within the MS–DRG. MS–DRGs that are part of an MS–DRG group will qualify under the DRG special payment policy if any one of the MS–DRGs that share that same base MS–DRG qualifies (§ 412.4(f)(6)).

2. Proposed Changes to the Postacute Care Transfer MS–DRGs

Based on our annual review of MS–DRGs, we have identified a number of MS–DRGs that should be included on the list of MS–DRGs subject to the postacute care transfer policy. As we discuss in section II.G. of this proposed rule, in response to public comments and based on our analysis of FY 2013 MedPAR claims data, we are proposing to make several changes to MS–DRGs to better capture certain severity of illness levels, to be effective for FY 2015. Specifically, we are proposing to modify the assignment of endovascular cardiac valve replacements currently assigned to MS–DRGs 216 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC), 217 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC), 218 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC), 219 (Cardiac Valve & Other Major Cardiothoracic Procedures

without Cardiac Catheterization with MCC), 220 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC), and 221 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC) to MS–DRGs 266 and 267 (Endovascular Cardiac Valve Replacement with and without MCC, respectively) to better reflect the differences in patients receiving endovascular cardiac valve replacements from patients who undergo an open chest cardiac valve replacement. We also are proposing to further refine back and neck procedures currently assigned to MS–DRGs 490 and 491 (Back & Neck Procedure Except Spinal Fusion with CC/MCC or Disc Device/Neurostimulator and without CC/MCC or Disc Device/Neurostimulator, respectively) into additional severity levels, now identified as MS–DRGs 518, 519, and 520 (Back & Neck Procedure Except Spinal Fusion with MCC or Disc Device/Neurostimulator, with CC, and without MCC/CC, respectively). Finally, we are proposing to remove the severity levels for reverse shoulder replacements, merging MS–DRGs 483 and 484 (Major Joint & Limb Reattachment Procedure of Upper Extremity with CC/MCC and without CC/MCC, respectively) into MS–DRG 483 (Major Joint/Limb Reattachment Procedure of Upper Extremities). A discussion of these proposed changes can be found in section II.G.4.c., II.G.5.c. and II.G.5.a., respectively, of the preamble of this proposed rule.

In light of these proposed changes to the MS–DRGs, according to the regulations under § 412.4(c), we evaluated these proposed FY 2015 MS–DRGs against the general postacute care transfer policy criteria using the FY 2013 MedPAR data. If an MS–DRG qualified for the postacute care transfer policy, we also evaluated that MS–DRG under the special payment methodology criteria according to regulations at § 412.4(f)(6). We continue believe it is appropriate to reassess MS–DRGs when proposing reassignment of diagnostic codes that would result in material changes to an MS–DRG. As a result of our review, we found that MS–DRGs 216 through 221 would require no revisions in postacute care transfer or special payment policy status. However, we are proposing to update the list of MS–DRGs that are subject to the postacute care transfer policy to include the proposed new MS–DRGs 266, 267, 518, 519, and 520. (These MS–DRGs are reflected in Table 5, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site, and also are listed in the charts at the end of this section.)

In addition, based on our evaluation of the proposed FY 2015 MS–DRGs using the FY 2013 Med PAR data, we have determined that proposed revised MS–DRG 483 would no longer meet the postacute care transfer criteria. Therefore, we are proposing that it be removed from the list of MS–DRGs subject to the postacute care transfer policy, effective FY 2015. We refer readers to the asterisk (*) bolded text in the following table for which criterion was not met in our analysis for each MS–DRG removed from the postacute care transfer policy list.

LIST OF MS–DRGS THAT WOULD CHANGE POSTACUTE CARE TRANSFER POLICY STATUS IN FY 2015

MS–DRG	MS–DRG Title	Total cases	Postacute care transfers (55th percentile: 1,471)	Short-stay postacute care transfers	Percent of short-stay postacute care transfers to all cases (55th percentile: 7.9060%) (percent)	Postacute transfer policy status
266	Endovascular Cardiac Valve Replacement with MCC	4,086	2,851	1,030	25.21	YES.
267	Endovascular Cardiac Valve Replacement w/o MCC.	4,476	2,800	835	18.66	YES.
483	Major Joint/Limb Reattachment Procedure of Upper Extremities.	41,372	17,289	2,271	*5.49	NO.
518	Back & Neck Procedure Except Spinal Fusion with MCC or Disc Device/Neurostimulator.	3,844	2,136	412	10.72	YES.
519	Back & Neck Procedure Except Spinal Fusion with CC.	15,238	7,405	1,126	*7.39	YES.**
520	Back & Neck Procedure Except Spinal Fusion without CC/MCC).	31,792	7,859	0	*0.00	YES.**

* Indicates a current postacute care transfer policy criterion that the MS–DRG did not meet.

** As described in the policy at 42 CFR 412.4(d)(3)(ii)(D), MS–DRGs that share the same base MS–DRG will all qualify under the postacute care transfer policy if any one of the MS–DRGs that share that same base MS–DRG qualifies.

Finally, we have determined that MS–DRGs 266, 267, 518, 519, and 520 also would meet the criteria for the special payment methodology. Therefore, we are proposing that they would be subject to the MS–DRG special payment methodology, effective FY 2015.

LIST OF MS–DRGS THAT WOULD CHANGE DRG SPECIAL PAYMENT POLICY STATUS IN FY 2015

MS–DRG	MS–DRG Title	Geometric mean length of stay	Average charges of 1-day discharges	50% of average charges for all cases within MS–DRG	Special pay policy status
266	Endovascular Cardiac Valve Replacement with MCC.	8.3643	$42,081	$126,326	YES.*

LIST OF MS–DRGS THAT WOULD CHANGE DRG SPECIAL PAYMENT POLICY STATUS IN FY 2015—Continued

MS–DRG	MS–DRG Title	Geometric mean length of stay	Average charges of 1-day discharges	50% of average charges for all cases within MS–DRG	Special pay policy status
267	Endovascular Cardiac Valve Replacement without MCC.	5.0271	128,013	95,141	YES.
518	Back & Neck Procedure Except Spinal Fusion with MCC or Disc Device/Neurostimulator.	4.2882	68,515	43,514	YES.
519	Back & Neck Procedure Except Spinal Fusion with CC.	3.0507	0	0	YES.*
520	Back & Neck Procedure Except Spinal Fusion without CC/MCC.	1.7315	0	0	YES.*

*As described in the policy at 42 CFR 412.4(d)(6)(iv), MS–DRGs that share the same base MS–DRG will all qualify under the DRG special payment policy if any one of the MS–DRGs that share that same base MS–DRG qualifies.

B. Proposed Changes in the Inpatient Hospital Update for FY 2015 (§ 412.64(d))

1. Proposed FY 2015 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.'' In FY 2014, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we set the applicable percentage increase under the IPPS by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of 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 0.3 percentage point as required by section 1886(b)(3)(B)(xii) of the Act. 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 2014 adjustment of 0.3 percentage point may result in the applicable percentage increase being less than zero.

For FY 2015, there are three statutory changes to the applicable percentage increase compared to FY 2014. First, under section 1886(b)(3)(B)(viii) of the Act, beginning with FY 2015, the reduction in the applicable percentage increase for hospitals that fail to submit quality information under rules established by the Secretary is one-quarter of the applicable percentage increase (prior to the application of statutory adjustments under sections 1886(b)(3)(B)(ix), 1886(b)(3)(B)(xi), and 1886(b)(3)(B)(xii) of the Act) or one-quarter of the applicable market basket update. For FY 2014, the reduction to the applicable percentage increase for hospitals that failed to submit quality information under rules established by the Secretary was 2.0 percentage points. Second, beginning with FY 2015, section 1886(b)(3)(B)(ix) requires that any hospital that is not a meaningful electronic health record (EHR) user (as defined in section1886(n)(3) of the Act and not subject to an exception under section1886(b)(3)(B)(ix) of the Act)) will have ''three-quarters'' of the applicable percentage increase (prior to the application of statutory adjustments under sections 1886(b)(3)(B)(viii), 1886(b)(3)(B)(xi), and 1886(b)(3)(B)(xii) of the Act), or three-quarters of the applicable market basket update, reduced by 33⅓ percent. The reduction to three-quarters of the applicable percentage increase for those hospitals that are not meaningful EHR users increases to 66⅔ percent for FY 2016, and, for FY 2017 and subsequent fiscal years, to 100 percent. Third, for FY 2015, section 1886(b)(3)(B)(xii) of the Act applies an additional reduction of 0.2 percentage point compared to 0.3 percentage point for FY 2014.

To summarize, for FY 2015, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a 33⅓ percent reduction to three-fourths of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment), and an additional reduction of 0.2 percentage point as required by section 1886(b)(3)(B)(xii) of the Act. As noted previously, 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 2015 adjustment of 0.2 percentage point may result in the applicable percentage increase being less than zero.

We note that, in compliance with section 404 of the MMA, in the FY 2014 IPPS/LTCH PPS final rule, we replaced the FY 2006-based IPPS operating and capital market baskets with the revised and rebased FY 2010-based IPPS operating and capital market baskets for FY 2014. We are proposing to continue to use the FY 2010-based IPPS operating and capital market baskets for FY 2015. We also are proposing to continue to use a labor-related share that is reflective of the FY 2010 base year. For FY 2015, we are proposing to continue using the labor-related share of 69.6 percent, which is based on the FY 2010-based IPPS market basket.

Based on the most recent data available for this FY 2015 proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are

proposing to base the proposed FY 2015 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Insight, Inc.'s (IGI's) first quarter 2014 forecast of the FY 2010-based IPPS market basket rate-of-increase with historical data through fourth quarter 2013, which is estimated to be 2.7 percent.

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 2015, we are not proposing to make any change in our methodology for calculating and applying the MFP adjustment. For FY 2015, we are proposing a MFP adjustment of −0.4 percentage point. Similar to the market basket adjustment, for this proposed rule, we used the most recent data available to compute the MFP adjustment.

For FY 2015, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount. Below we discuss these four options.

- For a hospital that submits quality data and is a meaningful EHR user, we are proposing an applicable percentage increase to the FY 2015 operating standardized amount of 2.1 percent (that is, the FY 2015 estimate of the market basket rate-of-increase of 2.7 percent less an adjustment of 0.4 percentage point for economy-wide productivity (that is, the MFP adjustment) and less 0.2 percentage point).
- For a hospitals that submits quality data and is not a meaningful EHR user, we are proposing an applicable percentage increase to the operating standardized amount of 1.425 percent (that is, the FY 2015 estimate of the market basket rate-of-increase of 2.7 percent, less an adjustment of 0.675 percentage point (the market basket rate-of-increase of 2.7 percent × 0.75)/3) for failure to be a meaningful EHR user, less an adjustment of 0.4 percentage point for the MFP adjustment, and less an additional adjustment of 0.2 percentage point).
- For a hospital that does not submit quality data and is a meaningful EHR user, we are proposing an applicable percentage increase to the operating standardized amount of 1.425 percent (that is, the FY 2015 estimate of the market basket rate-of-increase of 2.7 percent, less an adjustment of 0.675 percentage point (the market basket rate-of-increase of 2.7 percent/4) for failure to submit quality data, less an adjustment of 0.4 percentage point for the MFP adjustment, and less an additional adjustment of 0.2 percentage point).
- For a hospital that does not submit quality data and is not a meaningful EHR user, we are proposing an applicable percentage increase to the operating standardized amount of 0.75 percent (that is, the FY 2015 estimate of the market basket rate-of-increase of 2.7 percent, less an adjustment of 0.675 percentage point (the market basket rate-of-increase of 2.7 percent/4) for failure to submit quality data, less an adjustment of 0.675 percentage point (the market basket rate-of-increase of 2.7 percent × 0.75)/3) for failure to be a meaningful EHR user, less an adjustment of 0.4 percentage point for the MFP adjustment, and less an additional adjustment of 0.2 percentage point).

If more recent data become subsequently available (for example, a more recent estimate of the market basket and the MFP adjustment), we are proposing to use such data, if appropriate, to determine the FY 2015 market basket update and MFP adjustment in the final rule. Below we provide a table summarizing the four proposed applicable percentage increases.

FY 2015	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.675	−0.675
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−0.675	0.0	−0.675
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.4	−0.4	−0.4	−0.4
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.2	−0.2	−0.2	−0.2
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.1**	**1.425**	**1.425**	**0.75**

We are proposing to revise the existing regulations at 42 CFR 412.64(d) to reflect the current law for the FY 2015 update. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to add a new paragraph (vi) to § 412.64(d)(1) to reflect the applicable percentage increase to the FY 2015 operating standardized amount as the percentage increase in the market basket index, subject to a reduction of one-fourth of the applicable percentage increase (prior to the application of other statutory adjustments) 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 a 33⅓ percent reduction to three-fourths of the applicable percentage increase (prior to the application of other statutory adjustments) for a hospital that is not a meaningful EHR user in accordance with section 1886(b)(3)(B)(ix) of the Act, less an MFP adjustment and less an additional reduction of 0.2 percentage point.

In addition, we are proposing to make technical changes to §§ 412.64(d)(1), (d)(1)(i) through (d)(1)(v), (d)(2)(i), (d)(2)(ii), and (d)(3) introductory text to reflect the order in which CMS applies the statutory adjustments to the

applicable percentage increase under section 1886(b)(3)(B) of the Act. As mentioned above, consistent with section 1886(b)(3)(B) of the Act, CMS sets the applicable percentage increase under the IPPS by applying the following adjustments in the following sequence. Specifically, we set the applicable percentage increase under the IPPS equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas subject to a reduction for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and, beginning in FY 2015, a reduction for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act; and then subject to an adjustment based on changes in economy-wide productivity (the MFP adjustment), and an additional reduction as required by section 1886(b)(3)(B)(xii) of the Act.

The existing regulation text at § 412.64(d)(2) and (d)(3) describes the reductions for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act as reductions to ''the applicable percentage change specified in paragraph (d)(1) of this section.'' Section 412.64(d)(1) describes the applicable percentage change for the applicable fiscal year as the percentage increase in the market basket index less the MFP adjustment and less the additional reduction required by section 1886(b)(3)(B)(xii) of the Act. This text suggests that CMS applies the reduction for hospitals that fail to submit quality information and, beginning in FY 2015, the reduction for hospitals not considered to be meaningful EHR users, after it applies the MFP adjustment and the additional reduction under section 1886(b)(3)(B)(xii) of the Act. Therefore, we are proposing to revise the regulations in § 412.64(d) to reflect the order in which CMS applies the adjustments to the applicable percentage increase under section 1886(b)(3)(B) of the Act. We note that we also are proposing clarifying amendments to the regulatory text for prior fiscal years under §§ 412.64(d)(1)(i) through (d)(1)(v) to reflect the determination of the applicable percentage change for those prior years as well as other technical changes for readability.

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs and MDHs is also subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, for FY 2015, we are proposing the following updates to the hospital-specific rates applicable to SCHs and MDHs: An update of 2.1 percent for a hospital that submits quality data and is a meaningful EHR user; an update of 1.425 percent for a hospital that fails to submit quality data and is a meaningful EHR user; an update of 1.425 percent for a hospital that submits quality data and is not a meaningful EHR user; an update of 0.75 percent for a hospital that fails to submit quality data and is not a meaningful EHR user. (As noted below, under current law, the MDH program is effective for discharges occurring on or before March 31, 2015.) For FY 2015, the existing regulations in §§ 412.73(c)(16), 412.75(d), 412.77(e), 412.78(e), and 412.79(d) contain provisions that set the update factor for SCHs and MDHs equal to the update factor applied to the national standardized amount for all IPPS hospitals. Therefore, we are not proposing to make any further changes to these five regulatory provisions to reflect the FY 2015 update factor for the hospital-specific rates of SCHs and MDHs. As mentioned above, for this proposed rule, we used IGI's first quarter 2014 forecast of the FY 2010-based IPPS market basket update with historical data through fourth quarter 2013. Similarly, we used IGI's first quarter 2014 forecast of the MFP adjustment. For the final rule, we are proposing to use the most recent data available.

We note that, as discussed in section IV.G. of the preamble of this proposed rule, section 1106 of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), enacted on December 26, 2013, extended the MDH program from the end of FY 2013 through the first half of FY 2014 (that is, for discharges occurring before April 1, 2014). Subsequently, section 106 of the Protecting Access to Medicare Act of 2014, Public Law 113–93, enacted on April 1, 2014, further extended the MDH program through the first half of FY 2015 (that is, for discharges occurring before April l, 2015). Prior to the enactment of Public Law 113–67, the MDH program was to be in effect through the end of FY 2013 only. The MDH program expires for discharges beginning on April 1, 2015 under current law. Accordingly, the proposed update of the hospital-specific rates for FY 2015 for MDHs will apply in determining payments for FY 2015 discharges occurring before April 1, 2015.

2. FY 2015 Puerto Rico Hospital Update

Puerto Rico hospitals are paid a blended rate for their inpatient operating costs based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 1886(d)(9)(C)(i) of the Act is the basis for determining the applicable percentage increase applied to the Puerto Rico-specific standardized amount. Section 401(c) of Public Law 108–173 amended section 1886(d)(9)(C)(i) of the Act, which states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for fiscal year 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are proposing an applicable percentage increase to the Puerto Rico-specific operating standardized amount of 2.1 percent for FY 2015. We note that the provisions of section 1886(b)(3)(B)(viii) of the Act, which specify the adjustments to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, and the provisions of section 1886(b)(3)(B)(ix) of the Act, which specify the adjustments to the applicable percentage increase for ''subsection (d)'' hospitals that are not meaningful EHR users, are not applicable to hospitals located in Puerto Rico.

For FY 2015, the existing regulations in § 412.211(c) set the update factor for

Puerto Rico-specific standardized amount equal to the update factor applied to the national standardized amount for all IPPS hospitals. Therefore, we are not proposing to make any further changes to this regulatory provision to reflect the FY 2015 update factor for the Puerto Rico-specific standardized amount.

As mentioned previously, for this proposed rule, we used IGI's first quarter 2014 forecast of the FY 2010-based IPPS market basket update with historical data through fourth quarter 2013. For the final rule, we are proposing to use the most recent data available. Similarly, we used IGI's first quarter 2014 forecast of the MFP adjustment. For the final rule, we are proposing to use the most recent data available.

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

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

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs 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 2015 includes data from all urban hospitals nationwide, and the proposed regional values for FY 2015 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 2013 (October 1, 2012 through September 30, 2013), and include bills posted to CMS' records through December 2013.

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, 2014, they must have a CMI value for FY 2013 that is at least—

- 1.5730; 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 CMI values by region are set forth in the following table:

Region	Proposed case-mix index value
1. New England (CT, ME, MA, NH, RI, VT)	1.3602
2. Middle Atlantic (PA, NJ, NY)	1.4334
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.4815
4. East North Central (IL, IN, MI, OH, WI)	1.4915
5. East South Central (AL, KY, MS, TN)	1.4099
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.5498
7. West South Central (AR, LA, OK, TX)	1.6041
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.6583
9. Pacific (AK, CA, HI, OR, WA)	1.5680

We intend to update the preceding numbers in the FY 2015 final rule to reflect the updated FY 2013 MedPAR file, which would contain data from additional bills received through March 2014.

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its fiscal intermediary or MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. We are proposing to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2012 (that is October 1, 2011 through September 30, 2012), which are the latest cost report data available at the time this proposed rule was developed.

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, 2014, must have, as the number of discharges for its cost reporting period that began during FY 2012, 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)	7,679
2. Middle Atlantic (PA, NJ, NY)	10,661
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,591
4. East North Central (IL, IN, MI, OH, WI)	8,130
5. East South Central (AL, KY, MS, TN)	7,065
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,925
7. West South Central (AR, LA, OK, TX)	4,524
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,830
9. Pacific (AK, CA, HI, OR, WA)	8,261

We intend to update these numbers in the FY 2015 final rule based on the latest available cost report data.

We reiterate that, if an osteopathic hospital is to qualify for RRC status for cost reporting periods beginning on or after October 1, 2014, the hospital would be required to have at least 3,000 discharges for its cost reporting period that began during FY 2012.

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

1. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital that is paid under IPPS beginning in FY 2005. Sections 3125 and 10314 of the Affordable Care Act provided for a temporary change in the low-volume hospital payment policy for FYs 2011 and 2012. Section 605 of the American Taxpayer Relief Act of 2012 (ATRA) extended, for FY 2013, the temporary changes in the low-volume hospital payment policy provided for in FYs 2011 and 2012 by the Affordable Care Act. Prior to the enactment of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) on December 26, 2013 and section 106 of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) on April l, 2014, beginning with FY 2014, the low-volume hospital qualifying criteria and payment adjustment returned to the statutory requirements under section 1886(d)(12) of the Act that were in effect prior to the amendments made by the Affordable Care Act and the ATRA. (For additional information on the expiration of the temporary changes in the low-volume hospital payment policy for FYs 2011 through 2013 provided for by the Affordable Care Act and the ATRA, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50610 through 50613).)

Section 1105 of the Pathway for SGR Reform Act extended, for the first 6 months of FY 2014 (that is, through March 31, 2014), the temporary changes in the low-volume hospital payment policy provided for in FYs 2011 and 2012 by the Affordable Care Act and extended through FY 2013 by the ATRA. We addressed the extension of the temporary changes to the low-volume hospital payment policy through March 31, 2014 under the Pathway for SGR Reform Act in an interim final rule with comment period that appeared in the **Federal Register** on March 18, 2014 (79 FR 15022 through 15025). In that March 18, 2014 interim final rule with comment period, we also amended the regulations at 42 CFR 412.101 to reflect the extension of the temporary changes to the qualifying criteria and the payment adjustment for low-volume hospitals through March 31, 2014.

2. Provisions of the Protecting Access to Medicare Act of 2014

Section 105 of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) extends, for an additional year (that is, through March 31, 2015), the temporary changes in the low-volume hospital payment policy provided for in FYs 2011 and 2012 by the Affordable Care Act and extended through FY 2013 by the ATRA and the first half of FY 2014 by the Pathway for SGR Reform Act. We intend to address the extension of the temporary changes to the low-volume hospital payment policy for the second half of FY 2014 (that is, from April 1, 2014 through September 30, 2014) under Public Law 113–93 in a forthcoming **Federal Register** notice. However, in this proposed rule, we are proposing to make conforming changes to the existing regulations text at § 412.101 to reflect the extension of the changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals through the first half of FY 2015 (that is, through March 31, 2015) in accordance with section 105 of Public Law 113–93. Specifically, we are proposing to revise paragraphs (b)(2)(i), (b)(2)(ii), (c)(1), (c)(2), and (d) of § 412.101. Under these proposed changes to § 412.101, beginning with FY 2015 discharges occurring on or after April 1, 2015, consistent with section 1886(d)(12) of the Act, as amended, the low-volume hospital qualifying criteria and payment adjustment methodology would revert to that which was in effect prior to the amendments made by the Affordable Care Act and subsequent legislation (that is, the low-volume hospital payment adjustment policy in effect for FYs 2005 through 2010).

3. Low-Volume Hospital Definition and Payment Adjustment for FY 2015

As discussed above, under section 1886(d)(12) of the Act, as amended, the temporary changes in the low-volume hospital payment policy originally provided by the Affordable Care Act and extended through subsequent legislation, are effective for FY 2015 discharges occurring before April 1, 2015. To implement the extension of the temporary change in the low-volume hospital payment policy through the first half of FY 2015 (that is, for discharges occurring through March 31, 2015) provided for by Public Law 113–93, in accordance with proposed § 412.101(b)(2)(ii) and consistent with our historical approach, we are proposing to update the discharge data source used to identify qualifying low-volume hospitals and calculate the payment adjustment (percentage increase) for FY 2015 discharges occurring before April 1, 2015. Under existing § 412.101(b)(2)(ii), for the applicable fiscal years, a hospital's Medicare discharges from the most recently available MedPAR data, as determined by CMS, are used to determine if the hospital meets the discharge criteria to receive the low-volume payment adjustment in the current year. The applicable low-volume percentage increase, as originally provided for by the Affordable Care Act, is determined using a continuous linear sliding scale equation that results in a low-volume hospital payment adjustment ranging from an additional 25 percent for hospitals with 200 or fewer Medicare discharges to a zero percent additional payment adjustment for hospitals with 1,600 or more Medicare discharges. For FY 2015 discharges occurring before April 1, 2015, consistent with our historical policy, we are proposing that qualifying low-volume hospitals and their payment adjustment would be determined using the most recently available Medicare discharge data from the FY 2013 MedPAR file, as these data are the most recent data available. Table 14 listed in the Addendum of this proposed rule (which is available only through the Internet on the CMS Web site at *http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp*) lists the ''subsection (d)'' hospitals with fewer than 1,600 Medicare discharges based on the December 2013 update of the FY 2013 MedPAR file and their proposed low-volume payment adjustment for FY 2015 discharges occurring before April 1, 2015 (if eligible). Eligibility for the low-volume hospital payment adjustment for the first 6 months of FY 2015 would also be dependent upon meeting (in the case of a hospital that did not qualify for the low-volume hospital payment adjustment in FY 2014) or continuing to meet (in the case of a hospital that did qualify for the low-volume hospital payment adjustment in FY 2014) the mileage criterion specified at proposed § 412.101(b)(2)(ii). A hospital also must be located more than 15 road miles from any other IPPS hospital in order to qualify for a low-volume hospital payment adjustment for FY 2015 discharges occurring before April 1, 2015. We note that the list of hospitals with fewer than 1,600 Medicare discharges in Table 14 does not reflect whether or not the hospital meets the mileage criterion. If more recent Medicare discharge data become available, we intend to use updated data to determine the list of ''subsection (d)'' hospitals with fewer than 1,600 Medicare discharges based on the March 2014 update of the FY 2013 MedPAR file and their potential low-volume payment adjustment for FY 2015 discharges occurring before April 1, 2015 (if eligible) in Table 14 of the final rule.

Furthermore, in accordance with section 1886(d)(12) of the Act, as amended, beginning with FY 2015 discharges occurring on or after April 1, 2015, 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 and subsequent legislation (including the Protecting Access to Medicare Act). Therefore, consistent with section 1886(d)(12) of the Act, as amended, under the proposed conforming changes to § 412.101(b)(2), effective for FY 2015 discharges occurring on or after April 1, 2015 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. Under our existing policy, effective for FY 2015 discharges occurring on or after April 1, 2015 and subsequent years, qualifying hospitals would receive the low-volume hospital payment adjustment of an additional 25 percent for discharges occurring during the fiscal year (or portion of the fiscal year). Consistent with our existing policy for FYs 2005 through 2010, for FY 2015 discharges occurring on or after April 1, 2015 (and subsequent years), the discharge determination for the low-volume hospital payment adjustment would be made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges, as specified at proposed § 412.101(b)(2)(i). The hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume hospital payment adjustment in the current fiscal year. We use cost report data to determine if a hospital meets the discharge criterion because these data are the best available data source that includes information on both Medicare and non-Medicare discharges. In addition to a discharge criterion, eligibility for the low-volume hospital payment adjustment also depends on the hospital meeting a mileage criterion. As specified at proposed § 412.101(b)(2)(i), to meet the mileage criterion to qualify for the low-volume hospital payment adjustment for FY 2015 discharges occurring on or after April 1, 2015 (and subsequent years), a hospital must be located more than 25 road miles from the nearest subsection (d) hospital.

Consistent with our previously established procedure, for FY 2015, we are proposing the following process for requesting and obtaining the low-volume hospital payment adjustment. That is, in order to receive a low-volume hospital payment adjustment under § 412.101, a hospital must notify and provide documentation to its MAC that it meets the discharge and distance requirements under proposed § 412.101(b)(2)(ii) for FY 2015 discharges occurring before April 1, 2015, and under proposed § 412.101(b)(2)(i) for FY 2015 discharges occurring on or after April 1, 2015, if also applicable. The MAC will determine, based on the most recent data available, if the hospital qualifies as a low-volume hospital, so that the hospital would know in advance whether or not it will receive a payment adjustment. The 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. Consistent with our previously established procedure, for FY 2015, we are proposing that a hospital must make a written request for low-volume hospital status that is received by its MAC no later than September 1, 2014, in order for the applicable low-volume hospital payment adjustment to be applied to payments for its discharges

occurring on or after October 1, 2014, and through March 31, 2015, under proposed § 412.101(b)(2)(ii) or through September 30, 2015, for hospitals that also qualify under proposed § 412.101(b)(2)(i)). A hospital that qualified for the low-volume payment adjustment in FY 2014 may continue to receive a low-volume payment adjustment for FY 2015 discharges occurring before April 1, 2015, without reapplying if it continues to meet the Medicare discharge criterion established for FY 2015 (shown in Table 14, which is available via the Internet on the CMS Web site) and the distance criterion. However, the hospital must send written verification that is received by its MAC no later than September 1, 2014, that it continues to be more than 15 miles from any other ''subsection (d)'' hospital.

If a hospital's written request for low-volume hospital status for FY 2015 is received after September 1, 2014, and if the MAC determines that the hospital meets the criteria to qualify as a low-volume hospital under proposed § 412.101(b)(2)(ii), the MAC would apply the applicable low-volume hospital payment adjustment to determine the payment for the hospital's FY 2015 discharges, effective prospectively within 30 days of the date of its low-volume hospital status determination through discharges occurring on or before March 31, 2015. If the hospital also qualifies under proposed § 412.101(b)(2)(i), the MAC would apply the 25-percent low-volume hospital payment adjustment to determine the payment for the hospital's FY 2015 discharges occurring on or after April 1, 2015. If a hospital's written request for low-volume hospital status for FY 2015 is received on a later date such that the prospective effective date would be on or after April 1, 2015, and the hospital qualifies under proposed § 412.101(b)(2)(i), the MAC would apply the 25-percent low-volume hospital payment adjustment to determine the payment for the hospital's FY 2015 discharges occurring from the prospective effective date through September 30, 2015. (For additional details on our established process for the low-volume hospital payment adjustment, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53408).)

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

1. IME Adjustment Factor for FY 2015

Under the IPPS, an additional payment amount is made to hospitals with residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B) 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 2015, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2015 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. Proposed IME Medicare Part C Add-On Payments to Sole Community Hospitals (SCHs) That Are Paid According to Their Hospital-Specific Rates and Proposed Change in Methodology in Determining Payment to SCHs

Section 1886(d)(11) of the Act provides for an additional payment amount to a subsection (d) teaching hospital that has an approved medical residency training program for each applicable discharge of any individual who is enrolled under Medicare Managed Care under Part C. The amount of such payment is specified in section 1886(d)(11)(C) of the Act and ''shall be equal to the applicable percentage (as defined in subsection (h)(3)(D)(ii)) of the estimated average per discharge amount that would otherwise have been paid under paragraph (5)(B) if the individuals had not been enrolled as described in subparagraph (B).''

Under section 1886(d)(5)(D) of the Act, sole community hospitals (SCHs) are paid based on their hospital-specific rate from specified base years or the IPPS Federal rate, whichever yields the greatest aggregate payment for the hospital's cost reporting period. Payments based on the Federal rate are based on the IPPS standardized amount and include all applicable IPPS add-on payments, such as outliers, DSH, and IME, while payments based on the hospital-specific rate include no add-on payments. Under CMS' current payment system, both the IME add-on payment for Medicare Part A patient discharges under section 1886(d)(5)(B) of the Act and the IME add-on payment for Medicare Part C patient discharges under section 1886(d)(11) of the Act are included as part of the Federal rate payment, whereas neither of these add-on payments are included as part of the hospital-specific rate payment. We note that SCHs that are paid based on their hospital-specific rate do not receive an IME add-on payment for Medicare Part A patient discharges because, generally, the hospital-specific rate already reflects the additional costs that a teaching hospital incurs for its Medicare Part A patients, but they also do not receive the IME add-on payment for Medicare Part C patient discharges under section 1886(d)(11) of the Act. Therefore, in the case of Medicare Part C patients, there is no component of the hospital-specific rate that already accounts for the additional costs that SCHs incur for their Medicare Part C patients, and there is currently no payment mechanism for SCHs paid based on their hospital-specific rate to receive the IME add-on payment for Medicare Part C patients.

For the reasons specified below, effective for discharges occurring in cost reporting periods beginning on or after October 1, 2014, we are proposing: (1) To provide all SCHs that are subsection (d) teaching hospitals IME add-on payments for applicable discharges of Medicare Part C patients in accordance with section 1886(d)(11) of the Act, regardless of whether the SCH is paid based on the Federal rate or its hospital-specific rate; and (2) that, for purposes of the comparison of payments based on the Federal rate and payments based on the hospital-specific rate under section 1886(d)(5)(D) of the Act, IME payments under section 1886(d)(11) of the Act for Medicare Part C patients will no longer be included as part of the Federal rate payment. After the higher of the Federal rate payment amount or the hospital-specific rate payment amount is determined, any IME add-on payments under section 1886(d)(11) of the Act would be added to that payment for purposes of determining the hospital's total payment amount.

As noted above, under section 1886(d)(5)(D) of the Act, SCHs are paid based on their hospital-specific rate or the IPPS Federal rate, whichever yields the higher payment for the hospital's cost reporting period. For each cost reporting period, the MAC determines which of the payment options will yield the higher aggregate payment. Interim payments are automatically made on a claim-by-claim basis at the higher rate using the best data available at the time the MAC makes the payment determination for each discharge. However, it may not be possible for the MAC to determine in advance precisely

which of the rates will yield the higher aggregate payment by year's end. In many cases, it is not possible to forecast outlier payments or the final amount of the DSH payment adjustment or the IME adjustment until cost report settlement. As noted above, these adjustment amounts are applicable only to payments based on the Federal rate and not to payments based on the hospital-specific rate. The MAC makes a final adjustment at cost report settlement after it determines precisely which of the two payment rates would yield the higher aggregate payment to the hospital for its cost reporting period. This payment methodology makes SCHs unique because SCH payments can change on a yearly basis from payments based on the hospital-specific rate to payments based on the Federal rate, or vice versa.

As we stated earlier, section 1886(d)(11) of the Act provides for an additional payment for each applicable discharge of any subsection (d) teaching hospital for treating Medicare Part C patients. Section 1886(d)(11)(C) of the Act specifies that the amount of the payment ''shall be equal to the applicable percentage (as defined in subsection (h)(3)(D)(ii)) of the estimated average per discharge amount *that would otherwise have been paid under paragraph (5)(B)* if the individuals had not been enrolled as described in subparagraph (B)'' (emphasis added). Because an SCH that is paid based on its hospital-specific rate does not receive any IME add-on payment for Medicare Part A patients as provided under section 1886(d)(5)(B) of the Act because, generally, the hospital-specific rate already reflects the additional costs that a teaching hospital incurs for its Medicare Part A patients, CMS has interpreted section 1886(d)(11)(C) of the Act to mean that an SCH that is paid based on its hospital-specific rate also is not entitled to receive an additional payment for discharges of Medicare Part C patients under section 1886(d)(11) of the Act.

After further consideration of the language at section 1886(d)(11) of the Act, we believe that the statute would allow an SCH that is paid based on its hospital-specific rate to receive IME add-on payments for its Medicare Part C patient discharges. Section 1886(d)(11)(A) of the Act provides for an additional payment amount for each applicable discharge of a Medicare Part C patient of a subsection (d) hospital that has an approved medical residency training program. Section 1886(d)(11)(C) of the Act sets forth the amount of this additional payment, by reference to the amount that would otherwise have been paid under section 1886(d)(5)(B) of the Act. Although an SCH that is paid based on its hospital-specific rate does not receive any amount under section 1886(d)(5)(B) of the Act for discharges of Medicare Part A patients, we believe that section 1886(d)(11)(C) of the Act can be interpreted as simply establishing the methodology for calculating the amount of the add-on payment, without limiting the applicability of the add-on payment to those SCHs that are paid based on the Federal rate.

As noted earlier, in making the comparison of SCH payments under the Federal rate and the hospital-specific rate under section 1886(d)(5)(D) of the Act, the aggregate Federal rate payments are based on the IPPS standardized amount and include IME add-on payments for both Medicare Part A and Medicare Part C patient discharges. Payments based on the hospital-specific rate do not include the Medicare Part A IME add-on payment under section 1886(d)(5)(B) of the Act, under the rationale that, generally, the hospital-specific rate already reflects the additional costs that a teaching hospital incurs for its Medicare Part A patients. Payments based on the hospital-specific rate also do not include the IME add-on payment for Medicare Part C patient discharges under section 1886(d)(11) of the Act. As a result, under the current methodology, if an SCH that is a teaching hospital is paid based on its hospital-specific rate, it receives no IPPS payment that accounts for the additional costs that a teaching hospital incurs for its Medicare Part C patients.

In conjunction with our proposal to provide IME add-on payments under section 1886(d)(11) of the Act to SCHs, regardless of whether the SCH is paid based on the Federal rate or its hospital-specific rate, we also believe that, for purposes of the comparison of payments under the Federal rate and the hospital-specific rate for SCHs under section 1886(d)(5)(D) of the Act, it is no longer appropriate for IME add-on payments under section 1886(d)(11) of the Act to be included as part of the Federal rate payment. Therefore, we are proposing to no longer include these payments in the comparison in order to more accurately reflect comparable payments for Medicare Part A patient discharges. In addition, because the IME add-on payment for Medicare Part C patient discharges for a given SCH would be the same, regardless of whether it is paid based on the Federal rate or its hospital-specific rate, there would be no need to include the IME add-on payment for Medicare Part C patient discharges in the comparison. This is because the Part C IME adjustment is always multiplied by the Federal rate that is used under section 1886(d)(5)(B) of the Act, regardless of whether the hospital-specific rate is higher, in accordance with section 1886(d)(11) of the Act, which states that the IME Part C add-on amount ''shall be equal to the applicable percentage . . . of the estimated average per discharge amount that would otherwise have been paid under paragraph (5)(B).''

In summary, effective with discharges occurring in cost reporting periods beginning on or after October 1, 2014, we are proposing: (1) To provide all SCHs that are subsection (d) teaching hospitals IME add-on payments for Medicare Part C patient discharges in accordance with section 1886(d)(11) of the Act; and (2) that, for purposes of the comparison of payments based on the Federal rate and the hospital-specific rate for SCHs under section 1886(d)(5)(D) of the Act, IME add-on payments under section 1886(d)(11) of the Act for Medicare Part C patient discharges will no longer be included in the aggregate payment under the Federal rate. That is, for purposes of determining payment to an SCH under section 1886(d)(5)(D) of the Act, we are proposing to compare aggregate payments based on the Federal rate, including the IME add-on payment for Medicare Part A patients (where applicable), but not the IME add-on payment for Medicare Part C patients, to aggregate payments based on the hospital-specific rate, which as explained earlier, do not include any IME add-on payments for either Medicare Part A or Part C patients. After the higher of the Federal rate payment amount or the hospital-specific rate payment amount under section 1886(d)(5)(D) of the Act is determined, the Part C IME adjustment factor would be multiplied by the Federal rate payment amount to determine the add-on payment amount under section 1886(d)(11) of the Act, and then any IME add-on payments under section 1886(d)(11) of the Act would be added to the payment amount under section 1886(d)(5)(D) of the Act for purposes of determining the hospital's total payment amount. We are inviting public comments on both of these proposals and any alternatives that we should consider.

3. Other Proposed Policy Changes Affecting IME

In section IV.K. of the preamble of this proposed rule, we present other proposed policy changes relating to GME payments, which may also apply to IME payments. We refer readers to

that section of the preamble of this proposed rule where we present the proposed policies.

F. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) (§ 412.106)

1. Background

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to needy patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment adjustment, which is the most common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: The ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the DSH statutory references (under section 1886(d)(5)(F) of the Act) to ''days'' apply only to hospital acute care inpatient days. Regulations located at § 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

2. Impact on Medicare DSH Payment Adjustment of Proposed Implementation of New OMB Labor Market Delineations

As discussed in section III.B. of the preamble of this proposed rule, we are proposing to implement the new OMB labor market area delineations (which are based on 2010 Decennial Census data) for the FY 2015 wage index. This proposal also would have an impact on the calculation of Medicare DSH payments to certain hospitals. Hospitals that are designated as rural with less than 500 beds and that are not rural referral centers (RRCs) are subject to a maximum DSH payment adjustment of 12 percent. Accordingly, hospitals with less than 500 beds that are currently in urban counties that would become rural if we adopt the new OMB delineations, and that do not become RRCs, would be subject to a maximum DSH payment adjustment of 12 percent. (We note that urban hospitals are only subject to a maximum DSH payment adjustment of 12 percent if they have less than 100 beds.)

Under existing regulations at 42 CFR 412.102, a hospital located in an area that is reclassified from urban to rural, as defined in the regulations, may receive an adjustment to its rural Federal payment amount for operating costs for two successive fiscal years. Specifically, the regulations state that, in the first year after a hospital loses urban status, the hospital will receive an additional payment that equals two-thirds of the difference between the urban standardized amount and disproportionate share payments as applicable to the hospital before its redesignation from urban to rural and the rural standardized amount and disproportionate share payments otherwise applicable to the hospital subsequent to its redesignation from urban to rural. In the second year after a hospital loses urban status, the hospital will receive an additional payment that equals one-third of the difference between the urban standardized amount and disproportionate share payments applicable to the hospital before its redesignation from urban to rural and the rural standardized amount and disproportionate share payments otherwise applicable to the hospital subsequent to its redesignation from urban to rural.

We note that we no longer make a distinction between the urban standardized amount and the rural standardized amount. Rather, hospitals receive the same standardized amount regardless of their geographic designation. Accordingly, we are proposing to revise the regulation at § 412.102 to remove references to the urban and rural standardized amounts.

The provisions of § 412.102 would continue to apply with respect to the calculation of the DSH payments to hospitals that are currently located in urban counties that would become rural if we adopt the new OMB delineations. Specifically, the regulations would state that in the first year after a hospital loses urban status, the hospital will receive an additional payment that equals two-thirds of the difference between disproportionate share payments as applicable to the hospital before its redesignation from urban to rural and the disproportionate share payments otherwise applicable to the hospital subsequent to its redesignation from urban to rural. In the second year after a hospital loses urban status, the hospital will receive an additional payment that equals one-third of the difference between the disproportionate share payments applicable to the hospital before its redesignation from urban to rural and the disproportionate share payments otherwise applicable to the hospital subsequent to its redesignation from urban to rural.

For the purposes of ratesetting, calculating budget neutrality, and modeling payment impacts for this proposed rule, any hospital that was previously urban but would be changed to rural status in FY 2015 as a result of the proposed adoption of the new OMB labor market area delineations would have its DSH payments modeled such that the payment equals the amount of the rural disproportionate share payments plus two-thirds of the difference between the urban disproportionate share payments and the rural disproportionate share payments.

3. Payment Adjustment Methodology for Medicare Disproportionate Share Hospitals (DSHs) Under Section 3133 of the Affordable Care Act (§ 412.106)

a. General Discussion

Section 3133 of the Patient Protection and Affordable Care Act, as amended by section 10316 of the same act and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a new section 1886(r) to the Act that modifies the methodology for computing the

Medicare DSH payment adjustment beginning in FY 2014. For purposes of this proposed rule, we refer to these provisions collectively as section 3133 of the Affordable Care Act.

Medicare DSH adjustment payments are calculated under a statutory formula that considers the hospital's Medicare utilization attributable to beneficiaries who also receive Supplemental Security Income (SSI) benefits and the hospital's Medicaid utilization. Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under age 65 who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

As provided by section 3133 of the Affordable Care Act, section 1886(r) of the Act requires that, for FY 2014 and each subsequent fiscal year, a ''subsection (d) hospital'' that would otherwise receive a ''disproportionate share hospital payment . . . made under subsection (d)(5)(F)'' receives two separately calculated payments. Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such a subsection (d) hospital (including a Pickle hospital) 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for disproportionate share hospital payments, which represents ''the empirically justified amount for such payment, as determined by the Medicare Payment Advisory Commission in its March 2007 Report to the Congress.'' We refer to this payment as the ''empirically justified Medicare DSH payment.''

In addition to this payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to ''such subsection (d) hospital an additional amount equal to the product of'' three factors. The first factor is the difference between ''the aggregate amount of payments that would be made to subsection (d) hospitals under subsection (d)(5)(F) if this subsection did not apply'' and ''the aggregate amount of payments that are made to subsection (d) hospitals under paragraph (1)'' for each fiscal year. Therefore, this factor amounts to 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act.

The second factor is, for FYs 2014 through 2017, 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, determined by comparing the percent of such individuals who are uninsured in 2013, the last year before coverage expansion under the Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment), minus 0.1 percentage points for FY 2014, and minus 0.2 percentage points for FYs 2015 through 2017. For FYs 2014 through 2017, the baseline for the estimate of the change in uninsurance is fixed by the most recent estimate of the Congressional Budget Office before the final vote on the Health Care and Education Reconciliation Act of 2010, which is contained in a March 20, 2010 letter from the Director of the Congressional Budget Office to the Speaker of the House. (A link to this letter is included in section IV.F.3.d.(2) of the preamble of this proposed rule).

For FY 2018 and subsequent years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals ''who are uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary'' of CMS, and the percent of individuals ''who are uninsured in the most recent period for which data is available (as so estimated and certified), minus 0.2 percentage points for FYs 2018 and 2019.'' Therefore, for FY 2018 and subsequent years, the statute provides some greater flexibility in the choice of the data sources to be used for the estimate of the change in the percent of uninsured individuals.

The third factor is a percent that, for each subsection (d) hospital, ''represents the quotient of . . . the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data . . .),'' including the use of alternative data ''where the Secretary determines that alternative data is available which is a better proxy for the costs of subsection (d) hospitals for . . . treating the uninsured,'' and ''the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under this subsection.'' Therefore, this third factor represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in that fiscal year, expressed as a percent. For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment determined by these factors as the ''uncompensated care payment.''

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the DSH payment methodology made by section 3133 of the Affordable Care Act for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under the regulations at 42 CFR Part 412, Subpart M, which were established through the exercise of the Secretary's discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be ''no administrative or judicial review under section 1869, section 1878, or otherwise'' of ''any estimate of the Secretary for purposes of determining the factors described in paragraph (2),'' or of ''any period selected by the Secretary'' for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or the periods selected in order to develop such estimates.

b. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

As indicated earlier, the payment methodology under section 3133 of the Affordable Care Act applies to ''subsection (d) hospitals'' that would otherwise receive a ''disproportionate share payment . . . made under subsection (d)(5)(F).'' Therefore, eligibility for empirically justified Medicare DSH payments is unchanged under section 3133 of the Affordable Care Act. Consistent with the law, hospitals must receive empirically justified Medicare DSH payments in a fiscal year to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that ''[i]n addition to the payment made to a subsection (d) hospital under paragraph (1) . . . the Secretary shall pay to *such subsection (d) hospital* an additional amount . . .'' (emphasis supplied). Because paragraph (1) refers to empirically justified Medicare DSH payments, the additional payment under section 1886(r)(2) of the Act therefore, is limited to hospitals that receive empirically justified Medicare DSH payments in accordance with section 1886(r)(1) of the Act for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we provided that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). We indicated that our final determination on the hospital's eligibility for uncompensated care payments would be based on the hospital's actual DSH status on the cost report for that payment year.

In the FY 2014 IPPS/LTCH PPS final rule, we also considered whether several specific classes of hospitals are included within the scope of section 1886(r) of the Act. As we specified in that final rule (78 FR 50623), subsection (d) Puerto Rico hospitals that are eligible for DSH payments also are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology.

In addition, in the FY 2014 IPPS/LTCH PPS final rule, we considered whether Maryland hospitals that were paid under section 1814(b)(3) of the Act, would be eligible to receive uncompensated care payments. We explained that, under section 1814(b) of the Act, hospitals in the State of Maryland were subject to a waiver from the Medicare payment methodologies under which they would otherwise be paid. Because Maryland waiver hospitals were not paid under the IPPS (section 1886(d) of the Act), in the FY 2014 IPPS/LTCH PPS final rule, we determined that Maryland hospitals that operated under a waiver under section 1814(b)(3) of the Act were not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1886(r) of the Act (78 FR 50623). As stated in section IV.H. of the preamble of this proposed rule, effective January 1, 2014, the State of Maryland elected to no longer have Medicare pay Maryland hospitals in accordance with section 1814(b)(3) of the Act and entered into an agreement with CMS that Maryland hospitals would be paid under the Maryland All-Payor Model. However, under the Maryland All-Payor Model, Maryland hospitals still are not paid under the IPPS. Therefore, they remain ineligible to receive empirically justified Medicare DSH payments or the uncompensated care payments under section 1886(r) of the Act.

SCHs are paid based on their hospital-specific rate from certain specified base years or the IPPS Federal rate, whichever yields the greater aggregate payment for the hospital's cost reporting period. If an SCH is paid under its hospital-specific rate, it is not eligible for Medicare DSH payments. In order to implement the provisions of section 1886(r) of the Act, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50624), we specified that we will continue to determine interim payments for SCHs based on what we estimate and project their DSH status to be prior to the beginning of the Federal fiscal year (based on the best available data at that time), subject to settlement through the cost report. We also specified that SCHs that receive interim empirically justified Medicare DSH payments in a fiscal year would receive interim uncompensated care payments for that fiscal year on a per discharge basis, subject as well to settlement through the cost report. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly. Therefore, we follow the same processes of interim and final payments for SCHs that we follow for eligible IPPS DSH hospitals generally.

MDHs are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). The IPPS Federal rate used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Uncompensated care payments to MDHs were not explicitly addressed in the FY 2014 IPPS/LTCH PPS final rule because, at the time of the publication of the final rule, the MDH program was set to expire at the end of FY 2013. Since the publication of the FY 2014 IPPS/LTCH PPS final rule, the MDH program was extended from October 1, 2013, to March 31, 2014, under the Pathway for SGR Reform Act (Pub. L. 113–67) and was further extended an additional year from April 1, 2014, to March 31, 2015, by the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93). Because MDHs are paid under the IPPS Federal rate and, therefore, are eligible to receive Medicare DSH payments if their disproportionate patient percentage is at least 15 percent, we apply the same process to determine eligibility for Medicare DSH and the uncompensated care payment as we do for all other IPPS hospitals. That is, we make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available) and our final determination on the hospital's eligibility for uncompensated care payments would be based on the hospital's actual DSH status on the cost report for that payment year. In addition, as we do for all IPPS hospitals, we would calculate a numerator for Factor 3 for all MDHs, regardless of whether they are projected to be eligible for DSH during the fiscal year, but the denominator for Factor 3 would be based on the uncompensated care data from the hospitals that we have projected to be eligible for DSH during the fiscal year.

Furthermore, in the FY 2014 IPPS interim final rule with comment period (79 FR 15027), which addressed MDH payments for the first 6 months of FY 2014, we established a policy of including a pro rata share of the uncompensated care payment amount for that period as part of the Federal rate payment in the comparison of payments under the hospital-specific rate and the

Federal rate. Consistent with that policy, for MDH payments for the first 6 months of FY 2015, a pro rata share of the uncompensated care payment amount for that period will be included as part of the Federal rate payment in the comparison of payments under the hospital-specific rate and the Federal rate. That is, in making this comparison at cost report settlement, we will include the pro rata share of the uncompensated care payment amount that reflects the period of time the hospital was paid under the MDH program for its discharges occurring on or after October 1, 2014, and before April 1, 2015. Consistent with the policy for hospitals with Medicare cost reporting periods that span more than 1 Federal fiscal year, this pro rata share will be determined based on the proportion of the applicable Federal fiscal year that is included in that cost reporting period (78 FR 61192 through 61194). As noted previously, section 106 of Public Law 113–93 provides for an extension of the MDH program through March 31, 2015, only. Therefore, beginning April 1, 2015, all hospitals that previously qualified for MDH status will no longer have MDH status under current law.

IPPS hospitals that have elected to participate in the Bundled Payments for Care Improvement initiative receive a payment that links multiple services furnished to a patient during an episode of care. We have stated in previous rulemaking that those hospitals continue to be paid under the IPPS (77 FR 53342). Hospitals that elect to participate in the initiative can still receive DSH payments while participating in the initiative, if they otherwise meet the requirements for receiving such payments. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50625), we specified that we will apply the new DSH payment methodology to the hospitals participating in this initiative, so that eligible hospitals will receive empirically justified Medicare DSH payments and uncompensated care payments.

Section 410A of the Medicare Modernization Act established the Rural Community Hospital Demonstration Program. After the initial 5-year period, the demonstration was extended for an additional 5-year period by sections 3123 and 10313 of the Affordable Care Act. There are 23 hospitals currently participating in the demonstration. Under the payment methodology provided in section 410A, participating hospitals receive payment for Medicare inpatient services on the basis of a cost methodology. Specifically, for discharges occurring in the hospitals' first cost reporting period of the initial 5-year demonstration or the first cost reporting period of the 5-year extension, the hospitals participating in the demonstration receive payments for the reasonable cost of providing such services. For discharges occurring in subsequent cost reporting periods during the applicable 5-year period, hospitals receive the lesser of the current year's reasonable cost-based amount, or the previous year's amount updated by the percentage increase in the IPPS market basket (the target amount). The instructions (Change Request 5020 (April 14, 2006) and Change Request 7505 (July 22, 2011) for the demonstration require that the MAC not pay Medicare DSH payments in addition to the amount received under the reasonable cost-based payment methodology. Because hospitals participating in the demonstration do not receive DSH payments, we determined in the FY 2014 IPPS/LTCH PPS final rule that these hospitals also are excluded from receiving empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology (78 FR 50625).

c. Empirically Justified Medicare DSH Payments

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the DSH payment that would otherwise be made under subsection (d)(5)(F) to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the program to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it is necessary to develop any new operational mechanisms for making such payments. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision simply by revising the claims payment methodologies to adjust the interim claim payments to the requisite 25 percent of what would have otherwise been paid. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments can be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the final rule that can be found on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html.*

d. Uncompensated Care Payments

As we have discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the new uncompensated care payment is the product of three factors. These three factors represent our estimate of 75 percent of the amount of Medicare DSH payments that would otherwise have been paid, an adjustment to this amount for the percent change in the national rate of uninsurance compared to the rate of uninsurance in 2013, and each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals. Below we review the data sources and methodologies for computing each of these factors, our final policies for FY 2014, and our proposed policies for FY 2015.

(1) Proposed Calculation of Factor 1 for FY 2015

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. Section 1886(r)(2)(A) of the Act states that it is a factor ''equal to the difference between (i) the aggregate amount of payments that would be made to subsection (d) hospitals under subsection (d)(5)(F) if this subsection did not apply for such fiscal year (as estimated by the Secretary); and (ii) the aggregate amount of payments that are made to subsection (d) hospitals under paragraph (1) for such a fiscal year (as so estimated).'' Therefore, section 1886(r)(2)(A)(i) of the Act represents the estimated Medicare DSH payment that would have been made under section 1886(d)(5)(F) if section 1886(r) of the Act did not apply for such fiscal year. Under a prospective payment system, we would not know the precise aggregate Medicare DSH payment amount that would be paid for a Federal fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the Federal fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount, by specifying that, for each fiscal year to which the provision applies, such amount is to be ''estimated by the Secretary.'' Similarly, section 1886(r)(2)(A)(ii) of the Act represents the estimated empirically justified Medicare DSH payments to be made in a fiscal year, as prescribed under section 1886(r)(1) of the Act. Again, section

1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount.

Therefore, Factor 1 is the difference between our estimates of: (1) The amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of the new payment provision; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act. In other words, this factor represents our estimate of 75 percent (100 percent minus 25 percent) of our estimate of Medicare DSH payments that would otherwise be made, in the absence of section 1886(r) of the Act, for the fiscal year.

In order to determine Factor 1 in the uncompensated care payment formula, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50628 through 50630) and in the FY 2014 IPPS interim final rule with comment period (78 FR 61194), we adopted a policy under which we develop final estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments to hospitals under section 1886(r)(1) of the Act prior to each fiscal year to which the new provision applies. These estimates are not revised or updated after we know the final Medicare DSH payments for the fiscal year. Specifically, in order to determine the two elements of Factor 1 (Medicare DSH payments *prior* to the application of section 1886(r)(1) of the Act, and empirically justified Medicare DSH payments *after* application of section 1886(r)(1) of the Act), we use the most recently available projections of Medicare DSH payments for the fiscal year, as calculated by CMS' Office of the Actuary. The Office of the Actuary projects Medicare DSH payments on a biannual basis, typically in February of each year (based on data from December of the previous year) as part of the President's Budget, and in July (based on data from June) as part of the Midsession Review. The estimates are based on the most recently filed Medicare hospital cost report with Medicare DSH payment information, supplemental cost report data provided by Indian Health Service (IHS) hospitals to CMS, and the most recent Medicare DSH patient percentages and Medicare DSH payment adjustments provided in the IPPS Impact File.

Therefore, for the Office of the Actuary's February 2014 estimate, the data are based on the December 2013 update of the Medicare Hospital Cost Report Information System (HCRIS), supplemental cost report data provided by IHS hospitals to CMS as of December 2013 and the FY 2014 IPPS/LTCH PPS final rule IPPS Impact file, published in conjunction with the publication of the FY 2014 IPPS/LTCH PPS final rule. For the July 2014 estimate, we anticipate that the data will be based on the March 2014 update of the HCRIS data, supplemental cost report data provided by IHS hospitals to CMS as of March 2014, and the FY 2015 proposed rule's IPPS Impact file, published in conjunction with this proposed rule (and which is available via the Internet on the CMS Web site). For purposes of this proposed rule, we are using the February 2014 Medicare DSH estimates to calculate Factor 1 and to model the proposed impact of this provision. For the final rule, we intend to use the July 2014 Medicare DSH estimates to determine Factor 1 and to model the impact of this provision. In addition, because SCHs paid under their hospital-specific payment rate are excluded from the application of section 1886(r) of the Act, we also exclude SCHs that are projected to be paid under their hospital-specific rate from our Medicare DSH estimates. Similarly, because Maryland hospitals participating in the Maryland All-Payer Model and hospitals participating in the Rural Community Hospital Demonstration do not receive DSH payments, we also exclude these hospitals from our Medicare DSH estimates.

Using the data sources discussed above, the Office of the Actuary uses the most recently submitted Medicare cost report data to identify current Medicare DSH payments, supplemental cost report data provided by IHS hospitals to CMS, and the most recent DSH payment adjustments provided in the IPPS Impact File, and applies inflation updates and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year. The February 2014 Office of the Actuary estimate for Medicare DSH payments for FY 2015, without regard to the application of section 1886(r)(1) of the Act, is $14.205 billion. This estimate excludes Maryland hospitals participating in the Maryland All-Payer Model, SCHs paid under their hospital-specific payment rate, and hospitals participating in the Rural Community Hospital Demonstration as discussed above. Therefore, based on this estimate, the estimate for empirically justified Medicare DSH payments for FY 2015, with the application of section 1886(r)(1) of the Act, is $3.551 billion (25 percent of the total amount estimated). Under § 412.l06(g)(1)(i) of the regulations, Factor 1 is the difference between these two estimates of the Office of the Actuary. Therefore, for the purpose of modeling Factor 1, we are proposing that Factor 1 for FY 2015 would be $10.654 billion ($14.205 billion minus $3.551 billion). We are inviting public comment on our proposed calculation of Factor 1 for FY 2015.

(2) Proposed Calculation of Factor 2 for FY 2015

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Specifically, section 1886(r)(2)(B)(i) of the Act provides: ''For each of fiscal years 2014, 2015, 2016, and 2017, a factor equal to 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, as determined by comparing the percent of such individuals (I) who are uninsured in 2013, the last year before coverage expansion under the Patient Protection and Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment); and (II) who are uninsured in the most recent period for which data is available (as so calculated), minus 0.1 percentage points for fiscal year 2014 and minus 0.2 percentage points for each of fiscal years 2015, 2016, and 2017.''

Section 1886(r)(2)(B)(i)(I) of the Act further indicates that the percent of individuals under 65 without insurance in 2013 must be the percent of such individuals ''who are uninsured in 2013, the last year before coverage expansion under the Patient Protection and Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment).'' The Health Care and Education Reconciliation Act (Pub. L. 111–152) was enacted on March 30, 2010. It was passed in the House of Representatives on March 21, 2010, and by the Senate on March 25, 2010. Because the House of Representatives was the first House to vote on the Health Care and Education

Reconciliation Act of 2010 on March 21, 2010, we have determined that the most recent estimate available from the Director of the Congressional Budget Office ''*before* a vote in either House on the Health Care and Education Reconciliation Act of 2010 . . .'' (emphasis added) appeared in a March 20, 2010 letter from the director of the CBO to the Speaker of the House. Therefore, we believe that only the estimates in this March 20, 2010 letter meet the statutory requirement under section 1886(r)(2)(B)(i)(I) of the Act. (To view the March 20, 2010 letter, we refer readers to the Web site at: *http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/amendreconprop.pdf*.)

In its March 20, 2010 letter to the Speaker of the House of Representatives, the CBO provided two estimates of the ''post-policy uninsured population.'' The first estimate is of the ''Insured Share of the Nonelderly Population Including All Residents'' (82 percent) and the second estimate is of the ''Insured Share of the Nonelderly Population Excluding Unauthorized Immigrants'' (83 percent). In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50631), we used the first estimate that includes all residents, including unauthorized immigrants. We stated that we believe this estimate is most consistent with the statute which requires us to measure ''the percent of individuals under the age of 65 who are uninsured,'' and provides no exclusions except for individuals over the age of 65. In addition, we stated that we believe that this estimate more fully reflects the levels of uninsurance in the United States that influence uncompensated care for hospitals than the estimate that reflects only legal residents. The March 20, 2010 CBO letter reports these figures as the estimated percentage of individuals with insurance. However, because section 1886(r)(2)(B)(i) of the Act requires that we compare the percent of individuals who are uninsured in the applicable year with the percent of individuals who were uninsured in 2013, in the FY 2014 IPPS/LTCH PPS final rule, we used the CBO insurance rate figure and subtracted that amount from 100 percent (that is the total population without regard to insurance status) to estimate the 2013 baseline percent of individuals without insurance. Therefore, for FYs 2014 through 2017, our estimate of the uninsurance percentage for 2013 is 18 percent.

Section 1886(r)(2)(B)(i) of the Act requires that we compare the baseline uninsurance rate to the percent of such individuals ''who are uninsured in the most recent period for which data is available (as so calculated).'' In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50634), we used the same data source, CBO estimates, to calculate this percent of individuals without insurance. In response to public comments, we also agreed that we should normalize the CBO estimates, which are based on the calendar year, for the Federal fiscal years for which each calculation of Factor 2 is made (78 FR 50633). Therefore, in the FY 2014 IPPS/LTCH PPS final rule, we employed the most recently available estimate, specifically CBO's May 2013 estimates of the effects of the Affordable Care Act on health insurance coverage (which are available at: *http://www.cbo.gov/sites/default/files/cbofiles/attachments/44190_EffectsAffordableCareActHealthInsuranceCoverage_2.pdf*) as amended by CBO's July 2013 estimates of changes in estimates of the effects of insurance coverage provisions in the Affordable Care Act issued in conjunction with a memo regarding ''Analysis of the Administration's Announced Delay of Certain Requirements Under the Affordable Care Act,'' which are available at: *http://www.cbo.gov/sites/default/files/cbofiles/attachments/44465-ACA.pdf*. The CBO's May 2013 estimate of the rate of insurance for CY 2013 was 80 percent, and for CY 2014 was 84 percent. Therefore, the calculation of Factor 2 for FY 2014, employing a weighted average of the CBO projections for CY 2013 and CY 2014, was as follows:

- CY 2013 rate of insurance coverage (May 2013 CBO estimate): 80 percent.
- CY 2014 rate of insurance coverage (May 2013 CBO estimate, updated with July 2013 CBO estimate): 84 percent.
- FY 2014 rate of insurance coverage: (80 percent * .25) + (84 percent * .75) = 83 percent.
- Percent of individuals without insurance for 2013 (March 2010 CBO estimate): 18 percent.
- Percent of individuals without insurance for FY 2014 (weighted average): 17 percent.

1 − |[(0.17 − 0.18)/0.18]| = 1 − 0.056 = 0.944 (94.4 percent).

0.944 (94.4 percent) − 0.001 (0.1 percentage points) = 0.943 (94.3 percent).

0.943 = Factor 2

Therefore, in the FY 2014 IPPS/LTCH PPS final rule, we adopted 0.943 as the final determination of Factor 2 for FY 2014. In conjunction with this determination, we also determined in the FY 2014 IPPS/LTCH PPS final rule and later revised in the FY 2014 IPPS interim final rule with comment period (78 FR 61195) that the amount available for uncompensated care payments for FY 2014 would be approximately $9.046 billion (0.943 times our Factor 1 estimate of $9.593 billion).

For this FY 2015 proposed rule, we have used CBO's February 2014 estimates of the effects of the Affordable Care Act on health insurance coverage (which are available at *http://www.cbo.gov/publication/43900?utm_source=feedblitz&utm_medium=FeedBlitzEmail&utm_content=812526&utm_campaign=0*). The CBO's February 2014 estimate of individuals under the age of 65 with insurance in CY 2014 is 84 percent. Therefore, the CBO's most recent estimate of the rate of uninsurance in CY 2014 is 16 percent (that is, 100 percent minus 84 percent.) Similarly, the CBO's February 2014 estimate of individuals under the age of 65 with insurance in CY 2015 is 86 percent. Therefore, the CBO's most recent estimate of the rate of uninsurance in CY 2015 available during the development of this proposed rule is 14 percent (that is, 100 percent minus 86 percent.)

The calculation of the proposed Factor 2 for FY 2015, employing a weighted average of the CBO projections for CY 2014 and CY 2015, is as follows:

- CY 2014 rate of insurance coverage (February 2014 CBO estimate): 84 percent.
- CY 2015 rate of insurance coverage (February 2014 CBO estimate): 86 percent.
- FY 2015 rate of insurance coverage: (84 percent * .25) + (86 percent * .75) = 85.5 percent.
- Percent of individuals without insurance for 2013 (March 2010 CBO estimate): 18 percent
- Percent of individuals without insurance for FY 2015 (weighted average): 14.5 percent

1 − |[(0.145—0.18)/0.18]| = 1 − 0.19444 = 0.80556 (80.556 percent)

0.80556 (80.556 percent) − 0.002 (0.2 percentage points for FY 2015 under section 1886(r)(2)(B)(i) of the Act) = 0.8036 (80.36 percent)

0.8036 = Factor 2

Therefore, we are proposing that Factor 2 for FY 2015 would be 0.8036. Our proposal for Factor 2 is subject to change if more recent CBO estimates of the insurance rate become available at the time of the preparation of the final rule. We are inviting public comments on our proposed calculation of Factor 2 for FY 2015.

(3) Proposed Calculation of Factor 3 for FY 2015

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is ''equal to the percent, for each subsection (d) hospital, that represents the quotient of (i) the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data is available which is a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (ii) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under this subsection for such period (as so estimated, based on such data).''

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary to determine: (1) The definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (that is, the estimated uncompensated care amount for an individual hospital) and denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period ''based on appropriate data.'' In addition, we note that the statute permits the Secretary to use alternative data ''in the case where the Secretary determines that alternative data is available,'' which is a better proxy for the costs of subsection (d) hospitals for treating uninsured individuals.

In the course of considering how to determine Factor 3 during the rulemaking process for FY 2014, we considered defining the amount uncompensated care for a hospital as the uncompensated care costs of each hospital and considered potential data sources for those costs. For purposes of selecting an appropriate data source for this possible definition of uncompensated care costs, we reviewed the literature and available data sources and determined that Worksheet S–10 of the Medicare cost report could potentially provide the most complete data for Medicare hospitals. (We refer readers to the report ''Improvements to Medicare Disproportionate Share (DSH) Payments'' for a full discussion and evaluation of the available data sources. The report is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html*.) However, we noted that Worksheet S–10 is a relatively new data source that has been used for specific payment purposes only in relatively restricted ways (for example, to provide a source of charity care charges in the computation of EHR incentive payments (75 FR 44456)). We also noted that some stakeholders have expressed concern that hospitals have not had enough time to learn how to submit accurate and consistent data through this reporting mechanism. Other stakeholders have maintained that some instructions for Worksheet S–10 still require clarification in order to ensure standardized and consistent reporting by hospitals. At the same time, we noted that Worksheet S–10 is the only national data source that includes data for all Medicare hospitals and is designed to elicit data on uncompensated care costs. We discussed the possible use of data reported on Worksheet S–10 to determine uncompensated care costs in more detail in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27586).

Because of concerns regarding variations in the data reported on Worksheet S–10 of the Medicare cost report and the completeness of these data, we did not propose to use data from the Worksheet S–10 to determine the amount of uncompensated care. However, we stated our belief that Worksheet S–10 of the Medicare cost report would otherwise be an appropriate data source to determine uncompensated care costs. In particular, we noted that Worksheet S–10 was developed specifically to collect information on uncompensated care costs in response to interest by MedPAC and other stakeholders regarding the topic (for example, MedPAC's March 2007 Report to Congress) and that it is not unreasonable to expect information on the cost report to be used for payment purposes. Furthermore, hospitals attest to the accuracy and completeness of the information reported in the cost report at the time of submission. We indicated that we expect reporting on Worksheet S–10 to improve over time, particularly in the area of charity care which is already being used and audited for payment determinations related to the EHR Incentive Program, and that we will continue to monitor these data. Accordingly, we stated that we may proceed with a proposal to use data on the Worksheet S–10 to determine uncompensated care costs in the future, once hospitals are submitting accurate and consistent data through this reporting mechanism.

As a result of our concerns regarding the data reported on Worksheet S–10 of the Medicare cost report, we believed it was appropriate to consider the use of alternative data, at least in FY 2014, the first year that this provision is in effect, and possibly for additional years until hospitals have adequate experience reporting all of the data elements on Worksheet S–10. We noted that this approach is consistent with input we received from some stakeholders in response to the CMS National Provider Call in January 2013, who stated their belief that existing FY 2010 and FY 2011 data from the Worksheet S–10 should not be used for implementation of section 1886(r) of the Act and who requested the opportunity to resubmit the data once more specific instructions were issued by CMS. Accordingly, we examined alternative data sources that could be used to allow time for hospitals to gain experience with and to improve the accuracy of their reporting on Worksheet S–10 of the Medicare cost report. We stated in the FY 2014 IPPS/LTCH PPS final rule that we believe that data on utilization for insured low-income patients can be a reasonable proxy for the treatment costs of uninsured patients. Moreover, due to the concerns regarding the accuracy and consistency of the data reported on the Worksheet S–10, we also determined that these alternative data, which are currently reported on the Medicare cost report, would be a better proxy for the amount of uncompensated care provided by hospitals. Accordingly, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50639), we adopted the policy of employing the utilization of insured low-income patients defined as

inpatient days of Medicaid patients plus inpatient days of Medicare SSI patients as defined in 42 CFR 412.106(b)(4) and 412.106(b)(2)(i), respectively, to determine Factor 3. We also indicated that we remained convinced that the Worksheet S–10 could ultimately serve as an appropriate source of more direct data regarding uncompensated care costs for purposes of determining Factor 3 once hospitals are submitting more accurate and consistent data through this reporting mechanism. In the interim, we indicated that we would take steps such as revising and clarifying cost report instructions, as appropriate. We stated that it is our intention to propose introducing the use of the Worksheet S–10 data for purposes of determining Factor 3 within a reasonable amount of time.

Since the publication of the FY 2014 IPPS/LTCH PPS final rule, we have continued to evaluate and assess the comments we have received from stakeholders about Worksheet S–10 as well as evaluate what changes might need to be made to the instructions to make the data hospitals submit more accurate and consistent across hospitals. Although we have not yet developed revisions to the Worksheet S–10 instructions at this time, we remain committed to making improvements to Worksheet S–10. For that reason, we believe it would be premature to propose the use of Worksheet S–10 data for purposes of determining Factor 3 for FY 2015. Therefore, we are proposing to continue to employ the utilization of insured low-income patients defined as inpatient days of Medicaid patients plus inpatient days of Medicare SSI patients, as defined in § 412.106(b)(4) and § 412.106(b)(2)(i), respectively, to determine Factor 3 for FY 2015. Accordingly, we are proposing to revise the regulations at 42 CFR 412.106(g)(1)(iii)(C) to state that, for FY 2015, CMS will base its estimates of the amount of hospital uncompensated care on the most recent available data on utilization for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of that section of the regulations. We are inviting public comments on this proposal, and we will continue to work with the hospital community and others to develop the appropriate clarifications and revisions to Worksheet S–10 of the Medicare cost report for reporting uncompensated care data. In particular, we are inviting public comments on what would be a reasonable timeline for adopting Worksheet S–10 of the Medicare cost report as the data source for determining Factor 3.

As we did for the FY 2014 IPPS/LTCH PPS proposed rule, we are publishing on the CMS Web site a table listing Factor 3 for all hospitals that we estimate would receive empirically justified Medicare DSH payments in a fiscal year (that is, hospitals that we project would receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) and subsection (d) Puerto Rico hospitals that have the potential of receiving a DSH payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. Hospitals have 60 days from the date of public display of the IPPS/LTCH PPS proposed rule to review these tables and notify CMS in writing of a change in a hospital's subsection (d) hospital status, such as if a hospital has closed or converted to a CAH.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50639), we considered public comments which recommended that we use the wage index to adjust insured low-income days in determining Factor 3 in order to account for the differences in ''purchasing power'' in different regions of the country. With respect to these public comments, we agreed that there may be regional variation in uncompensated care costs due to regional variations in the costs of care generally. However, we stated that we did not believe that there was sufficient basis for believing that the wage index reflects the variations in uncompensated care costs well enough to adopt it as the basis for adjusting Factor 3. The wage index reflects the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. In computing the wage index, we derive an average hourly wage for each labor market area (total wage costs divided by total hours for all hospitals in the geographic area) and a national average hourly wage (total wage costs divided by total hours for all hospitals surveyed in the nation). A labor market area's wage index value is the ratio of the area's average hourly wage to the national average hourly wage. We note that, for FY 2014, 69.6 percent of the standardized amount is considered to be the labor-related share and, therefore, adjusted by the wage index. However, in addition to the labor-related share of the standardized amount being adjusted by the wage index, the entire standardized amount is also adjusted for the relative weight of the MS–DRG for each individual patient. In other words, the wage index only adjusts for a portion of the variation in costs, and does not address variations in resource use and patient severity. Therefore, we stated that we did not believe that there was sufficient basis for believing that adjusting low-income patient days by the wage index would better reflect variations in uncompensated care costs.

Since the publication of the FY 2014 IPPS/LTCH PPS final rule, we have continued to consider whether to propose employing the wage index to adjust insured low-income days in determining Factor 3. After this consideration, we continue to believe that a wage index adjustment to insured low-income days is not an appropriate measure to account for variations in the costs of uncompensated care among hospitals. The intensity of such care, and therefore the costs, may vary by hospital, but we still lack convincing evidence that the wage index data are an accurate measure of that intensity. Therefore, we are not proposing to adopt such an adjustment to low-income days for purposes of calculating Factor 3 in FY 2015.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50639), we also considered public comments that requested that we include insured low-income days from exempt units (specifically, inpatient rehabilitation units paid under the IRF PPS and inpatient psychiatric units paid under the IPF PPS) of the hospital in the computation of Factor 3, in order to better capture the treatment costs of the uninsured by the hospital. In response to those public comments, we stated our belief that there may be some merit to including insured low-income days from exempt units of the hospital in order to better capture the full costs of the treatment of the uninsured by the hospital insofar as those data may be publicly available, subject to audit, and used for payment purposes. We also indicated that we believed it would be prudent to consider the degree to which these data meet these conditions before adopting this recommendation. Therefore, we stated that we would consider including this recommendation among our proposals in future rulemaking.

Since the publication of the FY 2014 IPPS/LTCH PPS final rule, we have conducted an analysis of the impact of adopting this recommendation. That analysis has indicated that the inclusion of Medicaid and Medicare-SSI days for exempt inpatient units does not significantly change the distribution of uncompensated care payments to hospitals, with the exception of a few hospitals with high utilization associated with those exempt units that

would see increases in their uncompensated care payments. Furthermore, Medicaid and SSI days for inpatient rehabilitation units have been audited and are used for payment purposes under the IRF PPS; specifically, these data are used to calculate the low-income payment (LIP) adjustment under the IRF PPS. However, the data for inpatient psychiatric units are not generally audited and have not been used previously for payment purposes. Therefore, we are not proposing at this time to include those days in the calculation of a hospital's share of uncompensated care payments. As we indicated earlier, we believe it would be appropriate to include such data in the calculation of uncompensated care payments only insofar as those data may be publicly available, subject to audit, and used for payment purposes. The use of data for inpatient psychiatric units would fail the second and third conditions. At the same time, we do not believe that including only inpatient rehabilitation unit days without inpatient psychiatric unit days would improve the accuracy of the uncompensated care payment calculation. We also observe, as we have previously noted, that the statutory references under section 1886(d)(5)(F) of the Act to ''days'' apply only to hospital acute care inpatient days. Section 412.106(a)(1)(ii) of the regulations therefore provides that, for purposes of DSH payments, ''the number of patient days in the hospital includes only those days attributable to units or wards of the hospital providing acute care services generally payable under the prospective payment system and excludes'' other days. In the absence of compelling reasons to do otherwise, we believe it is preferable to maintain consistency with this longstanding precedent in the context of this temporary method for determining uncompensated care payments. However, we are inviting public comments on this issue.

The statute also allows the Secretary the discretion to determine the time periods from which we will derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as ''the amount of uncompensated care for such hospital *for a period selected by the Secretary. . . .''* (emphasis added). Section 1886(r)(2)(C)(ii) of the Act defines the denominator as ''the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under this subsection *for such period''* (emphasis added). In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments using the most recently available historical data and for those hospitals that we do not estimate will qualify for Medicare DSH payments but that may ultimately qualify for Medicare DSH payments at the time of cost report settlement.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), therefore, we adopted the policy to calculate the numerator and the denominator of Factor 3 for hospitals based on the most recently available full year of Medicare cost report data (including the most recently available data that may be used to update the SSI ratios) with respect to a Federal fiscal year. In other words, we use data from the most recently available full year cost report for the Medicaid days and the most recently available SSI ratios (that is, latest available SSI ratios before the beginning of the Federal fiscal year) for the Medicare SSI days. We noted that these data are publicly available, subject to audit, and used for payment purposes. While we recognized that older data also meet these criteria, we often use the most recently available data for payment determinations. Furthermore, in the FY 2014 IPPS interim final rule with comment period (78 FR 61195), we revised our policy to also include supplemental cost report data submitted to CMS only by IHS hospitals in order allow their Medicaid days to be used to calculate Factor 3.

Therefore, for FY 2014, we used data from the most recently available full year cost report for the Medicaid days and the most recently available SSI ratios, which meant data from the 2010/2011 cost reports for the Medicaid days, supplemental 2011 cost report data submitted to CMS by IHS hospitals, and the FY 2011 SSI ratios for the Medicare SSI days to estimate Factor 3 for FY 2014. For FY 2015, we are again proposing to use data from the most recently available full year cost report for the Medicaid days (that is, we are proposing to use the 2012 cost report, unless that cost report is unavailable or reflects less than a full 12-month year; in the event the 2012 cost report is for less than 12 months, we are proposing to use the cost report from 2012 or 2011 that is closest to being a full 12-month cost report), supplemental cost report data submitted to CMS only by IHS hospitals and the most recently available SSI ratios. For purposes of this proposed rule, we are using data from the December 2013 update of the 2011/2012 Medicare cost reports for the Medicaid days and the FY 2011 SSI ratios for the Medicare SSI days. Consistent with our FY 2014 IPPS interim final rule with comment period (78 FR 61195), for FY 2015, we also are using supplemental cost report data provided by IHS hospitals to CMS as of December 2013 in order to calculate the proposed Factor 3. For the FY 2015 IPPS final rule, we intend to use the March 2014 update of the 2011/2012 Medicare cost reports, supplemental cost report data submitted to CMS by IHS hospitals as of March 2014, and the most recently available SSI ratios (FY 2012 SSI ratios and, if not available, the FY 2011 SSI ratios) to calculate Factor 3. We believe the March update to the Medicare cost reports will be the most recently available data to calculate Factor 3 at the time of publication of the FY 2015 IPPS final rule. We believe this is consistent with CMS' historical policy to use the best available data when setting the payment rates and factors in both the proposed and final rules. Furthermore, this is consistent with our approach in other areas of IPPS, where we historically use the March update of cost report data and MedPAR claims data to calculate IPPS relative weights, budget neutrality factors, the outlier threshold, and the standardized amount for the IPPS final rule. If we were to wait for a later update of the cost report data to become available, this could cause delay of the publication of the IPPS final rule.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50642), we discussed several specific issues concerning the use of cost report data to determine Factor 3. One issue concerned the process and data to be employed in determining Factor 3 in the case of hospital mergers. Specifically, two hospitals that merged in 2011 with one surviving provider number requested that we account for the merger by including data from both hospitals' cost reports immediately prior to the merger in the calculation of the Factor 3 amount. In that final rule, we had calculated Factor 3 using only the surviving hospital's cost report data and SSI ratio data. In the final rule (78 FR

50602), we responded to the public comment that Factor 3 would be calculated based on the low-income insured patient days (that is, Medicaid days and SSI days) under the surviving CCN, based on the most recent available data for that CCN (for FY 2014, from the cost report for 2011 or 2010). We noted that this was consistent with the treatment of other IPPS payment factors, where data used to calculate a hospital's Medicare DSH payment adjustment, CCRs for outlier payments, and wage index values are tied to a hospital's CCN. Data associated with a CCN that is no longer in use are not used to determine those IPPS hospital payments under the surviving CCN.

Since the publication of the FY 2014 IPPS/LTCH PPS final rule, we have received additional input from hospitals that have undergone mergers that suggest using only the surviving CCN produces an estimate of the surviving hospital's uncompensated care burden that is lower than warranted. For FY 2015, for example, Factor 3 of the uncompensated care payment calculation would be determined using 2011/2012 cost reports. As a result, for any mergers occurring between FY 2011 and FY 2015, Factor 3 of the uncompensated care payment for FY 2015 would reflect only the data of the hospital with the surviving CCN, not the combination of the data from the two hospitals that merged. We believe that revising our methodology to incorporate data from both of the hospitals that merged could improve our estimate of the uncompensated care burden of the merged hospital. Accordingly, we are proposing to revise our methodology for determining Factor 3 to incorporate data from both merged hospitals until data for the merged hospitals become available under the surviving CCN.

In addition, because the data systems used to calculate Factor 3 do not identify hospitals that have merged, we also are proposing to establish a process to identify hospitals that have merged after the period of the historical data that are being used to calculate Factor 3, up to a point in time during ratesetting for that Federal fiscal year. Under this approach, we would combine the data for the merged hospitals to calculate Factor 3 of the uncompensated care payment. Specifically, we are proposing that we would identify the hospitals that merged after the period from which data are being used to calculate Factor 3 (for FY 2015, 2012 and 2011) but before the publication of each year's final rule. For purposes of this proposal, we are defining a merger to be an acquisition where the Medicare provider agreement of one hospital is subsumed into the provider agreement of the surviving provider. We would not consider an acquisition where the new owner voluntarily terminates the Medicare provider agreement of the hospital it purchased by rejecting assignment of the previous owner's provider agreement to be a merger. We believe it is appropriate to combine data to calculate Factor 3 for a merged hospital where the Medicare provider agreement of one hospital is subsumed into the provider agreement of the surviving provider because, in this type of acquisition as described in the September 6, 2013 Survey & Certification Memorandum S&C: 13–60–ALL (*http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-60.pdf*), the buyer is subject to all applicable statutes and regulations and to the terms and conditions under which the assigned agreement was originally issued. These include, but are not limited to, Medicare requirements to adjust payments to account for prior overpayments and underpayments, even if they relate to a pre-acquisition period (successor liability), and to adjust payments to collect civil monetary penalties. Therefore, we believe it is appropriate to also retain the data of the subsumed hospital to calculate the uncompensated care payment for the merged hospital. Conversely, by rejecting assignment of the Medicare provider agreement of the subsumed hospital, the surviving provider has voluntarily terminated the Medicare provider agreement and is precluded from having successor liability for Medicare overpayments or underpayments that would have otherwise been made to the subsumed provider. Furthermore, when the surviving hospital rejects automatic assignment of the existing provider agreement, but wishes to participate in the Medicare program, the merged hospital is considered an initial applicant to the Medicare program. In an instance in which the surviving provider has rejected assignment of the Medicare provider agreement of the subsumed provider, it would not seem appropriate to use data from the subsumed provider for purposes of Medicare payment, including for the calculation of a hospital's uncompensated care payment.

For FY 2015, we are proposing to identify mergers by querying the Medicare contractors. We believe it is appropriate to obtain merger information from the Medicare contractors, as a copy of each final sales agreement/transaction indicating the effective date of the acquisition is generally submitted to the Medicare contractors once an acquisition is finalized. For the purpose of this proposed rule, we requested that the Medicare contractors provide us with a list of mergers that occurred between October 1, 2010 (the first day of FY 2011, which is the earliest date that would be included in any 2011 cost report data that are used to calculate a hospital's Factor 3) through January 2014 (when we started preparing for the FY 2015 IPPS proposed rule). On the basis of this information, we would then combine the data elements of any hospitals that had merged to calculate the uncompensated care payment for the merged hospital. Specifically, we would combine the Medicaid days from the most recently available full year cost reports and the SSI days from the most recently available SSI ratios tied to the two CCNs prior to the merger to calculate the merged hospital's Factor 3. For FY 2015, we would combine the Medicaid days from either the 2011 or 2012 cost reports and would use the most recently available SSI ratios available at the time the final rule is developed.

In order to confirm these mergers and the accuracy of the data used to determine each merged hospital's uncompensated care payment, we are proposing to publish a table on the CMS Web site, in conjunction with the issuance of the proposed and final rules for a fiscal year, containing a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital. A copy of this table is being published on the CMS Web site in conjunction with the issuance of this proposed rule. The affected hospitals would then have the opportunity to comment during the public comment period on the accuracy of this information.

We are proposing to treat hospitals that merge after the development of the final rule similar to new hospitals. For these newly merged hospitals, we would not have data currently available to calculate a Factor 3 amount that accounts for the merged hospital's uncompensated care burden. In addition, we would not have data to determine if the newly merged hospital is eligible for Medicare DSH payment and, therefore, eligible for uncompensated care payments for the applicable fiscal year because the only data we would have to make this determination are those for the surviving CCN. Accordingly, we are proposing to treat newly merged hospitals in a similar manner as new

hospitals, such that the newly merged hospital's final uncompensated care payment would be determined at cost report settlement where the numerator of the newly merged hospital's Factor 3 would be based on the Medicaid days and SSI days reported on the cost report used for the applicable fiscal year. We are proposing that the interim uncompensated care payments for the newly merged hospitals would be based on only the data of the surviving hospital's CCN at the time of the preparation of the final rule for the applicable fiscal year. In other words, for newly merged hospitals, eligibility to receive interim uncompensated care payments and the amount of any interim uncompensated care payments would be based on the Medicaid days from either the 2011 or 2012 cost reports and the most recently available SSI ratios available at the time the final rule is developed for only the surviving CCN. However, at cost report settlement, we would determine the newly merged hospital's final uncompensated care payments based on the Medicaid days and SSI days reported on the cost report used for the applicable fiscal year. That is, we would revise the numerator of Factor 3 for the newly merged hospital to reflect the Medicaid and SSI days reported on the cost report for the applicable fiscal year. We are inviting public comment on our proposed change to the treatment of hospital mergers in the calculation of a hospital's uncompensated care payment.

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

1. Background

Section 1885(d)(5)(G) of the Act provides special payment protections, under the IPPS, to a Medicare-dependent, small rural hospital (MDH). (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.)) As we discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50287) and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684), section 3124 of the Affordable Care Act extended the expiration of 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.

Since the extension of the MDH program through FY 2012 provided by section 3124 of the Affordable Care Act, the MDH program has been further extended multiple times. First, section 606 of the ATRA of 2012 (Pub. L. 112–240) extended the MDH program through FY 2013 (that is, for discharges occurring before October 1, 2013.) Second, section 1106 of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) extended the MDH program through the first half of FY 2014 (that is, for discharges occurring before April 1, 2014.) In the FY 2014 interim final rule with comment period that appeared in the **Federal Register** on March 18, 2013 (79 FR 15025 through 15027), we discussed the expiration of the MDH program on March 31, 2014, and explained how providers may be affected by the 6-month extension of the MDH program under Public Law 113–67 and described the steps to reapply for MDH status for FY 2014, as applicable. Generally, a provider that was classified as an MDH as of September 30, 2013, was reinstated as an MDH effective October 1, 2013, with no need to reapply for MDH classification. However, if the MDH had classified as an SCH or cancelled its rural classification under § 412.103(g) effective on or after October 1, 2013, the effective date of MDH status may not be retroactive to October 1, 2013. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50647 through 50649) and the FY 2014 interim final rule with comment period (79 FR 15025 through 15027), we made conforming changes to the regulations at § 412.108(a)(1) and (c)(2)(iii) to reflect the extensions of the MDH program provided for by the ATRA and Pathway for SGR Reform Act, respectively. Lastly, under current law, section 106 of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) provides for a 1-year extension of the MDH program effective from April 1, 2014 through March 31, 2015. Specifically, section 106 of Public Law 113–93 amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act by striking ''April 1, 2014'' and inserting ''April 1, 2015''. Section 106 of Public Law 113–93 also made conforming amendments to sections 1886(b)(3)(D)(i) and 1886(b)(3)(D)(iv) of the Act.

We intend to address the extension of the MDH program for the second half of FY 2014 (that is, from April 1, 2014 through September 30, 2014) under Public Law 113–93 in a separate **Federal Register** notice. For additional information on the extensions of the MDH program after FY 2012, we refer readers to the following rules: The FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405 and 53413 through 53414); the FY 2013 IPPS notice that appeared in the **Federal Register** on March 7, 2013 (78 FR 14689); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50647 through 50649); and the FY 2014 interim final rule with comment period (79 FR 15025 through 15027).

2. Provisions of Public Law 113–93 for FY 2015

Prior to the enactment of Public Law 113–93, under section 1106 of Public Law 113–67, the MDH program authorized by section 1886(d)(5)(G) of the Act was set to expire midway through FY 2014. Section 106 of Public Law 113–93 amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to provide for an additional 1-year extension of the MDH program, effective from April 1, 2014 through March 31, 2015. Section 106 of Public Law 113–93 also made conforming amendments to sections 1886(b)(3)(D)(i) and 1886(b)(3)(D)(iv) of the Act.

In this proposed rule, we are proposing to make conforming changes to the regulations at §§ 412.108(a)(1) and (c)(2)(iii) to reflect the statutory extension of the MDH program for the first 6 months of FY 2015 made by section 106 of Public Law 113–93.

3. Expiration of the MDH Program

Because section 106 of Public Law 113–93 extends the MDH program through the first half of FY 2015 only, effective April 1, 2015, the MDH program will no longer be in effect. Because the MDH program is not authorized by statute beyond March 31, 2015, beginning April 1, 2015, all hospitals that previously qualified for MDH status will no longer have MDH status and will be paid based on the Federal rate. As noted earlier, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405), we revised our SCH policies to allow MDHs to apply for SCH status and be paid as such under certain conditions, following expiration of the MDH program at the end of FY 2012. We codified these changes in the regulations at § 412.92(b)(2)(i) and § 412.92(b)(2)(v). For additional information, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405 and 53674). We note that those same conditions apply to MDHs that intend to apply for SCH status with the expiration of the MDH program on March 31, 2015. Specifically, the existing regulations at § 412.92(b)(2)(i) and (b)(2)(v) allow for an effective date of approval of SCH status that is the day following the expiration date of the MDH program. In accordance with these regulations, in order for an MDH to receive SCH status

effective April 1, 2015, it must apply for SCH status at least 30 days before the end of the MDH program; that is, the MDH must apply for SCH status by March 1, 2015. The MDH also must request that, if approved as an SCH, the SCH status be effective with the expiration of the MDH program provision; that is, the MDH must request that the SCH status, if approved, be effective April 1, 2015, immediately after its MDH status expires with the expiration of the MDH program on March 31, 2015. We note that an MDH that applies for SCH status in anticipation of the expiration of the MDH program would not qualify for the April 1, 2015 effective date upon approval if it does not apply by the March 1, 2015 deadline. The provider would instead be subject to the usual effective date for SCH classification, that is, 30 days after the date of CMS' written notification of approval as specified at § 412.92(b)(2)(i).

H. Hospital Readmissions Reduction Program: Proposed Changes for FY 2015 Through FY 2017 (§§ 412.150 Through 412.154)

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 section 1886(q) to 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 applicable hospitals may 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. In accordance with 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 a hospital-specific adjustment factor that accounts for the hospital's excess readmissions. 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 adjustment payments, and add-on 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, including policies for SCHs and for MDHs for FY 2013. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374), we finalized policies to implement the statutory provisions related to the definition of ''base operating DRG payment amount'' with respect to those hospitals.

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 establishes 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 defines the terms ''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 readmissions ratio. . . for such hospital for such applicable period minus 1.'' The ''excess readmissions ratio'' is a hospital-specific ratio based on each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the excess readmissions ratio as the ratio of actual-over-expected readmissions; specifically, 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) [of the Act] . . . and such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital).'' 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 (76 FR 51671), the ''applicable period'' is the period during which data are collected in order to calculate various ratios and payment 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 (not just Medicare patients) for a broad range of both subsection (d) and non-subsection(d) hospitals, in order to calculate the hospital-specific readmission rates for all such hospital inpatients and to publicly report these ''all-patient'' readmission rates.

2. Regulatory Background

The payment adjustment factor set forth in section 1886(q) of the Act did not apply to discharges until FY 2013. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676), we addressed the issues of the selection of readmission measures and the calculation of the excess readmissions ratio, which will be used, in part, to calculate the readmissions adjustment factor. Specifically, in that final rule, we finalized policies that relate to the portions of section 1886(q) of the Act that address the selection of and measures for the applicable conditions, the definitions of ''readmission'' and ''applicable period,'' and the methodology for calculating the excess readmissions ratio. We also established policies with respect to measures for readmission for the applicable conditions and our methodology for calculating the excess readmissions ratio.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401), we finalized policies that relate to the portions of section 1886(q) of the Act that address the calculation of the hospital readmission payment adjustment factor and the process by which hospitals can review and correct their data. Specifically, in that final rule, we addressed the base operating DRG payment amount, aggregate payments for excess readmissions and aggregate payments for all discharges, the adjustment factor, applicable hospital, limitations on review, and reporting of hospital-specific information, including the process for hospitals to review readmission information and submit corrections. We also established a new Subpart I under 42 CFR part 412 (§§ 412.150 through 412.154) to codify rules for implementing the Hospital Readmissions Reduction Program.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676), we finalized our policies that relate to refinement of the readmissions measures and related methodology for the current applicable conditions, expansion of the ''applicable conditions'' beginning for FY 2015, and clarification of the process for reporting hospital-specific information, including the opportunity to review and submit corrections. We also established policies related to the calculation of the adjustment factor for FY 2014.

3. Overview of Proposals and Policies for the FY 2015 Hospital Readmissions Reduction Program

In this proposed rule, we are—

- Proposing to make refinements to the readmissions measures and related methodology for FY 2015 and subsequent years (section IV.H.4. of the preamble of this proposed rule);
- Proposing to expand the scope of ''applicable conditions'' for FY 2017 to include coronary artery bypass graft (CABG) (section IV.H.6. of the preamble of this proposed rule);
- Discussing the maintenance of technical specifications for quality measures (section IV.H.7. of the preamble of this proposed rule);
- Describing a waiver from the Hospital Readmissions Reduction Program for hospitals formerly paid under section 1814(b)(3) of the Act (§ 412.154(d)) (section IV.H.8. of the preamble of this proposed rule);
- Proposing to specify the adjustment factor floor for FY 2015 (section IV.H.9. of the preamble of this proposed rule);
- Proposing to specify the applicable period for FY 2015 (section IV.H.10. of the preamble of this proposed rule);
- Proposing to make changes to the calculation of the aggregate payments for excess readmissions to include two additional readmissions measures (chronic obstructive pulmonary disease (COPD) and THA/TKA) (section IV.H.11. of the preamble of this proposed rule); and
- Discussing whether to establish an exceptions process to address hospitals with extraordinary circumstances (section IV.H.12. of the preamble of this proposed rule).

4. Proposed Refinement of the Readmission Measures and Related Methodology for FY 2015 and Subsequent Years Payment Determinations

a. Proposed Refinement of Planned Readmission Algorithm for Acute Myocardial Infarction (AMI), Heart Failure (HF), Pneumonia (PN), Chronic Obstructive Pulmonary Disease (COPD), and Total Hip Arthroplasty and Total Knee Arthroplasty (THA/TKA) 30-Day Readmission Measures

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50651 through 50655), we finalized for 2014 and subsequent years' payment determinations the use of the CMS Planned Readmission Algorithm Version 2.1 in the AMI, HF, PN, COPD and THA/TKA readmission measures. The algorithm identifies readmissions that are planned and occur within 30 days of discharge from the hospital. A complete description of the CMS Planned Readmission Algorithm Version 2.1, which includes lists of planned diagnoses and procedures, can be found on our Web site (available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html).* NQF has endorsed the use of the algorithm for these measures.

Last year's stakeholder comments supported the incorporation of the CMS Planned Readmission Algorithm Version 2.1 and suggested that we update it on a regular basis. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50652), we agreed to continually review the CMS Planned Readmission Algorithm and make updates as needed. Subsequently we have identified and made improvements to the algorithm. We are proposing to use the revised version, the CMS Planned Readmission Algorithm Version 3.0, for the AMI, HF, PN, COPD, and THA/TKA readmission measures for FY 2015 and subsequent payment determinations. We are also proposing to use this algorithm for the CABG readmission measure proposed for inclusion in the Hospital Readmissions Reduction Program starting in FY 2017.

Version 3.0 incorporates improvements that were made based on a validation study of the algorithm. Researchers reviewed 634 patients' charts at 7 hospitals, classified readmission as planned or unplanned based on the chart review, and compared the results to the claims-based algorithm's classification of the readmissions. The findings suggested the algorithm was working well but could be improved.

Specifically, the study suggested the need to make small changes to the tables of procedures and conditions used in the algorithm to classify readmission as planned or unplanned. The algorithm uses the Agency for Healthcare Research and Quality's (AHRQ's) Clinical Classification Software (CCS) to group thousands of procedure and diagnosis codes into fewer categories of related procedures or diagnoses. The algorithm then uses four tables of procedures and diagnoses categories and a flow diagram to classify tables as planned or unplanned. For all measures, the first table identifies procedures that, if present in a readmission, classify the readmission as planned. The second table identifies primary discharge diagnoses that always classify readmissions as planned. Because almost all planned admissions are for

procedures or surgeries, a third table identifies procedures for which patients are typically admitted; if any of these procedures are coded in the readmission, we classify a readmission as planned as long as that readmission does not have an acute (unplanned) primary discharge diagnosis. The fourth table lists the acute (unplanned) primary discharge diagnoses that disqualify readmissions that include one or more of the potentially planned procedure in the third table as planned. These tables are structured the same across all measures but the specific procedure and conditions they contain vary slightly for certain measures based on clinical considerations for each cohort. The final proposed tables for each measure can be found on our Web site under the Measure Methodology reports (available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*).

Version 3.0 modifies two of these tables by removing or adding procedures or conditions to improve the accuracy of the algorithm. First, validation study revealed that the algorithm could be improved by removing two procedure CCS categories from the third table, the potentially planned procedure table: CCS 211—Therapeutic Radiation and CCS 224—Cancer Chemotherapy. Typically, patients do not require admission for scheduled Therapeutic Radiation treatments (CCS 211). The study found that readmissions that were classified as planned because they included Therapeutic Radiation were largely unplanned.

The algorithm was also more accurate when CCS 224—Cancer Chemotherapy was removed from the potentially planned procedure table. The second table of the algorithm classifies all readmissions with a *principal diagnosis* of Maintenance Chemotherapy as planned. Most patients who receive cancer chemotherapy have both a code for Cancer Chemotherapy (CCS 224) and a principal discharge diagnosis of Maintenance Chemotherapy (CCS 45). In the validation study, the readmissions for patients who received Cancer Chemotherapy (CCS 224) but who did not have a principal diagnosis of Maintenance Chemotherapy were largely unplanned, so removing CCS 224 from the potentially planned procedure table improved the algorithm's accuracy. Therefore, Version 3.0 removes CCS 211 and CCS 224 from the list of potentially planned procedures to improve the accuracy of the algorithm.

As noted above, the algorithm uses a table of acute principal discharge diagnoses to help identify unplanned readmissions. Readmissions that have a principal diagnosis listed in the table are classified as unplanned, regardless of whether they include a procedure in the potentially planned procedure table. The validation study identified one diagnosis CCS that should be added to the table of acute diagnoses to more accurately identify truly unplanned admissions as unplanned: Hypertension with Complications (CCS 99). Hypertension with complications is a diagnosis that is rarely associated with planned readmissions.

In addition, the validation study identified a subset of ICD–9–CM diagnosis codes within two CCS diagnosis categories that should be added to the acute diagnosis table to improve the algorithm. CCS 149, Pancreatic Disorders, includes the code for acute pancreatitis; clinically there is no situation in which a patient with this acute condition would be admitted for a planned procedure. Therefore, Version 3.0 adds the ICD–9 code for acute pancreatitis, 577.0, to the acute primary diagnosis table to better identify unplanned readmissions. Finally, CCS 149, Biliary Tract Disease, is a mix of acute and nonacute diagnoses. Adding the subset of ICD–9–CM codes within this CCS group that are for acute diagnoses to the list of acute conditions improves the accuracy of the algorithm for these acute conditions while still ensuring that readmissions for planned procedures, like cholecystectomies, are counted accurately as planned. For more detailed information on how the algorithm is structured and the use of tables to identify planned procedures and diagnoses, we refer readers to discussion of the CMS Planned Readmission Algorithm Version 2.1 in our reports (available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html).* As noted above, readers can find the specific Version 3.0 tables for each measure in the measure updates and specifications reports at the above link.

We invite public comment on these proposals.

b. Proposed Refinement of Total Hip Arthroplasty and Total Knee Arthroplasty (THA/TKA) 30-Day Readmission Measure Cohort

In this proposed rule, for FY 2015 and subsequent years, we are proposing to refine the measure cohort for the Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure.

Currently, the THA/TKA Readmission Measure adopted for the Hospital Readmissions Reduction Program is intended to only include patients who have an elective THA or TKA. This measure therefore excludes patients who have a principal discharge diagnosis of femur, hip, or pelvic fracture on their index admission since hip replacement for hip fracture is not an elective procedure. However, after hospitals reviewed their hospital-specific THA/TKA Readmission Measure data during the national dry run conducted during September and October of 2012, we learned that hospitals code hip fractures that occur during the same admission as a THA as either a principal or secondary diagnosis. According to feedback received from hospitals participating in the dry run, the measure methodology failed to identify and therefore appropriately exclude a small number of patients (that is, 0.42 percent of patients in 2009–2010 data) with hip fracture who had non-elective total hip arthroplasty.

To ensure that all such hip fracture patients are excluded from the measure, we are proposing to refine the measure to exclude patients with hip fracture coded as either principal or secondary diagnosis during the index admission. We believe this refinement is responsive to comments from hospitals and will allow us to accurately exclude patients who were initially admitted for a hip fracture and then underwent total hip arthroplasty, making their procedure nonelective.

We invite public comments on this proposal.

c. Anticipated Effect of Proposed Refinements on Measures

The proposed refinement of the CMS Planned Readmission Algorithm Version 2.1 to Version 3.0 would have had the following effects on the measures based on our analyses of discharges between July 2009 and June 2012, if these changes had been applied for FY 2014. We note that these statistics are for illustrative purposes only, and we are not proposing to revise the measure calculations for the FY 2014 payment determination. Rather, we are proposing to apply these changes to the readmission measures for the FY 2015 payment determination and subsequent years.

Among hospitals that were subject to the Hospital Readmissions Reduction Program in FY 2014 (Table IV.H.1), the number of eligible discharges based on

the July 2009 through June 2012 data were 494,121 discharges for AMI; 1,165,606 discharges for HF; 954,033 discharges for PN; 926,433 discharges for COPD; and 858,266 discharges for hip/knee.

The proposed 30-day readmission rate (excluding the planned readmissions) would remain constant for AMI and COPD; increase by 0.1 percentage points for HF and PN; and increase by 0.4 percentage points for hip/knee.

The new national readmission (unplanned) rate for each condition would have been 17.9 percent for AMI; 23.0 percent for HF; 17.7 percent for PN; 21.1 percent for COPD; and 5.27 percent for hip/knee.

The number of readmissions considered planned (and, therefore, not counted as a readmission) would decrease by 319 for AMI; 1,313 for HF; 866 for PN, 547 for COPD; and 298 for hip/knee.

The proposed modification of the hip/knee measure cohort would have had the following effects on the measure: the measure cohort would have been reduced by 0.37 percent; the crude readmission rate would have been reduced by 0.02 absolute percentage points; and the mean RSRR would have been reduced by 0.03 absolute percentage points.

TABLE IV.H.1.—COMPARISON OF PLANNED READMISSION ALGORITHMS V 2.1 AND 3.0 FOR AMI/HF/PN/COPD/HK READMISSION MEASURES

[Based on 2009–2012 discharges from 3,025 hospitals]

	AMI		HF		PN		COPD		Hip/Knee	
	V 3.0	V 2.1	V 3.0	V 2.1	V 3.0	V 2.1	V 3.0	V 2.1	V 3.0	V 2.1
Number of Discharges	494,121	494,121	1,165,606	1,165,606	954,033	954,033	926,433	926,433	858,266	858,266
Number of Unplanned Readmissions	88,567	88,248	268,072	266,759	169,213	168,347	195,595	195,048	45,205	44,907
Readmission Rate	17.9%	17.9%	23.0%	22.9%	17.7%	17.6%	21.1%	21.1%	5.27%	5.23%
Number of Planned Readmissions	11,577	11,896	15,293	16,606	5,867	6,733	5,858	6,405	2,283	2,581
Planned Readmission Rate	2.3%	2.4%	1.3%	1.4%	0.6%	0.7%	0.6%	0.7%	0.3%	0.3%
% of Readmissions that are Planned	11.6%	11.9%	5.4%	5.9%	3.4%	3.8%	2.9%	3.2%	4.8%	5.4%

5. No Proposed Expansion of the Applicable Conditions for FY 2016

In FY 2014 IPPS/LTCH PPS final rule we finalized for FY 2015 two new condition specific readmission measures: (1) Hospital-level 30-day all-cause risk-standardized readmission rate following elective total hip arthroplasty (THA) and total knee arthroplasty (TKA) (NQF #1551); (2) Hospital-level 30-day all-cause risk-standardized readmission rate following chronic obstructive pulmonary disease (COPD) (NQF #1891), bringing the total number of finalized applicable conditions to five over the past two years of implementation. We also noted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50657) that commenters requested that we delay adding other condition-specific measures. In view of these requests and our belief that it is reasonable to allow more time for hospitals to become familiar with these 5 applicable conditions, before adding other applicable conditions we are not proposing any new applicable conditions for FY 2016.

6. Proposed Expansion of the Applicable Conditions for FY 2017 to Include the Patients Readmitted Following Coronary Artery Bypass Graft (CABG) Surgery Measure

a. Background

Under section 1886(q)(5)(B) of the Act, ''[b]eginning with FY 2015, the Secretary shall, to the extent practicable, expand the applicable conditions beyond the 3 conditions for which measures have been endorsed as described in subparagraph (A)(ii)(I) . . . to the additional 4 conditions that have been identified by the Medicare Payment Advisory Commission [MedPAC] in its report to Congress in June 2007, and to other conditions and procedures as determined appropriate by the Secretary.'' The four conditions and procedures recommended by MedPAC are: (1) Coronary artery bypass graft (CABG) surgery; (2) chronic obstructive pulmonary disease (COPD); (3) percutaneous coronary intervention (PCI); and (4) other vascular conditions. Section 1886(q)(5)(A)(i) of the Act directs the Secretary, in selecting an ''applicable condition,'' to choose from among readmissions ''that represent conditions or procedures that are high volume or high expenditures under this title (or other criteria specified by the Secretary).''

In accordance with section 1886(q)(5)(A) of the Act, effective for the calculation of the readmissions payment adjustment factors in FY 2017, we are proposing to expand the scope of applicable conditions and procedures to include patients readmitted following CABG surgery. This proposal is consistent with the prior FY 2014 IPPS/LTCH PPS final rule (78 FR 50657) where we indicated our intent to explore quality measures that address CABG readmission rates. We describe this measure in detail below.

We are proposing the inclusion of the condition of CABG readmissions to the Hospital Readmissions Reduction Program based on MedPAC's recommendations. For this condition, we developed a Hospital-Level 30-Day All-Cause Unplanned Readmission Following Coronary Artery Bypass Graft (CABG) Surgery measure. The National Quality Forum (NQF) Measure Applications Partnership (MAP) Hospital workgroup conditionally supported this measure for use in the Hospital Readmissions Reduction Program. The condition for support is based on attainment of NQF endorsement. On February 5, 2014, we submitted the Hospital-Level 30-Day All-Cause Unplanned Readmission Following Coronary Artery Bypass Graft

(CABG) Surgery measure to NQF for endorsement.

The rationale for expanding the applicable conditions and the measures used to estimate the excess readmissions ratio is described in detail below.

b. Overview of the Proposed CABG Readmissions Measure: Hospital-Level, 30-Day, All-Cause, Unplanned Readmission Following Coronary Artery Bypass Graft (CABG) Surgery

Among the seven conditions MedPAC identified in its 2007 Report to Congress as having the highest potentially preventable readmission rate, CABG had the highest rate of readmissions within 15 days following discharge (13.5 percent) and second highest average Medicare payment per readmission ($8,136).[27] The annual cost to Medicare for potentially preventable CABG readmissions was estimated at $151 million.[28]

Evidence also shows variation in readmissions rates for patients with CABG surgery, supporting the finding that opportunities exist for improving care. The median, 30-day, risk-standardized readmission rate among Medicare fee-for-service patients aged 65 or older hospitalized for CABG in 2009 was 17.2 percent, and ranged from 13.9 percent to 22.1 percent across 1,160 hospitals.[29] Although data documenting readmission reductions in CABG are limited, there are data that support CABG readmission as an important quality metric.[30] Studying readmission rates after CABG surgery in New York, Hannan, et al. found: (1) Wide variation in readmission rates; (2) the most common cause of readmission after CABG is complication related to the surgery; and (3) that hospital-level variables such as use of cardiac rehabilitation and length of stay influenced readmission rates.[31] The authors also noted that readmission rates were not closely correlated to mortality rates and thus measuring readmission rates likely offers a complementary metric intended to assess a different domain of quality. Mortality measures are more likely to encourage improvements in clinical quality, including rapid triage, effective safety practices, and early intervention and coordination in the hospital. Readmission measures place an increased emphasis on aspects of quality related to effective transitions to the outpatient setting, clear communication with patients and caregivers, and collaboration across communities and providers. Together, these data suggest that reducing readmission rates following CABG surgery is an important target for quality improvement. In addition, inclusion of this measure in the Hospital Readmissions Reduction Program aligns with CMS' Quality Strategy objectives to promote successful transitions of care for patients from the acute care setting to the outpatient setting, and to reduce short-term readmission rates. In its final recommendations for rulemaking, the MAP conditionally supported the inclusion of the proposed CABG measure pending NQF endorsement and implementation. In order to address this concern, we submitted the CABG readmission measure to NQF for endorsement on February 5, 2014.

We believe the proposed Hospital-Level, 30-Day, All-Cause, Unplanned Readmission Measure Following CABG Surgery warrants inclusion in the Hospital Readmissions Reduction Program for FY 2017, because it meets the criteria in section 1886(q)(5)(A) of the Act, as a high cost, high volume condition that was recognized by MedPAC Report to Congress in 2007 as a specific medical condition to focus on for improving readmission rates. As with other readmission measures, this measure also excludes such unrelated readmissions as planned readmissions and transfers to other hospitals. For these reasons we believe this measure is appropriate for the Hospital Readmissions Reduction Program.

We invite public comments on this proposal.

c. Proposed Methodology for the CABG Measure: Hospital-Level, 30-Day, All-Cause, Unplanned Readmission Following Coronary Artery Bypass Graft (CABG) Surgery

The proposed CABG readmission measure assesses hospitals' 30-day, all-cause risk-standardized rate of unplanned readmission following admission for a CABG procedure. In general, the measure uses the same approach to risk-adjustment and hierarchical logistic modeling (HLM) methodology that is specified for the AMI, HF, PN, COPD and THA/TKA readmission measures that we previously adopted for this program. Information on how the measure employs HLM can be found in the 2012 CABG Readmission Measure Methodology Report (available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*). This approach appropriately accounts for the types of patients a hospital treats (that is, hospital case-mix), the number of patients it treats, and the quality of care it provides. The HLM methodology is an appropriate statistical approach to measuring quality based on patient outcomes when the patients are clustered within hospitals (and, therefore, the patients' outcomes are not statistically independent) and sample sizes vary across hospitals. The measure methodology defines hospital case-mix based on the clinical diagnoses provided in the hospitals' claims for the hospitals' patient inpatient and outpatient visits for the 12 months prior to the hospitalization for CABG, as well as those present in the claims for care at admission. However, the methodology specifically does not account for diagnoses present in the index admission that may indicate complications rather than patient comorbidities.

We discuss the measure methodology below.

(1) Data Sources

The proposed CABG readmission measure is based on data derived from administrative claims. It uses Medicare administrative data from hospitalizations for fee-for-service Medicare beneficiaries hospitalized for a CABG procedure.

(2) Definition of Outcome

The proposed CABG readmission measure defines 30-day, all-cause readmission as an unplanned subsequent inpatient admission to any applicable acute care facility for any cause within 30 days of the date of discharge from the index hospitalization. A number of studies demonstrate that improvements in care at the time of discharge can reduce 30-day readmission rates.[32] [33] Thirty days is

[27] Medicare Payment Advisory Committee. Report to the Congress: Promoting Greater Efficiency in Medicare, 2007.

[28] *Ibid.*

[29] Suter L.G., Wang, C., Vellanky S., Potteiger J., Curtis J., Lin Z., Geary L.L., Krumholz H.M., Drye E.D. Hospital-level 30-day All-Cause Unplanned Readmission Following Coronary Artery Bypass Graft Surgery: Report prepared for the Centers for Medicare & Medicaid Services. 2012.

[30] Rumsfield J, Allen L. Reducing Readmission Rates: Does Coronary Artery Bypass Graft Surgery Provide Clarity? *JACC Cardiovasc Interv.* May 2011;4(5):2.

[31] Hannan EL, Zhong Y, Lahey SJ, et al. 30-day readmissions after coronary artery bypass graft surgery in New York State. *JACC Cardiovasc Interv.* 2011;4(5):569–576.

[32] Gulshan Sharma, Kou Yong-Fang, Freeman Jean L, Zhang Dong D, Goodwin James S.: Outpatient Follow-up Visit and 30-Day Emergency Department Visit and Readmission in Patients Hospitalized for Chronic Obstructive Pulmonary Disease. Arch Intern Med. Oct. 2010;170:1664–1670.

[33] Nelson EA, Maruish ME, Axler JL.: Effects of Discharge Planning and Compliance with

Continued

a meaningful timeframe for hospitals because readmissions are more likely attributable to care received within the index hospitalization and during the transition to the outpatient setting.

The proposed CABG readmission measure assesses all-cause unplanned readmissions (excluding planned readmissions) rather than readmissions for CABG only. We include all unplanned readmissions for several reasons. First, from the patient perspective, a readmission for any reason is likely to be an undesirable outcome of care, even though not all readmissions are preventable. Second, limiting the measure to CABG-related readmissions may focus quality improvement efforts too narrowly rather than encouraging broader initiatives aimed at improving the overall care within the hospital and care transitions from the hospital setting. Moreover, it is often hard to exclude quality issues and accountability for a readmission based on the documented cause of readmission. For example, a patient who underwent a CABG surgery and developed a hospital-acquired infection might ultimately be readmitted for sepsis. It would be inappropriate to consider such a readmission to be unrelated to the care the patient received for their CABG surgery. Finally, while the measure does not presume that each readmission is preventable, quality improvement interventions generally have shown reductions in all types of readmissions.

The proposed measure does not count planned readmissions as readmissions. Planned readmissions are identified in claims data using the CMS Planned Readmission Algorithm Version 3.0 that detects planned readmissions that may occur within 30 days of discharge from the hospital. Version 2.1 of the algorithm was finalized for use in the Hospital Readmissions Reduction Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50651 through 50655). We have since updated the algorithm to Version 3.0 as part of yearly measure maintenance. The proposed CABG readmission measure uses the planned readmission algorithm, tailored for CABG patients. We adapted the algorithm for this group of patients with input from Cardiothoracic surgeons and other experts, narrowing the types of readmissions considered planned since planned readmissions following CABG are less common and less varied than among patients discharged from the hospital following a medical admission. More detailed information on how the proposed CABG readmission measure incorporates the CMS Planned Readmission Algorithm Version 3.0 can be found in the 2012 CABG Readmission Measure Methodology Report on the CMS Web site (available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*). For the proposed CABG readmission measure, unplanned readmissions that fall within the 30-day post-discharge timeframe from the index admission would not be counted as readmissions for the index admission if they were preceded by a planned readmission.

(3) Cohort of Patients

In order to include a clinically coherent set of patients in the measure, we sought input from clinical experts regarding the inclusion of other concomitant cardiac and non-cardiac procedures, such as valve replacement and carotid endarterectomy. Adverse clinical outcomes following such procedures are higher than those following ''isolated'' CABG procedures; that is, CABG procedures performed without concomitant high-risk cardiac and noncardiac procedures.[34] Limiting the measure cohort to ''isolated'' CABG patients is consistent with published reports of CABG outcomes; therefore, the proposed measure cohort considers only patients undergoing isolated CABG as eligible for inclusion in the measure. We defined isolated CABG patients as those undergoing CABG procedures without concomitant valve or other major cardiac, vascular or thoracic procedures. In addition, our clinical experts, consultants, and Technical Expert Panel (TEP) members agreed that an isolated CABG cohort is a clinically coherent cohort suitable for a risk-adjusted outcome measure. For detailed information on the cohort definition, we refer readers to the 2012 CABG Readmission Measure Methodology Report on the CMS Web site (available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*).

(4) Inclusion and Exclusion Criteria

The proposed CABG readmission measure includes hospitalizations for patients who are 65 years of age or older at the time of index admission and for whom there was a complete 12 months of Medicare fee-for-service enrollment to allow for adequate data for risk adjustment. The measure excludes the following admissions from the measure cohort: (1) Admissions for patients who are discharged against medical advice (excluded because providers do not have the opportunity to deliver full care and prepare the patient for discharge); (2) admissions for patients who die during the initial hospitalization (these patients are not eligible for readmission); (3) admissions for patients with subsequent qualifying CABG procedures during the measurement period (a repeat CABG procedure during the measurement period very likely represents a complication of the original CABG procedure and is a clinically more complex and higher risk surgery; therefore, we select the first CABG admission for inclusion in the measure and exclude subsequent CABG admissions from the cohort); and (4) admissions for patients without at least 30 days post-discharge enrollment in Medicare fee-for-service (excluded because the 30-day readmission outcome cannot be assessed in this group).

(5) Transferred Patients and Attribution of Readmission Outcome

Among medical conditions, such as AMI, heart failure and pneumonia, transfers between acute care facilities can occur for a variety of different reasons and it is likely that the discharging hospital has the most influence over a patient's risk of readmission and therefore the readmission outcome is appropriately assigned to the hospital that discharges the patient. For that reason, the currently publicly reported AMI, heart failure and pneumonia readmission measures attribute the readmission outcome to the hospital discharging the patient, even if that is not the hospital that initially admitted the patient.

In contrast, following CABG surgery, transfer to another acute care facility after CABG is most likely due to a complication of the CABG procedure or the peri-operative care the patient received. Therefore, the care provided by the hospital performing the CABG procedure likely dominates readmission risk, even among transferred patients. This viewpoint is supported by the high proportion of CABG readmissions for diagnoses such as heart failure, pleural effusion and pneumonia and endorsed by the clinical experts on both the Yale New Haven Hospital Health Services Corporation, Center for Outcomes Research and Evaluation (YNHHSC/CORE), and the Society of Thoracic Surgeons (STS) CABG readmission measure development working groups

Outpatient Appointments on Readmission Rates. Psychiatr Serv. July 1 2000;51(7):885–889.

[34] Hannan EL, Zhong Y, Lahey SJ, et al. 30-day readmissions after coronary artery bypass graft surgery in New York State. *JACC Cardiovasc Interv.* 2011;4(5):569–576.

and our TEP. Therefore, for this measure, the readmission outcome is attributed to the hospital performing the first (''index'') CABG, even if this is not the discharging hospital. For example, a patient may be admitted to hospital A for a CABG that qualifies them for inclusion in the measure and is then transferred to hospital B. The initial admission to hospital A and the admission to hospital B are considered one acute episode of care, made up of two inpatient admissions. The measure identifies transferred patients as those who are admitted to an acute care hospital on the same day or following day of discharge from an eligible admission.

(6) Risk-Adjustment

The proposed CABG readmission measure adjusts for differences across hospitals in the level of risk their patients have for readmission relative to patients cared for by other hospitals. The measure uses administrative claims data to identify patient clinical conditions and comorbidities to adjust patient risk for readmission across hospitals, but does not adjust for potential complications of care. The model does not adjust for socioeconomic status or race because risk adjusting for these characteristics would hold hospitals with a large proportion of patients of minority race or low socioeconomic status to a different standard of care than other hospitals. Rather, this measure seeks to illuminate quality differences, and risk adjustment for socioeconomic status or race would obscure such quality differences.

(7) Calculating the Excess Readmissions Ratio

The proposed CABG readmission measure uses the same methodology and statistical modeling approach as the other Hospital Readmissions Reduction Program measures. We published a detailed description of how the readmission measures estimate the excess readmissions ratio in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53380 through 53381).

In summary, we are proposing to adopt the Hospital-Level, 30-Day, All-Cause, Unplanned Readmission Following Coronary Artery Bypass Graft (CABG) Surgery measure in the Hospital Readmissions Reduction Program beginning in FY 2017.

We note that the set of hospitals for which this measure is calculated for the Hospital Readmissions Reduction Program differs from those used in calculations for the Hospital IQR Program. The Hospital Readmissions Reduction Program includes only subsection (d) hospitals as defined in 1886(d)(1)(B) of the Act (and, if not waived from participating, hospitals paid under section 1814(b)(3) of the Act), while the Hospital IQR Program calculations include non-IPPS hospitals such as CAHs, cancer hospitals, and hospitals located in the Territories of the United States. However, we believe that the CABG readmissions measure is appropriate for use in both programs.

We invite public comment on this proposal.

7. Maintenance of Technical Specifications for Quality Measures

Technical specification of the re admission measures are provided at our Web site in the Measure Methodology Reports (available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*). Additional resources about the Hospital Readmissions Reduction Program and measure technical specifications and methodology are on the QualityNet Web site on the Resources Web page (available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772412995*).

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 with 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.

We note that NQF's annual or triennial maintenance processes for endorsed measures may result in the NQF requiring updates to the measures. We believe that it is important to have in place a subregulatory process to incorporate nonsubstantive updates required by the NQF into the measure specifications we have adopted for the Hospital Readmissions Program so that these measures remain up-to-date. The NQF regularly maintains its endorsed measures through annual and triennial reviews, which may result in the NQF requiring updates to the measures. We note for this calendar year the AMI readmission measure is undergoing the NQF maintenance endorsement process.

For the Hospital Readmissions Reduction Program, we are proposing to follow the finalized processes outlined for addressing changes to adopted measures in the Hospital IQR Program ''Maintenance of Technical Specifications for Quality Measures'' section found in section IX.A.1.b. of the preamble of this proposed rule.

We believe this proposal adequately balances our need to incorporate NQF updates to NQF-endorsed Hospital Readmissions Reduction 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.

8. Waiver From the Hospital Readmissions Reduction Program for Hospitals Formerly Paid Under Section 1814(b)(3) of the Act (§ 412.152 and § 412.154(d))

The definition of ''applicable hospital'' under section 1886(q)(5)(C) of the Act also includes hospitals paid under section 1814(b)(3) of the Act. Section 1886(q)(2)(B)(ii) of the Act, however, allows the Secretary to exempt such hospitals from the Hospital Readmissions Reduction Program, provided that the State submit 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.''

The State of Maryland entered into an agreement with CMS, effective January 1, 2014, to participate in CMS' new Maryland All-Payer Model, a 5-year hospital payment model. This model is being implemented under section 1115A of the Act, as added by section 3021 of the Affordable Care Act, which authorizes the testing of innovative payment and service delivery models, including models that allow States to ''test and evaluate systems of all-payer payment reform for the medical care of residents of the State, including dual-eligible individuals.'' Section 1115A of the Act authorizes the Secretary to waive such requirements of titles XI and XVIII of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models.

As part of this agreement, the State of Maryland also elected to no longer have Medicare pay Maryland hospitals in accordance with section 1814(b)(3) of the Act. Therefore, section 1886(q)(2)(B)(ii) of the Act is no longer applicable to Maryland hospitals. The effect of Maryland hospitals no longer being paid under 1814(b)(3) of the Act is that they are not entitled to be exempted from the Hospital Readmissions Reduction Program under section 1886(q)(2)(B)(ii) of the Act and, but for the model, would be included in the Hospital Readmissions Reduction Program. In other words, the exemption from the Hospital Readmissions Reduction Program under section 1814(b)(3) of the Act no longer applies. However Maryland hospitals will not be participating in the Hospital Readmissions Reduction Program because section 1886(q) and its implementing regulations have been waived for purposes of the model, subject to the terms of the agreement.

We are proposing to make conforming changes to the implementing regulations to reflect this change. Under § 412.152, we are proposing to delete from the definition of an ''applicable hospital'' the following language: ''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.'' Under § 412.154, we are proposing to delete § 412.154(d) in its entirety. We invite public comment on these proposals.

9. Floor Adjustment Factor for FY 2015 (§ 412.154(c)(2))

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 . . . .'' The calculation of this ratio is codified 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 codified the floor adjustment factor at § 412.154(c)(2) of the regulations (77 FR 53386).

Consistent with 1886(q)(3) of the Act, codified at § 412.154(c)(2), the adjustment factor is either the greater of the ratio or, for FY 2015 and subsequent fiscal years, a floor adjustment factor of 0.97. Under our established policy, the ratio is rounded to the fourth decimal place. In other words, for FY 2015 and subsequent fiscal years, a hospital subject to the Hospital Readmissions Reduction Program will have an adjustment factor that is between 1.0 and 0.9700.

10. Applicable Period for FY 2015

Under section 1886(q)(5)(D) of the Act, the Secretary has the authority to specify the applicable period with respect to a fiscal year under the Hospital Readmissions Reduction Program. We finalized our policy to use 3 years of claims data to calculate the readmission measures in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671). In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53675), we codified the definition of ''applicable period'' in the regulations at 42 CFR 412.152 as the 3-year period from which data are collected in order to calculate excess readmissions ratios and adjustments for the fiscal year, which includes aggregate payments for excess readmissions and aggregate payments for all discharges used in the calculation of the payment adjustment.

Consistent with the definition at § 412.152, we established that the applicable period for FY 2014 under the Hospital Readmissions Reduction Program is the 3-year period from July 1, 2009, to June 30, 2012. That is, we determined the excess readmissions ratios and calculate the payment adjustment (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2014 using data from the 3-year time period of July 1, 2009 to June 30, 2012, as this was the most recent available 3-year period of data upon which to base these calculations (78 FR 50669).

In this proposed rule, for FY 2015, consistent with the definition at § 412.152, we are proposing an ''applicable period'' for the Hospital Readmissions Reduction Program to be the 3-year period from July 1, 2010 to June 30, 2013. In other words, we are proposing that the excess readmissions ratios and the payment adjustment (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2015 would be calculated based on data from the 3-year time period of July 1, 2010 to June 30, 2013. We note that for the purpose of modeling the readmissions payment adjustments for FY 2015 in this proposed rule, the excess readmissions ratios will be based on the applicable period from FY 2014 (that is July 1, 2009 to June 30, 2012) and the MedPAR claims data to calculate the readmissions payment adjustments will be based on the proposed applicable period for FY 2015 (that is July 1, 2010 to June 30, 2013).

We invite public comment on these proposals.

11. Proposed Inclusion of THA/TKA and COPD Readmissions Measures To Calculate Aggregate Payments for Excess Readmissions Beginning in FY 2015

Under the Hospital Readmissions Reduction Program the ''base operating DRG payment amount'' defined at § 412.152 is used both to determine the readmission adjustment factor that accounts for excess readmissions under section 1886(q)(3) of the Act and to determine which payment amounts will be adjusted to account for excess readmissions under section 1886(q) of the Act. Consistent with section 1886(q)(2) of the Act, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53383), under the regulations at § 412.152, we define the ''base operating DRG payment amount'' and specify that it does not include adjustments or add-on payments for IME, DSH, outliers and low-volume hospitals as required by section 1886(q)(2) of the Act. Furthermore, consistent with section 1886(q)(2)(B)(i) of the Act, for SCHs and for MDHs for FY 2013, the definition of ''base operating DRG payment amount'' at § 412.152 excludes the difference between the hospital's applicable hospital-specific payment rate and the Federal payment rate.

For FY 2015 and subsequent years, for purposes of calculating the payment adjustment factors and applying the payment methodology, we are proposing that the base operating DRG payment amount for MDHs includes the difference between the hospital-specific payment rate and the Federal payment rate (as applicable).

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. . . .'' The definition of ''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) are codified at § 412.154(c)(2) of the regulations (77 FR 53387).

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 readmissions ratio . . . for such hospital for such applicable period minus 1.'' We codified this definition of ''aggregate payments for excess readmissions'' under the regulations at § 412.152 as 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 readmissions ratio for the hospital for the applicable period minus 1 (77 FR 53675).

The excess readmissions ratio is a hospital-specific ratio calculated for each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the excess readmissions 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 readmissions 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 (as described in further detail later in this section).

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 codified this definition of ''aggregate payments for all discharges'' under the regulations at § 412.152 (77 FR 53387).

We finalized the inclusion of two additional applicable conditions, COPD and THA/TKA, to the Hospital Readmissions Reduction Program beginning for FY 2015 in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50657 through 50664). In this section, we discuss the proposed methodology to include these two additional measures in the calculation of the readmissions payment adjustment for FY 2015. Specifically, we are proposing how the addition of COPD and THA/TKA applicable conditions would be included in the calculation of the aggregate payments for excess readmissions, which is the numerator of the readmissions payment adjustment. We note that this proposal does not alter our established methodology for calculating aggregate payments for all discharges, that is, the denominator of the ratio (77 FR 53387).

As discussed above, when calculating the numerator (aggregate payments for excess readmissions), we determine the base operating DRG payments 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 readmissions ratio . . . for such hospital for such applicable period minus 1.''

When determining the base operating DRG payment amount for an individual hospital for such applicable period for such condition, we use Medicare inpatient claims from the MedPAR file with discharge dates that are within the same applicable period to calculate the excess readmissions ratio. We 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 to determine IPPS rates.

For FY 2015, we are proposing to use MedPAR claims with discharge dates that are on or after July 1, 2010, and no later than June 30, 2013. Under our established methodology that we use the update of the MedPAR file for each Federal fiscal year, which is updated 6 months after the end of each Federal fiscal year within the applicable period, as our data source (that is, the March updates of the respective Federal fiscal year MedPAR files) for the final rules.

The FY 2010 through FY 2013 MedPAR data files can be purchased from CMS. Use of these files allows the public to verify the readmissions adjustment factors. Interested individuals may order these files through the CMS Web site at: *http://www.cms.hhs.gov/LimitedDataSets/* by clicking on 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:

- 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.
- 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.

For 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, 2010, and no later than June 30, 2013. However, we note that for the purpose of modeling the proposed FY 2015 readmissions payment adjustment factors for this proposed rule, we are using excess readmissions ratios for applicable hospitals from the FY 2014 Hospital Readmissions Reduction Program applicable period. For the final rule, applicable hospitals will have had the opportunity to review and correct data from the proposed FY 2015 applicable period of July 1, 2010 to June 30, 2013 before they are made public under our policy regarding the reporting of hospital-specific information, which is discussed later in this section.

In this proposed rule, for FY 2015, we are proposing to use MedPAR data from July 1, 2010 through June 30, 2013. Specifically, in this proposed rule, we are using the March 2011 update of the FY 2010 MedPAR file to identify claims within FY 2010 with discharges dates that are on or after July 1, 2010, the March 2012 update of the FY 2011 MedPAR file to identify claims within FY 2011, the March 2013 update of the FY 2012 MedPAR file to identify claims within FY 2012, and the December 2013 update of the FY 2013 MedPAR file to identify claims within FY 2013 with

discharge dates no later than June 30, 2013. For the final rule, we are proposing to use the same MedPAR files as listed above for claims within FY 2010, FY 2011 and FY 2012. For claims within FY 2013, we are proposing to use in the final rule the March 2014 update of the FY 2013 MedPAR file.

In order to identify the admissions for each condition, including the two additional conditions THA/TKA and COPD, to calculate the aggregate payments for excess readmissions for an individual hospital, for FY 2015, we are proposing to identify each applicable condition using the ICD–9–CM codes used to identify applicable conditions to calculate the excess readmissions ratios. Under our existing policy, 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 (76 FR 51669). The discharge diagnoses for each applicable condition are based on a list of specific ICD–9–CM codes for that condition. These codes are posted on the QualityNet Web site at: *http://www.QualityNet.org* > Hospital-Inpatient > Claims-Based Measures > Readmission Measures > Measure Methodology.

In order to identify the applicable conditions to calculate the aggregate payments for excess readmissions, for FY 2015, we are proposing to identify the claim as an applicable condition consistent with the methodology to identify conditions to calculate the excess readmissions ratio. In other words, the applicable conditions of AMI, HF and PN are identified for the calculation of aggregate payments for excess readmissions if the ICD–9–CM code for that condition is listed as the principal diagnosis on the claim.

In order to identify claims with the applicable condition of THA/TKA, we are proposing that any claim that has the procedure codes for THA/TKA listed in any diagnosis/procedure field of the claim would be included in the calculation of aggregate payments for readmissions, consistent with the methodology to calculate the excess readmissions ratio for THA/TKA. In order to identify claims with the applicable condition of COPD, we are proposing to identify claims that either have the ICD–9–CM code for that condition is listed as the principal diagnosis on the claim or has a principal diagnosis of some respiratory failure along with secondary diagnosis of COPD.

Under our established methodology for calculating aggregate payments for readmissions, admissions that are not considered index admissions for the purpose of the readmissions measures are excluded from the calculation of the excess readmissions ratio, and therefore also are not considered admissions for the purposes of determining a hospital's aggregate payments for excess readmissions (78 FR 50670 through 50876). With the addition of THA/TKA and COPD as applicable conditions beginning in FY 2015, we are proposing to modify our current methodology to identify the admissions included in the calculation of ''aggregate payments for excess readmissions'' for THA/TKA and COPD in the same manner as the original applicable conditions (AMI, HF and PN). That is, THA/TKA and COPD admissions that would not considered index admissions in the readmissions measures also would not considered admissions for the purposes of calculation a hospital's aggregate payments for excess readmissions.

In this proposed rule, for FY 2015, we are proposing to continue to apply the same exclusions to the claims in the MedPAR file as we applied for FY 2014 (78 FR 50670 through 50673), and we are proposing to apply those exclusions for the two additional applicable conditions, THA/TKA and COPD. For FY 2015, in order to have the same types of admissions to calculate aggregate payments for excess readmissions as is used to calculate the excess readmissions ratio, we are proposing to identify admissions for all five applicable conditions, AMI, HF, PN, THA/TKA and COPD, for the purposes of calculating aggregate payments for excess readmissions as follows:

- We would exclude admissions that are identified as an applicable condition if the patient died in the hospital, as identified by the discharge status code on the MedPAR claim.
- We would exclude admissions identified as an applicable condition for which the patient was transferred to another provider that provides acute care hospital services (that is, a CAH or an IPPS hospital), as identified through examination of contiguous stays in MedPAR at other hospitals.
- We would exclude admissions identified as an applicable condition for patients who are under the age of 65, as identified by linking the claim information to the information provided in the Medicare Enrollment Database.
- For conditions identified as AMI, we would exclude claims that are same day discharges, as identified by the admission date and discharge date on the MedPAR claim.
- We would exclude admissions for patients who did not have Medicare Parts A and B FFS enrollment in the 12 months prior to the index admission, based on the information provided in the Medicare Enrollment Database.
- We would exclude admissions for patients without at least 30 days post-discharge enrollment in Medicare Parts A and B fee-for-service, based on the information provided in the Medicare Enrollment Database.
- We would exclude all multiple admissions within 30 days of a prior index admission's discharge date, as identified in the MedPAR file, consistent with how multiple admissions within 30 days of an index admission are excluded from the calculation of the excess readmissions ratio.

These exclusions are consistent with our current methodology, which was established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50671).

In addition to the exclusions described above for all five applicable conditions, for FY 2015, we are proposing the following steps to identify admissions specifically for THA/TKA for the purposes of calculating aggregate payments for excess readmissions:

- We are proposing to exclude admissions for THA/TKA for all transfer cases regardless of whether the discharge was a transfer to another hospital or from another hospital, consistent with the calculation of the excess readmissions ratio for THA/TKA.
- We are proposing to exclude admissions for THA/TKA for cases where the discharge includes a femur, hip, or pelvic fracture coded in the principal or secondary diagnosis fields, consistent with the calculation of the excess readmissions ratio for THA/TKA.
- We are proposing to exclude admissions for THA/TKA for cases where the discharge includes a mechanical complication coded in the principal diagnosis field, consistent with the calculation of the excess readmissions ratio for THA/TKA.
- We are proposing to exclude admissions for THA/TKA for cases where the discharge includes a malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal diagnosis field, consistent with the calculation of the excess readmissions ratio for THA/TKA.
- We are proposing to exclude admissions for THA/TKA for cases where the discharge includes more than two hip/knee procedures.
- We are proposing to exclude admissions for THA/TKA for cases that meet either any of the following conditions or following procedures

concurrent with THA/TKA: revision procedures; partial hip arthroplasty (PHA) procedures; resurfacing procedures; and removal of implanted devices/prostheses.

Furthermore, we are proposing to only identify Medicare FFS claims that meet the criteria (that is, claims paid for under Medicare Part C (Medicare Advantage) would not be included in this calculation), consistent with the methodology to calculate excess readmissions ratios based solely on admissions and readmissions for Medicare FFS patients. Therefore, consistent with our established methodology, for FY 2015, we would exclude admissions for patients enrolled in Medicare Advantage as identified in the Medicare Enrollment Database. This proposal is consistent with how admissions for Medicare Advantage patients are identified in the calculation of the excess readmissions ratios under our established methodology. 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 for FY 2015. The tables include the ICD–9–CM codes we are proposing to use to identify the two conditions, THA/TKA and COPD, added to the Hospital Readmissions Reduction Program beginning for FY 2015. These ICD–9–CM codes also would be used to identify the applicable conditions to calculate the excess readmissions ratios, consistent with our established policy (76 FR 51673 through 51676).

ICD–9–CM CODES TO IDENTIFY PNEUMONIA (PN) 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 (HF) 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.
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 (AMI) 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.

ICD–9–CM CODES TO IDENTIFY CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) CASES

ICD–9–CM Code	Description of code
491.21	Obstructive chronic bronchitis; With (acute) exacerbation; acute exacerbation of COPD, decompensated COPD, decompensated COPD with exacerbation.
491.22	Obstructive chronic bronchitis; with acute bronchitis.
491.8	Other chronic bronchitis. Chronic: tracheitis, tracheobronchitis.
491.9	Unspecified chronic bronchitis.
492.8	Other emphysema; emphysema (lung or pulmonary): NOS, centriacinar, centrilobular, obstructive, panacinar, panlobular, unilateral, vesicular. MacLeod's syndrome; Swyer-James syndrome; unilateral hyperlucent lung.
493.20	Chronic obstructive asthma; asthma with COPD, chronic asthmatic bronchitis, unspecified.
493.21	Chronic obstructive asthma; asthma with COPD, chronic asthmatic bronchitis, with status asthmaticus.
493.22	Chronic obstructive asthma; asthma with COPD, chronic asthmatic bronchitis, with (acute) exacerbation.
496	Chronic: nonspecific lung disease, obstructive lung disease, obstructive pulmonary disease (COPD) NOS. NOTE: This code is not to be used with any code from categories 491–493.
518.81 *	Other diseases of lung; acute respiratory failure; respiratory failure NOS.
518.82 *	Other diseases of lung; acute respiratory failure; other pulmonary insufficiency, acute respiratory distress.
518.84 *	Other diseases of lung; acute respiratory failure; acute and chronic respiratory failure.
799.1 *	Other ill-defined and unknown causes of morbidity and mortality; respiratory arrest, cardiorespiratory failure.

** Principal diagnosis when combined with a secondary diagnosis of AECOPD (491.21, 491.22, 493.21, or 493.22).*

ICD–9–CM CODES TO IDENTIFY TOTAL HIP ARTHROPLASTY/TOTAL KNEE ARTHROPLATY (THA/TKA) CASES

ICD–9–CM Code	Description of code
81.51	Total hip arthroplasty.
81.54	Total knee arthroplasty.

For FY 2015, we are proposing to calculate aggregate payments for excess readmissions, using MedPAR claims from July 1, 2010 to June 30, 2013, to identify applicable conditions based on the same ICD–9–CM codes used to identify the conditions for the readmissions measures, and to apply the proposed exclusions for the types of admissions discussed above. To calculate aggregate payments for excess readmissions, we are proposing to calculate the base operating DRG payment amounts for all claims in the 3-year applicable period for each applicable condition (AMI, HF, PN, COPD and THA/TKA) based on the claims we have identified as described above. Once we have calculated the base operating DRG amounts for all the claims for the five applicable conditions, we are proposing to sum the base operating DRG payments amounts by each condition, resulting in five summed amounts, one amount for each of the five applicable conditions. We are proposing to then multiply the amount for each condition by the respective excess readmissions ratio minus 1 when that excess readmissions ratio is greater than 1, which indicates that a hospital has performed, with respect to readmissions for that applicable condition, worse than the average hospital with similar patients. Each product in this computation represents the payments 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). Because this calculation is performed separately for each of the five conditions, a hospital's excess readmissions ratio must be less than or equal to 1 on each measure to aggregate payments for excess readmissions (and thus a payment reduction under the Hospital Readmissions Reduction Program). We note that we are not proposing any changes to our existing methodology to calculate ''aggregate payments for all discharges'' (the denominator of the ratio).

We are proposing the following methodology for FY 2015 as displayed in the chart below.

FORMULAS TO CALCULATE THE READMISSIONS ADJUSTMENT FACTOR

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

* Note, if a hospital's excess readmissions ratio for a condition is less than/equal to 1, then there are no aggregate payments for excess readmissions for that condition included in this calculation.

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).

Proposed Readmissions Adjustment Factor for FY 2015 is the higher of the ratio or 0.9700.

* Based on claims data from July 1, 2010 to June 30, 2013 for FY 2015.

We invite public comment on these proposals.

12. Hospital Readmissions Reduction Program Extraordinary Circumstances Exceptions

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50676), we indicated that commenters had requested a potential waiver or exemption process for hospitals located in areas that experience disasters or other extraordinary circumstances, even though we had not proposed an extraordinary circumstance exceptions/exemptions (ECE) policy for the Hospital Readmissions Reduction Program. We noted that there are several policy and operational considerations in developing a disaster exemption process for the Hospital Readmissions Reduction Program.

We welcome public comment on whether an exemption process should be implemented, and the policy and operational considerations for a potential Hospital Readmissions Reduction Program ECE policy.

I. 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 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 2014, the available funding pool was equal to 1.25 percent of the base-operating DRG payments to all participating hospitals, as estimated by the Secretary. The size of the applicable percentage has increased to 1.50 percent for FY 2015 and will increase to 1.75 percent for FY 2016, and to 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 Previous Hospital VBP Program Rulemaking

We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547), FY 2012 IPPS/LTCH PPS final rule (76 FR 51653 through 51660), CY 2012 OPPS/ASC final rule with comment period (76 FR 74527 through 74547), FY 2013 IPPS/LTCH PPS final rule (77 FR 53567 through 53614), FY 2014 IPPS/LTCH PPS final rule (78 FR 50676 through 50707), and CY 2014 OPPS/ASC final rule with comment period (78 FR 75120 through 75121) for further descriptions of our policies for the Hospital VBP Program.

We have also codified certain requirements for the Hospital VBP Program at §§ 412.160 through 412.167 of our regulations.

3. FY 2015 Payment Details

a. Payment Adjustments

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum total of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. We finalized details on how we would implement these provisions in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573) and refer readers to that rule for further details.

Under section 1886(o)(7)(C)(iii) of the Act, the applicable percent for the FY 2015 Hospital VBP Program is 1.50 percent. Using the methodology we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2015 is $1.4 billion, based on the December 2013 update of the FY 2013 MedPAR file. We intend to update this estimate for the FY 2015 IPPS/LTCH PPS final rule, using the March 2014 update of the FY 2013 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule, as referenced above, we will utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its TPS. We will then calculate a value-based incentive payment adjustment factor that will be applied to the base operating DRG payment amount for each discharge occurring in FY 2015, on a per-claim basis. We are publishing proxy value-

based incentive payment adjustment factors in Table 16 of this proposed rule (which is available via the Internet on the CMS Web site). The proxy factors are based on the TPSs from the FY 2014 Hospital VBP Program. These FY 2014 performance scores are the most recently available performance scores that hospitals have been given the opportunity to review and correct. The slope of the linear exchange function used to calculate those proxy value-based incentive payment adjustment factors was 2.0952951561. This slope, along with the estimated amount available for value-based incentive payments, is also published in Table 16.

We intend to update this table as Table 16A in the final rule (which will be available via the Internet on the CMS Web site) to reflect changes based on the March 2014 update to the FY 2013 MedPAR file. We also intend to update the slope of the linear exchange function used to calculate those updated proxy value-based incentive payment adjustment factors. The updated proxy value-based incentive payment adjustment factors for FY 2015 will continue to be based on historic FY 2014 Program TPSs because hospitals will not have been given the opportunity to review and correct their actual TPSs for the FY 2015 Hospital VBP Program until after the FY 2015 IPPS/LTCH PPS final rule is published. After hospitals have been given an opportunity to review and correct their actual TPSs for FY 2015, we will add Table 16B (which will be available via the Internet on the CMS Web site) to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2015 Hospital VBP Program. We expect that Table 16B will be posted on the CMS Web site in October 2014.

b. Base Operating DRG Payment Amount Definition for Medicare-Dependent Small Rural Hospitals (MDHs)

Section 106 of Public Law 113–93, the Protecting Access to Medicare Act of 2014 (PAMA), extended the MDH program through March 31, 2015. We note that that the special treatment for MDHs under section 1886(o)(7)(D)(ii)(I) of the Act, with regard to definition of base operating DRG payment amount, does not apply to discharges occurring after FY 2013.

For FY 2015 and subsequent years, for purposes of calculating the payment adjustment factors and applying the payment methodology, we are proposing that the base operating DRG payment amount for MDHs will include the difference between the hospital-specific payment rate and the Federal payment rate (as applicable). We are also proposing to revise the definition of base operating DRG payment amount in § 412.160 paragraph (2) of our regulations to reflect this change. We welcome comments on this proposal.

4. Measures for the FY 2017 Hospital VBP Program

a. Measures Previously Adopted

In the FY 2013 IPPS/LTCH PPS final rule, we finalized our proposal to readopt measures from the prior program year for each successive program year, unless proposed and finalized otherwise (for example, because one or more of the measures is ''topped-out'' or for other policy reasons). We stated our belief that this policy would facilitate measure adoption for the Hospital VBP Program for future years, as well as align the Hospital VBP Program with the Hospital IQR Program (77 FR 53592). The FY 2016 Hospital VBP Program includes the following measures:

FINALIZED MEASURES FOR THE FY 2016 HOSPITAL VBP PROGRAM

Clinical Process of Care Domain	
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival.
IMM–2	Influenza Immunization.
PN–6	Initial Antibiotic Selection for CAP in Immunocompetent Patient.
SCIP–Inf–2	Prophylactic Antibiotic Selection for Surgical Patients.
SCIP–Inf–3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time.
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 Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery.
Patient Experience of Care Domain	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey.
Outcome Domain	
CAUTI	Catheter-Associated Urinary Tract Infection.
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.
PSI–90	Complication/patient safety for selected indicators (composite).
SSI	Surgical Site Infection: • Colon. • Abdominal Hysterectomy.
Efficiency Domain	
MSPB–1	Medicare Spending per Beneficiary.

b. Proposed Changes Affecting Topped Out Measures

(1) Proposed Removal of Six Topped-Out Measures

For the FY 2017 Hospital VBP Program measure set, we evaluated whether any measures that we previously adopted are now ''topped out'' by focusing on two criteria: (1) National measure data showing statistically indistinguishable performance levels at the 75th and 90th percentiles; and (2) national measure data showing a truncated coefficient of variation (TCV) less than 0.10. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26496 through 26497) for further discussion of these current ''topped-out'' criteria and to our proposal below to modify the second criterion.

Based on our evaluation of the most recently available data, we believe that PN–6, SCIP–Card–2, SCIP–Inf–2, SCIP–Inf–3, SCIP–Inf–9, and SCIP–VTE–2 are all now ''topped-out.'' Therefore, we are proposing to remove these six measures from the FY 2017 Hospital VBP measure set because measuring hospital performance on these measures will have no meaningful effect on a hospital's TPS. We believe that removing these ''topped-out'' measures will continue to ensure that we make valid statistical comparisons through our finalized scoring methodology, and will reduce the reporting burden on participating hospitals.

We welcome public comment on this proposal.

(2) Proposed Change to Truncated Coefficient of Variation Criterion to Determine Whether a Measure is Topped Out

As stated above, we have adopted two criteria for determining the ''topped-out'' status of Hospital VBP Program measures:

- Statistically indistinguishable performance at the 75th and 90th percentiles; and
- Truncated coefficient of variation < 0.10.

We are proposing to modify the second criterion to the following:

- Truncated coefficient of variation ≤ 0.10.

The coefficient of variation (CV) is a common statistic that expresses the standard deviation as a percentage of the sample mean in a way that is independent of the units of observation. Applied to this analysis, a large CV would indicate a broad distribution of individual hospital scores, with large and presumably meaningful differences between hospitals in relative performance. A small CV would indicate that the distribution of individual hospital scores is clustered tightly around the mean value, suggesting that it is not useful to draw distinctions among individual hospitals' measure performance. By proposing to change the truncated CV from ''less than'' to ''less than or equal to'' 0.10 under our ''topped out'' test, we will better be able to distinguish measures with significant variation in performance among hospitals and more accurately apply determine what measures are ''topped out'' for purposes of the Program.

We welcome public comments on this proposal.

c. Proposed New Measures for the FY 2017 Hospital VBP Program

We considered if we should adopt additional measures for the FY 2017 Hospital VBP Program. We considered which measures are eligible for adoption based on the statutory requirements, including specification under the Hospital IQR Program and posting dates on the *Hospital Compare* Web site, and our priorities for quality improvement as outlined in the NQS (available for download at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf*).

We believe that the following three proposed measures meet the statutory requirements for inclusion in the FY 2017 Hospital VBP Program. We also believe that these measures represent important components of quality improvement in the acute inpatient hospital setting.

(1) Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia (NQF #1716)

Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia (NQF #1716) is a risk-adjusted outcome measure monitoring hospital onset of MRSA bloodstream infection events using the standardized infection ratio (MRSA bacteremia SIR) among all inpatients in the facility, and is reported via CDC's National Healthcare Safety Network (NHSN). We adopted this measure beginning with the FY 2015 payment determination under the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51630), and initial measure data were posted on *Hospital Compare* in December 2013.

We remain concerned about the persistent public health threat presented by MRSA infections. According to a 2013 study available at the NIH Web site, MRSA ''results in longer hospitalization, increased expenses, and poorer patient prognosis,'' and MRSA ''has been swiftly increasing worldwide over the past several decades.'' [35] As we noted in the FY 2012 IPPS/LTCH PPS final rule, invasive MRSA infections may cause about 18,000 deaths during a hospital stay a year.[36]

The MAP supported the direction of the MRSA bacteremia measure for inclusion in the Hospital VBP Program in the MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS found at *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72746*. The MAP noted that the measure addresses an NQS priority not adequately addressed in the program measure set, the measure should be applied following public reporting on *Hospital Compare,* and that the most recent version of the NQF-endorsed measure should be applied.

We believe that this measure is eligible for the Hospital VBP Program based on the MAP recommendation, our adoption of the most recent NQF-endorsed version under the Hospital IQR Program, and our posting of measure data on *Hospital Compare.* Based on the continued danger that MRSA infections present to patients and to the public health, we further believe that this measure is appropriate for the Hospital VBP Program. Therefore, we are proposing to adopt the MRSA bacteremia measure for the FY 2017 Hospital VBP Program, and we are proposing to place the measure into the Safety domain.

We invite public comment on this proposal.

(2) *Clostridium difficile* Infection (NQF #1717)

Clostridium difficile Infection (NQF #1717) is a risk-adjusted outcome measure monitoring hospital onset of *C. difficile* infection events using the standardized infection ratio (*C. difficile* SIR) among all inpatients in the facility, and is reported via CDC's NHSN. We adopted this measure for the FY 2015 payment determination under the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51630 through 51631), and initial measure data were posted on *Hospital Compare* in December 2013.

As with MRSA infections, we are concerned about the seriousness of *C. difficile* infections. According to a 2012

[35] Tatokoro et al. BMC Urology 2013, 13:35. Available at *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3720197/pdf/1471-2490-13-35.pdf.*

[36] Catherine Liu, Arnold Bayer, et al., Clinical practice Guidelines for the treatment of Methicillin-Resistant Staphylococcus aureus Infections in Adult and Children. Infectious Disease Society of America 2011; 52:e18.

study, ''infection with *Clostridium difficile* is associated with poor outcomes for patients. Previous work has determined that, regardless of baseline risk of death, for every 10 patients that acquire *C. difficile* in hospital, 1 patient will die. *Clostridium difficile* is also associated with increased health care costs. One of the primary mechanisms by which *C. difficile* increases costs is by increasing the length of time patients spend in hospital.'' [37] As we stated in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51630 through 51631), *C. difficile* infections have become more frequent, more severe, and more difficult to treat in recent years. Each year, tens of thousands of people in the United States get sick from *C. difficile,* including some otherwise healthy people who are not hospitalized or taking antibiotics.

The MAP supported the direction of the *C. difficile* infection measure for inclusion in the Hospital VBP Program in the MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS found at *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72746.* The MAP noted that the measure addresses an NQS priority not adequately addressed in the program measure set, the measure should be applied following public reporting on *Hospital Compare,* and that the most recent version of the NQF-endorsed measure should be applied.

We believe that this measure is eligible for the Hospital VBP Program based on the MAP recommendation, our adoption of the most recent NQF-endorsed version under the Hospital IQR Program, and our posting of measure data on *Hospital Compare,* as well as the continued danger that *C. difficile* infections present to patients and the public health. Therefore, we are proposing to adopt the *C. difficile* SIR measure for the FY 2017 Hospital VBP Program, and we are proposing to place the measure into the Safety domain.

We invite public comment on this proposal.

(3) PC–01: Elective Delivery Prior to 39 Completed Weeks Gestation (NQF #0469)

PC–01: Elective Delivery Prior to 39 Completed Weeks Gestation (NQF #0469) is a chart-abstracted measure that we adopted beginning with the FY 2015 payment determination for the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53528 through 53530). Initial measure data were posted on *Hospital Compare* in December 2013. Although this is a chart-abstracted measure, we finalized our policy in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53528 through 53529) that this measure would be collected in aggregated numerator, denominator, and exclusion counts per hospital via a Web-based tool, instead of collecting patient-level data from hospitals.

As we described in the FY 2013 IPPS/LTCH PPS final rule referenced above, the Strong Start Initiative (*http://www.innovation.cms.gov/initiatives/strong-start/*) was launched to help reduce early elective births. At launch, the HHS Secretary stated that more than half a million infants are born prematurely in America each year. Fortunately, the early elective birth rate has steadily decreased. In 2012, the number of early elective births had decreased to approximately 456,000 or 11.55 percent of the total number of births.[38] Early elective births may require additional medical attention and early intervention services. 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. [39] [40] [41] [42] Early elective births are a public health problem that has significant consequences for families well into a child's life.

As a public campaign to reduce early elective 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 MAP supported adoption of the PC–01 Elective Delivery measure for inclusion in the Hospital VBP Program in the MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS found at *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72746.* The MAP noted that the measure addresses an NQS priority not adequately addressed in the program measure set.

We are proposing to adopt this measure for the Hospital VBP Program and we are proposing to place the measure into the Clinical Care—Process domain because we believe this measure furthers the NQS's three-part aim of better health care for individuals, better health for populations, and lower costs for health care. In addition, although the PC–01 measure captures data from all applicable patients, we also believe that the measure is specifically relevant to the nearly 2 million Medicare beneficiaries who are aged 44 and under, most of who are dual eligible beneficiaries, who have the potential to be impacted by early elective births. In 2011, Medicare paid for roughly 14,000 births.

We welcome public comment on this proposal.

d. Proposed Adoption of the Current CLABSI Measure (NQF #0139) for the FY 2017 Hospital VBP Program

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50682 and 50686), we adopted the CLABSI measure for the FY 2016 Hospital VBP Program. We stated our belief that adopting the current CLABSI measure is consistent with the MAP's recommendations in the MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS found at *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72746,* to use the standardized infection ratio version of the measure until the reliability-adjusted CLABSI

[37] Forster et al. ''The effect of hospital-acquired infection with *Clostridium difficile* on length of stay in hospital.'' *Canadian Medical Association Journal,* January 10, 2012. Available at *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3255231/pdf/1840037.pdf.*

[38] Martin, JA, Hamilton, BE, Osterman, MJK, Curtin, SC, Mathews, TJ. (2013). Births: Final data for 2012. Natl Vital Stat Rpt. 62(9). Retrieved from *http://www.cdc.gov/nchs/data/nvsr/nvsr62/nvsr62_09.pdf.*

[39] Glantz, J. (Apr. 2005). Elective induction vs. spontaneous labor associations and outcomes. J Reprod Med. 50(4):235–40.

[40] Vardo, J., Thornburg, L., Glantz J., (2011). Maternal and neonatal morbidity among nulliparous women undergoing elective induction of labor. J. report med. 56(1–2): 25–30.

[41] 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.

[42] 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.

measure is NQF-endorsed. We have stated our intent to consider adopting the reliability-adjusted CLABSI measure in future rulemaking.

The reliability-adjusted standardized infection ratio (SIR) is an outcome measure that summarizes the healthcare-associated infection experience by type of infection (for example, central-line associated bloodstream infection, surgical site infection) for individual hospitals. The reliability-adjusted measure enables more meaningful statistical differentiation between hospitals by accounting for differences in patient case-mix, exposures to medical devices or procedures (for example, central line days, surgical procedure volume), and unmeasured factors that are not reflected in the unadjusted SIR and that cause variation in outcomes between hospitals. Accounting for these sources of variability enables better measure discrimination between hospitals and leads to more reliable quality measurements.

However, in the absence of NQF endorsement of the reliability-adjusted measure and any additional MAP recommendations, and unless and until the Hospital IQR Program adopts the reliability adjustments, we believe we may only consider the current version of the CLABSI measure for adoption under the Hospital VBP Program. We continue to believe that the CLABSI measure encourages hospitals to minimize infection events that present significant health risks to patients. Therefore, we are proposing to adopt the current version of the CLABSI measure for the FY 2017 Hospital VBP Program and subsequent years. If a reliability-adjusted version of the measure becomes available to us in the future, we will consider adopting it.

We welcome public comment on this proposal.

e. Summary of Previously Adopted and Proposed New Measures for the FY 2017 Hospital VBP Program

The following table outlines the measures for the FY 2017 Hospital VBP Program that we are readopting, as well as those measures we are proposing to adopt. As discussed further below, this table includes the FY 2017 domains in which we would place the previously adopted measures, as well as the proposed domains in which we would place the newly proposed measures.

PREVIOUSLY ADOPTED AND PROPOSED NEW MEASURES FOR THE FY 2017 HOSPITAL VBP PROGRAM

Measure	Description	Domain
CAUTI *	Catheter-Associated Urinary Tract Infection (NQF #0138)	Safety.
CLABSI **	Central Line-Associated Blood Stream Infection (NQF #0139)	Safety.
C. difficile ***	*Clostridium difficile* Infection (NQF #1717)	Safety.
MRSA ***	Methicillin-Resistant *Staphylococcus aureus* Bacteremia (NQF #1726)	Safety.
PSI–90 *	Complication/patient safety for selected indicators (composite) (NQF #0531)	Safety.
SSI *	Surgical Site Infection: (NQF #0753) • Colon • Abdominal Hysterectomy	Safety.
MORT–30–AMI *	Acute Myocardial Infarction (AMI) 30-day mortality rate (NQF #0230)	Clinical Care—Outcomes.
MORT–30–HF *	Heart Failure (HF) 30-day mortality rate (NQF #0229)	Clinical Care—Outcomes.
MORT–30–PN *	Pneumonia (PN) 30-day mortality rate (NQF #0468)	Clinical Care—Outcomes.
AMI–7a *	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival (NQF #0164)	Clinical Care—Process.
IMM–2 *	Influenza Immunization (NQF #1659)	Clinical Care—Process.
PC–01 ***	Elective Delivery Prior to 39 Completed Weeks Gestation (NQF #0469)	Clinical Care—Process.
MSPB–1 *	Medicare Spending per Beneficiary (NQF #2158)	Efficiency and Cost Reduction.
HCAHPS *	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (NQF #0166)	Patient and Caregiver Centered Experience of Care/Care Coordination.

* Measures readopted for the FY 2017 Hospital VBP Program.
** Measure adopted for the FY 2016 Hospital VBP Program but not previously subject to automatic readoption.
*** Measures proposed for the FY 2017 Hospital VBP Program.

5. Proposed Additional Measures for the FY 2019 Hospital VBP Program

a. Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA)

Hospital-level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) (NQF #1550) is an outcome measure that we adopted beginning with the FY 2015 payment determination under the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53516 through 53518). The 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. We posted THA/TKA measure data on the *Hospital Compare* Web site in December 2013. We refer readers to the FY 2013 IPPS/LTCH PPS final rule and to the THA/TKA complication methodology report (*http://qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890067881&blobheader=multipart%2Foctet-stream&blobheadername1=Content-*

Disposition&blobheadervalue1=attachment%3Bfilename%3DTHK_CmpMsrUpdtSpecs_080113.pdf&blobcol=urldata&blobtable=MungoBlobs) for additional details on the THA/TKA measure.

We continue to believe that measuring and reporting risk-standardized complication rates will inform health care providers about opportunities to improve care, strengthen incentives for quality improvement, and promote improvements in the quality of care received by patients and in the outcomes they experience. We believe that THA/TKA is an important measure of clinical outcomes, and we therefore are proposing to adopt it for the FY 2019 Hospital VBP Program and subsequent years. The MAP supported the adoption of the measure for inclusion in the Hospital VBP Program in its MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS found at *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72746*, noting it addresses a high-volume elective procedure with variation in performance. We are proposing to adopt this measure for FY 2019 based on the length of the measure's reporting period and the time necessary to complete scoring calculations. Because it is an outcome measure, we are proposing to place it in the Clinical Care—Outcomes domain.

We welcome public comments on this proposal.

b. PSI–90 Measure

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50698), we declined to finalize the PSI–90 measure for the FY 2019 Hospital VBP Program in order to adopt a more recent baseline period than would have been possible at that time. However, we did not intend to signal that we would not adopt the PSI–90 measure for FY 2019 and subsequent years. We continue to believe that adopting this AHRQ PSI composite measure provides strong incentives for hospitals to ensure that patients are not harmed by the medical care they receive, which is a critical consideration in quality improvement. In order to clarify the measure's status under the Hospital VBP Program and ensure that there is no confusion about our intent, we are proposing to readopt the PSI–90 measure for FY 2019 Hospital VBP Program and subsequent years.

We welcome public comments on this proposal.

6. Possible Measure Topics for Future Program Years

a. Care Transition Measure (CTM–3) Items for HCAHPS Survey

We are considering proposing to add the Care Transition Measure from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey to the Patient and Caregiver Centered Experience of Care/Care Coordination (PEC/CC) domain of the FY 2018 Hospital VBP Program. We seek public comments on this topic.

The Care Transition Measure (CTM) was added to the HCAHPS Survey of hospital inpatients in January 2013 (77 FR 53513 through 53516). Three items were added to the HCAHPS Survey to create the new Care Transition Measure composite. After collecting four quarters of data on these items (January 2013 through December 2013), we intend to publicly report CTM scores for the first time on our *Hospital Compare* Web site in October 2014.

Once the Care Transition Measure has been publicly reported on *Hospital Compare* for one year, in accordance with the statutory requirements of the Hospital VBP Program, we are considering proposing to adopt CTM as the ninth dimension of the HCAHPS survey in the PEC/CC domain for the FY 2018 Hospital VBP Program. We intend to propose that the PEC/CC domain in the FY 2018 Hospital VBP Program would have a baseline period of January 1, 2014 through December 31, 2014, and a performance period of January 1, 2016 through December 31, 2016.

Currently, the PEC/CC domain (formerly known as the Patient Experience of Care domain) is comprised of eight dimensions of the HCAHPS Survey. Scoring in this domain is based on two elements: the HCAHPS Base Score and HCAHPS Consistency Points Score. For additional information on the calculation of the PEC/CC domain score, we refer readers to ''*A Step-by-Step Guide to Calculating the Patient Experience of Care Domain Score in the Hospital Value-Based Purchasing FY 2013 Actual Percentage Payment Summary Report,*'' at: *http://www.hcahpsonline.org/HospitalVBP.aspx*.

We specifically seek public comments on how the new CTM dimension should be included in the scoring methodology that we have adopted for the PEC/CC domain. In accordance with the finalized Hospital VBP Program scoring methodology for other domains, we are considering the ''normalization'' approach, which would introduce only minor changes to the original scoring formula, as follows.

For purposes of the HCAHPS Base Score, the new CTM dimension would be calculated in the same manner as the eight existing HCAHPS dimensions; for further details, we refer readers to ''*A Step-by-Step Guide to Calculating the Patient Experience of Care Domain Score in the Hospital Value-Based Purchasing FY 2013 Actual Percentage Payment Summary Report,*'' at: *http://www.hcahpsonline.org/HospitalVBP.aspx*. For each of the nine dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) would be calculated, the larger of which will be summed across the nine dimensions to create a pre-normalized HCAHPS Base Score (0–90 points, as compared to 0–80 points when only eight dimensions were included). The pre-normalized HCAHPS Base Score would then be multiplied by 8/9 (0.88888) and rounded according to standard rules (values of 0.5 and higher are rounded up, values below 0.5 are rounded down) to create the normalized HCAHPS Base Score. Each of the nine dimensions would be of equal weight, so that, as before, the normalized HCAHPS Base Score would range from 0 to 80 points.

HCAHPS Consistency Points would then be calculated in the same manner as before and would continue to range from 0 to 20 points. The Consistency Points Score would now consider scores across all nine of the PEC/CC domain dimensions, whereas before it considered only the eight dimensions that preceded the CTM measure.

The final element of the scoring formula would be the sum of the HCAHPS Base Score and the HCAHPS Consistency Points Score and would range from 0 to 100 points, as before.

We welcome public comments on this approach to including the CTM–3 dimension in the PEC/CC domain score.

b. Possible Future Efficiency and Cost Reduction Domain Measure Topics

In the interest of expanding the Efficiency domain to include a more robust measure set, including measures that supplement the Medicare Spending per Beneficiary (MSPB) measure with more condition and/or treatment specific episodes, as well as facilitating alignment with the Physician Value-Based Payment Modifier (VM) Program, we are considering proposing to add new episode-based payment measures to the Hospital VBP Program through future rulemaking. Expanding the Efficiency domain to include such measures would create incentives for coordination between hospitals and physicians to optimize the care they provide to Medicare beneficiaries and

would increase alignment between the Hospital VBP and Physician VM Programs. Any future Hospital VBP Program measures would first be finalized for inclusion in the Hospital IQR Program and included on the *Hospital Compare* Web site for one year, as required by section 1886(o)(2)(C) of the Act.

The six episode-based standardized payment measures we are considering are discussed below and are similar in many ways to the NQF-endorsed MSPB measure already included in the Efficiency domain. Like the MSPB measure, these episode-based standardized payment measures would include services initiated during an episode that spans from 3 days prior to a hospital admission through 30 days post-discharge from the hospital. We would sum the standardized Medicare payment amounts for Part A and Part B services provided during this timeframe and attribute them to the hospital at which the index admission occurred. Medicare payments included in these episode-based measures would be standardized according to the CMS standardization methodology finalized for the MSPB measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51626).

Episodes in the six new measures would be risk-adjusted in a manner similar to the MSPB measure risk adjustment methodology finalized in the FY 2013 IPPS/LTCH PPS final rule (76 FR 51625 through 51626). The difference between the risk adjustment approaches stems from the fact that MSPB episodes are standardized at the Major Diagnostic Category (MDC) level, whereas two of the new episode-based measures, the hip episode measure and the knee episode measure, represent conditions that are in the same MDC. Accordingly, the new episode-based measures would be individually risk-adjusted at the specific episode type level, in order to recognize the distinctions.

The payment standardization methodology is available in the document entitled ''CMS Price Standardization'' and the MSPB risk adjustment methodology is included in the document entitled ''MSPB Measure Information Form,'' both available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350*. The risk adjustment methodology specific to these six episode-based standardized payment measures can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing*. Risk adjustment and payment standardization would allow us to compare performance on these measures across hospitals.

In contrast to the MSPB measure, we would only include Medicare payments for services that are clinically related to the health conditions treated during the hospital stay that triggered the episode. The aim of including these episode-based payment measures in the Hospital VBP Program would be to differentiate between hospitals that provide care efficiently (that is, high quality care at a lower cost to Medicare). We believe that risk-adjusted standardized Medicare payments are an appropriate indicator of efficiency as they allow us to compare hospitals without regard to such factors as geography and teaching status. This comparison is particularly important with clinically coherent episodes because it distinguishes the degree to which practice pattern variation influences the cost of care. We believe that creating incentives for appropriately reducing practice pattern variation is an important part of our aims to lower the cost of care appropriately and create better coordinated care for Medicare beneficiaries.

Another notable difference between the episode-based measures we are considering and the MSPB measure occurs when, during the 30 days following discharge from an index admission, a beneficiary is readmitted for a condition that is clinically related to the index admission and that also triggers an episode-based cost measure episode. For example, if a beneficiary were discharged after a hip replacement, then readmitted for a revision 15 days later, the standardized Medicare payments associated with the revision would count toward the initial hip replacement/revision episode and would also trigger a new hip replacement/revision episode where the index admission would be that for the revision. Details of which admissions would begin a new episode and contribute to a preceding episode may be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing*.

We are considering three medical and three surgical episodes for the initial expansion of the Efficiency domain. The medical episodes would address the following conditions: (1) Kidney/urinary tract infection; (2) cellulitis; and (3) gastrointestinal hemorrhage. A medical episode would be 'triggered' by an inpatient claim with a specified MS–DRG. The surgical episodes currently under consideration are (1) hip replacement/revision; (2) knee replacement/revision; and (3) lumbar spine fusion/refusion. A surgical episode would be triggered when an inpatient claim has one of the specified MS–DRGs and at least one of the procedure codes specified for that episode. We welcome public comment on the three medical and three surgical conditions that we are considering as new episode-based measures for initial expansion of the Efficiency domain.

There are a number of other types of episodes that could also meet the episode selection criteria we describe below, including those related to heart and lung (for example, heart failure and pneumonia). We note that we are exploring data related to episodes for these types of conditions under the Physician VM Program. We welcome comment regarding the applicability of episode-based measures for these or other conditions for future expansion of the Efficiency domain.

In selecting the six conditions around which we would develop episode measures for future expansion of the Efficiency domain, we considered the following five criteria: (1) The condition constitutes a significant share of Medicare payments for hospitalized patients during and surrounding the hospital stay; (2) the degree to which clinical experts consulted for this project agree that standardized Medicare payments for services provided during the episode can be linked to the care provided during the hospitalization; (3) episodes of care for the condition are comprised of a substantial proportion of payments for post-acute care, indicating episode payment differences are driven by utilization outside of the MS–DRG payment; (4) episodes of care for the condition reflect high variation in post-discharge payments, enabling differentiation between hospitals; and, (5) the medical condition is managed by general medicine physicians or hospitalists and the surgical conditions are managed by surgical subspecialists, enabling comparison between similar practitioner types within each episode measure.

For analysis purposes, the five selection criteria were applied to 2012 Medicare acute inpatient hospital data in a hierarchical manner, to prioritize the inpatient conditions. After the selection criteria were applied, we narrowed the medical and surgical episodes to those episodes that are less complex, in order to allow CMS and hospitals to gain experience with this new measure type. Full details of the

episode selection criteria are available on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing*. We welcome public comments on the episode selection criteria we utilized.

Complete episode specifications, including the MS–DRG and ICD–9–CM procedure codes used to identify each of the episodes, details of episode construction methodology, and information on the clinical expert reviewers for this project are available on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing*. We welcome public comments on these specifications and the construction of the six episode-based payment measures that we are considering.

7. Previously Adopted and Proposed Performance Periods and Baseline Periods for the FY 2017 Hospital VBP Program

a. Background

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. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50689 through 50692) and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75020 through 75021) for the performance periods and baseline periods for the Clinical Process of Care, Patient Experience of Care, Outcome, and Efficiency domains for the FY 2016 Hospital VBP Program.

As discussed further below, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50702 through 50704), we adopted new NQS-based quality domains for FY 2017, and we are proposing to adopt performance and baseline periods using those new domains for the FY 2017 Hospital VBP Program.

b. Previously Adopted Baseline and Performance Periods for the FY 2017 Hospital VBP Program

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50692 through 50694 and 50698 through 50699), because of the time needed to process measure data for the three 30-day mortality measures (Clinical Care—Outcomes domain) and the PSI–90 measure (also referred to in previous rulemaking as the AHRQ patient safety PSI–90 composite measure) (Safety domain), and in consideration of our policy goal to collect enough data to generate the most reliable scores possible, we adopted performance periods and performance standards for the 30-day mortality measures for FY 2017, FY 2018, and FY 2019, and for the PSI–90 measure for FY 2017 and FY 2018.

c. Proposed Clinical Care—Process Domain Performance Period and Baseline Period for the FY 2017 Hospital VBP Program

In the FY 2014 IPPS/LTCH PPS final rule, we adopted a 12-month performance period for the FY 2016 Clinical Process of Care domain measures of CY 2014 (January 1, 2014 through December 31, 2014). We also adopted a corresponding 12-month baseline period of CY 2012 (January 1, 2012, through December 31, 2012), for purposes of calculating improvement points and performance standards.

Based on our review of FY 2013 and FY 2014 Hospital VBP performance period denominator data, we continue to believe that a 12-month performance period provides us with reliable and sufficient data for scoring Clinical Care—Process domain measures under the Hospital VBP Program. These data are available for public review on our *Hospital Compare* Web site. We are therefore proposing to adopt a 12-month performance period for FY 2017 Clinical Care—Process domain measures (including the proposed PC–01 measure) of CY 2015 (January 1, 2015, through December 31, 2015). We also are proposing to adopt a corresponding 12-month baseline period of CY 2013 (January 1, 2013, through December 31, 2013) for purposes of calculating improvement points and calculating performance standards.

We invite public comment on these proposals.

d. Proposed Patient and Caregiver-Centered Experience of Care/Care Coordination (PEC/CC) Domain Performance Period and Baseline Period for the FY 2017 Hospital VBP Program

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50689), we adopted a 12-month performance period for FY 2016 Patient Experience of Care domain measures of CY 2014, or January 1, 2014 through December 31, 2014, for the FY 2016 Hospital VBP Program. We also adopted a corresponding 12-month baseline period of CY 2012 (January 1, 2012 through December 31, 2012), for purposes of calculating improvement points and calculating performance standards. We continue to believe that a 12-month performance period provides us sufficient HCAHPS data on which to score hospital performance, which is an important goal both for CMS and for stakeholders.

We are proposing to adopt a 12-month performance period for the FY 2017 PEC/CC domain of CY 2015 (January 1, 2015 through December 31, 2015). We also are proposing to adopt a corresponding 12-month baseline period of CY 2013 (January 1, 2013 through December 31, 2013) for purposes of calculating improvement points and calculating performance standards.

We invite public comment on these proposals.

e. Proposed Safety Domain Performance Period and Baseline Period for NHSN Measures for the FY 2017 Hospital VBP Program

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75121), for the three NHSN HAI measures that we have adopted for the FY 2016 Hospital VBP Program (CAUTI, CLABSI, and SSI), we adopted an FY 2016 performance period of CY 2014 (January 1, 2014 through December 31, 2014), with a corresponding baseline period of CY 2012 (January 1, 2012 through December 31, 2012) for purposes of calculating improvement points and calculating performance standards.

We continue to believe that a 12-month performance period provides us with sufficient data on which to score hospital performance on NHSN measures in the Safety domain. We also note that 12-month performance and baseline periods are consistent with the reporting periods used for these measures under the Hospital IQR Program (78 FR 50689). Therefore, for the FY 2017 NHSN measures in the Safety domain (including the proposed CLABSI, *C. difficile* infection and MRSA bacteremia measures), we are proposing to adopt a performance period of CY 2015 (January 1, 2015 through December 31, 2015), and a corresponding baseline period of CY 2013 (January 1, 2013 through December 31, 2013) for purposes of calculating improvement points and calculating performance standards.

We invite public comment on these proposals.

f. Proposed Efficiency and Cost Reduction Domain Performance Period and Baseline Period for the FY 2017 Hospital VBP Program

In the FY 2014 IPPS/LTCH PPS final rule, we adopted a 12-month performance period for the MSPB measure for the FY 2016 Hospital VBP Program of CY 2014 (January 1, 2014, through December 31, 2014), with a

corresponding baseline period of CY 2012 (January 1, 2012, through December 31, 2012). This performance and baseline period enable us to collect sufficient measure data, while allowing time to calculate and incorporate MSPB measure data into the Hospital VBP Program scores in a timely manner.

We are proposing to adopt a 12-month performance period for the FY 2017 Efficiency and Cost Reduction domain of CY 2015 (January 1, 2015 through December 31, 2015), with a corresponding baseline period of CY 2013 (January 1, 2013 through December 31, 2013). We note that this proposed performance and baseline period aligns with the performance and baseline periods for Clinical Care—Process, PEC/CC, and certain Safety measures under the new domain structure.

We invite public comments on these proposals.

g. Summary of Previously Adopted and Proposed Performance Periods and Baseline Periods for the FY 2017 Hospital VBP Program

The table below summarizes the proposed baseline and performance periods for the FY 2017 Hospital VBP Program (with previously adopted baseline and performance periods for the mortality and AHRQ PSI composite (PSI–90) measures noted).

PREVIOUSLY ADOPTED AND PROPOSED PERFORMANCE AND BASELINE PERIODS FOR THE FY 2017 HOSPITAL VBP PROGRAM

Domain	Baseline period	Performance period
Safety:		
• PSI–90*	• October 1, 2010–June 30, 2012*	• October 1, 2013–June 30, 2015.*
• NHSN (CAUTI, CLABSI, SSI, C. difficile Infection, MRSA Bacteremia).	• January 1, 2013–December 31, 2013	• January 1, 2015–December 31, 2015.
Clinical Care—Outcomes:.		
• Mortality* (MORT–30–AMI, MORT–30–HF, MORT–30–PN)	• October 1, 2010–June 30, 2012*	• October 1, 2013–June 30, 2015.*
Clinical Care—Process:		
• (AMI–7a, IMM–2, PC–01)	January 1, 2013–December 31, 2013	January 1, 2015–December 31, 2015.
Efficiency and Cost Reduction (MSPB–1)	January 1, 2013–December 31, 2013	January 1, 2015–December 31, 2015.
Patient and Caregiver-Centered Experience of Care/Care Coordination (HCAHPS).	January 1, 2013–December 31, 2013	January 1, 2015–December 31, 2015.

*Previously adopted performance and baseline periods.

We note that we intend to propose additional baseline and performance periods for the FY 2018 Hospital VBP Program in future rulemaking.

8. Previously Adopted and Proposed Performance Periods and Baseline Periods for Certain Measures for the FY 2019 Hospital VBP Program

a. Previously Adopted and Proposed Performance Period and Baseline Period for the FY 2019 Hospital VBP Program for Clinical Care—Outcomes Domain Measures

As described above, we have previously adopted the FY 2019 performance and baseline periods for the three 30-day mortality measures that we have adopted for the former Outcome domain and that we have since placed into the Clinical Care—Outcomes domain under the new domain structure.

In this proposed rule, we are proposing to adopt the THA/TKA measure for the FY 2019 Hospital VBP Program and to place that measure in the Clinical Care—Outcomes domain. THA/TKA is reported to the Hospital IQR Program for 36-month time periods. However, we do not believe that we can feasibly adopt a 36-month performance period for this measure and adopt it for the FY 2019 Hospital VBP Program. Based on the time needed to complete measure calculations and performance scoring, we believe that we must conclude the performance period for this measure by June 30, 2017. We believe that a 30-month performance period will result in sufficiently reliable quality measure data for purposes of Hospital VBP Program scoring, and our analysis of historic data supports our belief that comparisons between a 36-month baseline period and a 30-month performance period will not result in significant differences in measure scores. Further, adopting this proposed performance period would enable us to include the measure in the FY 2019 Hospital VBP Program, which would ensure that hospitals continue focusing on measures of outcomes under the Hospital VBP Program and that we continue transitioning the Hospital VBP Program from its initial focus on process measures to outcome measures.

We note that we have proposed below to adopt a 36-month performance period for the THA/TKA measure for the FY 2020 Hospital VBP Program. We have examined the correlation between hospitals' performance on the THA/TKA measure for 30-month and 36-month periods, and we believe that the 30-month period meets our standard for moderate reliability of quality measure data during the specified time period. However, as with the 30-day mortality and PSI–90 measures, we are attempting to align performance periods under the Hospital VBP Program with reporting periods under the Hospital IQR Program, while introducing measures covering important clinical topics into the Hospital VBP Program as quickly as possible. We believe that our proposal for a 30-month performance period for this measure for the FY 2019 Hospital VBP Program allows us to bring the measure into the Program in FY 2019 and to accomplish that alignment beginning with the FY 2020 Hospital VBP Program.

Therefore, we are proposing to adopt an FY 2019 performance period of January 1, 2015, through June 30, 2017, for the THA/TKA measure. Further, we are proposing to adopt an FY 2019 baseline period for this measure of July 1, 2010 to June 30, 2013, for purposes of calculating performance standards and awarding improvement points.

We welcome public comments on these proposals.

b. Proposed Performance Period and Baseline Period for the PSI–90 Safety Domain Measure for the FY 2019 Hospital VBP Program

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50692 through 5094), we adopted performance periods and baseline periods for the PSI–90 measure for the FY 2017 and FY 2018 Hospital VBP Programs. We adopted this policy in light of the time needed to process measure data and our policy goal to collect enough data to generate the most reliable measure scores possible. We stated our belief that aligning the Hospital VBP Program performance periods with the Hospital IQR Program reporting period duration would allow hospitals to review *Hospital Compare* measure rates when they are updated and incorporate this information into their quality improvement efforts, rather than having to wait until the Hospital VBP Program provides its scoring reports to hospitals. We stated our further belief that aligning the Hospital IQR Program and the Hospital VBP Program in this manner will minimize the burden on participating hospitals by aligning the time periods during which they must monitor their performance on this measure.

We did not finalize a baseline period and performance period for the AHRQ PSI–90 measure for FY 2019 in that final rule (78 FR 50692 through 50694). We stated that, by declining to finalize the measure's FY 2019 performance and baseline periods in that final rule, we would be able to adopt a more recent baseline period than we initially proposed. We stated that we intended to propose baseline and performance periods for the AHRQ PSI measure for the FY 2019 Hospital VBP Program in future rulemaking.

We continue to believe that we should adopt performance and baseline periods of 24 months for the PSI–90 measure. Therefore, we are proposing to adopt an FY 2019 performance period for the PSI–90 measure of July 1, 2015 through June 30, 2017, with a corresponding 24-month baseline period of July 1, 2011 through June 30, 2013, for purposes of calculating performance standards and awarding improvement points.

We welcome public comments on these proposals.

c. Summary of Previously Adopted and Proposed Performance Periods and Baseline Periods for Certain Measures for the FY 2019 Hospital VBP Program

The following table summarizes previously adopted and proposed performance and baseline periods for the FY 2019 Hospital VBP Program:

PREVIOUSLY ADOPTED AND PROPOSED PERFORMANCE AND BASELINE PERIODS FOR CERTAIN MEASURES FOR THE FY 2019 HOSPITAL VBP PROGRAM

Domain	Baseline period	Performance period
Safety:		
• PSI–90	• July 1, 2011–June 30, 2013	• July 1, 2015–June 30, 2017.
Clinical Care–Outcomes:		
• Mortality* (MORT–30–AMI, MORT–30–HF, MORT-30–PN)	• July 1, 2009–June 30, 2012*	• July 1, 2010–June 30, 2013.
• THA/TKA	• July 1, 2010–June 30, 2013*	• January 1, 2015–June 30, 2017.

* Previously adopted performance and baseline periods.

We welcome public comment on these proposals.

9. Proposed Performance Period and Baseline Period for the Clinical Care—Outcomes Domain for the FY 2020 Hospital VBP Program

As described above with respect to the mortality measures, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50692 through 50694), we adopted performance periods and baseline periods for the three 30-day mortality measures for the FY 2017, FY 2018, and FY 2019 Hospital VBP Programs. We adopted this policy in light of the time needed to process measure data and to ensure that we collect enough measure data for reliable performance scoring, as described further above. We continue to believe that we should adopt 36-month performance and baseline periods for the mortality measures when possible to accommodate those durations.

We believe that a similar rationale applies to the new THA/TKA measure that we are proposing to adopt for the Clinical Care—Outcomes domain for the FY 2019 Hospital VBP Program, and which, under our policy of measure readoption, we generally would readopt for the FY 2020 Hospital VBP Program if finalized. As stated above, we have examined the correlation between hospitals' performance on the THA/TKA measure for 30-month and 36-month periods, and we believe that the 30-month period meets our standard for moderate reliability of quality measure data during the specified time period. However, as with the 30-day mortality and PSI–90 measures, we are attempting to align performance periods under the Hospital VBP Program with reporting periods under the Hospital IQR Program, while introducing measures covering important clinical topics into the Program as quickly as possible. We believe that our proposal for a 30-month performance period for this measure for FY 2019 allows us to accomplish that alignment beginning with the FY 2020 Program.

Therefore, we are proposing to adopt a 36-month performance period for the measures in the Clinical Care—Outcomes domain in the FY 2020 Hospital VBP Program (including the proposed THA/TKA measure for FY 2020, if that measure is adopted for the FY 2020 Hospital VBP Program) of July 1, 2015 through June 30, 2018, with a corresponding 36-month baseline period of July 1, 2010 through June 30, 2013, for purposes of calculating performance standards and awarding improvement points.

The following table summarizes the proposed performance and baseline period for the Clinical Care—Outcomes domain for the FY 2020 Hospital VBP Program:

PROPOSED PERFORMANCE AND BASELINE PERIOD FOR THE CLINICAL CARE—OUTCOMES DOMAIN FOR THE FY 2020 HOSPITAL VBP PROGRAM

Domain	Baseline period	Performance period
Clinical Care—Outcomes:		
• Mortality (MORT–30 AMI, MORT–30–HF, MORT–30–PN).	• July 1, 2010–June 30, 2013	• July 1, 2015–June 30, 2018.
• THA/TKA	• July 1, 2010–June 30, 2013	• July 1, 2015–June 30, 2018.

We welcome public comment on these proposals.

10. Proposed Performance Standards for the Hospital VBP Program

a. Background

Section 1886(o)(3)(A) of the Act requires the Secretary to establish performance standards for the measures selected under the Hospital VBP Program for a performance period for the applicable fiscal year. The performance standards must include levels of achievement and improvement, as required by section 1886(o)(3)(B) of the Act, and must be established 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. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for further discussion of achievement and improvement standards under the Hospital VBP Program.

In addition, when establishing the performance standards, section 1886(o)(3)(D) of the Act requires the Secretary to consider appropriate factors, such as: (1) Practical experience with the measures, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods; (2) historical performance standards; (3) improvement rates; and (4) the opportunity for continued improvement.

b. Performance Standards for the FY 2016 Hospital VBP Program

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53599 through 53604), we adopted performance standards for FY 2015 and certain FY 2016 Hospital VBP Program measures. We also finalized our policy to update performance periods and performance standards for future Hospital VBP Program years via notice on the CMS Web site or another publicly available Web site.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50694 through 50698), we revised our regulatory definitions of ''achievement threshold'' and ''benchmark'' at § 412.160 and adopted performance standards for additional FY 2016 Hospital VBP Program measures. We also adopted an interpretation of ''achievement threshold'' and ''benchmark'' under § 412.160 to not include the numerical values that result when the performance standards are calculated. We further adopted a policy under which we may update a measure's performance standards for a fiscal year once if we identify data issues, calculation errors, or other problems that would significantly affect the displayed performance standards. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50695 through 50698) for the complete set of FY 2016 performance standards.

c. Previously Adopted Performance Standards for the FY 2017, FY 2018, and FY 2019 Hospital VBP Programs

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50698 through 50699), we adopted performance standards for the three 30-day mortality measures for the FY 2017, FY 2018, and FY 2019 Hospital VBP Programs and for the PSI–90 measure for the FY 2017 and FY 2018 Hospital VBP Programs. We refer readers to that final rule for those performance standards.

d. Proposed Additional Performance Standards for the FY 2017 Hospital VBP Program

In accordance with our finalized methodology for calculating performance standards (discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513)), we are proposing to adopt the following additional performance standards for the FY 2017 Hospital VBP Program. We note that the numerical values for the performance standards displayed below represent estimates based on the most recently available data, and we intend to update the numerical values in the FY 2015 IPPS/LTCH PPS final rule. We note further that the MSPB measure's performance standards are based on performance period data; therefore, we are unable to provide numerical equivalents for the standards at this time.

We note further that the performance standards for the NHSN measures (CAUTI, SSI, and proposed CLABSI, MRSA Bacteremia, and *C. difficile* Infection), the PSI–90 measure, and the MSPB measure are calculated with lower values representing better performance, in contrast to other measures, on which higher values indicate better performance. As discussed further in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50684), the performance standards for SSI are computed separately for each measure stratum, and we will award achievement and improvement points to each stratum separately, then compute a weighted average of the points awarded to each stratum by predicted infections.

PREVIOUSLY ADOPTED AND PROPOSED PERFORMANCE STANDARDS FOR THE FY 2017 HOSPITAL VBP PROGRAM: SAFETY, CLINICAL CARE—OUTCOMES, CLINICAL CARE—PROCESS, AND EFFICIENCY AND COST REDUCTION MEASURES

Measure ID	Description	Achievement threshold	Benchmark
Safety Measures			
CAUTI	Catheter-Associated Urinary Tract Infection	0.8371	0.0000
CLABSI	Central Line-Associated Blood Stream Infection	0. 4483	0.0000
C. difficile	*Clostridium difficile* Infection	0.7927	0.0000
MRSA bacteremia	Methicillin-Resistant *Staphylococcus aureus* Bacteremia.	0.8613	0.0000

PREVIOUSLY ADOPTED AND PROPOSED PERFORMANCE STANDARDS FOR THE FY 2017 HOSPITAL VBP PROGRAM: SAFETY, CLINICAL CARE—OUTCOMES, CLINICAL CARE—PROCESS, AND EFFICIENCY AND COST REDUCTION MEASURES—Continued

Measure ID	Description	Achievement threshold	Benchmark
PSI–90 *	Complication/patient safety for selected indicators (composite) *.	0.577321 *	0.397051 *
SSI	Surgical Site Infection.		
	• Colon	• 0.7117	• 0.0000
	• Abdominal Hysterectomy	• 0.7509	• 0.0000
Clinical Care—Outcomes Measures			
MORT–30–AMI *	Acute Myocardial Infarction (AMI) 30-day mortality rate *.	0.851458 *	0.871669 *
MORT–30–HF *	Heart Failure (HF) 30-day mortality rate *	0.881794 *	0.903985 *
MORT–30–PN *	Pneumonia (PN) 30-day mortality rate *	0.882986 *	0.908124 *
Clinical Care—Process Measures			
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival.	0.954545	1.000000
IMM–2	Influenza Immunization	0.995882	1.000000
PC–01	Elective Delivery Prior to 39 Completed Weeks Gestation.	0.031250	1.000000
Efficiency and Cost Reduction Measure			
MSPB–1	Medicare Spending per Beneficiary	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Previously adopted performance standards.

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2017 HOSPITAL VBP PROGRAM PATIENT AND CAREGIVER-CENTERED EXPERIENCE OF CARE/CARE COORDINATION DOMAIN

HCAHPS survey dimension	Floor (percent)	Achievement threshold	Benchmark (percent)
Communication with Nurses	56.90	78.08	86.41
Communication with Doctors	62.03	80.43	88.71
Responsiveness of Hospital Staff	36.46	64.83	79.62
Pain Management	49.47	70.20	78.18
Communication about Medicines	42.89	62.82	73.15
Hospital Cleanliness & Quietness	43.46	65.26	79.06
Discharge Information	61.86	85.59	91.04
Overall Rating of Hospital	35.00	69.81	84.27

We note that we intend to propose additional performance standards for the FY 2018 Hospital VBP Program in future rulemaking.

We welcome public comments on these proposed performance standards.

e. Proposed Performance Standards for the FY 2019 and FY 2020 Hospital VBP Programs

As discussed further above, we have adopted certain Safety and Clinical Care—Outcomes domain measures for future program years in order to ensure that we can adopt performance periods and baseline periods of sufficient length for performance scoring purposes. We are also proposing to adopt the PSI–90 measure in the Safety domain and the THA/TKA measure in the Clinical Care—Outcomes domain for the FY 2019 Hospital VBP Program. We note that, as described above with respect to the NHSN measures, the PSI–90 measure, and the MSPB measure, for the THA/TKA measure, better performance is represented by lower values. Therefore, we are proposing to adopt the following performance standards for the FY 2019 Hospital VBP Program:

PREVIOUSLY ADOPTED AND PROPOSED PERFORMANCE STANDARDS FOR CERTAIN SAFETY AND CLINICAL CARE—OUTCOMES DOMAIN MEASURES FOR THE FY 2019 HOSPITAL VBP PROGRAM

Measure ID	Description	Achievement threshold	Benchmark
	Safety Measures		
PSI–90	Complication/patient safety for selected indicators (composite)	0.840421	0.589716
	Outcomes Measures		
MORT–30–AMI *	Acute Myocardial Infarction (AMI) 30-day mortality rate *	* 0.850671	* 0.873263
MORT–30–HF *	Heart Failure (HF) 30-day mortality rate *	* 0.883472	* 0.908094
MORT–30–PN *	Pneumonia (PN) 30-day mortality rate *	* 0.882334	* 0.907906
THA/TKA	Hospital-level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA).	0.032521	0.022895

* Previously adopted performance standards.

We welcome public comments on these proposed performance standards.

We also are proposing to adopt the following performance standards for the FY 2020 Hospital VBP Program:

PROPOSED PERFORMANCE STANDARDS FOR CLINICAL CARE—OUTCOMES DOMAIN MEASURES FOR THE FY 2020 HOSPITAL VBP PROGRAM

Measure ID	Description	Achievement threshold	Benchmark
	Clinical Care—Outcomes Measures		
MORT–30–AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate	0.853511	0.875840
MORT–30–HF	Heart Failure (HF) 30-day mortality rate	0.881394	0.905962
MORT–30–PN	Pneumonia (PN) 30-day mortality rate	0.882281	0.909460
THA/TKA	Hospital-level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA).	0.032521	0.022895

We welcome public comments on these proposed performance standards.

f. Proposed Technical Updates Policy for Performance Standards

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50694 through 50698), we revised our regulatory definitions of ''achievement threshold'' and ''benchmark'' at § 412.160 and adopted performance standards for additional FY 2016 Hospital VBP Program measures. We also adopted an interpretation of ''achievement threshold'' and ''benchmark'' under § 412.160 to not include the numerical values that result when the performance standards are calculated. We further adopted a policy under which we may update a measure's performance standards for a fiscal year once if we identify data issues, calculation errors, or other problems that would significantly change the displayed performance standards.

Our historic practice has been to display Hospital VBP Program performance standards' numerical values in rulemaking. We adopted this practice for the convenience of the public. Although we have typically expressed the performance standards for each Hospital VBP measure as a numerical value prior to the start of the performance period for that measure, we do not display numerical values for the MSPB measure because the measure is constructed as a measure of costs attributable to patient care during a specified episode of care during the performance period itself (77 FR 53601). We have stated that with respect to the MSPB measure, we do not believe it is helpful for hospitals to be compared against performance standards constructed from baseline period data given the potential changes in market forces and utilization practices that occur over time.

Further, during the long interval between the time we first display the performance standards for all measures but the MSPB measure and the time that we calculate the achievement and improvement scores for those measures based on actual hospital performance, one or more of those measures might have been technically updated in a way that inhibits our ability to ensure that we are making appropriate comparisons between the baseline and performance period. For example, the software used to calculate the PSI–90 measure is regularly updated to incorporate coding changes, refinements based on the consensus development process, and refinements to improve specificity and sensitivity. The statistical modeling we use to adjust measure calculations for PSI–90 and HCAHPS also needs to be periodically updated to incorporate coefficient factors that more properly account for patient mix (both measures) and the HCAHPS survey data collection mode (HCAHPS survey). These types of technical updates do not substantively affect the measure rate calculation methodology, but they do sometimes affect our ability to make appropriate comparisons between the baseline and performance period if, for example, the baseline performance standards are tabulated using one version of the software and hospital performance during subsequent performance periods is tabulated with another version. We believe that in order to make the most accurate comparison of hospital performance across time, we should use the most updated version of the measure that is available at the time we calculate that performance because the updated version will produce the most valid measure rates.

Further, as part of its regular maintenance process for NQF-endorsed performance measures, 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 with 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.

The NQF's annual or triennial maintenance processes for endorsed measures may result in the NQF requiring updates to the measures in order to maintain endorsement status. We believe that it is important to incorporate nonsubstantive updates required by the NQF, as well as nonsubstantive updates made to other measures, into the measure specifications we have adopted for the Hospital VBP Program so that these measures remain up-to-date and ensure that we make fair comparisons between the performance and baseline periods that we adopt under the Program. We also recognize that some updates to measures are substantive in nature and might not be appropriate for adoption without further rulemaking.

With respect to what constitutes substantive versus nonsubstantive changes to measures, we would make this determination on a case-by-case basis. Examples of nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures). We believe that nonsubstantive changes may include updates to measures based upon changes to guidelines upon which the measures are based.

Therefore, we are proposing to amend the definition of ''performance standards'' under § 412.160 to enable us to update performance standards' numerical values to incorporate nonsubstantive technical updates that are made to Hospital VBP Program measures between the time that they are adopted for a particular program year and the time that we actually calculate hospital performance on those measures after the performance period for the program year has concluded. Further, we are proposing to inform hospitals of these technical updates through postings on our Hospital VBP Program Web site, the QualityNet Web site, other educational outreach efforts, and/or the scoring reports that we provide for each program year. We note that these proposals, if finalized, may have the effect of superseding the performance standards that we establish prior to the start of the performance period for the affected measures, but we believe them to be necessary to ensure that the performance standards in the Hospital VBP Program's scoring calculations enable the fairest comparisons between performance measured during the baseline period and performance period.

We would continue to use rulemaking to adopt substantive updates to the measures we have adopted for the Hospital VBP Program. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example: changes in acceptable timing of medication, procedure/process, or test administration). We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process.

We are also proposing to include in our revised definition of ''performance standards'' under § 412.160 of our regulations the policy we adopted in the FY 2013 IPPS/LTCH final rule to update the performance standards once if we identify data issues, calculation errors, or other problems that would significantly change the standards (78 FR 50695). We are proposing to make this change so that our policies governing updates to the performance standards appear together.

We welcome public comments on these proposals. We also specifically seek public comments on what we should consider to be substantive changes in measures' performance standards, including whether or not we should consider certain changes in performance standards as a result of technical or non-substantive updates to be substantive.

g. Request for Public Comments on ICD–10–CM/PCS Transition

The ICD–10–CM/PCS transition is scheduled to take place on October 1, 2015. After that date, we will collect nonelectronic health record-based quality measure data coded only in ICD–10–CM/PCS. Even though we expect that the endorsement status of the measures we have adopted for the Hospital VBP Program will remain the same, we are concerned that the transition to a new coding system might have unintended consequences on quality measure data denominators, statistical adjustment coefficients, and measure rates. We are concerned about the possible impacts on the Hospital VBP Program, and request public comments on how we should accommodate the transition.

Specifically, we request comments on how, if at all, we should adjust performance scoring under the Hospital VBP Program to accommodate quality data coded under ICD–10–CM/PCS, or otherwise ensure fair and accurate comparisons under the Hospital VBP Program once the transition date has passed. For example, we could consider analyzing the effects of the ICD–10–CM/PCS transition on hospitals' measured performance and, if substantive differences result, retrospectively adjusting performance standards in order to ensure that they accurately reflect the underlying methodology. We could also consider performing similar adjustments to hospitals' measure rates, measure scores, or TPSs once our analysis is completed. We also might consider scoring hospitals only on achievement if analysis indicates that we are unable to reliably and validly calculate improvement scores when comparing ICD–9–CM based baseline period data to ICD–10–CM/PCS based performance period data. However, while we intend to analyze the effects of the ICD–10–CM/PCS transition on hospitals' performance, we do not have the necessary data for all hospitals at this time.

We intend to take two steps to analyze ICD–10–CM/PCS potential impact before receiving ICD–10–CM/PCS-based fall 2015 discharge data in May 2016. First, we will assess measure specifications to qualitatively assess impact to measure denominators after CMS releases ICD–10–CM/PCS-based measure specifications in the future. Second, we intend to voluntarily solicit information from no more than 9 hospitals before October 1, 2015 to estimate the impact of ICD–10–CM/PCS on their Hospital VBP measure rates and denominator counts. We intend to use this information to inform both proposed and future Hospital VBP Program policy and measures.

We welcome public comments on this topic.

11. Proposed FY 2017 Hospital VBP Program Scoring Methodology

a. Proposed General Hospital VBP Program Scoring Methodology

In the Hospital Inpatient VBP Program final rule (76 FR 26514), 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. 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 similar scoring methodology for the MSPB measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656).

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53604 through 53605), for the FY 2015 Hospital VBP Program, we finalized our proposal to use these same general scoring methodologies to score hospital performance for the FY 2015 Hospital VBP Program. In that rule, we stated that we believe these scoring methodologies continue to appropriately capture hospital quality as reflected by the finalized quality measure sets. We also noted that readopting the finalized scoring methodology from prior program years represents the simplest and most consistent policy for providers and the public. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50699), we readopted the finalized general scoring methodology adopted for the FY 2015 Hospital VBP Program for the FY 2016 Hospital VBP Program.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50702 through 50704), we adopted new quality domains based on the NQS for FY 2017 and subsequent years.

We continue to agree with the reasoning for the scoring methodology outlined in the FY 2013 IPPS/LTCH PPS final rule and summarized above. Therefore, we are proposing to adopt the general scoring methodology adopted for the FY 2016 Hospital VBP Program for the FY 2017 Hospital VBP Program, with appropriate modifications to accommodate the new quality domains that we have previously adopted. These proposed modifications to our scoring methodology are limited to reclassified quality domains, new placements for measures within those domains, and domain weighting. We discuss below a proposal to revise the finalized domain weighting for FY 2017.

We welcome public comment on this proposal.

b. Proposed Domain Weighting for the FY 2017 Hospital VBP Program for Hospitals That Receive a Score on All Domains

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50702 through 50704), we adopted our proposal to align the Hospital VBP Program's quality measurement domains with the NQS' quality priorities, with certain modifications. We adopted this realignment beginning with the FY 2017 Hospital VBP Program. We also adopted the following domains and domain weights for the FY 2017 Hospital VBP Program for hospitals that receive a score in all newly aligned domains.

PREVIOUSLY ADOPTED DOMAINS AND DOMAIN WEIGHTS FOR THE FY 2017 HOSPITAL VBP PROGRAM FOR HOSPITALS RECEIVING A SCORE ON ALL NEWLY ALIGNED DOMAINS

Domain	Weight
Safety	15 percent.
Clinical Care:	35 percent.
• Clinical Care—Outcomes	• 25 percent.
• Clinical Care—Process	• 10 percent.
Efficiency and Cost Reduction	25 percent.
Patient and Caregiver Centered Experience of Care/Care Coordination	25 percent.

However, as discussed in more detail above, we are proposing to remove six ''topped out'' measures from the FY 2017 Clinical Care—Process subdomain. We believe that the proposed substantial reduction in the number of measures adopted for the Clinical Care—Process subdomain, if finalized, warrants reconsideration of the finalized domain weighting for FY 2017 that we adopted in the FY 2014 IPPS/LTCH PPS final rule.

As described in more detail above, we are proposing to re-adopt the CLABSI measure and to adopt two new measures (MRSA Bacteremia and *C. difficile* Infection) for the Safety domain for FY 2017 Hospital VBP Program and subsequent years, and, if finalized, they would raise the total number of measures in this domain for FY 2017 to six. Because we are proposing to make changes in the number of measures in only two domains (Safety and Clinical Care), we focused our proposed domain weighting changes in this proposed rule on these domains only. Because we continue to believe that hospitals should be provided strong incentives to perform well on measures of patient safety, in view of the new measures we are proposing to add to that domain, we are proposing to revise the previously finalized domain weighting for the FY 2017 Hospital VBP Program for hospitals receiving a score on all newly aligned domains as follows:

PROPOSED REVISED DOMAIN WEIGHTS FOR THE FY 2017 HOSPITAL VBP PROGRAM FOR HOSPITALS RECEIVING A SCORE ON ALL NEWLY ALIGNED DOMAINS

Domain	Weight
Safety	20 percent.
Clinical Care:	30 percent.
• Clinical Care—Outcomes	• 25 percent.
• Clinical Care—Process	• 5 percent.
Efficiency and Cost Reduction	25 percent.

PROPOSED REVISED DOMAIN WEIGHTS FOR THE FY 2017 HOSPITAL VBP PROGRAM FOR HOSPITALS RECEIVING A SCORE ON ALL NEWLY ALIGNED DOMAINS—Continued

Domain	Weight
Patient and Caregiver Centered Experience of Care/Care Coordination	25 percent.

We welcome public comments on this proposal.

c. Proposed Domain Weighting for the FY 2017 Hospital VBP Program 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, because the Hospital VBP Program has evolved from its initial two domains to an expanded measure set with additional domains, we considered whether it was appropriate to continue this policy.

Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53606 through 53607), we finalized our proposal that, for the FY 2015 Hospital VBP Program and subsequent years, hospitals with sufficient data to receive at least two out of the four domain scores that existed for the FY 2015 Hospital VBP Program (that is, sufficient cases and measures to receive a domain score on at least two domains) will receive a TPS. We also finalized our proposal that, for hospitals with at least two domain scores, TPSs would 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 weighting which occurs when there are scores in all four domains. We believe that this approach 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.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50701 through 50702), we continued this approach for the FY 2016 Hospital VBP Program and subsequent fiscal years for purposes of eligibility for the program even though, based on the NQS, we adopted four NQS-based domains for the FY 2017 Hospital VBP Program (78 FR 50702 through 50704), which include the subdivided Clinical Care domain.

In light of the four NQS-based domains we have adopted, we have reconsidered the appropriate minimum number of domains (that is, the number of domains on which hospitals must receive scores) in order to receive a TPS. We are concerned that requiring just two out of the four NQS-based domains in order to receive a TPS may be insufficient to ensure robust quality measurement under the Hospital VBP Program. Further, given the transition to NQS-based domains that we have adopted, we believe an additional independent analysis of appropriate minimum numbers of domains under the new domain structure is appropriate. We commissioned that analysis from our Reports & Analytics contractor for the Hospital VBP Program. The results of that analysis informed our proposal below, and we intend to post a summary of the reliability and minimum numbers analysis on the CMS Web site during the public comment period. We believe that requiring three out of the four NQS-based domains appropriately balances our desire to be as inclusive as possible with Hospital VBP Program requirements while ensuring that TPSs under the Program are sufficiently reliable.

Therefore, we are proposing to require that, for the FY 2017 Hospital VBP Program and subsequent years, hospitals must receive domain scores on at least three quality domains in order to receive a TPS. For purposes of the Clinical Care domain score, we are proposing to consider either the Clinical Care—Process or Clinical Care—Outcome subdomains as one domain in order to meet this proposed requirement. By adopting this policy, we believe we will continue to allow as many hospitals as possible may participate in the program while ensuring that reliable TPSs result. However, we would only reweight hospitals' TPSs once, and will therefore not reallocate the Clinical Care—Process and Clinical Care—Outcome subdomains' weighting within the Clinical Care domain if a hospital does not have sufficient data for one of the subdomains. For example, a hospital receiving domain scores on all domains except the Clinical Care—Process subdomain would not have the 5 percent weighting from the Clinical Care—Process subdomain reallocated entirely to the Clinical Care—Outcome subdomain. Instead, the 5 percent weighting from the Clinical Care—Process subdomain would be proportionately reallocated across all domains.

We welcome public comments on this proposal.

12. Proposed Minimum Numbers of Cases and Measures for the FY 2016 and FY 2017 Hospital VBP Program's Quality Domains

a. Previously Adopted Minimum Numbers of Cases and FY 2016 Proposed Minimum Numbers of Cases

In the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531), we adopted minimum numbers of at least 10 cases on at least 4 measures for hospitals to receive a Clinical Process of Care domain score. In the same final rule, we adopted a minimum number of 100 HCAHPS surveys for a hospital to receive a Patient Experience of Care domain score. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74532 through 74534), we adopted a minimum number of 10 cases for the mortality measures that we adopted for FY 2014. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53609), we adopted a new minimum number of 25 cases for the mortality measures for FY 2015. In the same final rule, we adopted a minimum number of 25 cases for the MSPB measure (77 FR 53609 through 53610), a minimum of three cases for any underlying indicator for the PSI–90 measure based on AHRQ's measure methodology (77 FR 53608 through 53609), and a minimum of one predicted infection for NHSN-based surveillance measures based on CDC's minimum case criteria (77 FR 53608 through 53609). However, we note that we adopted these case minimums for FY 2015 only, although we intended to adopt them for FY 2015 and subsequent years. We continue to believe that the finalized minimum numbers of cases described above are appropriate and provide sufficiently reliable data for scoring purposes under the Hospital VBP Program. Therefore, we are proposing to adopt the specified case minimums for the FY 2016 Hospital VBP Program and subsequent years.

We welcome public comment on this proposal. We note that we are proposing below to specify minimum numbers of measures for the FY 2017 Hospital VBP Program and subsequent years based on the new domain structure.

b. Proposed Minimum Number of Measures—Safety Domain

As described in more detail above, we have proposed to adopt six quality measures in the Safety domain for the FY 2017 Hospital VBP Program. Of these measures, five are NHSN-based surveillance measures, and one is the PSI–90 measure. After consideration of these measures and of previous independent analyses of the necessary minimum number of measures adopted for the Outcome domain, whose measures formed the basis for part of the new Safety domain, we are proposing to adopt a minimum number of three measures for the Safety domain for FY 2017 and subsequent years. We believe this proposal balances our desire to be as inclusive as possible with the Hospital VBP Program and the need for reliable quality measurement data on which to base TPSs. We would also like to clarify that we will continue to score hospitals on NHSN measures if, as we discussed with respect to the CLABSI measure (77 FR 53608) and the SSI measure (78 FR 50684), the hospital has met CDC's minimum case criteria, or one predicted infection during the applicable period.

We welcome public comments on this proposal.

c. Proposed Minimum Number of Measures—Clinical Care Domain

(1) Background

In the FY 2014 IPPS/LTCH PPS final rule, we adopted a new domain structure for the FY 2017 Hospital VBP Program and subsequent years based on the National Quality Strategy. In that final rule, we adopted a Clinical Care domain that was subdivided into the Clinical Care—Process and Clinical Care—Outcomes subdomains. We adopted these subdomains in order to ensure that we place the appropriate domain weighting on measures of clinical processes and measures of clinical outcomes. We believe the same consideration is appropriate for determining minimum numbers of measures for each subdomain, and based on prior independent analyses conducted of the appropriate minimum numbers for the Clinical Process of Care and Outcome domains whose measures formed the basis for the new Clinical Care domain, are proposing separate minimum numbers for each of these subdomains below. As described further above, we also attempted to balance our desire to be as inclusive as possible with the Hospital VBP Program and the need for reliable quality measurement data on which to base Total Performance Scores.

(2) Clinical Care—Outcomes Subdomain

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707), we adopted a minimum number of two measures in the former Outcome domain. We stated our belief that this minimum number is appropriate for the expanded Outcome domain that formed the basis for the Clinical Care—Outcomes subdomain because adding measure scores beyond the minimum number of measures has the effect of enhancing the domain score's reliability.

As noted above, the Clinical Care—Outcomes subdomain now contains the three 30-day mortality measures, and based on previous independent analysis of the appropriate minimum number of measures for the Outcome domain that formed the basis for the Clinical Care—Outcomes domain (available on our Web site at: *http://cms.hhs.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf*), we continue to believe that a minimum number of two measures within the subdomain appropriately balances scoring reliability with inclusiveness under the Program. As noted above, we intend to post a summary of the reliability and minimum numbers analysis on the CMS Web site during the public comment period. Therefore, we are proposing to adopt a minimum number of two measures in the Clinical Care—Outcomes subdomain for FY 2017 and subsequent years.

We welcome public comment on this proposal.

(3) Clinical Care—Process Subdomain

We have reconsidered the finalized minimum number of measures given the significant reduction in Clinical Care—Process measures due to ''topped-out'' removals that we are proposing in this proposed rule. We are concerned that requiring hospitals to report on all three proposed Clinical Care—Process measures for the FY 2017 Hospital VBP Program, or even requiring two out of three measures, could prevent a significant proportion of participating hospitals from receiving a Clinical Care—Process subdomain score. We are aware that relatively few hospitals report data for the AMI–7a measure, and the proposed PC–01 measure will only include hospitals that provide maternity services. In accordance with our preference for including as many hospitals as possible in the Hospital VBP Program while ensuring the reliability of the domain score and based on a prior independent analysis conducted with respect the Clinical Process of Care domain that formed the basis for the Clinical Care—Process domain, we are proposing to require hospitals to report a minimum of one measure in the Clinical Care—Process subdomain for the FY 2017 Hospital VBP Program and subsequent years to receive a domain score.

We welcome public comment on this proposal.

d. Proposed Minimum Number of Measures—Efficiency and Cost Reduction Domain

Because the MSPB measure remains the only measure within the Efficiency and Cost Reduction domain for FY 2017, we are proposing to require that hospitals receive a MSPB measure score in order to receive an Efficiency and Cost Reduction domain score. If we adopt additional measures for this domain in the future, we will consider if we should revisit this policy.

We welcome public comments on this proposal.

e. Proposed Minimum Number of Measures—Patient and Caregiver Centered Experience of Care/Care Coordination (PEC/CC) Domain

As with the MSPB measure adopted for the Efficiency and Cost Reduction domain described further above, we have not adopted additional measures for the PEC/CC domain. Because the HCAHPS survey measure remains the only measure within the PEC/CC domain for FY 2017, we are proposing to require that hospitals receive a HCAHPS survey measure score in order to receive a PEC/CC domain score. If we adopt additional measures for this domain in the future, we will consider if we should revisit this policy.

We welcome public comments on this proposal.

13. Applicability of the Hospital VBP Program to Maryland Hospitals

Section 1886(o)(1)(C) of the Act specifies the hospitals for which the Hospital VBP Program applies. 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. 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 have interpreted the reference to section 1814(b)(3) of the Act to mean those Maryland hospitals that were paid under section 1814(b)(3) of the Act and that, absent the ''waiver'' provided by section 1814(b)(3) of the Act, would have been paid under the IPPS.

The State of Maryland entered into an agreement with CMS, effective January 1, 2014, to participate in CMS' new Maryland All-Payer Model, a 5-year hospital payment model. This model is being implemented under section 1115A of the Act, as added by section 3021 of the Affordable Care Act, which authorizes the testing of innovative payment and service delivery models, including models that allow States to ''test and evaluate systems of all-payer payment reform for the medical care of residents of the State, including dual-eligible individuals.'' Section 1115A of the Act authorizes the Secretary to waive such requirements of titles XI and XVIII of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models.

Under the agreement with CMS, Maryland will limit per capita total hospital cost growth for all payers, including Medicare. In order to implement the new model, effective January 1, 2014, Maryland elected to no longer have Medicare pay Maryland hospitals in accordance with section 1814(b)(3) of the Act. Maryland also represented that it is no longer in continuous operation of a demonstration project reimbursement system since July 1, 1977, as specified under section 1814(b)(3) of the Act. Because Maryland hospitals are no longer paid under section 1814(b)(3) of the Act, they are no longer subject to those provisions of the Act and related implementing regulations that are specific to hospitals paid under section 1814(b)(3)of the Act, including but not limited to section 1886(o)(1)(C)(iv) of the Act, which provides an exemption for hospitals paid under section 1814(b)(3) of the Act from the application of the Hospital VBP Program if the State which is paid under that section meets certain requirements.

In order to implement the Maryland All-Payer Model, we have waived certain provisions of the Act, and the corresponding implementing regulations, as set forth in the agreement between CMS and Maryland and subject to Maryland's compliance with the terms of the agreement. The effect of Maryland hospitals no longer being paid under 1814(b)(3) is that they are not entitled to be exempted from the Hospital VBP Program under section 1886(o)(1)(C)(iv) of the Act and, but for the model, would be included in the Hospital VBP Program. In other words, although the exemption from the Hospital VBP Program no longer applies, Maryland hospitals will not be participating in the Hospital VBP Program because section 1886(o) of the Act and its implementing regulations have been waived for purposes of the model, subject to the terms of the agreement.

Accordingly, we are proposing to make conforming revisions to § 412.160, in the definition of ''base-operating DRG payment amount'' and to § 412.161, which describes the applicability of the Hospital VBP Program. We are proposing to delete references in these regulations to hospitals paid under section 1814(b)(3) of the Act because, at this time, there are no hospitals paid under that section.

We welcome public comment on these proposals.

14. Disaster/Extraordinary Circumstance Exception Under the Hospital VBP Program

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50704 through 50706), we adopted a disaster/extraordinary circumstance exception. We refer readers to that final rule for the policy's details.

We note that we are currently in the process of revising the Extraordinary Circumstances/Disaster Extension or Waiver Request form, previously approved under OMB control number 0938–1171.

J. Proposed Changes to the Hospital-Acquired Condition (HAC) Reduction Program

1. Background

We refer readers to section V.I.1.a. of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program.

2. Statutory Basis for the HAC Reduction Program

Section 3008 of the Affordable Care Act added section 1886(p) to the Act to provide an incentive for applicable hospitals to reduce the incidence of HACs. Section 1886(p) of the Act requires the Secretary to make an adjustment to payments to ''applicable hospitals'' effective beginning on October 1, 2014 and for subsequent programs years. Section 1886(p)(1) of the Act sets forth the requirements by which payments to ''applicable hospitals'' will be adjusted to account for HACs with respect to discharges occurring during FY 2015 or later. The amount of payment shall be equal to 99 percent of the amount of payment that would otherwise apply to such discharges under section 1886(d) or 1814(b)(3) of the Act, as applicable. Section 1886(p)(2)(A) of the Act defines ''applicable hospitals'' as subsection (d) hospitals that meet certain criteria. Section 1886(p)(2)(B)(i) of the Act defines these criteria and specifies that the payment adjustment would apply to an applicable hospital that ranks in the top quartile (25 percent) of all subsection (d) hospitals, relative to the national average, of conditions acquired during the applicable period, as determined by the Secretary. Section 1886(p)(2)(B)(ii) of the Act requires the Secretary to establish and apply a risk-adjustment methodology.

Sections 1886(p)(3) and (p)(4) of the Act define ''hospital-acquired conditions'' and ''applicable period'', respectively. The term ''hospital-acquired condition'' means ''a condition identified in subsection 1886(d)(4)(D)(iv) of the Act and any other condition determined appropriate by the Secretary that an individual acquires during a stay in an applicable hospital, as determined by the Secretary.'' The term ''applicable period'' means, with respect to a fiscal year, a period specified by the Secretary.

Section 1886(p)(5) of the Act requires that, prior to FY 2015 and each subsequent fiscal year, the Secretary provides the delivery of confidential reports to applicable hospitals with respect to HACs of the applicable hospital during the applicable period. Section 1886(p)(6)(A) of the Act sets forth the reporting requirements by which the Secretary would make information available to the public regarding HACs for each applicable hospital. Section 1886(p)(6)(B) of the Act requires the Secretary to ensure that an applicable hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to the HACs of the applicable hospital prior to such information being made public. Section 1886(p)(6)(C) of the Act requires that, once corrected, the HAC information be posted on the *Hospital Compare* Web site on the Internet in an easily understandable format.

Section 1886(p)(7) of the Act limits administrative and judicial review of certain determinations made pursuant to section 1886(p) of the Act. These determinations include what qualifies

as an applicable hospital, the specifications of a HAC, the Secretary's determination of an applicable period, the provision of confidential reports submitted to the applicable hospital, and the information publically reported on the *Hospital Compare* Web site.

3. Implementation of the HAC Reduction Program for FY 2015

a. Overview

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729), we presented the general framework for implementation of the HAC Reduction Program for the FY 2015 implementation. We included the following provisions for the program: (a) The relevant definitions applicable to the program; (b) the payment adjustment under the program; (c) the measure selection and conditions for the program, including a risk-adjustment and scoring methodology; (d) performance scoring; (e) the process for making hospital-specific performance information available to the public, including the opportunity for a hospital to review the information and submit corrections; and (f) limitation of administrative and judicial review.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50967), we established the rules governing the payment adjustment under the HAC Reduction Program at Subpart I of 42 CFR Part 412 (§§ 412.170 and 412.172). We also amended existing § 412.150 (the section that describes the basis and scope of Subpart I of Part 412, which contains the regulations governing adjustments to the base operating DRG payment amounts under the IPPS for inpatient operating costs) to incorporate the basis and scope of §§ 412.170 and 412.172 for the HAC Reduction Program.

In accordance with the provisions of section 1886(p) of the Act, in the FY 2014 IPPS/LTCH PPS final rule, we included, under § 412.170, definitions for the terms ''hospital-acquired condition,'' ''applicable hospital,'' and ''applicable time period'' (78 FR 50967). In § 412.170, we defined ''hospital-acquired condition'' as a condition as described in section 1886(d)(4)(D)(iv) of the Act and any other condition determined appropriate by the Secretary that an individual acquires during a stay in an applicable hospital, as determined by the Secretary. We defined an ''applicable hospital'' as ''a hospital described in section 1886(d)(1)(B) of the Act (including 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) as long as the hospital meets the criteria specified under § 412.172(e)'' (78 FR 50967). We specified that this definition does not include hospitals and hospital units excluded from the IPPS, such as LTCHs, cancer hospitals, children's hospitals, IRFs, IPFs, CAHs, and Puerto Rico hospitals. We defined the ''applicable period'' as, with respect to a fiscal year, the 2-year period (as specified by the Secretary) from which data are collected in order to calculate the Total HAC Score for the HAC Reduction Program.

Below we summarize the specific provisions for the HAC Reduction Program that were established in the FY 2014 IPPS/LTCH PPS final rule for implementation in FY 2015.

b. Payment Adjustment Under the HAC Reduction Program, Including Exemptions

(1) Basic Payment Adjustment

Section 1886(p)(1) of the Act sets forth the requirements by which payments to ''applicable hospitals'' will be adjusted to account for HACs with discharges beginning on October 1, 2014. Section 1886(p)(1) of the Act specifies that the amount of payment shall be equal to 99 percent of the amount of payment that would otherwise apply to such discharges under section 1886(d) or 1814(b)(3) of the Act, as applicable. As specified in the statute, this payment adjustment is calculated and made after payment adjustments under sections 1886(o) and 1886(q) of the Act, the Hospital VBP Program and the Hospital Readmissions Reduction Program respectively, are calculated and made. (We note that the Hospital VBP Program is discussed in section IV.I. of the preamble of this proposed rule and the Hospital Readmissions Reduction Program is discussed in section IV.H. of the preamble of this proposed rule.) Section 1886(p)(2)(A) of the Act defines ''applicable hospitals'' as subsection (d) hospitals that meet certain criteria. Section 1886(p)(2)(B)(i) of the Act defines these criteria and specifies that the payment adjustment would apply to an applicable hospital that ranks in the top quartile (25 percent) of all subsection (d) hospitals, relative to the national average of hospitals that report conditions acquired during the applicable period, as determined by the Secretary.

Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR50967), we specified in § 412.172(b) of the regulations that, for applicable hospitals, beginning with discharges occurring during FY 2015, the amount of payment under § 412.172, or section 1814(b)(3) of the Act, as applicable, for such discharges shall be equal to 99 percent of the amount of payment that would otherwise apply to such discharges under § 412.172, or section 1814(b)(3) of the Act. This amount of payment will be determined after the application of the payment adjustment under the Hospital Readmissions Reduction Program under § 412.154, and the adjustment made under the Hospital VBP Program under § 412.162, and section 1814(l)(4) but without regard to this section 1886(p) of the Act.

(2) Applicability to Maryland Hospitals

Section 1886(p)(2)(c) of the Act specifies that the Secretary may exempt hospitals paid under 1814(b)(3) ''from the application of this subsection if the State which is paid under such section 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 this subsection.'' Accordingly, a program established by the State of Maryland that could serve to exempt hospitals in the State from the HAC Reduction Program would focus on 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 this provision. As we stated in section IV.J.3. of the preamble of this proposed rule, because hospitals paid under section 1814(b)(3) of the Act are subsection (d) hospitals, they are included in determining ''applicable hospitals'' (subject to the payment adjustment under the HAC Reduction Program), and unless the Secretary exempts these hospitals from the application of payment adjustments under the HAC Reduction Program under the authority of section 1886(p)(2)(C) of the Act, they are considered to be ''applicable hospitals'' (subject to the payment adjustments in the HAC Reduction Program) under the HAC Reduction Program.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50967 through 50968), we established criteria for evaluation to determine whether Maryland will be exempted from the application of the payment adjustments under the HAC Reduction Program for a given fiscal year. Under § 412.172(c), we specified that ''CMS will determine whether to exempt Maryland hospitals that are paid under section 1814(b)(3) of the Act and not under the hospital inpatient

prospective payment system. . . .'' and that, absent the provisions of section 1814(b)(3) of the Act, to make payment under section 1886(d) of the Act exempt from the application of payment adjustments under the HAC Reduction Program, provided that the State submits an annual report to the Secretary describing how a similar program to reduce hospital acquired conditions in that State achieves or surpasses the measured results in terms of health outcomes and cost savings for the HAC Reduction Program as applied to hospitals described in section 1886(d)(1)(B) of the Act. We specified in the regulations that ''CMS will establish criteria for evaluation of Maryland's annual report to the Secretary to determine whether Maryland will be exempted from the application of payment adjustments under this program for a given fiscal year.'' We also specified that Maryland's annual report to the Secretary and request for exemption from the HAC Reduction Program must be resubmitted and reconsidered annually. We provided that, for FY 2015, Maryland must submit a preliminary report to us by January 15, 2014 and a final report to us by June 1, 2014.

We noted that our criteria to evaluate Maryland's program is for FY 2015, the first year of the payment adjustment under the HAC Reduction Program, and that our evaluation criteria may change through notice and comment rulemaking as this program evolves.

The State of Maryland entered into an agreement with CMS, effective January 1, 2014, to participate in CMS' new Maryland All-Payer Model, a 5-year hospital payment model. This model is being implemented under section 1115A of the Social Security Act (''Act''), as added by section 3021 of the Affordable Care Act, which authorizes the testing of innovative payment and service delivery models, including models that allow states to ''test and evaluate systems of all-payer payment reform for the medical care of residents of the State, including dual eligible individuals.'' Section 1115A of the Act authorizes the Secretary to waive such requirements of titles XI and XVIII of the Act as may be necessary solely for purposes of carrying out Section 1115A with respect to testing models.

Under the agreement with CMS, Maryland will limit per capita total hospital cost growth for all payers, including Medicare. In order to implement the new model, effective January 1, 2014, Maryland elected to no longer have Medicare reimburse Maryland hospitals in accordance with section 1814(b)(3) of the Act. Maryland also represented that it is no longer in continuous operation of a demonstration project reimbursement system since July 1, 1977, as specified under Section 1814(b)(3) of the Act. Because Maryland hospitals are no longer reimbursed under section 1814(b)(3) of the Act, they are no longer subject to those provisions of the Act and related implementing regulations that are specific to section 1814(b)(3) hospitals, including but not limited to section 1886(p)(2)(C) of the Act, which provides exemptions for hospitals paid under section 1814(b)(3) from the application of the HAC Reduction Program.

However, in order to implement the Maryland All-Payer Model, CMS has waived certain provisions of the Act for Maryland hospitals, including section 1886(p), and the corresponding implementing regulations, as set forth in the agreement between CMS and Maryland and subject to Maryland's compliance with the terms of the agreement. In other words, although section 1886(p)(2)(C) of the Act no longer applies to Maryland hospitals, Maryland hospitals will not be participating in the HAC Reduction Program because section 1886(p) of the Act and its implementing regulations have been waived for purposes of the model, subject to the terms of the agreement. Consequently, we are proposing that the Total HAC scores for Maryland hospitals will not be included when identifying the top quartile of all hospitals with respect to their Total HAC Score during the applicable period.

As a result of changes to the status of Maryland hospitals under 1814(b)(3) of the Act described above, we are proposing conforming changes to these regulations and seek public comment on this proposal. Specifically, we are proposing to remove the entire contents of paragraph (c) under § 412.172 and reserve the paragraph (c) designation.

c. Measure Selection and Conditions, Including a Risk-Adjustment Scoring Methodology

(1) General Selection of Measures

We are not proposing any new measures for the HAC Reduction Program in this FY 2015 proposed rule. Although we are not required under section 1886(p) of the Act to address specific measure scoring methodologies and domain weights regarding the HAC Reduction Program in notice-and-comment rulemaking, as required under the Hospital VBP program, we believe that it is important to set forth such scoring methodologies for each individual HAC measure, in order for the public to understand how the measures adopted in previous rulemaking relate to the performance methodology used to determine the applicable hospitals subject to the payment adjustment under the HAC Reduction Program. However, below we set forth the specific measure scoring methodology and domain weights regarding the HAC Reduction Program for FY 2015 as finalized in the FY 2014 IPPS/LTCH PPS final rule.

(2) Updates on AHRQ PSI–90, and CDC NHSN CLABSI and CAUTI Measures

For FY 2015, we will keep the AHRQ PSI–90 composite measure (in Domain 1) that we adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717) as it is currently endorsed by NQF. However, we note that the AHRQ PSI–90 composite measure is currently undergoing NQF maintenance review. The PSI–90 composite consists of eight component indicators: PSI–3 Pressure ulcer rate; PSI–6 Iatrogenic pneumothorax rate; PSI–7 Central venous catheter-related blood stream infections rate; PSI–8 Postoperative hip fracture rate; PSI–12 Postoperative PE/DVT rate; PSI–13 Postoperative sepsis rate; PSI–14 Wound dehiscence rate; and PSI–15 Accidental puncture & laceration rate. AHRQ is considering the addition of PSI–9 (Perioperative hemorrhage rate), PSI–10 (Perioperative physiologic metabolic derangement rate) and PSI–11 (Post-operative respiratory failure rate) or a combination of these three measures into the PSI–90 composite. We consider the inclusion of measures in the PSI–90 composite to be a significant change to the PSI–90 composite that we finalized in the FY 2014 IPPS/LTCH PPS final rule. Should the changes be significant, we will issue notice-and-comment rulemaking prior to requiring reporting of this composite.

Similarly, the CDC NHSN Catheter-Associated Urinary Tract Infection (CAUTI) and Central Line-Associated Blood Stream Infection (CLABSI) measures in Domain 2 that we adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717) for FY 2015 also are currently undergoing NQF maintenance review. Should the changes be significant, we will issue notice-and-comment rulemaking prior to requiring reporting of the changes made to CDCs NHSN CLABSI and CAUTI measures. For FY 2015, we will keep CDC's NHSN CAUTI and CLABSI measures in Domain 2 as they are currently endorsed.

(3) Measure Selection

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized the following measures for selection: (i) The AHRQ PSI–90 composite measure for Domain 1 and the CDC NHSN measures CAUTI and CLABSI for Domain 2 for FY 2015; (ii) addition of CDC NHSN Surgical Site Infection (SSI) measure for FY 2016; and (iii) addition of CDC NHSN Methicillin-Resistant Staphylococcus aureus (MRSA) Bactremia and *C. difficile* measures for FY 2017. Several of these measures are already part of the Hospital IQR Program and are reported on the *Hospital Compare* Web site.

(4) Measure Risk-Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule, we established that we will use the existing measure-level risk-adjustment that is already part of the methodology for the individual measures for Domains 1 and 2 in order to fulfill this requirement (78 FR 50719). We codified the use of this methodology under § 412.172(d) of the regulations. The AHRQ PSI–90 composite measure and the CDC NHSN measures selected for the program are risk-adjusted and reliability-adjusted. Specifically, risk factors such as the patient's age, gender, comorbidities, and complications will be considered in the calculation of the measure rates so that hospitals serving a large proportion of sicker patients are not unfairly penalized. We noted that the risk-adjustment methodology for these measures meets NQF endorsement criteria. We believe that such risk-adjustment is appropriate, pursuant to section 1886(p) of the Act.

We will continue to examine the impact of the additional measures in the program, and propose refinements to the program if necessary. Should changes to the risk-adjustment models for the measures be adopted during NQF endorsement maintenance processes, we will propose adopting these changes as soon as possible through rulemakings.

(5) Measure Calculations

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717 through 50719), we established that we will perform measure calculations for the AHRQ PSI–90 composite measure under Domain 1 and the CDC NHSN measures under Domain 2. We stated that measure calculations for the AHRQ PSI–90 composite measures included using ICD–9–CM diagnosis and/or procedure codes and, for the principal and secondary diagnoses, a present on admission (POA) indicator value associated with all diagnoses on the claim. We also stated that subsection (d) Maryland hospitals paid under the waiver at section 1814(b)(3) of the Act also must report on whether a diagnosis is present on admission (78 FR 50718). (As noted in section IV.J.3.b.(2) of the preamble of this proposed rule, in order to implement the new Maryland All-Payer Model, Maryland elected to no longer have Medicare payment made to Maryland hospitals in accordance with section 1814(b)(3) of the Act, effective January 1, 2014. Although CMS has waived certain provisions of the Act for Maryland hospitals as set forth in the agreement between CMS and Maryland and subject to Maryland's compliance with the terms of the agreement, CMS has not waived the POA indicator reporting requirement. In other words, the changes to the status of Maryland hospitals under section 1814(b)(3) of the Act as described above do not in any way change the POA indicator reporting requirement for Maryland hospitals.) We also finalized that the same rules under the Hospital IQR Program be applied to determine how the AHRQ PSI–90 composite measure and CDC NHSN measures are applied and calculated.

(6) Applicable Time Period

In the FY 2014 IPPS/LTCH final rule (78 FR 50717), we adopted a 2-year applicable period to collect data that would be used to calculate the Total HAC Score for FY 2015. For Domain 1 (AHRQ PSI–90 composite measure), we established a 2-year data period to calculate the measures based on recommendations from AHRQ, the measure developer, as we believed that the 24-month data period will provide hospitals and the general public the most current data available. The 24-month data period also will allow time to complete the complex calculation process for these measures, to perform comprehensive quality assurance to enhance the accuracy of measure results, and to disseminate confidential reports on hospital-level results to individual hospitals.

As such, for FY 2015, we will use the 24-month period from July 1, 2011 through June 30, 2013 as the applicable time period for the AHRQ PSI–90 composite measure. The claims for all Medicare FFS beneficiaries discharged during this period will be included in the calculation of measure results for FY 2015. This includes claims data from the 2011, 2012, and 2013 Inpatient Standard Analytic Files (SAFs).

The CDC NHSN measures, CAUTI and CLABSI, are currently collected and calculated on a quarterly basis. However, for the purpose of the HAC Reduction Program, we will use 2 years of data to calculate the Domain 2 score. For FY 2015, we will use calendar years 2012 and 2013 for the HAC Reduction Program. As noted above, we codified the definition of ''applicable time period'' in the FY 2014 IPPS/LTCH PPS final rule at § 412.170.

d. Criteria for Applicable Hospitals and Performance Scoring Policy

The HAC Reduction Program does not contain specific statutory directives on scoring methods, as found with other programs. Therefore, our main concern when establishing scoring methods for the HAC Reduction Program was to align with existing scoring methodologies in similar hospital programs. Accordingly, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50721), we finalized a scoring methodology that aligns with the achievement scoring methodology currently used under the Hospital VBP Program (78 FR 27629). We believe aligning the scoring methodologies reduces confusion associated with multiple scoring methodologies. Additionally, we note that alignment benefits the hospital stakeholders who have prior experience with the Hospital VBP Program.

In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27629), we proposed to implement a methodology for assessing the top quartile of applicable hospitals for HACs based on performance standards, where we would score each hospital based on whether they fall in the top quartile for each applicable measure and where in the top quartile they fall. In addition, we *proposed* to calculate a Total HAC Score for each hospital by summing the hospital's performance score on each measure within a domain to determine a score for each domain, then multiplying each domain score by a proposed weight (Domain 1—AHRQ Patient Safety Indicators 50 percent, Domain 2—CDC NHSN Measures 50 percent), and adding together the weighted domain scores to determine the Total HAC Score.

We reviewed the public input on the proposed 75th percentile benchmark. Several commenters requested that a change to the proposed minimum benchmark for scoring each measure was necessary. We agreed with these commenters, and in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50722), we modified our proposal and established that the scoring will begin at the minimum value for each measure rather than the 75th percentile. The methodology finalized in the FY 2014

IPPS/LTCH PPS final rule will assess the top quartile of applicable hospitals for HACs based on the Total HAC Score. The support for Domain 2 measures in general, coupled with multiple recommendations, and specifically those from MedPAC, to provide more weight to Domain 2 measures led us to conclude that such scoring changes are necessary. Therefore, we finalized a different weight for each Domain than originally proposed (78 FR 50721).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50722), we further specified that we will calculate a Total HAC Score for each hospital by using the hospital's performance score on each measure within a domain to determine a score for each domain, then multiply each domain score by the following weights: Domain 1—(AHRQ PSI–90 composite measure), 35 percent; and Domain 2—(CDC NHSN measures), 65 percent; and combine the weighted domain scores to determine the Total HAC Score (§ 412.172(e)(3)). We use each hospital's Total HAC Score to determine the top quartile of subsection (d) hospitals (applicable hospitals) that are subject to the payment adjustment beginning with discharges on or after October 1, 2014. With respect to a subsection (d) hospital, we identify the top quartile of all hospitals that are subsection (d) hospitals with respect to their rate of HACs during the applicable period (§ 412.172(e)(1)). We use a Total HAC Score to identify applicable hospitals and identify the 25 percent of hospitals with the highest Total HAC Scores as applicable hospitals (§ 412.172(e)(2)).

We finalized the PSI–90 composite measure for Domain 1. Because hospitals may not have complete data for every AHRQ indicator in the composite measure for this Domain 1 measure, we finalized the same methodology used for the Hospital VBP Program to determine the minimum number of indicators with complete data to be included in the calculation of the Domain measure.

Additionally, we finalized the following rules to determine the number of AHRQ indicators to be included in the calculation for a hospital's Domain 1 score. In this discussion, ''complete data'' refers to whether a hospital has enough eligible discharges to calculate a rate for a measure. Complete data for the AHRQ PSI–90 composite measure means the hospital has three or more eligible discharges for at least one component indicator. Specifically—

If a hospital does not have ''complete data'' for the PSI–90 composite, we will not calculate a Domain 1 score for that hospital.

If a hospital has ''complete data'' for at least one indicator for the AHRQ PSI–90 composite, we will calculate a Domain 1 score.

The calculation of the SIR for the CDC measures requires that the facility have a ≥ 1 predicted HAI event. The predicted number of events is calculated using the national HAI rate and the denominator counts (that is, number of device days, procedure days, or patient days depending on the HAI). In the event an SIR cannot be calculated because the facility has <1 predicted infection, Domain 1 scores exclusively will be used to calculate a HAC score. In other words, we will exclude from the overall HAC score calculation any measure for which an SIR cannot be calculated for the reason set out above.

Because of the differences among the measures for the HAC Reduction Program and the distribution of measure results, simply adding up the measure results to calculate the domain or Total HAC Score will make the scores less meaningful to hospitals and the general public. As a result, as we indicated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50720 through 50725), points will be assigned to hospitals' performance for each measure. This approach aligns with the Hospital VBP Program for measuring hospital achievement. In particular, the Hospital VBP Program assigns up to 10 points for each measure based on a hospital's performance result for that measure for a given time period. We note that, for the HAC Reduction Program, unlike the Hospital VBP Program where a higher score means better performance, the more points a hospital receives on a measure corresponds with a poorer score performance. For the HAC Reduction Program, we finalized use of a slightly different methodology for scoring points, depending on the specific measure (Table C in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50723), which is also included below). Specifically—

- For the AHRQ Patient Safety for Selected Condition (PSI–90) composite in Domain 1, point assignment will be based on a hospital's score for the composite measure.
- For the PSI–90 composite measure, 1 to 10 points will be assigned to the hospital.
- For the CDC NHSN measures in Domain 2, point assignment for each measure will be based on the SIR for that measure.
- For each SIR, 1 to 10 points will be assigned to the hospital for each measure (CAUTI and CLABSI for FY 2015).
- The Domain 2 score will consist of the average of points assigned to the SIR (CAUTI and CLABSI for FY 2015).

TABLE C—CALCULATION OF DOMAIN 1 AND 2 MEASURES FOR FY 2015

Measure name	Measure result	Scenario	Individual measure score (points)
Domain 1 AHRQ PSI–90 ***	Weighted average of rates of component indicators.	Composite value	1—10.
Domain 2 CDC NHSN CAUTI CLABSI.	Standard Infection Ratio (SIR)	SIR	1—10 (refer to Figure A).

*** These measure rates are risk-adjusted and reliability-adjusted.

For all measures finalized for the HAC Reduction Program, we will use the following rules to determine the number of points assigned to a measure (78 FR 50723 through 50725). Based on the distribution for PSI–90 rates for all the hospitals, we will divide the results into percentiles in increments of 10 with the lowest percentile ranges meaning better performance. Hospitals with PSI–90 rates within the lowest tenth percentile will be given one point; those with PSI–90 rates within the second lowest percentile range (between the 11th and 20th percentile) will be given 2 points, and so forth.

FIGURE A—POINT ASSIGNMENT FOR HOSPITAL A'S PSI–90 SCORE

If Hospital A's PSI–90 rate falls into this percentile	Then assign this number of points
1st–10th	1
11th–20th	2
21st–30th	3

FIGURE A—POINT ASSIGNMENT FOR HOSPITAL A'S PSI–90 SCORE—Continued

If Hospital A's PSI–90 rate falls into this percentile	Then assign this number of points
31st–40th	4
41st–50th	5
51st–60th	6
61st–70th	7
71st–80th	8
81st–90th	9
91st–100th	10

For Domain 2, we will obtain measure results that hospitals submitted to the CDC NHSN for the Hospital IQR Program. The CDC NHSN HAI measures capture adverse events that occurred within intensive care units (ICUs), including pediatric and neonatal units. For the Hospital IQR Program, hospitals that elected to participate in the reporting program (that is, had an active IQR pledge), but did not have ICUs, can apply for an ICU waiver so that they will not be subject to the 2-percent payment reduction for nonsubmission of quality reporting data.

In the FY 2014 IPPS/LTCH PPS final rule, we noted in the second quarter of 2012, among the 3,321 IPPS hospitals with an active IQR pledge for data submission, 377 (or 10.1 percent) applied and received an ICU waiver. At the same time, 2,939 hospitals (88.5 percent) of the IPPS hospitals did not have an ICU waiver and submitted data for the CDC HAI CLABSI measure, while 4 hospitals (0.1 percent) that had no ICU waiver failed to submit data to the NHSN. For the same quarter, of the 3,321 IPPS hospitals with an active IQR pledge, 2,935 (88.4 percent) that did not have an ICU waiver submitted data for the CDC HAI CAUTI measure, whereas 8 hospitals (0.2 percent) did not submit data. Because data availability for the two CDC HAI measures impact the score for Domain 2 and eventually the Total HAC Score, we aim to encourage hospitals with an ICU that did not submit data to begin data submission, and to reward hospitals that have already submitted data to continue data submission for all the CDC HAI measures. To this end, we finalized the following rules (Figure B in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50724), which is included below):

- If a hospital has an ICU waiver for the CDC HAI measures, we will use only the Domain 1 score to calculate its Total HAC Score.
- If a hospital does not have an ICU waiver for a CDC HAI measure:
  - If the hospital does not submit data for the CDC HAI measures, we will assign 10 points to that measure for that hospital.
  - If the hospital does submit data for at least one CDC NHSN measure:
    - If there are ''complete data'' (that is, enough adverse events to calculate the SIR) for at least one measure, we will use those data to calculate a Domain 2 score and use the hospital's Domain 1 and Domain 2 scores to calculate the Total HAC Score.
    - If there are not enough adverse events to calculate the SIR for any of the measures, we will use only the hospital's Domain 1 score to calculate its Total HAC Score.

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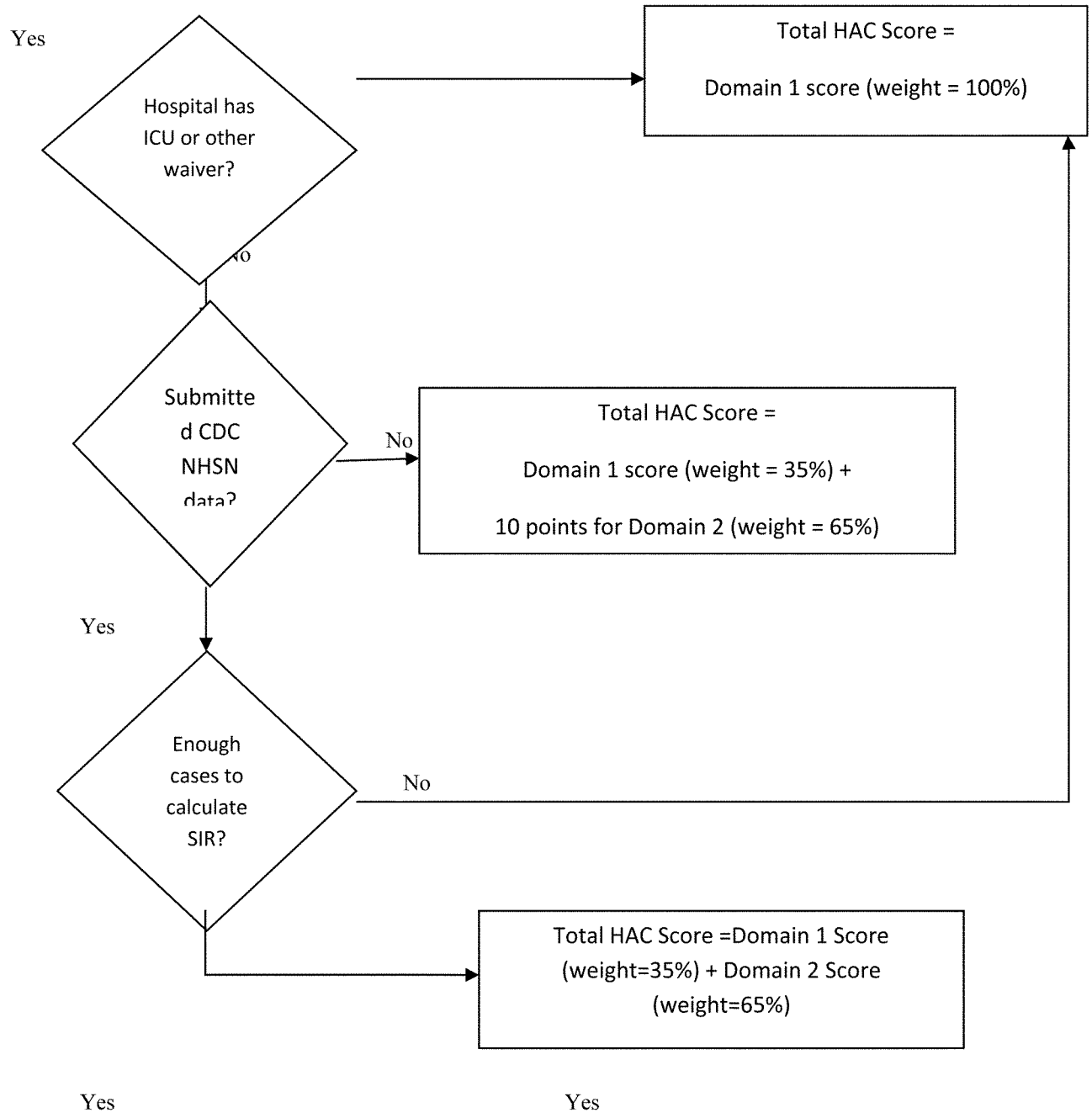
Figure B. Calculation of Total HAC Score for Domain 2 CDC NHSN Measures for FY 2015



Key:
Domain 1 = AHRQ Patient Safety Indicators
Domain 2 = CDC NHSN measures

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(1) Clarification of Finalized Measure Result Scoring for FY 2015 and Subsequent Years

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50723), we finalized for the HAC Reduction Program a scoring methodology that divides the measure results into percentiles in increments of 10 and assigns points (1 to 10) in accordance with the percentile into which the hospital's measure result falls. Our preliminary analysis of the measures showed that multiple hospitals had the same measure results, and that in certain instances, the number of hospitals with the same measure results exceeded the number of hospitals for their appropriate percentile. Consequently a few hospitals with the same measure results fall into

the next higher percentile. In these instances, we will assign the same point for all hospitals with the same measure results, and that point will be based on the prior or the lowest appropriate percentile.

For example, if, for the CAUTI measure, 13 percent of hospitals have an SIR of 0, we will assign a point of 1 to all 13 percent of hospitals, even though, arguably, 10 percent of them fall into the first percentile, and 3 percent of the 13 percent fall into the second percentile. Because each percentile range ideally represents 10 percent of hospitals, we will assign a point of 2 to the remaining 7 percent of hospitals in the second percentile because their SIR is larger than 0. We believe this is the most favorable method for scoring measure results for hospitals. We note that randomly assigning some hospitals with the same SIR a higher (for example, less favorable) score would be both arbitrary and capricious, which are prohibited by the Administrative Procedure Act.

(2) Proposed Clarification of FY 2015 Finalized Narrative of Rules To Calculate the Total HAC Score

In the FY 2014 IPPS/LTCH PPS final rule, we finalized a series of rules to determine how to calculate the Domain 2 score and ultimately the Total HAC Score when there were waivers for the collection of CDC NHSN HAI measures (78 FR 50723). We also illustrated and finalized these rules in Figure B of the final rule (78 FR 50724). We are proposing to clarify that the narrative for Figure B should also include ''other waivers'' that waive hospitals from collecting CDC HAI measure data. The clarified rules that we are proposing are as follows for the collection of CDC HAI measures:

- If a hospital has an ICU waiver *or other waiver* for the CDC NHSN HAI measures, we will use only the Domain 1 score to calculate its Total HAC Score.
- If a hospital does not have an ICU waiver *or other waiver* for the CDC HAI measures:
  - If the hospital does not submit data for the CDC HAI measures, we will assign 10 points to that measure for that hospital.
  - If the hospital does submit data for at least one CDC NHSN measure:
    - If there are ''complete data'' (that is, enough adverse events to calculate the SIR) for at least one measure, we will use those data to calculate a Domain 2 score and use the hospital's Domain 1 and Domain 2 scores to calculate the Total HAC Score.
    - If there are not enough adverse events to calculate the SIR for any of the measures, we will use only the hospital's Domain 1 score to calculate its Total HAC Score.

As discussed earlier, if a hospital has enough data to calculate the PSI–90 composite score for Domain 1 and ''complete data'' for at least one measure in Domain 2, the scores of the two domains will contribute to the Total HAC Score at 35 percent for Domain 1 and 65 percent for Domain 2. However, if a hospital does not have enough data to calculate the PSI–90 composite score for Domain 1 but it has ''complete data'' for at least one measure in Domain 2, its Total HAC Score will depend entirely on its Domain 2 score. Similarly, if a hospital has ''complete data'' to calculate the PSI–90 composite score in Domain 1 but none of the measures in Domain 2, its Total HAC Score will be based entirely on its Domain 1 score. If the hospital does not have ''complete data'' to calculate the PSI–90 composite score for Domain 1 or any of the measures in Domain 2, we will not calculate a Total HAC Score for this hospital.

e. Reporting Hospital-Specific Information, Including the Review and Correction of Information

(1) Confidential Reports to Applicable Hospitals

Section 1886(p)(5) of the Act requires the Secretary to provide confidential reports to the applicable hospitals with respect to HACs. To meet the requirements under section 1886(p)(5) of the Act, in the FY 2014 IPPS/LTCH PPS final rule, we finalized the provision of confidential reports for the HAC Reduction Program to include information related to claims-based measure data for the PSI measures, the domain score for each domain, and the Total HAC Score (78 FR 50725). We noted that we use chart-abstracted measures in the HAC Reduction Program, and such information will be contained in the reports hospitals currently receive as part of the Hospital IQR Program and can be reviewed and corrected through the process specified for that program. We stated that we believe that this method would reduce the burden on hospitals, by alleviating the need to correct data present in two different programs.

(2) Availability of Information to the Public

Section 1886(p)(6)(A) of the Act requires the Secretary to ''make information available to the public regarding HAC rates of each subsection (d) hospital'' under the HAC Reduction Program. Section 1886(p)(6)(C) of the Act requires the Secretary to post the HAC information for each applicable hospital on the *Hospital Compare* Web site in an easily understood format. Section 1886(p)(6)(B) of the Act also requires the Secretary to ''ensure that an applicable hospital has the opportunity to review, and submit corrections for, the HAC information to be made public for each hospital.''

To meet the requirements under section 1886(p)(6)(C) of the Act, in the FY 2014 IPPS/LTCH PPS final rule, we finalized policies that the following information will be made public on the *Hospital Compare* Web site relating to the HAC Reduction Program: (1) Hospital scores with respect to each measure; (2) each hospital's domain specific score; and (3) the hospital's Total HAC Score (78 FR 50725).

(3) Review and Correction of Information

Section 1886(p)(6)(B) 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 available to the public with respect to each hospital under section 1886(p)(6)(A) of the Act prior to such information being made available to the public.

In the FY 2014 IPPS/LTCH PPS final rule, we codified the reporting of hospital-specific information at § 412.172(f) (78 FR 50968), in which CMS will make information available to the public regarding HAC rates of all hospitals described in section 1886(d)(1)(B) of the Act, including hospitals in Maryland paid under section 1814(b)(3) of the Act, under the HAC Reduction Program (paragraph (f)). As noted in section IV.J.3.b.(2) of the preamble of this proposed rule, in order to implement the new Maryland All-Payer Model, Maryland elected to no longer have Medicare pay Maryland hospitals in accordance with section 1814(b)(3) of the Act, effective January 1, 2014.

In summary, we established that CMS will provide each hospital with confidential hospital-specific reports and discharge level information used in the calculation of its Total HAC Score (paragraph (f)(1) of § 412.172). Hospitals will have a period of 30 days after receipt of the information provided under paragraph (f)(1) to review and submit corrections for the hospital-acquired conditions domain score for each condition that is used to calculate the Total HAC Score for the fiscal year. The administrative claims data used to calculate a hospital's Total HAC Score for those conditions for a fiscal year will not be subject to review and correction

(paragraph (f)(2)). CMS will post the Total HAC Score for the applicable conditions for a fiscal year for each applicable hospital on the *Hospital Compare* Web site. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50725 through 50728) for detailed discussions of the above provisions.

(4) Preliminary Analysis of the HAC Reduction Program

In order to model estimated payment changes for this FY 2015 IPPS/LTCH PPS proposed rule, we conducted a preliminary analysis of the HAC Reduction Program using currently available historical data as a proxy for the actual data that will be used to determine hospital performance under the program. The results of this preliminary analysis can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* under the FY 2015 IPPS Proposed Rule Home Page link as Table 17.—FY 2015 Preliminary Analysis of the Hospital-Acquired Condition Reduction Program. When the actual data for the performance periods finalized in the FY 2014 IPPS/LTCH PPS rule for each measure are available, hospitals will have an opportunity to review and submit corrections as discussed in section IV.J.3.e.(3) of the preamble of this proposed rule.

f. Limitation on Administrative and Judicial Review

Section 1886(p)(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 criteria describing an applicable hospital under section 1886(p)(2)(A) of the Act.
- The specification of hospital acquired conditions under section 1886(p)(3) of the Act.
- The specification of the applicable period under section 1886(p)(4) of the Act.
- The provision of reports to applicable hospitals under section 1886(p)(5) of the Act.
- The information made available to the public under section 1886(p)(6) of the Act.

In the FY 2014 IPPS/LTCH PPS final rule, we included these statutory provisions under § 412.172(g) of the regulations (78 FR 50729 and 50968). We note that section 1886(p)(6) of the Act requires the Secretary to make information available to the public regarding HAC scores of each applicable hospital under the HAC Reduction Program. Section 1886(p)(6)(B) of the Act also requires the Secretary to ensure that an applicable hospital has the opportunity to review, and submit corrections for, the information to be made available to the public, prior to that information being made public. We believe that the review and correction process explained above in section IV.I.3.e. of the preamble of this proposed rule will provide hospitals with the opportunity to correct data prior to its release on the *Hospital Compare* Web site.

4. Proposed Maintenance of Technical Specifications for Quality Measures

Technical specifications of the HAC measures for the Agency for Health Research and Quality (AHRQ) Patient Safety Indicator 90 (PSI–90) in Domain 1 can be found at AHRQ's Web site at: *http://qualityindicators.ahrq.gov/Modules/PSI_TechSpec.aspx*. Technical specifications for the CDC NHSN's HAI measures in Domain 2 can be found at CDC's NHSN Web site at: *http://www.cdc.gov/nhsn/acute-care-hospital/index.html*. Both Web sites provide measure updates and other information necessary to guide hospitals participating in the collection of HAC Reduction Program data.

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 with 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.

We note that NQF's annual or triennial maintenance processes for endorsed measures may result in the NQF requiring updates to the measures. We believe that it is important to have in place a subregulatory process to incorporate nonsubstantive updates required by the NQF into the measure specifications we have adopted for the HAC Reduction Program, so that these measures remain up-to-date.

For the HAC Reduction Program, we are proposing to follow the finalized processes outlined for addressing changes to adopted measures in the Hospital IQR Program ''Maintenance of Technical Specifications for Quality Measures'' section found in section IX.A.1.b. of the preamble of this proposed rule.

We believe this proposal adequately balances our need to incorporate updates to HAC Reduction 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 comments on this proposal.

5. Extraordinary Circumstances Exceptions/Exemptions

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50711), we indicated that we had received public comments requesting a potential waiver or exemption process for hospitals located in areas that experience disasters or other extraordinary circumstances (EC), even though we did not propose an extraordinary circumstance exceptions/exemptions (ECE) policy for the HAC Reduction Program. We stated in the FY 2014 IPPS/LTCH PPS final rule that we were reviewing this issue and might consider such a proposal in future rulemaking. We also noted that should we consider a policy we intend to focus on several policy and operational considerations in developing a disaster exemption process for the HAC Reduction Program. We welcome public comments on whether an exemption process should be implemented and the policy and operational considerations for a potential HAC Reduction Program ECE policy.

6. Implementation of the HAC Reduction Program for FY 2016

a. Measure Selection and Conditions, Including a Risk-Adjustment Scoring Methodology

(1) General Selection of Measures

In the FY 2014 IPPS/LTCH PPS final rule, we finalized measures for FY 2015 and onwards, but only finalized a scoring methodology for FY 2015 for the HAC Reduction Program (78 FR 50712 through 50713). We are not proposing any new additional measures for the HAC Reduction Program for FY 2016 in this proposed rule. We note that AHRQ's PSI–90 Composite measure and CDC's NHSN CLABSI (NQF #0138) and CAUTI (NQF #0139) measures were submitted in January 2014 and December 2013, respectively, as part of the NQF maintenance endorsement process. As noted in the FY 2014 IPPS/

LTCH PPS final rule (78 FR 50719), should changes to the risk-adjustment models for the measures be adopted during NQF endorsement maintenance processes, CMS will adopt these changes as soon as possible. Finally, although we are not required under section 1886(p) of the Act to address specific measure scoring methodologies regarding the HAC Reduction Program in notice-and-comment rulemaking, as required under the Hospital VBP Program, we believe that it is important to set forth such scoring methodologies for each individual HAC measure, in order for the public to understand how the measures discussed and finalized in this year's rulemaking relate to the performance methodology used to determine the applicable hospitals subject to the payment adjustment under the HAC Reduction Program.

(2) Measure Selection and Scoring Methodology for FY 2016

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50713), we finalized for FY 2016 and onwards CDC's NHSN Surgical Site Infection measure (NQF #0753) and its measure methodology. The SSI and other measure specifications are available at: *http://www.qualityforum.org/QPS/QPSTool.aspx.* To locate a specific measure, search by the NQF number: (1) for the SSI measure use NQF #0753; (2) for the CLABSI measure use NQF #0139; and (3) for the CAUTI measure use NQF #0138. For SSI updates related to CMS programs and the use of CDC's NHSN measures, we refer readers to the Web site at: *http://www.cdc.gov/nhsn/acute-care-hospital/ssi.* The SSI measure explanation of SIR in the *NHSN e-newsletter* is available at: *http://www.cdc.gov/nhsn/PDFs/Newsletters/NHSN_NL_OCT_2010SE_final.pdf.*

CDC's SSI measure was finalized as a Domain 2 measure in the calculation of the Total HAC Score. We are not proposing to change CDC's measure methodology for the SSI measure.

b. Measure Risk-Adjustment

In the FY 2014 IPPS/LTCH PPS final rule, we finalized the measure risk-adjustment for AHRQ's PSI–90 Composite for Domain 1 and the risk-adjustment for CDC's NHSN measures for Domain 2. In this proposed rule, we are not proposing any risk-adjustment changes for any of the measures finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50718 through 50719).

c. Measure Calculations

In the FY 2014 IPPS/LTCH PPS final rule, we finalized the measure calculations for AHRQ's PSI–90 Composite measure for Domain 1 and the measure calculations for CDC's NHSN measures for Domain 2. In this proposed rule, we are not proposing any measure calculation changes for any of the measures finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50718 through 50719).

d. Applicable Time Period

In the FY 2014 IPPS/LTCH PPS final rule, we finalized and codified policy at § 412.170 that there will be a 2-year applicable time period to collect data used to calculate the Total HAC Score (78 FR 50717).

For the Domain 1 AHRQ PSI–90 Composite measure, we are proposing for FY 2016 a 24-month period from July 1, 2012 through June 30, 2014 as the applicable time period. The claims for all Medicare FFS beneficiaries discharged during this period would be included in the calculation of measure results for FY 2016. This includes claims data from the 2012, 2013, and 2014 Inpatient Standard Analytic Files (SAFs).

The Domain 2 CDC NHSN measures (CAUTI, CLABSI, and SSI) are currently collected and calculated on a quarterly basis. However, for the purpose of the HAC Reduction Program, we will use 2 years of data to calculate the Domain 2 score. For FY 2016, we are proposing to use calendar years 2013 and 2014 for all three Domain 2 measures in the HAC Reduction Program.

e. Criteria for Applicable Hospitals and Performance Scoring

For FY 2016, we are proposing a change to the scoring methodology of the Total HAC Score. This proposal is intended to address the implementation of CDC's NHSN SSI measure in Domain 2 finalized for implementation in FY 2016.

(1) Finalized Scoring Methodology for Domains 1 and 2 for FY 2015

We finalized a scoring methodology for the Total HAC Score in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50722). This finalized scoring methodology is similar to the achievement scoring methodology currently used under the Hospital VBP Program. With respect to an applicable hospital, we finalized that CMS will identify the top quartile of all hospitals with respect to their Total HAC Score during the applicable period (§ 412.170). In addition, we finalized that the Total HAC Score will be determined by the following three steps: (1) Each measure result will be scored as outlined in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50723); (2) Domain scores will be determined by the scores assigned to the measures within the domain; and (3) the Total HAC Score will be determined by the sum of the weighted domains. For FY 2015, the Total HAC Score is the sum of the Domain 1 score multiplied by 35 percent plus the Domain 2 score multiplied by 65 percent. For further details of the general scoring methodology finalized for the HAC Reduction Program, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50719 through 50725).

(2) Proposed Scoring Methodology of Domain 2 and New Weighting of Domains 1 and 2 for FY 2016

We are proposing to adjust the scoring methodology of Domain 2 and the weighting of Domains 1 and 2 beginning in FY 2016 due to the addition of CDC's NHSN SSI measure. For the scoring of CDC's NHSN SSI measure, we are proposing an identical process of assigning points to the SSI measure results. We note that the SSI measure, reported via CDC's NHSN, is currently specified under the Hospital IQR program and is restricted to colon procedures (including incision, resection or anastomosis of the large intestine and large-to-small and small-to-large bowel anastomosis), and abdominal hysterectomy procedures including those performed by laparoscope. The SSI measure assesses SSIs based on the type of surgery procedures (that is, the SSI measure is stratified into infections that occur with colonic procedures and those that occur in abdominal hysterectomy procedures). We also note that patient age and a preoperative health score are risk factors taken into account using the Standardized Infection Ratio (SIR) (78 FR 20625). Use of an SIR is consistent with CDC's NHSN CLABSI and CAUTI measures that also report SIRs. In order to calculate an SSI measure score for Domain 2, we are proposing to calculate an abdominal hysterectomy procedure SSI SIR and a colonic procedure SSI SIR and pool both SIRs for each hospital. We are proposing pooling the abdominal hysterectomy SSI SIR and colonic procedure SSI SIR as this would provide a single SSI SIR, which is consistent with reporting a single SSI SIR as meant by design of the NQF endorsed measure (NQF #0753), and would allow a risk-adjusted weighting of the surgical volume among the two procedures. We are proposing that a pooled SSI SIR for an applicable hospital is the sum of all observed infections among abdominal hysterectomy and colonic procedures divided by the sum of all predicted

infections among abdominal hysterectomy and colonic procedures performed at the applicable hospital. The pooled SSI SIR would be scored in the same manner as all measures finalized for the HAC Reduction Program (refer to Figure A in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50723), which is also included above in this proposed rule). To determine a Domain 2 score, we are proposing taking the average of the three CDC HAI SIR scores. We noted in the FY 2014 IPPS/LTCH PPS final rule that there will be instances in which applicable hospitals may not have data on all four measures and therefore a set of rules was finalized to determine how to score each Domain. We are proposing to follow the same finalized rules used to determine scoring of Domains 1 and 2 (FY 2014 IPPS/LTCH PPS final rule (78 FR 50723 through 50725)0 and the proposed changes in section IV.I.6.b. of this proposed rule. We invite public comments on this proposal.

In addition, for FY 2016 we are proposing to weight Domain 1 at 25 percent, and Domain 2 at 75 percent. We are proposing to decrease Domain 1's weight from 35 percent to 25 percent for two reasons. First, with the implementation of CDC's SSI measure, we believe the weighting of both domains needs to be adjusted to reflect the addition of a fourth measure; and second, in keeping with public comments from the FY 2014 IPPS/LTCH PPS final rule, MedPAC and others stated that Domain 2 should be weighted more than Domain 1. Finally, the Total HAC Score for applicable hospitals would be the sum of the weighted scores from Domain 1 (weighted at 25 percent) and Domain 2 (weighted at 75 percent). We invite public comments on this proposal.

f. Proposed Rules To Calculate the Total HAC Score for FY 2016

We are proposing to adopt the ''Proposed Clarification of FY 2015 Finalized Narrative of Rules to Calculate the Total HAC Score'' as discussed in section IV.I.3.e. of the preamble of this proposed rule. We invite public comments on this proposal.

7. Future Considerations for the Use of Electronically Specified Measures

We believe that collection and reporting of data through health information technology will greatly simplify and streamline reporting for many CMS quality reporting programs. Through electronic reporting, hospitals will be able to leverage EHRs to capture, calculate, and electronically submit quality data submitted to CMS for the Hospital IQR Program. CMS has become aware of some hospitals and health systems that have developed or adopted a methodology to identify and measure all-cause harm through their electronic health record (EHR) systems. Some hospitals and health systems are able to use the results of these electronic measures to address adverse events at the point of care and to track improvement over time. Many of these measures capture a broad range of common hospital-acquired conditions that may not be captured by existing national measures (examples include measures of adverse drug events and hypoglycemia). Given that these measures are captured using clinical data from EHR systems, collection of HAC data will allow CMS to align measures across multiple settings.

We are seeking comment as to whether the use of a standardized electronic composite measure of all-cause harm should be used in the HAC reduction program in future years in addition to, or in place of, claims-based measures assessing HACs. We welcome any suggestions of specific all-cause harm electronic measures, including detailed measure specifications. Specifically, we invite public comments on the feasibility and the perceived value of such a measure, and what would be the most appropriate weighting of this measure in the Total HAC Performance Score. In addition, we are requesting suggestions on the timeframe for which such standardized electronic composite measure of all-cause harm should be proposed.

We intend for the future direction of electronic quality measure reporting to significantly enhance the tracking of HACs under the HAC Reduction Program. We will continue to work with measure stewards and developers to develop new measure concepts, and conduct pilot, reliability and validity testing as part of efforts to promote the adoption of Certified Electronic Health Record Technology in hospitals.

K. Payments for Indirect and Direct Graduate Medical Education (GME) Costs (§§ 412.105 and 413.75 Through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) 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. Therefore, 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. Regulations implementing these changes are discussed in the November 24, 2010 final rule (75 FR 72133) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53416).

2. Proposed Changes in the Effective Date of the FTE Resident Cap, 3-Year Rolling Average, and Intern- and Resident-to-Bed (IRB) Ratio Cap for New Programs in Teaching Hospitals

Section 1886(h)(4)(H)(i) of the Act requires the Secretary to establish rules for calculating the direct GME caps for new teaching hospitals that are training residents in new medical residency training programs established on or after January 1, 1995. Under section 1886(d)(5)(B)(viii) of the Act, such rules also apply to the establishment of a hospital's IME cap on the number of FTE residents training in new programs. We implemented these statutory requirements in rules published in the August 29, 1997 **Federal Register** (62 FR 46002 through 46008) and in the May 12, 1998 **Federal Register** (63 FR 26323 through 26325 and 26327 through 26336). Generally, under existing regulations at 42 CFR 413.79(e)(1) (for direct GME) and 42 CFR 412.105(f)(1)(vii) (for IME), 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 medical residency training 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 sum of the product of the highest number of FTE residents in any program year during the third year of the first new program's existence, for each 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. 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 may be possible for that ''new'' teaching hospital to receive a temporary cap adjustment if it enters into a Medicare GME affiliation agreement with the existing teaching hospital as specified at § 413.79(f) (for direct GME) and § 412.105(f)(1)(vi) (for IME). (For a detailed discussion of the distinctions between a new medical residency training program and an existing medical residency training program, we refer readers to the August 27, 2009 final rule (74 FR 43908 through 43920). For a detailed discussion regarding participation in Medicare GME affiliation agreements, we refer readers to 74 FR 43574.)

For new programs started prior to October 1, 2012, hospitals that did not yet have an FTE resident cap established had a ''3-year window'' in which to participate in and ''grow'' new programs, before the FTE resident caps for IME and direct GME were permanently set for the hospital beginning with the fourth program year of the first new program start. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53415 through 53425), we revised the regulations at § 413.79(e) to increase the cap-building period for new programs from 3 years to 5 years. That is, for a hospital that did not yet have an FTE resident cap established, the hospital's FTE resident cap is effective beginning with the sixth program year of the first new program's existence. This revised policy is effective for urban hospitals that first begin to participate in training residents in their first new program on or after October 1, 2012, and for rural hospitals that start a new program on or after October 1, 2012. In that final rule, we also finalized a methodology used to calculate a cap adjustment for an individual hospital if residents in a new program rotate to more than one hospital (or hospitals). The methodology is based on the sum of the products of the following three factors: (1) The highest total number of FTE residents trained in any program year, during the fifth year of the first new program's existence at all of the hospitals to which the residents in that program rotate; (2) the number of years in which residents are expected to complete the program, based on the minimum accredited length for each type of program; and (3) the ratio of the number of FTE residents in the new program that trained at the hospital over the entire 5-year period to the total number of FTE residents that trained at all hospitals over the entire 5-year period. Finally, we made minor revisions to the regulation text at §§ 413.79(e)(2) through (e)(4) for purposes of maintaining consistency throughout § 413.79(e). We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53415 through 53425) for further details regarding the methodology for calculating the FTE resident caps.

While the FY 2013 IPPS/LTCH PPS final rule discussed the methodology for calculating the FTE resident caps to be effective beginning with the sixth program year of the first new program's existence, for hospitals that do not yet have FTE resident caps established, that final rule did not discuss when the 3-year rolling average for IME and direct GME or the intern- and resident-to-bed (IRB) ratio cap for IME is effective for FTE residents training in new programs. The regulations regarding the 3-year rolling average and the IRB ratio cap with respect to new medical residency training programs were established in the following **Federal Register** rules: the FY 1998 IPPS final rule with comment period (62 FR 46002 through 46008); the May 12, 1998 final rule (63 FR 26323 through 26325 and 26327 through 26336); FY 2000 IPPS final rule (64 FR 41518 through 41523); and the FY 2002 IPPS final rule (66 FR 39878 through 39883). Specifically, the regulations at § 412.105(f)(1)(v) regarding the 3-year rolling average and new medical residency training programs for IME state: ''If a hospital qualified for an adjustment to the limit established under paragraph (f)(1)(iv) of this section for new medical residency programs created under paragraph (f)(1)(vii) of

this section, the count of residents participating in new medical residency training programs above the number included in the hospital's FTE count for the cost reporting period ending during calendar year 1996 is added after applying the averaging rules in this paragraph (f)(l)(v) for a period of years. Residents participating in new medical residency training programs are included in the hospital's FTE count before applying the averaging rules after the period of years has expired. For purposes of this paragraph, for each new program started, the period of years equals the minimum accredited length for each new program. The period of years for each new program begins when the first resident begins training in each new program.'' In addition, the regulations for the interaction of the IRB ratio cap and new medical residency training programs for IME at § 412.105(a)(1)(ii) state: ''The exception for new programs described in paragraph (f)(1)(vii) of this section applies to each new program individually for which the full-time equivalent cap may be adjusted based on the period of years equal to the minimum accredited length of each new program.''

The regulations at § 413.79(d)(5) regarding the interplay of the 3-year rolling average with new medical residency training programs for direct GME similarly state: ''If a hospital qualifies for an adjustment to the limit established under paragraph (c)(2) of this section for new medical residency programs created under paragraph (e) of this section, the count of the residents participating in new medical residency training programs above the number included in the hospital's FTE count for the cost reporting period ending during calendar year 1996 is added after applying the averaging rules in this paragraph (d), for a period of years. Residents participating in new medical residency training programs are included in the hospital's FTE count before applying the averaging rules after the period of years has expired. For purposes of this paragraph (d), for each new program started, the period of years equals the minimum accredited length for each new program. The period of years begins when the first resident begins training in each new program.''

Therefore, the FTE resident caps for IME and direct GME are *always* effective beginning with the start of the sixth program year of the first new program started for urban hospitals that do not yet have FTE resident caps established (§ 413.79(e)(1)(iii)), and for rural hospitals, beginning with the start of the sixth program year of each new individual program started (§ 413.79(e)(3)), regardless of the fact that other new programs may have started after the start of the first new program. However, the timing of when the 3-year rolling average for IME and direct GME and the IRB ratio cap for IME are first applied is dependent upon the minimum accredited length of each new program started within the 5-year window. For example, new teaching Hospital A participates in training residents in new medical residency training programs for the first time beginning on July 1, 2013. On July 1, 2013, Hospital A participates in training residents in a new family medicine program (minimum accredited length is 3 years), on July 1, 2014, it also participates in training residents in a new sports medicine fellowship (minimum accredited length is 1 year), and on July 1, 2015, it also participates in training residents in a new general surgery program (minimum accredited length is 5 years). For the purpose of establishing Hospital A's FTE resident caps, the 5-year growth window for Hospital A closes on June 30, 2018, and the IME and direct GME FTE resident caps for Hospital A are effective on July 1, 2018, the beginning of the sixth program year of the first new program's existence; that is, family medicine. However, the 3-year rolling average and the IRB ratio cap are effective at different points in time. Because the family medicine residency is 3 years in length, FTE residents in the new family medicine program are subject to the 3-year rolling average and the IRB ratio cap beginning on July 1, 2016. Because the sports medicine fellowship is a 1-year program, and it started on July 1, 2014, the number of sports medicine FTE residents must be included in the 3-year rolling average and is subject to the IRB ratio cap effective on July 1, 2015. Lastly, the FTE residents in the new general surgery program would only be subject to the rolling average and the IRB ratio cap effective July 1, 2020. The Medicare cost report worksheets on CMS Form 2552–10 for IME (Worksheet E, Part A) and for direct GME (Worksheet E–4) currently can accommodate reporting of FTE residents separately based on whether those FTE residents are in new medical residency training programs and are not subject to the FTE resident cap (line 16 of Worksheet E, Part A, and line 15 of Worksheet E–4). However, these cost report worksheets are not designed to accommodate reporting of FTE residents that are exempt from the FTE resident cap, but *are* subject to the rolling average and IRB ratio cap, because the ''period of years'' equal to the minimum accredited length of each new program started has already expired. The reverse also may occur, as in the example above with the new general surgery program started by Hospital A, where the FTE resident caps are effective July 1, 2018, but the number of FTE residents in the general surgery program would not be subject to the rolling average or the IRB ratio cap until July 1, 2020. Complicating matters further is the fact that, while the effective dates of these policies associated with new medical residency training program FTE residents are effective on a program year basis (that is, July 1), many teaching hospitals do not have a fiscal year that begins on July 1. Therefore, under the existing policy, the number of FTE residents needs to be prorated, and special accommodations need to be made to calculate the portion of FTE residents that are subject to the FTE resident cap, the 3-year rolling average, and the IRB ratio cap for the respective portions of the hospital's cost reporting period occurring on and after July 1. Integrating the rolling average, the IRB ratio cap, and the FTE resident caps for residents in new medical residency training programs in an accurate manner on the Medicare cost report has proved challenging to the point where we have had to deal with each instance brought to our attention by the new teaching hospital or by a Medicare contractor on an individual and manual basis (in order to ensure application of a consistent methodology). In fact, the Medicare cost report instructions direct the hospital to do the following: for CMS Form 2552–10, Worksheet E, Part A, line 10—''. . . Contact your contractor for instructions on how to complete this line if you have a new program for which the period of years is less than or more than three years. . . .''; for CMS Form 2552–10, Worksheet E–4, line 6—''. . . Contact your contractor for instructions on how to complete this line if you have a new program for which the period of years is less than or greater than 3 years. . . .''

The Medicare contractors, in turn, have been instructed to contact CMS for instructions on how to report the number of FTE residents that are still within the ''period of years'' of the new program. The ''three years'' referenced in the Form 2552–10 cost report instructions are based on the 3-year growth window for new medical residency training programs that is in effect for new programs started prior to October 1, 2012, when, within the 3-year growth window, new teaching hospitals also may have started new

medical residency training programs with different minimum accredited lengths. (We note that while the previous Form 2552–96 cost report did not include the same instructions, CMS did deal with the reporting of the number of FTE residents in new medical residency training programs on an individual basis when requests for assistance were brought to its attention.) However, these instructions also apply for new medical residency training programs started with different minimum accredited lengths on and after October 1, 2012.

In this proposed rule, we are proposing to simplify and streamline the timing of when FTE residents in new medical residency training programs are subject to the FTE resident cap, the 3-year rolling average, and the IRB ratio cap, both for urban teaching hospitals that have not yet had FTE resident caps established under § 413.79(e)(1) and for rural teaching hospitals that may or may not have FTE resident caps established under § 413.79(e)(3). That is, we are proposing that the methodology for calculating the FTE resident caps for hospitals that participate in training residents in new medical residency training programs would continue to be the same methodology instituted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53415 through 53425) for new medical residency training programs started on or after October 1, 2012, specified at § 413.79(e)(1). However, once the FTE resident caps are calculated, we are proposing to change the timing of when the FTE resident caps would be effective, to synchronize the effective dates and the application of the 3-year rolling average and the IRB ratio cap with each applicable hospital's fiscal year begin date. Specifically, we are proposing that the FTE resident caps would continue to be calculated as finalized in the FY 2013 IPPS/LTCH PPS final rule—the methodology is based on the sum of the products of the following three factors: (1) The highest total number of FTE residents trained in any program year, during the fifth year of the first new program's existence at all of the hospitals to which the residents in that program rotate; (2) the number of years in which residents are expected to complete the program, based on the minimum accredited length for each type of program; and (3) the ratio of the number of FTE residents in the new program that trained at the hospital over the entire 5-year period to the total number of FTE residents that trained at all hospitals over the entire 5-year period. However, once calculated in this manner, we are proposing that, instead of the FTE resident caps being effective beginning with the sixth program year of the first new program start, those *FTE resident caps, rolling average, and IRB ratio cap would be effective beginning with the applicable hospital's cost reporting period that precedes the start of the sixth program year of the first new program started.* Using the example of Hospital A that we presented earlier, assume Hospital A has a January 1 to December 31 cost reporting year. The first new program started, family medicine, was started on July 1, 2013. A sports medicine fellowship and a general surgery program also were started timely within the 5-year growth window. Hospital A has 5 program years to grow its FTE resident caps, from July 1, 2013 through June 30, 2018. The FTE resident caps would be calculated based on the 5 program years in accordance with the methodology established at § 413.79(e)(1) in the FY 2013 IPPS/LTCH PPS final rule; therefore, the hospital would wait until after June 30, 2018 to obtain the FTE counts to calculate the FTE resident caps. However, we are proposing that those IME and direct GME FTE resident caps, once calculated after June 30, 2018, instead of being effective on July 1, 2018, *would be effective at the beginning of Hospital A's cost reporting period that precedes July 1, 2018; that is, the FTE resident caps for Hospital A would be effective permanently on January 1, 2018, the start of Hospital A's cost reporting period that precedes the start of the sixth program year of the first new program started.* The hospital could file its fiscal year end December 31, 2018 cost report including the FTE resident caps applicable to the entire cost reporting period accordingly.

As noted earlier, we are proposing that, for all new medical residency training programs in which the hospital participates during the 5-year growth window, the FTEs in those new programs also would be subject to the 3-year rolling average and the IRB ratio cap simultaneously with the effective date of the FTE resident caps, at the beginning of the applicable hospital's cost reporting period that precedes the beginning of the sixth program year of the first new program started. Again, using the example of Hospital A that we presented earlier, the FTE residents in the family medicine program, the sports medicine fellowship, and the general surgery program would all be subject to the 3-year rolling average and IRB ratio cap beginning on January 1, 2018. With regard to reporting on the Medicare cost report, for Hospital A's fiscal year end dates of December 31, 2013 through and including December 31, 2017, we are proposing that the number of FTE residents in the family medicine program, the sports medicine fellowship, and the general surgery program would be reported so as *not* to be included in the IME rolling average or the IRB ratio cap, and so as *not* to be included in the direct GME rolling average. (On the CMS Form 2552–10, for Hospital A's fiscal year end dates of December 31, 2013 through and including December 31, 2017, this means that the number of FTE residents in the family medicine program, the sports medicine fellowship, and the general surgery program would be reported on Worksheet E, Part A, line 16, and on Worksheet E–4, line 15). However, on Hospital A's cost report for fiscal year ending December 31, 2018, the number of FTE residents in these three programs would be subject to the FTE resident cap, the 3-year rolling average, and the IRB ratio cap, and would be reported accordingly. (On the CMS Form 2552–10, for Hospital A's cost report for fiscal year ending December 31, 2018, this means that none of the FTE residents in these three programs would be reported on Worksheet E, Part A, line 16 for IME, and Worksheet E–4, line 15 for direct GME. Instead, all of the FTE residents would be reported on Worksheet E, Part A, line 10 for IME, and Worksheet E–4, line 6 for direct GME, in order to be subject to the FTE resident cap, the 3-year rolling average, and the IRB ratio cap.) We note that once the 3-year rolling average is effective in that cost reporting period that includes the sixth program year of the first new program started, the number of FTE residents in the new programs also must be reported both as part of the prior year FTE resident counts and the penultimate FTE resident counts, in order to effectuate the 3-year rolling average calculation on the IME Worksheet E, Part A, and the direct GME Worksheet E–4, respectively.

In the example that we presented earlier, Hospital A has a fiscal year that begins on January 1. If Hospital A's fiscal year begin date would have been October 1, then, as proposed, while the sixth program year of the first new program started would still be July 1, 2018, the FTE residents caps, the 3-year rolling average, and the IRB ratio cap would be effective on October 1, 2017, the fiscal year begin date that precedes July 1, 2018, the sixth program year. If Hospital A's fiscal year begin date would have been July 1, the FTE

residents caps, the 3-year rolling average, and the IRB ratio cap would instead be effective on July 1, 2017, the fiscal year begin date that precedes July 1, 2018, the sixth program year.

We understand that this proposal, if finalized, would reduce the amount of time that the new medical residency training programs would be exempt from the FTE resident caps. However, even though we are proposing to make the effective date of the FTE resident caps earlier than under current policy, because we also are proposing that the calculation of the FTE resident caps would still be based on the highest total number of FTE residents trained in any program year, during the fifth year of the first new program's existence at all of the hospitals to which the residents in that program rotate, a new teaching hospital would still have the full 5 program years to grow its program(s), and its FTE resident caps would reflect a full 5 years of growth. Therefore, because, by the fifth program year, a program should, in most typical circumstances, have grown to its full capacity, barring unusual circumstances, the FTE resident caps that would take effect under the proposed policy at the beginning of the fiscal year that precedes the sixth program year should accommodate the FTE resident count training in the fifth and subsequent program years. Therefore, we believe that this proposal to streamline and synchronize the effective dates of the FTE resident caps, the 3-year rolling average, and the IRB ratio cap not only is easier to comprehend and to implement, but also is reasonable and equitable in its effect on the IME and direct GME payments of hospitals establishing FTE resident caps. Specifically, if this proposal is finalized, there would no longer be a need for CMS Form 2552–10, Worksheet E, Part A, line 10 and Worksheet E–4, line 6 to instruct hospitals to contact their contractor for instructions on how to complete those lines, as both hospitals and Medicare contractors would understand how to report the number of FTE residents in new programs, even when those programs have different accredited lengths. Instead, hospitals and Medicare contractors would follow the methodology instituted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53415 through 53425) to calculate the FTE resident caps for new medical residency training programs started on or after October 1, 2012, and once the FTE resident caps are calculated, hospitals and Medicare contractors would implement the FTE resident caps, the 3-year rolling average, and the IRB ratio cap effective beginning with the applicable hospital's cost reporting period that precedes the start of the sixth program year of the first new program started. Under this proposed methodology, FTE residents and FTE resident caps would no longer need to be prorated, and we would no longer need to make special accommodations to calculate the portion of FTE residents that are subject to the FTE resident cap, the 3-year rolling average, and the IRB ratio cap for the respective portions of the hospital's cost reporting period occurring on and after July 1. The existing CMS Form 2552–10 already accommodates this proposed methodology, unlike the complicated process currently in place. Thus, clarity, efficiency, and payment accuracy would be improved for hospitals, contractors, and CMS.

With regard to rural hospitals that, under § 413.79(e)(3) of the regulations, may receive FTE resident cap adjustments at any time for participating in training residents in new programs, we are proposing a similar policy, with modifications reflecting the fact that each new program in which the rural hospital participates receives its own 5-year growth window before the rural hospital's FTE resident cap is adjusted based on that new program. That is, we are proposing that, for rural hospitals, the FTE resident caps, the 3-year rolling average, and the IRB ratio cap *for each new program started would be effective beginning with the applicable hospital's cost reporting period that precedes the start of the sixth program year of each new program started.* For example, rural Hospital B has a fiscal year that begins on January 1. It starts a family medicine program on July 1, 2013, and a general surgery program on July 1, 2016. The sixth program year for the family medicine program begins on July 1, 2018. The sixth program year for the general surgery program begins on July 1, 2021. With regard to Medicare cost reporting, during Hospital B's fiscal years end dates of December 31, 2013 through and including December 31, 2017, the number of family medicine FTE residents would be reported so as *not* to be included in the IME 3-year rolling average or the IRB ratio cap, and so as *not* to be included in the direct GME 3-year rolling average. (This means that on CMS Form 2552–10, during Hospital B's fiscal year end dates of December 31, 2013 through and including December 31, 2017, the number of family medicine FTE residents would be reported on Worksheet E, Part A, line 16 for IME, and on Worksheet E–4, line 15, for direct GME. Instead, the number of family medicine FTE residents would be reported on Worksheet E, Part A, line 16, and Worksheet E–4, line 15.) Then, beginning with Hospital B's cost report for fiscal year ending December 31, 2018, the number of FTE residents in *only the family medicine program* would be subject to the FTE residents caps, the 3-year rolling average, and the IRB ratio cap, and would be reported accordingly in order to be subject to the FTE resident cap, the 3-year rolling average, and the IRB ratio cap. (This means that on CMS Form 2552–10, beginning with Hospital B's cost report ending December 31, 2018, the number of family medicine FTE residents would be reported on Worksheet E, Part A, line 10 for IME, and Worksheet E–4, line 6 for direct GME.) Because the general surgery program started on July 1, 2016, for Hospital B's fiscal year end dates of December 31, 2016 through and including fiscal year end date of December 31, 2020, the number of general surgery FTE residents would be reported (on Worksheet E, Part A, line 16) so as *not* to be included in the IME 3-year rolling average or the IRB ratio cap, and (on Worksheet E–4, line 15), so as *not* to be included in the direct GME 3-year rolling average. Then, beginning with Hospital B's cost report for fiscal year ending December 31, 2021, the number of FTE residents in the *general surgery program* would be subject to the FTE resident caps, the 3-year rolling average, and the IRB ratio cap, and would be reported accordingly (on Worksheet E, Part A, line 10 for IME, and Worksheet E–4, line 6 for direct GME), in order to be subject to the FTE resident cap, the 3-year rolling average, and the IRB ratio cap. We note that once the 3-year rolling average is effective in that cost reporting period that includes the sixth program year of each new program started, the number of FTE residents in the new programs also must be reported as part of the prior year FTE resident counts, and the penultimate FTE resident counts, in order to effectuate the 3-year rolling average calculation on the IME Worksheet E, Part A, and the direct GME Worksheet E–4, respectively.

We are proposing that this policy regarding the effective dates of the FTE residency caps, the 3-year rolling average, and the IRB ratio cap for FTE residents in new medical residency training programs would be consistent with the methodology for calculation of the FTE resident caps as described in the FY 2013 IPPS/LTCH PPS final rule, and implemented in the regulations at

§§ 413.79(e)(1) and (e)(3). That is, because the policy providing a 5-year growth period for establishing the FTE resident caps (§§ 413.79(e)(1) and (e)(3)) is effective for new programs started on or after October 1, 2012, this proposal is effective for urban hospitals that first begin to participate in training residents in their first new medical residency training program, and for rural hospitals, on or after October 1, 2012. We also are proposing to revise the regulations for IME and direct GME, respectively, at § 412.105(a)(1)(ii) for the IME IRB ratio cap, at § 412.105(f)(1)(v) for the IME 3-year rolling average, and at § 413.79(d)(5) for the direct GME 3-year rolling average to reflect that the exception from the IRB ratio cap and the 3-year rolling average for new programs applies to each new program individually during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that precedes the start of the sixth program year of the first new program started, for hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(1), and prior to the beginning of the applicable hospital's cost reporting period that precedes the start of the sixth program year of each individual new program started, for hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(3). After the applicable hospital's cost reporting period that precedes the start of the sixth program year of the first new program started for hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(1), and after the applicable hospital's cost reporting period that precedes the start of the sixth program year of each individual new program started for hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(3), FTE residents participating in new medical residency training programs are included in the hospital's IRB ratio cap and the 3-year rolling average.

3. Proposed Changes to IME and Direct GME Policies as a Result of New OMB Labor Market Area Delineations

a. New Program FTE Resident Cap Adjustment for Rural Hospitals Redesignated as Urban

As stated earlier in this proposed rule, under existing regulations, a new teaching hospital that starts training residents for the first time on or after October 1, 2012, has 5 years from when it first begins training residents in its first new program to build its FTE resident cap. If the teaching hospital is a rural teaching hospital, it can continue to receive permanent cap adjustments for training residents in new programs after the initial 5-year cap-building period that applies to new teaching hospitals ends. (We refer readers to section IV.K.2. of the preamble of this proposed rule for a discussion of our proposal to change the effective dates for when the FTE resident cap, the 3-year rolling average, and the IRB ratio cap are applied to new teaching hospitals and to new programs at rural teaching hospitals.)

In section III.B. of the preamble of this proposed rule, we discuss the policies we are proposing to implement as a result of the new OMB labor market area delineations announced in the February 28, 2013 OMB Bulletin No. 13–01. As a result of the new OMB delineations, some teaching hospitals may be redesignated from being located in a rural area to an urban area, thereby losing their ability to increase their FTE resident caps for new programs started after their initial 5-year cap-building period ends. We have been asked whether a rural teaching hospital that already has a cap and is redesignated as urban while it is in the process of establishing another new program(s) can still receive a permanent cap adjustment for that new program(s). We believe that because the hospital had already started training residents in the new program(s) while it was rural, the former rural hospital should be permitted to continue building its new program(s) and receive a permanent FTE resident cap adjustment for that new program(s). Therefore, we are proposing to revise the regulations to allow a hospital that was rural as of the time it started training residents in a new program(s) and is redesignated as urban for Medicare payment purposes during its cap-building period for that program(s) to be able to continue building that program(s) for the remainder of the cap-building period and receive a permanent FTE resident cap adjustment for that new program(s). Once the cap-building period for the new program(s) that was started while the hospital was still rural expires, the teaching hospital that has been redesignated as urban would no longer be able to receive any additional permanent cap adjustments. We are proposing that the teaching hospital must be actively training residents in the new program while it is still rural, that is, prior to the redesignation taking effect, in order for the hospital to continue receiving a cap adjustment for the new program. For example, if a rural hospital begins training residents in a new internal medicine program on July 1, 2013, and begins training residents in a new general surgery program on July 1, 2014, and the rural hospital is redesignated as urban effective on October 1, 2014, the teaching hospital would be able to continue receiving a cap adjustment for both the new internal medicine program and the new general surgery program after it has been redesignated as urban. However, if the rural hospital is redesignated as urban effective on October 1, 2014, and started training residents in a new internal medicine program on July 1, 2013, but did not start training residents in a new general surgery program while it was still rural, that is, prior to October 1, 2014, the teaching hospital would receive a permanent cap adjustment for the new internal medicine program, but would not receive a cap adjustment for the new general surgery program. We are proposing to revise the regulations at § 412.105(f)(1)(iv)(D) for IME and § 413.79(c)(6) for direct GME to implement this proposed change. We are proposing that these regulatory revisions be effective for cost reporting periods beginning on or after October 1, 2014. The proposed regulations at § 412.105(f)(1)(iv)(D) read as follows: ''A rural hospital redesignated as urban after September 30, 2004, as a result of the most recent census data and implementation of the new labor market area definitions announced by OMB on June 6, 2003, may retain the increases to its FTE resident cap that it received under paragraphs (f)(1)(iv)(A) and (f)(1)(vii) of this section while it was located in a rural area. Effective for cost reporting periods beginning on or after October 1, 2014, if a rural hospital is redesignated as urban due to the most recent OMB standards for delineating statistical areas adopted by CMS and was training residents in a new program prior to the redesignation becoming effective, the redesignated urban hospital may retain any existing increases to its FTE resident cap and receive an increase to its FTE resident cap for the new program in which it was training residents when the redesignation became effective, in accordance with paragraph (f)(1)(vii) of this section.'' The proposed regulations at § 413.79(c)(6) read as follows: ''A rural hospital redesignated as urban after September 30, 2004, as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003, may retain the increases to its FTE resident cap that it received under paragraphs (c)(2)(i), (e)(1)(iii), and (e)(3) of this section while it was located in a rural area. Effective for cost reporting

periods beginning on or after October 1, 2014, if a rural hospital is redesignated as urban due to the most recent OMB standards for delineating statistical areas adopted by CMS, and was training residents in a new program prior to the redesignation becoming effective, the redesignated urban hospital may retain any existing increases to its FTE resident cap, and receive an increase to its FTE resident cap for the new program in which it was training residents when the redesignation became effective, in accordance with paragraph (e) of this section.''

b. Participation of Redesignated Hospital in Rural Training Track

To encourage the training of residents in rural areas, section 407(c) of Public Law 106–113 amended section1886(h)(4)(H) of the Act to add a provision that, in the case of a hospital that is not located in a rural area (an urban hospital) that establishes separately accredited approved medical residency training programs (or rural tracks) in a rural area or has an accredited training program with an integrated rural track, the Secretary shall adjust the urban hospital's cap on the number of FTE residents under subparagraph (F), in an appropriate manner in order to encourage training of physicians in rural areas. Section 407(c) of Public Law 106–113 was made effective for direct GME payments to hospitals for cost reporting periods beginning on or after April 1, 2000, and for IME payments applicable to discharges occurring on or after April 1, 2000. We refer readers to the August 1, 2000 interim final rule with comment period (65 FR 47033 through 47037) and the FY 2002 IPPS final rule (66 FR 39902 through 39909) where we implemented section 407(c) of Public Law 106–113.

The regulations at § 413.79(k) specify that, subject to certain criteria, an urban hospital may count the FTE residents in the rural track in addition to those FTE residents subject to its cap up to a ''rural track FTE limitation'' for that hospital. In the FY 2006 IPPS final rule, we revised the regulations at § 413.79(k) to add a new paragraph (7) to state that if an urban hospital had established a rural track program with a rural hospital and that hospital subsequently becomes urban due to the implementation of the new labor market area definitions announced by OMB on June 6, 2003, the urban hospital may continue to adjust its FTE resident limit for rural track programs established before the implementation of the new labor market area definitions. We also stated that, in order for the urban hospital to receive a cap adjustment for a new rural track program, the urban hospital must establish a rural track program with hospitals that are designated rural based on the most recent geographical location designations adopted by CMS (70 FR 47456; 47489).

As discussed earlier in this section, we are proposing to implement, effective October 1, 2014, the new OMB labor market area delineations announced in the February 28, 2013 OMB Bulletin No. 13–01. As a result of the new delineations, certain areas can be redesignated from urban to rural or from rural to urban, which may, in turn, affect GME policies that require the participation of rural teaching hospitals. For example, as noted above, in order for an urban teaching hospital to receive a FTE resident cap adjustment for training residents in a rural track, the residents must rotate for more than one-half of the duration of the program to a rural hospital(s) or rural nonprovider(s) site. We have received a question as to what happens to a rural track when a rural hospital that is participating as the rural site is redesignated as urban, while the rural track for the urban hospital is in the process of being established. That is, what happens to the rural track when the rural hospital is redesignated as urban during the period that is used to establish the urban hospital's rural track FTE limitation, *prior* to the effective date of the urban hospital's rural track FTE limitation being established?

Existing regulations at § 413.79(k)(7) address the scenario where a rural hospital that is participating as the rural site is redesignated as urban, *after* the rural track FTE limitation for the urban hospital has already become effective. Specifically, the regulations at § 413.79(k)(7) state that if an urban hospital had established a rural track with a hospital located in a rural area and that rural area subsequently becomes an urban area due to the most recent census data and implementation of new labor market area definitions announced by OMB June 6, 2003, the urban hospital may continue to adjust its FTE resident limit for the rural track programs established prior to the adoption of the new labor market area definitions. Therefore, consistent with the existing regulations at § 413.79(k)(7) and with our proposal to allow rural hospitals redesignated as urban to continue receiving a FTE resident cap adjustment for new programs that started while the redesignated hospital was still rural, we are proposing to revise the existing regulations applicable to urban hospitals generally. Specifically, we are proposing to address the status of the ''original'' urban hospital's rural track FTE limitation, in the situation where a rural hospital that is participating in the original urban hospital's rural track is located in an area redesignated by OMB as urban *during the 3-year period* that is used to calculate the urban hospital's rural track FTE limitation. We are proposing that, in these situations, the original urban hospital's opportunity to receive a rural track FTE limitation would not be negatively impacted by the fact that the rural hospital with which it has partnered to be the rural site for its rural training track is located in an area redesignated by OMB as urban *during the 3-year period* that is used to calculate the urban hospital's rural track FTE limitation. That is, we are proposing that the original urban hospital may receive a rural track FTE limitation for that new rural track program.

With regard to the status of the rural hospital that is partnered with the urban hospital to serve as a rural training site for the rural training track program, as mentioned earlier, existing regulations at § 413.79(k)(7) address the scenario where a rural hospital that is participating as the rural site is redesignated as urban, *after* the rural track FTE limitation for the urban hospital has already become effective. (We note that we are proposing to apply the existing policy at § 413.79(k)(7), which applies to redesignations that occurred on June 6, 2003, in a similar manner, to redesignations announced by OMB after June 6, 2003, as well.) In addition, we are proposing that once the rural hospital is redesignated as located in an urban area due to the implementation of the new OMB labor market area delineations, regardless of whether that redesignation occurs during the 3-year period that is used to establish the rural track FTE limitation for the urban hospital, or after the 3-year period that is used to establish the rural track FTE limitation for the urban hospital, the redesignated urban hospital can no longer qualify as the rural site and the ''original'' urban hospital would not be able to count those residents under its rural track FTE limitation if it continues to use the redesignated urban hospital as the rural site for purposes of the rural track. However, because the redesignated urban hospital was rural when residents started training in the rural track, we are proposing to provide for a 2-year transition period during which either of the following two conditions must be met in order for the ''original'' urban hospital to be able to count the residents under its rural track FTE limitation

when the 2-year transition period ends: (1) the redesignated newly urban hospital must reclassify back to rural under § 412.103 of the regulations; or (2) the ''original'' urban hospital must find a new geographically rural site to participate as the rural site for purposes of the rural track. We note that we are proposing to apply these two criteria both in the case where the rural hospital is redesignated as urban *after* the urban hospital already has its rural track FTE limit established, and also in the case where the rural hospital is redesignated as urban *during* the 3-year period when the rural track program is still growing, *prior* to the rural track FTE limit being established. This 2-year transition period would begin when new OMB labor market area delineations take effect for Medicare payment purposes and would end exactly 2 years from that date. During this 2-year transition period, we would hold the ''original'' urban hospital harmless and would pay the ''original'' urban hospital for the FTE residents in the rural track. At the end of the 2-year transition period, in order for the urban hospital to receive payment for a rural track program under § 413.79(k)(1) or (k)(2), either the redesignated urban hospital must be granted reclassification as rural under § 412.103 or the ''original'' urban hospital must already be training FTE residents at a geographically rural site. We note that, because the rural reclassification provision of § 412.103 only applies to IPPS hospitals and for purposes of section 1886(d) of the Act, it only applies to IPPS hospitals for IME payment purposes and not for direct GME payment purposes because direct GME is authorized under section 1886(h) of the Act. Therefore, if the redesignated hospital reclassifies as rural under § 412.103, the ''original'' urban hospital would only be able to count FTE residents towards its rural track FTE limitation for IME payment purposes, but not for direct GME payment purposes. In addition, we note that this discussion has centered on the scenario where a rural hospital that is the rural site for purposes of the rural track has been redesignated as urban. Under such a scenario, the redesignated urban hospital does have an option to reclassify as rural. However, as noted above, the reclassification only applies to IPPS hospitals for IME payment purposes. If a nonprovider site is functioning as the rural site under § 413.79(k)(2) for purposes of the rural track and the area where that nonprovider site is located is redesignated as urban, the nonprovider site would not have the option of reclassifying as rural and, therefore, the ''original'' urban hospital would be required to find a new geographically rural site within the 2-year transition period in order for the ''original'' urban hospital to receive payment for a rural track program under § 413.79(k)(1) or (k)(2).

The following examples illustrate how the proposed policy would be applied to a rural track in which the rural site is a hospital and the rural hospital has been redesignated as urban:

- An urban teaching hospital and a rural teaching hospital are participating in training residents in a new rural track program that begins July 1, 2014. Effective October 1, 2014, the rural hospital is redesignated as urban. We are proposing that the timeframe for the urban hospital to build the rural track program for purposes of calculating its rural track FTE limitation would continue to be through June 30, 2017. During the time period of October 1, 2014 to September 30, 2016, the redesignated urban hospital would continue participating as a rural hospital and the urban hospital would count FTE residents it is training that are in the rural track for IME and direct GME. However, in order for the ''original'' urban hospital to continue to get paid for its rural track program after September 30, 2016, then, by September 30, 2016, the redesignated urban hospital must either reclassify as rural under § 412.103 of the regulations for purposes of IME payment only, or the urban hospital must find a new geographically rural hospital or nonprovider site to train the residents in the rural track for more than one-half of their training. If neither of these conditions is met, by September 30, 2016, the ''original'' urban hospital would not able to receive payment for that specific program as a rural training track under § 413.79(k)(1) or (k)(2) because it would no longer meet the requirement that more than one-half of the training must be provided in a rural setting.
- Another scenario could be one in which the rural hospital is redesignated as urban after the 3-year cap-building period for the rural track has passed. For example, the rural track program began July 1, 2007, but effective October 1, 2014, the rural hospital is redesignated as urban. We are proposing in this scenario that, by September 30, 2016, either the redesignated urban hospital must reclassify to rural under § 412.103 for purposes of IME payment only, or the ''original'' urban hospital must find a new geographically rural site that can participate as the rural site for purposes of the rural track. If neither of these conditions is met by September 30, 2016, the ''original'' urban hospital would not be able to receive payment for that specific program as a rural track under § 413.79(k)(1) or (k)(2) because it would no longer meet the requirement that more than one-half of the training must be provided in a rural setting.

We note that if the ''original'' urban hospital was not able to meet one of the two proposed conditions noted earlier in this section by the end of the 2-year transition period, but at some point later is able to meet one of the two proposed conditions, we are proposing that the ''original'' urban hospital would be able to ''revive'' and use its already established rural track FTE limitation from that point forward. In the instance where the ''original'' urban hospital's rural track FTE limitation was not set because the hospital was not able to meet one of the two proposed conditions by the end of the 2-year transition period, which fell within the 3-year cap-building timeframe, but at some point later is able to meet one of the two proposed conditions, we are proposing that the ''original'' urban hospital would be able to have a rural track FTE limitation calculated and established based on the highest number of FTE residents in any program year training in the rural track in the third year of the program, even if during the third year of the program, the ''original'' urban hospital was not in compliance with the two proposed conditions. Consistent with similar policy discussed in the FY 2002 IPPS final rule (66 FR 39905), it would be the responsibility of the hospitals involved to provide the necessary information regarding the rotations of the residents in the third program year to the Medicare contractor in order for the calculation to be completed and the rural track FTE limit to be set.

In summary, we are proposing that any time a rural hospital participating in a rural track is in an area redesignated by OMB as urban after residents started training in the rural track and during the 3-year period that is used to calculate the urban hospital's rural track FTE limitation, the urban hospital may receive a cap adjustment for that rural track after it has been redesignated as urban. Furthermore, we are proposing that, regardless of whether the redesignation of the rural hospital occurs during the 3-year period that is used to calculate the urban hospital's rural track FTE limitation, or after the 3-year period used to calculate the urban hospital's rural track FTE limitation, the redesignated urban hospital can continue to be considered a rural hospital for purposes of the rural track

for up to 2 years. However, by the end of those 2 years, either the redesignated urban hospital must reclassify as rural under § 412.103 for purposes of IME payment only (in addition, this reclassification option only applies to IPPS hospitals, not nonprovider sites) or the ''original'' urban hospital must have found a new site in a geographically rural area that will serve as the rural site for purposes of the rural track in order for the ''original'' urban hospital to receive payment under § 413.79(k)(1) or (k)(2).

We are proposing to revise the regulations at § 413.79(k)(7) to implement these provisions and to establish that these changes would be effective for cost reporting periods beginning on or after October 1, 2014. The proposed regulations at § 413.79(k)(7) read as follows: ''(i) Effective for cost reporting periods beginning prior to October 1, 2014, if an urban hospital had established a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and that rural area subsequently becomes an urban area due to the most recent census data and implementation of the new labor market area definitions announced by OMB on June 6, 2003, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) for the rural track programs established prior to the adoption of such new labor market area definitions. In order to receive an adjustment to its FTE resident cap for a new rural track residency program, the urban hospital must establish a rural track program with hospitals that are designated rural based on the most recent geographical location designations adopted by CMS. (ii) Effective for cost reporting periods beginning on or after October 1, 2014, if an urban hospital had started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and, during the 3-year period that is used to calculate the urban hospital's rural track FTE limit, that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) and subject to paragraph (k)(7)(iii) for the rural track programs established prior to the adoption of such new OMB standards for delineating statistical areas. (iii) Effective for cost reporting periods beginning on or after October 1, 2014, if an urban hospital had established a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, regardless of whether the redesignation of the rural hospital occurs during the 3-year period that is used to calculate the urban hospital's rural track FTE limit, or after the 3-year period used to calculate the urban hospital's rural track FTE limit, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) based on the rural track programs established prior to the change in the hospital's geographic designation. In order for the urban hospital to receive or use the adjustment to its FTE resident cap for training FTE residents in the rural track residency program that was established prior to the most recent OMB standards for delineating statistical areas adopted by CMS, one of the following two conditions must be met by the end of a 2-year period that begins when the most recent OMB standards for delineating statistical areas are adopted by CMS: The hospital that has been redesignated from rural to urban must reclassify as rural under § 412.103 of this chapter, for purposes of IME only; or the urban hospital must find a new site that is geographically rural consistent with the most recent geographical location delineations adopted by CMS. In order to receive an adjustment to its FTE resident cap for an additional new rural track residency program, the urban hospital must establish a rural track program with sites that are geographically rural based on the most recent geographical location delineations adopted by CMS.''

We also have determined that there is an outdated, incorrect reference included in the definition of ''Rural track FTE limitation'' under § 413.75(b). The reference included in the definition is ''§ 413.79(l)''. The correct reference is ''§ 413.79(k)''. Therefore, we are proposing to make a technical correction to the definition of ''Rural track FTE limitation'' so that it reads ''means the maximum number of residents (as specified in § 413.79(k)) training in a rural track residency program that an urban hospital may include in its FTE count and that is in addition to the number of FTE residents already included in the hospital's FTE cap.''

4. Proposed Clarification of Policies on Counting Resident Time in Nonprovider Settings Under Section 5504 of the Affordable Care Act

In the November 24, 2010 final rule with comment period (75 FR 71808, 72134 through 72141, and 72153), we implemented section 5504 of the Affordable Care Act regarding counting resident time in nonprovider settings. We also mentioned the scope of section 5504 of the Affordable Care Act in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27638) and final rule (78 FR 50735). Section 5504(a) of the Affordable Care Act made changes to section 1886(h)(4)(E) of the Act to reduce the costs that hospitals must incur for residents training in nonprovider sites in order to count the FTE residents for purposes of Medicare direct GME payments on a prospective basis. Notably, section 5504(a)(3) of the Affordable Care Act amended the Act effective for ''cost reporting periods beginning on or after July 1, 2010,'' for direct GME, to permit hospitals to count the time that a resident trains in activities related to patient care in a nonprovider site in its FTE count if the hospital incurs the costs of the residents' salaries and fringe benefits for the time that the resident spends training in the nonprovider site. Section 5504(b)(2) of the Affordable Care Act made similar changes to section 1886(d)(5)(B)(iv) of the Act for IME payment purposes, with the provision being effective for discharges occurring on or after July 1, 2010, for IME. In connection with those periods and discharges, if more than one hospital incurs the residency training costs in a nonprovider setting, under certain circumstances, sections 5504(a)(3) and (b)(2) of the Affordable Care Act allow each hospital to count a proportional share of the training time that a resident spends training in that setting, as determined by a written agreement between the hospitals. When Congress enacted section 5504 of the Affordable Care Act, it retained the statutory language which provides that a hospital can only count the time so spent by a resident under an approved medical residency training program in its FTE count if that one single hospital by itself ''incurs all, or substantially all, of the costs for the training program in that setting.'' In doing so, Congress also revised the statutory language in sections 5504(a)(1) and (b)(1) to explicitly make this longstanding substantive standard and requirement applicable to ''cost reporting periods beginning before July 1, 2010'' for direct GME, and to ''discharges occurring on

or after October 1, 1997, and before July 1, 2010,'' for IME (sections 1886(d)(5)(B)(iv)(I) and 1886(h)(4)(E)(i) of the Act). Beginning at least as early as 1988, the Secretary consistently noted in the preamble of various rules that the statute only allowed a hospital to count the time that its residents spent training in a nonprovider site in the FTE resident count for direct GME and IME purposes if that single hospital incurred ''all of substantially all'' of the costs of the training program in that setting. For a full discussion of the longstanding substantive standard and requirement that a hospital can only count residents training if that one single hospital incurs all or substantially all of the costs for the training, we refer readers to the discussion in the November 24, 2010 final rule with comment period (75 FR 72134 through 72141), in the May 11, 2007 final rule (72 FR 26953 and 26969), and in the August 1, 2003 final rule (68 FR 45439).

Section 5504(c) of the Affordable Care Act specifies that the amendments made by the provisions of sections 5504(a) and (b) ''shall not be applied in a manner that requires reopening of any settled hospital cost reports as to which there is not a jurisdictionally proper appeal pending as of the date of the enactment of this Act on the issue of payment for indirect costs of medical education . . . or for direct graduate medical education costs. . . .'' The date of enactment of the Affordable Care Act was March 23, 2010.

In the November 24, 2010 final rule with comment period, we revised the regulations at § 412.105(f)(1)(ii)(E) for IME and §§ 413.78(f) and (g) for direct GME to reflect the changes made by section 5504 of the Affordable Care Act. Section 413.78(g) is the implementing regulation that corresponds to the statutory amendments set forth in sections 5504(a)(3) and (b)(2) of the Affordable Care Act. The introductory regulatory language of § 413.78(g) explicitly states that paragraph (g) governs only ''cost reporting periods beginning on or after July 1, 2010.'' Paragraph (g)(5) of § 413.78 also expressly states that the paragraph is limited to ''cost reporting periods beginning on or after July 1, 2010.'' Accordingly, we have repeatedly stated, and we believe that the existing regulation makes plain, that paragraph (g) of § 413.78 ''is explicitly made applicable only to 'cost reporting periods beginning on or after July l, 2010,' whereas earlier cost reporting periods are governed by other preceding paragraphs of § 413.78'' (78 FR 50735). In addition, we also revised the definition of ''all or substantially all of the costs for the training program in the nonhospital setting'' in the regulations at § 413.75(b) to reflect that both the statute and regulations require that, for cost reporting periods beginning on and after July 1, 2007 and before July 1, 2010, one hospital must by itself incur ''all or substantially all of the costs'' of the residents training in the nonprovider site in order for the hospital to receive Medicare IME and direct GME payment for that training. Finally, we also revised the IME regulations at § 412.105 to reflect these statutory amendments, by incorporating by reference § 413.78(g).

Despite the fact that sections 5504(a) and (b) of the Affordable Care Act provide clear effective dates with respect to the amendments provided therein to sections 1886(h)(4)(E) and 1886(d)(5)(B)(iv) of the Act, and that the preamble discussion of the implementation of these provisions and further discussion of the statutory amendments in the November 24, 2010 final rule with comment period and in the August 19, 2013 final rule provide further explanation that, specifically, nothing in section 5504(c) overrides those effective date (75 FR 72136), we have received questions about the applicability of section 5504(c) and the associated regulation text at § 413.78(g)(6). Specifically, questions have been raised with respect to the applicability of sections 5504(c) of the Affordable Care Act and § 413.78(g)(6) of the regulations to periods prior to July 1, 2010, particularly if a hospital had, as of March 23, 2010, appealed an IME or direct GME issue for a settled cost reporting period occurring prior to July 1, 2010. As noted earlier, section 5504(c) of the Affordable Care Act provides that the amendments made by the provisions of sections 5504(a) and (b) ''shall not be applied in a manner that requires reopening of any settled hospital cost reports as to which there is not a jurisdictionally proper appeal pending as of . . . [March 23, 2010] on the issue of payment for indirect costs of medical education . . . or for direct graduate medical education costs. . . .''

Upon revisiting the existing regulation text, we determined that § 413.78(g)(6) was not written in a manner that is as consistent with section 5504(c) of the Affordable Care Act and reflective of our reading of that provision and our policy as it could be. Specifically, § 413.78(g)(6) states, ''The provisions of paragraphs (g)(1)(ii), (g)(2), (g)(3), and (g)(5) of this section cannot be applied in a manner that would require the reopening of settled cost reports, except those cost reports on which there is a jurisdictionally proper appeal pending on direct GME or IME payments as of March 23, 2010.'' In this proposed rule, we are reiterating our existing interpretation of the statutory amendments made by sections 5504(a), (b), and (c) of the Affordable Care Act and also proposing to clarify the regulation text implementing these provisions by revising the language at § 413.78(g)(6) to read more consistently with the language in section 5504(c) of the Affordable Care Act and to ensure no further confusion with respect to the applicability of section 5504(c) of the Affordable Care Act and § 413.78(g)(6) of the regulations.

We believe that sections 5504(a) and (b) of the Affordable Care Act contained three primary directives (a fourth regarding recordkeeping requirement is tangential to this discussion): (1) Under sections 5504(a)(1) and (b)(1) of the Affordable Care Act (sections 1886(h)(4)(E)(i) and 1886(d)(5)(B)(iv)(I) of the Act), for ''cost reporting periods beginning before July 1, 2010'' for direct GME, and for ''discharges occurring on or after October 1, 1997, and before July 1, 2010'' for IME, these sections explicitly retained the statutory language that provides that a hospital can only count the time so spent by a resident under an approved medical residency training program in its FTE count if a hospital by itself ''incurs all, or substantially all, of the costs for the training program in that setting''; (2) under sections 5504(a)(3) and (b)(2) of the Affordable Care Act (sections 1886(h)(4)(E)(ii) and 1886(d)(5)(B)(iv)(II) of the Act), for ''cost reporting periods beginning on or after July 1, 2010'' for direct GME, and for ''discharges occurring on or after July 1, 2010'' for IME, these sections eliminated the ''all or substantially all'' requirement, instead requiring a hospital to incur the residents' salaries and fringe benefits for the time spent at the nonprovider site; and (3) under sections 5504(a)(3) and (b)(2) of the Affordable Care Act (sections 1886(h)(4)(E)(ii) and 1886(d)(5)(B)(iv)(II) of the Act), for ''cost reporting periods beginning on or after July 1, 2010'' for direct GME, and for ''discharges occurring on or after July 1, 2010'' for IME, these sections created a new provision with regard to allowing more than one hospital to share the costs of residents training in a nonprovider setting under certain circumstances, in order for each hospital to count a proportional share of the FTE training time in the nonprovider setting.

Separately from sections 5504(a) and (b) of the Affordable Care Act, section 5504(c) of the Affordable Care Act, as mentioned earlier, specifies that the

amendments made by the provisions of sections 5504(a) and (b) ''shall not be applied in a manner that requires reopening of any settled hospital cost reports as to which there is not a jurisdictionally proper appeal pending as of'' March 23, 2010, the date of the enactment of the Affordable Care Act, on the issue of payment for IME and direct GME. When we proposed to implement section 5504(c) in the August 3, 2010 proposed rule (75 FR 46385) and when we implemented section 5504(c) in the November 24, 2010 final rule with comment period (75 FR 72136), we had to consider what new meaning it was adding to sections 5504(a) and (b) of the Affordable Care Act because unlike, for example, section 5505 of the Affordable Care Act which has an effective date *prior* to enactment of the Affordable Care Act and, therefore, would apply to prior cost reporting periods, section 5504's applicable effective date for the new standards it creates was July 1, 2010, a date that came *after* enactment of the Affordable Care Act and was fully prospective. As we stated in the November 24, 2010 final rule with comment period (75 FR 72136), ''Section 5504(c) is fully prospective with an explicit effective date of July 1, 2010, for the new standards it creates. Nothing in section 5504(c) overrides that effective date. Section 5504(c) merely notes that the usual discretionary authority of Medicare contractors to reopen cost reports is not changed by the provisions of section 5504; it simply makes clear that Medicare contractors are not required by reason of section 5504 to reopen any settled cost report as to which a provider does not have a jurisdictionally proper appeal pending. It does not require reopening in any circumstance; and the new substantive standard is, in any event, explicitly prospective. We believe if Congress had wanted to require such action or to apply the new standards to cost years or discharges prior to July 1, 2010, it would have done so in far more explicit terms.'' We also noted in that rule (75 FR 72139) that ''[the] statute does not provide CMS discretion to allow the counting of resident time spent in shared nonprovider site rotations for cost reporting periods beginning prior to July l, 2010.'' We continue to believe that Congress was clear in amending sections 1886(h)(4)(E) and 1886(d)(5)(B)(iv) of the Act to provide for new standards to be applied only prospectively, effective for cost reporting periods beginning on or after, and discharges occurring on or after, July 1, 2010. We also continue to believe that the plain meaning of section 5504(c) of the Affordable Care Act is that the Secretary is not required to reopen a cost report when there is *no* jurisdictionally proper appeal pending as of March 23, 2010, the date of the enactment of the Affordable Care Act, on the issue of payment for IME and direct GME. Therefore, we believe that section 5504(c) of the Affordable Care Act is merely a confirmation of the Secretary's existing discretionary authority in one particular context, and that sections 5504(a) and (b) of the Affordable Care Act and their effective dates become all the more prominent, and are not affected by section 5504(c).

As noted earlier, we revised the regulations at § 412.105(f)(1)(ii)(E) for IME, and § 413.78(g) for direct GME, to reflect the changes made by section 5504 of the Affordable Care Act in the November 24, 2010 final rule with comment period. We reiterate here that the introductory language of § 413.78(g) explicitly states that paragraph (g) governs only ''cost reporting periods beginning on or after July 1, 2010'' and paragraph (g)(5) also expressly states that the paragraph is limited to ''cost reporting periods beginning on or after July 1, 2010'' (78 FR 50735 and 78 FR 27639). As we noted before, we believe that the paragraphs of the regulations which precede paragraph (g), particularly paragraphs (c) through (f), consistent with the statute, make clear that a hospital may only count the time so spent by a resident under an approved medical residency training program in its FTE count, in connection with its pre-July l, 2010 cost reporting periods and pre-July l, 2010 patient discharges, if that one single hospital by itself ''incurs all, or substantially all, of the costs for the training program in that setting.'' Separately, we believe that the new standards set forth in sections 5504(a)(3) and (b)(2) of the Affordable Care Act and implemented by regulation at §§ 413.78(g) and 412.105(f)(1)(ii)(E), allowing cost sharing under certain circumstances do *not* ever apply to pre-July 1, 2010 cost reporting periods and pre-July l, 2010 patient discharges. Moreover, we continue to believe the language in paragraph (g)(6) (along with the remainder of paragraph (g)) only applies to cost reporting periods beginning on or after July 1, 2010 and does *not* apply retroactively to cost reporting periods beginning before July 1, 2010. We had intended that the language under § 413.78(g) do no more than simply paraphrase the language in section 5504(c) of the Affordable Care Act.

Accordingly, we believe that it is apparent that the provisions of sections 5504(a)(3) and (b)(2) of the Affordable Care Act are not to be applied prior to July l, 2010, irrespectively of whether a hospital may have had a jurisdictionally proper appeal pending as of March 23, 2010, on an IME or direct GME issue from a cost reporting period occurring prior to July 1, 2010.

In this proposed rule, we are reiterating our existing interpretation of the statutory amendments made by sections 5504(a) and (b) of the Affordable Care Act and also are proposing to clarify the regulatory text that implements these provisions by revising the § 413.78(g)(6) to be more consistent with the language at section 5504(c) of the Affordable Care Act. We are proposing to revise the regulatory language to read as follows: ''The provisions of paragraphs (g)(1)(ii), (g)(2), (g)(3), and (g)(5) of this section shall not be applied in a manner that requires reopening of any settled cost reports as to which there is not a jurisdictionally proper appeal pending as of March 23, 2010, on direct GME or IME payments. Cost reporting periods beginning before July 1, 2010 are not governed by paragraph (g) of this section.'' The IME regulations at § 412.105(f)(1)(ii)(E) include a reference to § 413.78(g)(6); therefore, no proposed change is needed to this section.

5. Proposed Changes to the Review and Award Process for Resident Slots Under Section 5506 of the Affordable Care Act

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. 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 resident caps so that it may receive direct GME and IME payment associated with those displaced FTE residents. However, those temporary FTE resident caps are tied to those specific displaced FTE residents, and the temporary caps expire when those displaced residents complete their training program.

Section 5506 of the Affordable Care Act amended 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 aggregate number of FTE resident cap slots distributed shall be equal to the aggregate number of slots in the closed hospital's direct GME and IME FTE resident caps, respectively. For a detailed discussion of the regulations implementing section 5506 of the Affordable Care Act, we refer readers to the November 24, 2010 final rule with comment period (75 FR 72212 through 72238) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434 through 53448).

a. Effective Date of Slots Awarded Under Section 5506 of the Affordable Care Act

In distributing slots permanently under the provisions of section 5506 of the Affordable Care Act, section 5506(d) provides 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 consideration of this statutory language, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53437), we stated that in distributing slots permanently under section 5506, we would 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 slots associated with those displaced residents would then be available for permanent redistribution. Therefore, in initially developing ranking criteria and application materials that we would use to award available slots, we considered how to interpret this statutory language at section 5506(d) of the Affordable Care Act within the context of our existing GME regulations and section 5506's amendment to section 1886(h) of the Act generally.

In the November 24, 2010 final rule with comment period and the FY 2013 IPPS/LTCH PPS final rule (75 FR 72216 and 77 FR 53436, respectively), we discussed the various ranking criteria that we would use for hospitals applying for slots from closed hospitals. Currently, if after distributing the slots from a closed hospital to increase the FTE caps for applying hospitals that fall within Ranking Criteria One, Two, and Three, there are still excess slots available and any of those excess slots are associated with displaced residents for whom temporary cap adjustments under § 413.79(h) are in place, any slots awarded to hospitals that fall within Ranking Criteria Four through Eight are permanently assigned only once the displaced residents have completed their training and the temporary cap adjustments associated with those residents have expired. That is, in applying the requirement for ''no duplication of FTE slots'' set forth in section 5506(d), we currently consider all temporary cap adjustments received by hospitals on a national basis and not specifically the hospital that is applying for cap slots under section 5506, when deciding the effective date for slots permanently awarded to hospitals applying under Ranking Criteria Four through Eight. Specifically, in the November 24, 2010 final rule with comment period, we stated that we believe the ''no duplication of FTE slots'' requirement applies across all hospitals. Therefore, although a hospital may not have received a temporary cap adjustment under § 413.79(h), other hospitals may have taken in residents and received temporary cap adjustments for the same program, and we believed that the appropriate policy was to delay the slots associated with that program from being permanently distributed until it is known that any and all temporary cap adjustments for those slots have expired (75 FR 72227) Applying this policy to an example, if Hospital A is training displaced residents and is receiving a temporary cap adjustment under § 413.79(h) for training those residents and Hospital B, which is not receiving a temporary cap adjustment for training any displaced residents, has applied under Ranking Criterion Five to expand its internal medicine program, as explained in the November 24, 2010 final rule with comment period, we would only award permanent slots under section 5506 to Hospital B on a flow basis; that is, effective after each displaced resident completes his/her training, and, therefore, the temporary cap adjustments associated with that resident expire at Hospital A.

However, the policy of applying the ''no duplication of FTE slot'' requirement at section 5506(d) of the Affordable Care Act to all hospitals rather than simply to each specific hospital that is applying for slots has thus far proven to be a very complex process due to the number of displaced residents and the timing of multiple graduation dates which must be tracked and considered when awarding slots on a permanent basis. We believe this practice has delayed the awarding of slots and is also unnecessarily burdensome for hospitals applying under Ranking Criteria Four through Eight that are not receiving any cap adjustments for training displaced residents under § 413.79(h). We believe the current policy that we apply for ''no duplication of FTE slots'' is unnecessarily burdensome for these hospitals because, instead of receiving their permanent slots under section 5506 as soon as possible, the hospitals may receive their section 5506 awards with staggered effective dates due to the graduation dates of displaced FTE residents training at other hospitals that did receive temporary adjustments under § 413.79(h). While we believe that awarding permanent slots to a hospital that is simultaneously receiving a temporary cap adjustment for training displaced FTE residents under § 413.79(h) would clearly be a duplication of FTE slots and contrary to the statutory directive, we believe there is flexibility in interpreting this statutory language and that the statute does not require such a policy to be applied to hospitals that are *not* receiving temporary cap adjustments under § 413.79(h). Furthermore, in considering the specific statutory language regarding ''no duplication of FTE slots,'' section 5506(d) in part provides that ''The Secretary of Health and Human Services shall give consideration to the effect of the amendments made by this section on any temporary adjustment to a hospital's FTE cap under section 413.79(h) of title 42, Code of Federal Regulations (as in effect on the date of enactment of this Act) in order to ensure that there is no duplication of FTE slots.'' Because this language refers to ''a hospital,'' we believe the statute provides us with the flexibility to apply the ''no duplication of FTE slots'' requirement on a hospital-specific basis, considering separately whether each hospital did or did not receive a temporary cap adjustment under § 413.79(h), rather than on a national all-hospital basis. Bearing in mind the statutory language and our experience to date in awarding slots as well as the unnecessary burden placed on hospitals that are receiving section 5506 slots, but are not receiving temporary cap adjustments under § 413.79(h), we believe it is appropriate to propose a policy that would provide for a more efficient and faster method for awarding of slots to hospitals applying under Ranking Criteria Four through Eight. Therefore, we are proposing that, effective for section 5506 application

rounds announced on or after October 1, 2014, for purposes of applying the requirement for ''no duplication of FTE slots,'' we would only require that there be no duplication of FTE slots on a hospital-specific basis. That is, in determining the effective date for slots awarded permanently under section 5506, we would only be concerned with whether the hospital that is applying for slots is also receiving a temporary cap adjustment under § 413.79(h) for training displaced residents. When awarding slots to the applying hospital, we would not be concerned whether any other hospital is receiving a temporary cap adjustment for training displaced residents under § 413.79(h). For example, if Hospital A is receiving a temporary cap adjustment under § 413.79(h) for training displaced residents in its general surgery program but is applying under Ranking Criterion Five to start a pediatrics program and Hospital B is *not* receiving a temporary cap adjustment for training displaced residents and is applying under Ranking Criterion Eight to expand a cardiology program, in awarding section 5506 slots, we would only allow Hospital A to receive a permanent adjustment to its FTE cap for training residents in its pediatrics program once its temporary adjustments for the displaced residents training in the general surgery program have expired. We would not consider displaced residents when awarding section 5506 slots to Hospital B.

In conjunction with our proposal to interpret the ''no duplication of FTE slots'' requirement to apply on a hospital-specific basis to hospitals that are receiving temporary cap adjustments under § 413.79(h), we are proposing to amend the effective dates of section 5506 slots received under Ranking Criteria Four through Eight for those hospitals that are *not* receiving temporary cap adjustments under § 413.79(h). (We refer readers to section IV.K.5.c. of the preamble of this proposed rule where we discuss our proposal to amend Ranking Criteria Seven and Eight.) Existing policy requires that slots awarded under Ranking Criteria Four through Eight for expanding an existing residency training program or starting a new residency training program are effective the later of when a hospital can demonstrate to the MAC that the slots associated with a new program or program expansion are actually filled and, therefore, are needed as of a particular date (usually July 1, possibly retroactive), or the July 1 after displaced residents complete their training. If a hospital is awarded slots under Ranking Criterion Eight for cap relief, slots are effective the date of CMS' award announcement, or the July 1 after displaced residents complete their training, whichever is later. However, because we are proposing an alternative approach to interpreting section 5506(d) that would permit us to apply the ''no duplication of FTE slots'' requirement on a hospital-specific basis, we are proposing to change the effective date for slots received under Ranking Criteria Four through Eight so that if a hospital is *not* receiving a temporary cap adjustment under § 413.79(h), the slots awarded under section 5506 would be effective when the hospital can demonstrate to its MAC that the slots needed for a new program or program expansion are actually filled and, therefore, are needed as of a particular date (usually July 1, possibly retroactive). If a hospital is awarded slots under Ranking Criteria Four through Eight and *is* receiving a temporary cap adjustment to train displaced residents under § 413.79(h), the current policy would apply such that the slots are awarded on a permanent basis, the later of when a hospital can demonstrate to the MAC that the slots associated with a new program or program expansion are actually filled and, therefore, are needed as of a particular date (usually July 1, possibly retroactive), or the July 1 after an equivalent amount of a displaced FTE resident(s) complete their training. For example, assume in a hypothetical situation that there is a closed teaching hospital, and that another hospital takes in two displaced FTE residents, for which the hospital is receiving a temporary cap adjustment under § 413.79(h). One resident is graduating on June 30, 2016, and the second resident is graduating on June 30, 2018. Assume that when the section 5506 Round is announced, the hospital also applies for two slots to expand an internal medicine program under Ranking Criterion Five. In January of 2017, CMS awards two permanent slots to the hospital under Ranking Criterion Five. For the program year starting July 1, 2017, the hospital successfully demonstrates to the MAC that it filled the two additional internal medicine positions. Because one displaced FTE resident already graduated on June 30, 2016, the MAC may approve one slot on a permanent basis effective July 1, 2017. However, the hospital would have to wait until July 1, 2018, to receive from the MAC the permanent slot for the second displaced internal medicine resident because the second displaced FTE resident is not graduating until June 30, 2018.

We are not proposing any changes to the effective date for slots awarded under Ranking Criterion One, Ranking Criterion Two, or Ranking Criterion Three. Consistent with existing policy, if a hospital is applying under Ranking Criterion One or Ranking Criterion Three and is *not* receiving a temporary cap adjustment for training displaced residents under § 413.79(h), the effective date of the section 5506 slots is the date of the hospital closure. If a hospital is applying under Ranking Criterion One or Ranking Criterion Three and is receiving a temporary cap for training displaced residents under § 413.79(h), the effective date of the section 5506 slots is after the displaced resident(s) graduate. If a hospital *is* receiving a temporary cap for training displaced residents under § 413.79(h), and is applying under Ranking Criterion One or Ranking Criterion Three and is also separately applying under Ranking Criterion Four or subsequent Ranking Criteria, for slots awarded under Ranking Criteria One or Three, the effective date of the section 5506 slots is after the displaced resident(s) graduate. For slots awarded under Ranking Criteria Four or subsequent Ranking Criteria, the slots are awarded the later of when a hospital can demonstrate to the MAC that the slots associated with a new program or program expansion are actually filled and, therefore, are needed as of a particular date (usually July 1, possibly retroactive), or the July 1 after an equivalent amount of a displaced FTE resident(s) at the hospital complete their training. Therefore, for such a hospital, the effective dates of slots awarded under Ranking Criteria One/Three, and Ranking Criteria Four through Eight might coincide. Also, consistent with existing policy, if a hospital is applying under Ranking Criterion Two, the effective date of the permanent award of section 5506 slots is the date of the hospital closure. We discuss these existing policies in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53437 through 53445).

The following list includes the current and proposed ranking criteria along with the current and proposed effective dates.

- *Current 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).

• *Proposed 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). The applying hospital's FTE resident caps were erroneously reduced by CMS under section 1886(h)(8)(A)(i) of the Act, contrary to the statutory exception at section 1886(h)(8)(A)(ii)(I) of the Act, and CMS Central Office was made aware of the error prior to posting of the FY 2015 IPPS proposed rule on the CMS Web site. (This language reflects the proposed modification of Ranking Criterion One. We refer readers to section IV.K.5.c. of the preamble of this proposed rule where we discuss this proposed modification.)

○ *Current Policy:* If the hospital is receiving a temporary cap adjustment, slots are effective the day after the graduation date(s) of actual displaced resident(s). If the hospital is not receiving a temporary cap adjustment, slots are effective with the date of the hospital closure.

○ *Proposed Policy:* No change.

• *Current 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.

• *Clarified 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 or emergency 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 or emergency 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, or emergency Medicare GME affiliation agreement. If the most recent Medicare GME affiliation agreement or emergency 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 or emergency 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. (This language reflects our clarification in this proposed rule regarding inclusion of emergency Medicare GME affiliation agreements in Ranking Criterion Two. We refer readers to section IV.K.5.d. of the preamble of this proposed rule where we discuss this clarification.)

○ *Current Policy:* Slots are effective with the date of the hospital closure.

○ *Proposed Policy:* No change.

• *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).

○ *Current Policy:* If the hospital is receiving temporary cap adjustment, slots are effective the day after the graduation date(s) of actual displaced resident(s). If the hospital is not receiving a temporary cap adjustment, slots are effective with the date of the hospital closure.

○ *Proposed Policy:* No change.

• *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.

• *Current Ranking Criterion Seven:* The applying hospital will use additional slots to establish or expand a primary care or general surgery program, but the program does not meet Ranking Criterion 5 or 6 because the hospital is also separately applying under Ranking Criterion 8 for slots to establish or expand a nonprimary care or nongeneral surgery program and/or for cap relief.

• *Proposed Ranking Criterion Seven:* The applying hospital will use additional slots to establish or expand a primary care or general surgery program, but the program does not meet Ranking Criterion 5 or 6 because the hospital is also separately applying under Ranking Criterion 8 for slots to establish or expand a nonprimary care or nongeneral surgery program. (This language reflects our proposal in this proposed rule to revise Ranking Criteria Seven and Eight. We refer readers to section IV.K.5.c. of the preamble of this proposed rule where we discuss our proposals to amend Ranking Criteria Seven and Eight.)

○ *Current Policy for Ranking Criteria Four through Seven:* The later of when the hospital can demonstrate to the MAC that the slots associated with a new program or program expansion are actually filled, and therefore, are needed as of a particular date (usually July 1, possibly retroactive), or the July 1 *after* displaced residents complete their training.

○ *Proposed Policy for Ranking Criterion Four through Proposed Ranking Criterion Seven:* If the hospital is receiving a temporary cap adjustment for training displaced residents, the later of when the hospital can demonstrate to the MAC that the slots associated with a new program or program expansion are actually filled, and therefore, are needed as of a particular date (usually

July 1, possibly retroactive), or the July 1 *after* displaced residents complete their training. If the hospital is *not* receiving a temporary cap adjustment, when the hospital can demonstrate to the MAC that the slots needed for a new program or program expansion are actually filled, and therefore, are needed as of a particular date (usually July 1, possibly retroactive).

- *Current Ranking Criterion Eight:* The program does not meet Ranking Criteria 1 through 7, and the applying hospital will use additional slots to establish or expand a nonprimary care or a nongeneral surgery program or for cap relief.
- *Proposed Ranking Criterion Eight:* The program does not meet Ranking Criteria 1 through 7, and the applying hospital will use additional slots to establish or expand a nonprimary care or a nongeneral surgery program. (This language reflects our proposal in this proposed rule to revise Ranking Criterion Eight. We refer readers to section IV.K.5.c. of the preamble of this proposed rule where we discuss our proposals to amend Ranking Criterion Eight.)

○ *Current Policy:* If slots are for starting or expanding a nonprimary care or nongeneral surgery program, the effective date is same as that for Ranking Criteria Four through Seven. If slots are for cap relief (under current policy), the effective date is the effective date of CMS' award announcement, or *after* displaced residents complete their training, whichever is later.

○ *Proposed Policy for Proposed Ranking Criterion Eight:* If the hospital is receiving a temporary cap adjustment for training displaced residents, the later of when the hospital can demonstrate to the MAC that the slots associated with a new program or program expansion are actually filled and, therefore, are needed as of a particular date (usually July 1, possibly retroactive), or the July 1 *after* displaced residents complete their training. If the hospital is not receiving a temporary cap adjustment, when the hospital can demonstrate to the MAC that the slots needed for a new program or program expansion are actually filled, and therefore, are needed as of a particular date (usually July 1, possibly retroactive).

In summary, we are proposing that, effective for section 5506 application rounds announced on or after October 1, 2014, the statutory provision at section 5506(d) requiring the Secretary to consider temporary cap adjustments under § 413.79(h) and to ensure no duplication of FTE slots, be interpreted in a manner such that the requirement for ''no duplication of FTE slots'' is applied on a hospital-specific basis rather than across all hospitals receiving temporary cap adjustments under § 413.79(h). Consistent with this proposed change, we are proposing to amend the effective date for slots received under Ranking Criteria Four through Eight so that if a hospital is *not* receiving a temporary cap adjustment under § 413.79(h), the slots awarded under section 5506 would be effective when the hospital can demonstrate to its MAC that the slots needed for a new program or program expansion are actually filled and, therefore, are needed as of a particular date (usually July 1, possibly retroactive).

b. Proposal To Remove Seamless Requirement

Under current policy, if a hospital is applying under Ranking Criterion One or Three, the hospital must show that it is seamlessly replacing displaced FTE residents with new FTE residents once the displaced residents graduate (75 FR 72219 and 72221 through 72222). We have stated that in instances where a hospital seamlessly operates an entire program or part of a program from the closed hospital (or takes over an entire program prior to the hospital's closure), such a hospital is demonstrating a strong commitment to maintain GME programs in the community for the long term and should we awarded slots under higher ranking criteria (75 FR 72216). Therefore, we required that, in order to receive slots under Ranking Criterion One and Three, the applying hospital must demonstrate that upon graduation of the displaced FTE residents that it is training, the slots held by those displaced FTEs are seamlessly replaced with new FTE residents (75 FR 72219 and 72221 through 72222). In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53441), in response to concerns associated with the seamless requirement and timeline used by the National Resident Match Program or other resident match services, we revised the seamless requirement. We stated that in the instance where a teaching hospital closed after December 31 of an academic year, in order for a hospital to qualify under Ranking Criterion One or Three for cap slots associated with displaced FTE residents who will graduate June 30 of the academic year in which the applying hospital took in the displaced FTE residents, the applying hospital must be able to demonstrate that it will fill slots vacated by displaced FTE residents by July 1 of the second academic year following the hospital closure. However, in the instance where a teaching hospital closed before December 31 of an academic year, in order for a hospital to qualify under Ranking Criterion One or Three for cap slots associated with displaced FTE residents who will graduate June 30 of the academic year in which the applying hospital took in the displaced FTE residents, the applying hospital must be able to demonstrate that it will seamlessly fill slots vacated by displaced FTE residents by that July 1; that is, the day immediately after the June 30 that the displaced FTE residents graduate (77 FR 53441 through 53442). We also revised the CMS Application Form to instruct a hospital applying under Ranking Criterion One or Three to list the names and graduation dates of specific displaced residents who, upon their graduation, have been or will be seamlessly replaced by new residents (77 FR 53446). Because Ranking Criteria One and Three fall under Demonstrated Likelihood Criterion 2, the hospital is taking over all of part of an existing residency program from the closed hospital, or expanding an existing residency training program, the requirement to include a list with the names and graduation dates of specific displaced residents who have been or will be seamlessly replaced was added under Demonstrated Likelihood Criterion 2 on the CMS Application Form.

In addition to the match deadlines associated with the National Resident Matching Program and match deadlines associated with matching into osteopathic programs, we have recently been made aware of other match deadlines associated with certain fellowship programs. From the experience we have had so far in reviewing section 5506 applications, where we have observed the complexity of tracking various match deadlines as well as the intersection between these deadlines and when the section 5506 awards are announced by CMS, we are proposing to remove the seamless requirement for slots awarded under Ranking Criterion One and Three effective for section 5506 application rounds announced on or after October 1, 2014. We are not proposing to make any other additional changes to Ranking Criterion One or Three; that is, the hospital must still be training displaced residents and must either take over or have taken over an entire program from the closed hospital and continue operating that program in the same manner in which it was operated by the closed hospital or the hospital must take over part of a closed hospital's program and permanently expand its own program as a result of training displaced

residents. Hospitals would continue to be required to submit supporting documentation when applying under Ranking Criterion One or Three that indicates that they have made a commitment to take over the closed hospital's program or that they have made the commitment to permanently expand their own residency training program resulting from taking over part of a closed hospital's program.

In determining the effective date of slots awarded under Ranking Criterion One or Three where the hospital has been training residents that were displaced by the closed hospital and receiving a temporary cap adjustment under § 413.79(h), the hospital would work with its MAC to determine when it could be permanently awarded the slots based on the graduation dates of the displaced residents it is training. Consistent with our proposal, we are proposing to remove the following requirement under Demonstrated Likelihood Criterion 2 on the CMS Application Form: ''Hospitals applying for slots under option (a) which correlates to Ranking Criterion 1 or (b) which correlates to Ranking Criterion 3 must list the names and graduation dates of specific displaced residents who, upon their graduation, have been or will be seamlessly replaced by new residents. The list may be added as an attachment to this application.'' We are proposing to replace this requirement with the following requirement under Demonstrated Likelihood Criteria 1 and 2'' ''Please indicate Y or N: As of the time of submitting this application, are you receiving a temporary cap adjustment for IME and/or direct GME under 42 CFR 413.79(h) for residents displaced by the closure of the hospital subject to this Round of section 5506? (Y/N)'' so that we are aware which hospitals are receiving temporary cap adjustments for training displaced residents under § 413.79(h), and when we award slots, we would know which hospitals to instruct to work with their MACs to determine when the slots could be permanently awarded to them based on the graduation dates of the displaced residents they are training.

In summary, we are proposing to remove the seamless requirement currently included as part of Ranking Criterion One or Three. We also are proposing to remove from the CMS Application Form, the following requirement: ''Hospitals applying for slots under option a) which correlates to Ranking Criterion 1 or b) which correlates to Ranking Criterion 3 must list the names and graduation dates of specific displaced residents who, upon their graduation, have been or will be seamlessly replaced by new residents. This list may be added as an attachment to this application.''

c. Proposed Revisions to Ranking Criteria One, Seven, and Eight for Applications 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 assignment of slots under section 5506 of the Affordable Care Act. 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 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 submitted during 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 indicate a need to further prioritize among the applicants that would have qualified under Ranking Criterion Seven. Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434 through 53437), we finalized changes to the Ranking Criteria, replacing Ranking Criterion Seven with two separate Ranking Criteria (Ranking Criterion Seven and Ranking Criterion Eight) resulting in a total of eight Ranking Criteria. Under the Ranking Criteria, as modified by the FY 2013 IPPS/LTCH PPS final rule, a hospital that is applying both for the purpose of establishing or expanding primary care or general surgery programs, and in addition is requesting slots for the purpose of establishing or expanding nonprimary care or nongeneral surgery programs and/or for cap relief must submit an application requesting additional FTE slots for its primary care or general surgery programs under Ranking Criterion Seven. The hospital's request for additional FTE slots to establish or expand a nonprimary care or nongeneral surgery program and/or for additional FTE slots for cap relief would then be made under Ranking Criterion Eight. Prior to this change, if a hospital applied for additional FTE slots to establish or expand both a primary care or general surgery program in addition to a nonprimary care or nongeneral surgery program and/or for additional FTE slots for cap relief, all of its applications (with the exception of Ranking Criteria One through Three) would fall under Ranking Criteria Seven. For a complete list of the Ranking Criteria, we refer readers to section IV.K.5.a. of the preamble of this proposed rule, which discusses the background for preservation of resident cap positions from closed hospitals under section 5506 of the Affordable Care Act.

After reviewing applications and making awards under several more rounds of section 5506 applications, we have observed that, as hospital closings continue to occur, there has been a significant increase in the time between a hospital's closure and the announcement of section 5506 awards by CMS. We believe that this delay is partly due to the administratively burdensome task of processing, reviewing, and responding to such a large number of applications for each hospital closure, or each round of section 5506 awards. When implementing section 5506 in the November 24, 2010 final rule with comment period (75 FR 72212 through 72249), we initially envisioned the reviewing of applications and awarding of section 5506 FTE slots as being a more streamlined and expedient process. However, as a practical matter, we have found that process has been much more resource and time intensive than we had originally anticipated. This is partly due to the time and resources needed to properly apply the process established by CMS in reviewing section 5506 applications and awarding FTE cap slots. Since the initial implementation of section 5506, we have attempted to be responsive to these unexpected delays by refining the ranking criteria to make the review process less administratively burdensome. However, these changes did not alleviate the process to the desired extent. Furthermore, we have observed that, while many of the applications submitted to CMS are applications requesting FTE slots for purposes of general cap relief, we have more often than not awarded no slots at all for cap relief. This is due in large part to the limited number of slots

available (many of the closed teaching hospitals did not have large FTE resident caps) and an overwhelming demand for those slots from applicants who apply for FTE slots for reasons other than cap relief. Since we finalized the modified Ranking Criterion Seven and added Ranking Criterion Eight in the FY 2013 IPPS/LTCH PPS final rule, we have announced three new rounds of section 5506 applications due to the closures of six hospitals. We have received a total of 424 applications from hospitals seeking cap relief. Of those 424 applications, only 6 applications were ultimately awarded FTE slots, which is only 1.42 percent of the total cap relief applications. We believe that the ratio of cap relief awardees to cap relief applications does not warrant the administrative burden and the delay in announcements of section 5506 awards that result from the large number of cap relief applications submitted to CMS that are invariably denied. Therefore, in an effort to streamline the review process and to facilitate publishing section 5506 awards in a more timely manner, we are proposing to modify Ranking Criterion Eight so that Ranking Criterion Eight would only apply to hospitals seeking FTE slots to establish or expand a nonprimary care or nongeneral surgery program. Ranking Criterion Eight would no longer be applicable to hospitals seeking FTE cap slots for cap relief. Our proposal to eliminate section 5506 awards of FTE slots for cap relief is consistent with current policy goals to increase training in primary care and general surgery. By proposing to eliminate awarding of FTE slots for residents that are already being trained by a hospital, there will be more FTE resident slots available to award to other hospitals seeking to establish or expand a primary care or general surgery program under Ranking Criteria Four through Seven.

Accordingly, we are proposing to revise Ranking Criterion Eight so that it reads as follows:

Proposed Ranking Criterion Eight: The program does not meet Ranking Criteria 1 through 7, and the applying hospital will use additional slots to establish or expand a nonprimary care or a nongeneral surgery program.

In light of the modifications we are proposing to Ranking Criterion Eight, we believe it is also necessary to modify the language of proposed Ranking Criterion Seven to specify the types of applications that would properly be made under this Ranking Criterion; that is, we are proposing to remove the reference to cap relief from Ranking Criterion Seven so that it read as follows:

Proposed Ranking Criterion Seven: The applying hospital will use additional slots to establish or expand a primary care or general surgery program, but the program does not meet Ranking Criterion 5 or 6 because the hospital is also separately applying under Ranking Criterion 8 for slots to establish or expand a nonprimary care or nongeneral surgery program.

Separately, we also are proposing a change related to Ranking Criterion One. Current ranking Criterion One is for an applying hospital that assumed an entire program or programs from the hospital that closed. We are proposing to revise Ranking Criterion One to provide priority to hospitals in one scenario. Section 5503 of the Affordable Care Act amended section 1886(h) of the Act by adding new paragraph (8), which provided for the permanent reduction and distribution of residency slots. Section 1886(h)(8)(A)(ii) of the Act provides specific exceptions to the application of the reduction at section 1886(h)(8)(A)(i) of the Act, and expressly states: ''Exceptions—This subparagraph shall not apply to (I) a hospital located in a rural area (as defined in subsection (d)(2)(D)(ii)) with fewer than 250 acute care inpatient beds.'' The November 24, 2010 final rule with comment period (75 FR 72147) describes the agency's interpretation of this statutory provision. As of the time that this proposed rule is posted on the CMS Web site, we are aware of one instance in which CMS erroneously reduced a hospital's FTE resident cap contrary to this statutory exception. We are proposing to amend Ranking Criterion One under section 5506 to provide priority to a hospital which had FTE resident cap slots erroneously removed under section 5503 contrary to the statutory exception at section 1886(h)(8)(A)(ii)(I) of the Act. We are proposing to revise Ranking Criterion One as follows:

□ *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). The applying hospital's FTE resident caps were erroneously reduced by CMS under section 1886(h)(8)(A)(i) of the Act, contrary to the statutory exception at section 1886(h)(8)(A)(ii)(I) of the Act, and CMS Central Office was made aware of the error prior to posting of the FY 2015 IPPS proposed rule on the CMS Web site.*

d. Clarification to Ranking Criterion Two Regarding Emergency Medicare GME Affiliation Agreements

Ranking Criterion Two gives preference to applying hospitals that received slots under the terms of a Medicare GME affiliation agreement from the closed hospital. Under section 1886(h)(4)(H)(ii) of the Act, hospitals may form a Medicare GME affiliated group and elect to aggregate their respective FTE resident caps and apply them on an aggregate basis. The regulations at 42 CFR 413.75(b) and 413.79(f) implemented this statutory provision, providing specific rules for sharing FTE resident cap slots among members of the Medicare GME affiliated group, one such rule being that member hospitals must have a ''shared rotational arrangement.'' A ''shared rotational arrangement'' is defined at 42 CFR 413.75(b) as a residency training program under which a resident(s) participates in training at two or more hospitals in that program. Specifically, Ranking Criterion Two states the following:

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.

A question has been raised as to whether hospitals that were members of an emergency Medicare GME affiliation agreement with the closed hospital prior to its closure may be considered under Ranking Criterion Two as well. The regulations at 42 CFR 413.79(f)(7)

govern emergency Medicare GME affiliation agreements, which are applicable in the instance where a statutory section 1135 waiver is invoked. In this situation, due to emergency conditions, the ''home'' hospital is unable to continue to train its residents. Therefore, under the terms of the emergency Medicare GME affiliation agreement, the ''home'' hospital may agree to temporarily transfer FTE resident cap slots to ''host'' hospitals that would train the displaced residents during the emergency period.

In the November 24, 2010 final rule with comment period (75 FR 72216), we stated that ''section 1886(h)(4)(H)(vi) of the Act, as added by section 5506(a) of the Affordable Care Act, directs the Secretary to give preference to hospitals that are members of the same affiliated group as the hospital that closed. We believe that, generally, if the applying hospital was affiliated to receive slots from the hospital that closed, then the applying hospital was relying on that number of FTE resident slots that it received in order to maintain its fair share of the cross-training of the residents in the jointly operated programs. In the absence of those slots received from the closed hospital, the applying hospital may not be able to continue training that number of FTE residents, and those same residents would not only be displaced from the closed hospital, but might essentially become 'displaced' from the affiliated hospitals in which they were used to doing a portion of their training. Accordingly, we proposed this ranking criterion to allow hospitals that were affiliated with the closed hospitals to at least maintain their fair share of the training of the residents in the programs that they had jointly operated with the closed hospital.''

In determining whether Ranking Criterion Two may encompass emergency Medicare GME affiliation agreements, we considered the key differences and similarities between regular Medicare GME affiliation agreements and emergency Medicare GME affiliation agreements. Regarding the differences, in the case of emergency affiliations, there may not have been historical cross-training or jointly operated programs between the applicant hospital and the hospital that closed. Furthermore, after the natural disaster that precipitates the section 1135 waiver, the ''home'' hospital would be in no condition to train its share of residents, which is why the ''shared rotational arrangement'' requirements at 42 CFR 413.79(f)(2) for regular Medicare GME affiliation agreements are waived for emergency Medicare GME affiliation agreements. However, it is often true with emergency affiliations that a hospital agrees to take over the training of the hospital in need, ''receiving'' FTE cap slots and residents from the ''home'' hospital, thereby creating the training relationship. In the event where, following the disaster that triggers the section 1135 waiver, a hospital should actually close, the ''host'' hospital that accepted the residents perhaps might even continue to train its share of the residents in the program after the hospital closes. Therefore, emergency affiliation agreements are similar to regular affiliation agreements in that the ''host'' hospital *received* FTE cap slots from the ''home'' hospital to train the ''home'' hospital's residents. Further, in the event that the ''home'' hospital closes, triggering a Round of section 5506, the ''host'' hospital also would need those FTE cap slots in order to continue training the share of its program for which it had taken responsibility under the emergency Medicare GME affiliation agreement before the ''home'' hospital closed.

As we stated in the November 24, 2010 final rule with comment period (75 FR 72219 through 72220), ''we believe the intent of section 5506 is to *promote continuity and limit disruption in residency training.* In that light, we believe it is logical to give preference to a hospital that received slots under the terms of the Medicare GME affiliation agreement *so that the hospital could continue to train at least the number of FTE residents it had trained under the terms of the Medicare GME affiliation agreement, avoiding the displacement of even more residents. . . .*'' We further stated that we ''. . . are only giving preference to hospitals that *received* slots from the closed hospital under the terms of the Medicare GME affiliation agreement, so that the hospital could continue to train at least the number of FTE residents it had trained under the terms of the Medicare GME affiliation agreement. . . .'' Finally, we stated ''that the hospital or hospitals that were most recently affiliated with and received slots from the closed hospital would have the most immediate need for those slots.''

While the circumstances may vary, we believe that ''host'' hospitals under emergency Medicare GME affiliation agreements could fulfill much of the same role as hospitals that received slots from the hospital that closed under regular Medicare GME affiliation agreements. That is, continuity of training would be encouraged and disruption would be mitigated, to the extent that the ''host'' hospital could document to CMS that it would continue to ''train at least the number of FTE residents it had trained under the terms of the'' emergency Medicare GME affiliation agreement, and in doing so, would demonstrate it has the ''most immediate need for those slots'' as compared to another hospital. Given these similarities between regular Medicare GME affiliation agreements and emergency Medicare GME affiliation agreements, we believe that the existing Ranking Criterion Two may be read to already encompass emergency Medicare GME affiliation agreements. Accordingly, we are clarifying the existing Ranking Criterion Two to include emergency Medicare GME affiliation agreements, to read as follows:

☐ *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 or emergency 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 or emergency 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, or emergency Medicare GME affiliation agreement. If the most recent Medicare GME affiliation agreement or emergency 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 or emergency 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.*

We are making these changes to Ranking Criterion Two in the Section 5506 Application Form.

We are including below a revised Section 5506 Application Form that reflects all of the proposed changes discussed above.

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 slots for a particular program, but the requested slots in that program qualify under two different ranking criteria, submit two separate application forms accordingly. If the hospital is applying for slots associated with a Medicare GME affiliation agreement with a hospital that closed, that application must be submitted separately from an individual program request.

NAME OF HOSPITAL: _____

MEDICARE PROVIDER NUMBER (CCN): _____

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. Medicare GME Affiliated Group: ____

(Check one): □ Allopathic Program

□ Osteopathic Program

NUMBER OF FTE SLOTS REQUESTED FOR SPECIFIC PROGRAM (OR OVERALL IF SEEKING SLOTS ASSOCIATED WITH A MEDICARE 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.

Please indicate Y or N: As of the time of submitting this application, are you receiving a temporary cap adjustment for IME and/or direct GME under 42 CFR 413.79(h) for residents displaced by the closure of the hospital subject to this Round of section 5506? (Y/N)_____

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.

Please indicate Y or N: As of the time of submitting this application, are you receiving a temporary cap adjustment for IME and/or direct GME under 42 CFR 413.79(h) for residents displaced by the closure of the hospital subject to this Round of section 5506? (Y/N) _____

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 by Virtue of Medicare GME Affiliated Group Agreement or Emergency 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 ***or emergency 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 ***or emergency 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 ***or emergency Medicare GME affiliation agreement.*** If the most recent Medicare GME affiliation agreement ***or emergency 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 ***or emergency 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 (or emergency 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. Ranking 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). The applying hospital's FTE resident caps were erroneously reduced by CMS under section 1886(h)(8)(A)(i) of the Act, contrary to the statutory exception at section 1886(h)(8)(A)(ii)(I) of the Act, and CMS Central Office was made aware of the error prior to posting of the FY 2015 IPPS proposed rule on the CMS Web site.*

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* ***or emergency 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* ***or emergency 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,* ***or emergency Medicare GME affiliation agreement.*** *If the most recent Medicare GME affiliation agreement* ***or emergency 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* ***or emergency 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 applying hospital will use additional slots to establish or expand a primary care or general surgery program, but the program does not meet Ranking Criterion 5 or 6 because the hospital is also separately applying under Ranking Criterion 8 for slots to establish or expand a nonprimary care or non-general surgery program.*

Ranking Criterion Eight: *The program does not meet Ranking Criteria 1 through 7, and the applying hospital will use additional slots to establish or expand a nonprimary care or a nongeneral surgery program.*

Application Process and CMS Central Office Mailing Address 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. 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, with 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.''

CMS Central Office Mailing Address

Centers for Medicare & Medicaid Services (CMS)
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6. Proposed Clarification and Policy Change Applicable To Direct GME Payments to Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) for Training Residents in Approved Programs

Under section 1886(k) of the Act, and as implemented in the regulations at 42 CFR 405.2468(f), federally qualified health centers (FQHCs) and rural health clinics (RHCs) may receive payment for the costs of direct GME for training residents in an approved program under certain circumstances. Specifically, the regulations at § 405.2468(f)(1) state: ''Effective for that portion of cost reporting periods occurring on or after January 1, 1999, if an RHC or an FQHC incurs 'all or substantially all' of the costs for the training program in the nonhospital setting as defined in § 413.75(b) of this chapter, the RHC or FQHC may receive direct graduate medical education payment for those residents.'' We refer readers to the July 31, 1998 final rule (63 FR 40986) for a detailed discussion of this longstanding policy. As noted earlier, the regulatory text of § 405.2468(f)(1) incorporates the definition of ''all or substantially all of the costs for the training program in a nonhospital setting'' that is defined at § 413.75(b), as part of a number of definitions applicable generally to hospital direct GME payments and those regulations at § 413.76 through § 413.83. Section 413.75(b) is based on the statutory provision at section 1886(h)(4)(E) of the Act, which establishes the requirements that hospitals must meet in order to receive direct GME payment for residents training in nonprovider settings.

The statutory use of the phrase ''all or substantially all of the costs for the training program in that setting'' is located in section 1886(h)(4)(E) of the Act, as added by section 9314 of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509) (OBRA '86). For a detailed discussion of the implementation of section 9314 of OBRA '86, we refer readers to the September 29, 1989 final rule (54 FR 40292). Section 1886(h)(4)(E) of the Act, as added by OBRA '86, established the requirements that hospitals must meet in order to receive direct GME payment for residents training in nonprovider settings. However, section 5504(a) of the Affordable Care Act made changes to section 1886(h)(4)(E) of the Act to reduce the costs that hospitals must incur for residents training in nonprovider sites in order to count the FTE residents for purposes of direct GME payments. In making these changes to section 1886(h)(4)(E) of the Act, section 5504(a) of the Affordable Care Act amended the Act prospectively, effective with ''cost reporting periods beginning on or after July 1, 2010'' for direct GME, by removing the phrase ''all or substantially all of the costs for the training program in that setting'' and instead permitting hospitals to count the time that residents train in activities related to patient care in a nonprovider site if the hospital incurs the costs of the residents' salaries and fringe benefits for the time that the resident spends training in the nonprovider site. In effect, this amendment reduced the costs that hospitals must incur for residents training in nonprovider settings.

Based on this statutory amendment, in the November 24, 2010 final rule with comment period (75 FR 72134), we revised the regulations at § 412.105(f)(1)(ii)(E) for IME and §§ 413.78(f) and (g) for direct GME to reflect the changes made by section 5504(a) of the Affordable Care Act. In addition, we revised the regulatory definition of ''all or substantially all of the costs for the training program in the nonhospital setting'' in order to implement the statutory amendment and apply the effective date as set forth in the statute to cost reporting periods beginning on or after July 1, 2010. Specifically, the regulations at § 413.75(b), which define ''all or substantially all of the costs for the training program in the nonhospital setting'' were revised as follows:

''(1) Effective on or after January 1, 1999 and for cost reporting periods beginning before July 1, 2007, the residents' salaries and fringe benefits (including travel and lodging where applicable) and the portion of the cost of teaching physicians' salaries and fringe benefits attributable to direct graduate medical education (GME); and

''(2) Effective for cost reporting periods beginning on or after July 1, 2007 and before July 1, 2010, at least 90 percent of the total of the costs of the residents' salaries and fringe benefits (including travel and lodging where applicable) and the portion of the cost of teaching physicians' salaries attributable to nonpatient care direct GME activities.''

Ultimately, with regard to the costs that hospitals must incur for residents training in nonprovider sites in order to count the FTE residents for purposes of direct GME payments, the phrase ''all or substantially all of the costs for the training program in the nonhospital setting'' no longer applies, effective for cost reporting periods beginning on and after July 1, 2010.

In the November 24, 2010 final rule with comment period (75 FR 72134), we amended the regulations applicable to direct GME payments to hospitals at §§ 413.75(b) and 413.78(g) to reflect the changes made by section 5504(a) of the Affordable Care Act. However, at that time, we inadvertently did not make conforming changes to the regulations at § 405.2468(f)(1) to clarify the requirements that FQHCs and RHCs must meet in order to receive direct GME payment for training residents in their facilities. Therefore, in compliance with our longstanding policy that FQHCs and RHCs must meet the same requirements applicable to teaching hospitals for direct GME payments with respect to training residents in nonprovider settings, in this proposed rule, we are providing clarification that, based on statutory amendments discussed earlier, the applicable policy cross-referenced in § 405.2468(f)(1) has changed for cost reporting periods beginning on or after July 1, 2010. In addition, to ensure statutory and regulatory consistency, we are proposing to revise the regulations at § 405.2468(f)(1) to add a sentence at the end of the paragraph as follows: ''However, in connection with cost reporting periods for which 'all or substantially all of the costs for the training program in the nonhospital setting' is not defined in § 413.75(b) of this chapter, if an RHC or an FQHC incurs the salaries and fringe benefits (including travel and lodging where applicable) of residents training at the RHC or FQHC, the RHC or FQHC may receive direct graduate medical education payment for those residents.''

L. 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 reporting periods 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 hospital 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 seven 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 Pub. L. 108–173, as added by section 3123(a) and amended by section 10313 of the Affordable Care Act). Further, the Secretary is required to use the same criteria and data that the Secretary used to determine the States under section 410A(a)(2) of Public Law 108–173 for purposes of the initial 5-year period. The Affordable Care Act also allows not more than 30 rural community hospitals in such States to participate in the demonstration program during the 5-year extension period (section 410A(g)(3) of 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 were 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 reporting periods for which they would have begun the demonstration. In addition to the 7 hospitals that were selected in either 2004 or 2008, the new selection led to a total of 23 hospitals in the demonstration. During CY 2013, one additional hospital among the set selected in 2011 withdrew from the demonstration, similarly citing a relative financial advantage to returning to the customary SCH payment methodology, which left 22 hospitals participating 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 10 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 2014 IPPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, and 78 FR 50740, 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, in this FY 2015 IPPS/LTCH PPS proposed rule, we are proposing to continue to use the methodology we finalized in FY 2013 to calculate a budget neutrality adjustment factor to the FY 2015 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. Prior to FY 2013, 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. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53452), we used ''as submitted'' cost reports (for cost reporting periods ending in CY 2010) for each hospital participating in the demonstration in estimating the costs of the demonstration. In addition, in FY 2013, we incorporated 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. Finally, in each of the previous years, 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 rules for FYs 2012, 2013, and 2014, 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. (We note that section 410A of Pub. L. 108–173 was later amended by the Affordable Care Act.) The reasonable cost-based methodology authorized by section 410A of Public Law 108–173, as amended, is hereafter referred to as the ''reasonable cost methodology.'' (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 adjustment. For the FY 2010 IPPS/RY 2010 LTCH PPS 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/RY 2010 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/RY 2010 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 noted in the FYs 2011, 2012, and 2013 IPPS final rules that, because of a delay affecting the settlement process for cost reports for IPPS hospitals occurring on a larger scale than merely for the demonstration, we were 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.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53449 through 53453), we adopted changes to the methodology for calculating the budget neutrality offset amount in an effort to further improve and refine it. We noted that the revised methodology varied, in part, from that finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51698 through

51705). Specifically, in adopting refinements to the methodology, our objective was to simplify the calculation so that it included as few steps as possible. In addition, we incorporated 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. We stated that we believed this approach would maximize the precision of our calculation because it would more closely replicate payments made with and without the demonstration. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53449 through 53453) for a detailed discussion of the methodology we used for FY 2013. We noted that, although we were making changes to certain aspects of the budget neutrality offset amount calculation for FY 2013, several core components of the methodology would remain unchanged. For example, we continued to include in the budget neutrality offset amount methodology the estimate of the demonstration costs for the upcoming fiscal year and the amount by which the actual demonstration costs corresponding to an earlier year (which would be determined 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, finalized cost reports for the hospitals participating in the demonstration were not available for FYs 2007, 2008, 2009, and 2010 at the time of development of the FY 2013 IPPS/LTCH PPS final rule. Therefore, we were unable to finalize this component of the budget neutrality offset calculation. We stated in the final rule that we expected settled cost reports for all of the demonstration hospitals that participated in the applicable fiscal year (FYs 2007, 2008, 2009, and 2010) to be available prior to the FY 2014 IPPS/LTCH PPS proposed rule.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50739 through 50744), we determined the final budget neutrality offset amount to be applied to the FY 2014 IPPS rates to be $52,589,741. This amount was comprised of two distinct components: (1) the final resulting difference between the estimated reasonable cost amount to be paid under the demonstration to the 22 participating hospitals in FY 2014 for covered inpatient hospital services and the estimated amount that would otherwise be paid to such hospitals in FY 2014 without the demonstration (this amount was $46,549,861); and (2) the amount by which the actual costs of the demonstration for FY 2007, as shown in the finalized cost reports for the hospitals that participated in the demonstration during FY 2007, exceeded the budget neutrality offset amount that was finalized in the FY 2007 IPPS final rule (this amount, $6,039,880, was derived from finalized cost reports for cost reporting periods beginning in FY 2007 for the 9 hospitals that participated in the demonstration during that year).

2. Proposed FY 2015 Budget Neutrality Offset Amount

For the reasons discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53449 through 53453), we are proposing in this FY 2015 IPPS/LTCH PPS proposed rule to continue to use the methodology finalized in the FY 2013 IPPS/LTCH PPS final rule to calculate a budget neutrality adjustment factor to be applied to the FY 2015 national IPPS payment rates. As we stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53451), we revised our methodology in that final rule to further improve and refine the calculation of the budget neutrality offset amount and to simplify the methodology so that it includes only a few steps. Consistent with the methodology finalized in the FY 2013 IPPS/LTCH PPS final rule, the proposed methodology for calculating the estimated FY 2015 demonstration cost for the participating hospitals is as follows:

Step 1: For each of the 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 2012). The general reasonable cost amount calculated under the reasonable cost methodology is hereafter referred to as the ''reasonable cost amount.'' As we explained in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53451), we believe that a way to streamline our methodology for calculating the budget neutrality offset amount would be to use cost reports with the same status and from the same time period for all hospitals participating in the demonstration. Because ''as submitted'' cost reports ending in CY 2012 are the most recent available cost reports, we believe they would be an accurate predictor of the costs of the demonstration in FY 2015 because they give us a recent picture of the participating hospitals' costs.

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 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 2012 reasonable cost amount for covered inpatient hospital 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 2012 for this calculation.

We are proposing to sum the two above-referenced amounts to calculate the general total estimated FY 2012 reasonable cost amount for covered inpatient hospital services for all participating hospitals.

We are proposing to multiply this sum (that is, the general total estimated FY 2012 reasonable cost amount for covered inpatient hospital services for all participating hospitals) by the FY 2013, FY 2014, and FY 2015 IPPS market basket percentage increases, which are formulated by the CMS Office of the Actuary. In this proposed rule, the current estimate of the FY 2015 IPPS market basket percentage increase provided by the CMS Office of the Actuary is specified in section IV.B.1. of the preamble of this proposed rule. We are proposing to use the final FY 2015 IPPS market basket percentage increase in the final rule. We also are proposing to then multiply the product of the general total estimated FY 2012 reasonable cost amount for all participating hospitals and the market basket percentage increases applicable to the years involved by a 3-percent annual volume adjustment for FYs 2013 through 2015—the result would be the general total estimated FY 2015 reasonable cost amount for covered inpatient hospital services for all participating hospitals.

We are proposing to apply the IPPS market basket percentage increases applicable for FYs 2013 through 2015 to the FY 2012 reasonable cost amount described above to model the estimated FY 2015 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 by the CMS Office of the Actuary and is being 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 participating hospitals, we are proposing to identify the general estimated amount that would otherwise be paid in FY 2012 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 2012) 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 2012) and include it in the total FY 2012 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 2012 total payments that generally would otherwise be paid for covered inpatient hospital services for all participating hospitals without the demonstration.

We are proposing to multiply the above amount (that is, the estimated FY 2012 total payments that generally would otherwise be paid for covered inpatient hospital services for all participating hospitals without the demonstration) by the FYs 2013 through 2015 IPPS applicable percentage increases. In this proposed rule, the current estimate of the FY 2015 applicable percentage increase is specified in section IV.B. of this preamble. 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 2012 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 are proposing to use the final FY 2015 applicable percentage increase in the final rule.) Then we are proposing to multiply the product of the estimated FY 2012 total payments that generally would otherwise be made without the demonstration and the applicable IPPS percentage increases for the years involved by a 3-percent annual volume adjustment for FYs 2013 through 2015. The result would be the general total estimated FY 2015 costs that would otherwise be paid without the demonstration for covered inpatient hospital services to the participating hospitals.

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 participating hospitals for covered inpatient hospital services for FY 2015 if the demonstration were 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 participating hospitals for covered inpatient hospital services for FY 2015). We are proposing that the resulting difference would be one component of the estimated amount for which an adjustment to the national IPPS rates would be calculated (as further discussed below).

For this proposed rule, the resulting difference is $53,673,008. This estimated amount is based on the specific assumptions identified regarding the data sources used, that is, ''as submitted'' recently available cost reports. Also, we note that if updated data become available prior to the FY 2015 IPPS/LTCH PPS final rule, we would use them to the extent appropriate to estimate the costs of the demonstration program in FY 2015. Therefore, this estimated budget neutrality offset amount might change in the final rule, depending on the availability of updated data.

In addition, similar to previous years, we are proposing to include in the budget neutrality offset amount the amount by which the actual demonstration costs corresponding to an earlier given year (which would be determined once we had finalized cost reports for that year) exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule. For this FY 2015 IPPS/LTCH PPS proposed rule, we have calculated the amount by which the actual costs of the demonstration in FY 2008 (that is, the costs of the demonstration for the 10 hospitals that participated in FY 2008, as shown in these hospitals' finalized cost reports for the cost report period beginning in that fiscal year), exceeded the budget neutrality offset amount that was finalized in the FY 2008 IPPS final rule. We have calculated this amount to be $10,389,771 for this proposed rule. However, we are noting that if updated data become available prior to the FY 2015 IPPS/LTCH PPS final rule, we would use them to the extent appropriate to determine this amount. Therefore, this amount might change in the final rule, depending on the availability of updated data. We also are currently working with the MACs that service the hospitals participating in the demonstration to obtain finalized cost reports for FYs 2009, 2010, and 2011. Similar to previous years, we are proposing that if settled cost reports for all of the demonstration hospitals that participated in an applicable year (FYs 2009, 2010, or 2011) are available prior to the FY 2015 IPPS/LTCH PPS final rule, we would include in the budget neutrality offset amount any additional amounts by which the final settled costs of the demonstration for the year (FYs 2009, 2010, or 2011) exceed the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule.

Therefore, the total budget neutrality offset amount that we are proposing to be applied to the FY 2015 IPPS rates is $64,062,779. This is the sum of two separate components: (1) The difference between the total estimated FY 2015 reasonable cost amount to be paid under the demonstration to the 22 participating hospitals for covered inpatient hospital services and the total estimated amount that would otherwise be paid to the participating hospitals in FY 2015 without the demonstration ($53,673,008); and (2) the amount by which the actual costs of the demonstration for FY 2008 (as shown in the finalized cost reports for cost reporting periods beginning in FY 2008 for the hospitals that participated in the demonstration during FY 2008) exceed the budget neutrality offset amount that was finalized in the FY 2008 IPPS final rule ($10,389,771). We are proposing that the resulting total ($64,062,779) would be the amount for which an adjustment to the national IPPS rates would be calculated.

M. Requirement for Transparency of Hospital Charges Under the Affordable Care Act

1. Overview

Hospitals determine their charges for items and services provided to patients. While Medicare does not pay billed charges, hospital reported charges are used in determining Medicare's national payment rates (for example, billed charges are adjusted to cost to determine how much to pay for one type of case relative to another). Although the Medicare payment amount for a discharge under the IPPS or a service furnished under the OPPS is not based directly on the hospital's charges for the individual services provided, we believe that hospital charges nevertheless remain an important component of our healthcare system. For example, hospital charges are often billed, in full, to uninsured patients who cannot benefit from discounts negotiated by insurance companies. Hospital charges also vary significantly by hospital, making it challenging for patients to compare the cost of similar services across hospitals.

In 2013, we released data that demonstrated significant variation across the country and within communities in what hospitals charge for a number of common inpatient and outpatient services. These data also showed that hospital charges for services furnished in both the inpatient setting and the outpatient setting were, in general, significantly higher than the amount paid by Medicare under the IPPS or the OPPS. The data that we released are posted on the Web site at: *https://www/cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/index.html*. Our intent in releasing these data was to enable the public to examine the relationship between the amounts charged by individual hospitals for comparable services and Medicare's payment for that inpatient or outpatient care. We believe that providing charge data comparisons is introducing both transparency and accountability to hospital pricing, and we are continuing to pursue opportunities to report on hospital charging practices.

2. Transparency Requirement Under the Affordable Care Act

The Affordable Care Act contains a provision that is consistent with our effort to improve the transparency of hospital charges. As a result of the Affordable Care Act, section 2718(e) of the Public Health Service Act requires that ''[e]ach hospital operating within the United States shall for each year establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act.''

In this proposed rule, we are reminding hospitals of their obligation to comply with the provisions of section 2718(e) of the Public Health Service Act. Hospitals are responsible for establishing their charges and are in the best position to determine the exact manner and method by which to make those charges available to the public. Therefore, we are providing hospitals with the flexibility to determine how they make a list of their standard charges public. Our guidelines for implementing section 2718(e) of the Public Health Service Act are that hospitals either make public a list of their standard charges (whether that be the chargemaster itself or in another form of their choice), or their policies for allowing the public to view a list of those charges in response to an inquiry. We encourage hospitals to undertake efforts to engage in consumer friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain at the hospital, and to enable patients to compare charges for similar services across hospitals. We expect that hospitals will update the information at least annually, or more often as appropriate, to reflect current charges.

We are confident that hospital compliance with this statutory transparency requirement will greatly improve the public accessibility of charge information. As hospitals make data publicly available in compliance with section 2718(e) of the Public Health Service Act, we also will continue to review and post relevant charge data in a consumer friendly way, as we previously have done by posting on the CMS Web site the following hospital and physician charge information: May and June 2013 hospital charge data releases; 2013 physician data requests for information; and the April 2014 physician data releases and data provided on geographic variation in payments and payments per beneficiary.

N. Medicare Payment for Short Inpatient Hospital Stays

Some members of the hospital community have expressed support for the general concept of an alternative payment methodology under the Medicare program for short inpatient hospital stays. We are interested in public comments on such a payment methodology, specifically how it might be designed. There are several issues of consideration that would inform how such a payment methodology would be devised. Below we outline some specific questions and considerations that we have identified as critical for developing such a methodology. This list of questions and considerations is not exhaustive, and we welcome additional questions, suggestions, and input from stakeholders.

- *Defining short or low cost inpatient hospital stays:*

One issue would be how to define a short inpatient hospital stay for the purpose of determining the appropriate Medicare payment. For instance, would a short inpatient hospital stay be one where the average length of stay for the MS–DRG is short or would it be atypically short or low cost cases relative to other cases within same MS–DRG? There are significant differences in mean lengths of stay among MS–DRGs. (We refer readers to Table 5.—List of Proposed Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay for this proposed rule, which is available via the Internet on the CMS Web site.) For example, many frequently billed MS–DRGs have historically had mean lengths of stay of approximately 2 days, such as MS–DRG 313 (Chest Pain). Other MS–DRGs such as MS–DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation 96+ hours with MCC) have had longer lengths of stay.

If we adopted a policy that paid less for atypically low-cost or short-stay cases relative to the average case in the same MS–DRG, we believe such a policy is more likely to affect an MS–DRG like MS–DRG 871 that has a longer average length of stay or higher average cost associated with the typical patient. Such a policy is less likely to apply to MS–DRG 313 because the typical case is already low cost or short stay.

- *Determining appropriate payment for short inpatient hospital stays:*

Another issue would be how to determine the appropriate payment once a short stay has been identified. Some have suggested a per diem based payment amount, perhaps modelled on the existing transfer payment policy. Again, such a policy is far more likely to affect payment for an atypically short-stay or low-cost case in an MS–DRG with a longer average length of stay. For short-stay cases in an MS–DRG where the average length of stay for the MS–DRG is short, this methodology would

be unlikely to affect payment as the full IPPS payment would be made in 1 or 2 days.

For these types of short-stay cases, one relevant issue to address may be that payment for the same case will be very different under the OPPS and the IPPS depending upon whether the patient has been formally admitted to the hospital as an inpatient, pursuant to a physician order. Under what circumstances should the IPPS payment amount be limited to the OPPS payment amount and under what circumstances might it be appropriate for the payment amount to be higher? If it were appropriate for the payment amount to be higher, how would the amount of the additional payment be determined?

We welcome input on these and other issues related to an alternative payment methodology under the Medicare program for short inpatient hospital stays.

O. Suggested Exceptions to the 2-Midnight Benchmark

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954), we discussed modifications and clarifications to CMS' longstanding policy on how Medicare contractors review inpatient hospital and CAH admissions for payment purposes. Under that final rule, we established a 2-midnight benchmark for determining the appropriateness of an inpatient hospital admission versus treatment on an outpatient basis. We provided in regulations at § 412.3(e)(1) that, in addition to services designated as inpatient only, surgical procedures, diagnostic tests, and other treatments are generally appropriate for inpatient hospital admission and payment under Medicare Part A when the physician (1) expects the beneficiary to require a medically necessary hospital stay that crosses at least 2 midnights and (2) admits the beneficiary to the hospital based upon that expectation. The FY 2014 policy responded to both hospital calls for more guidance about when an inpatient admission and Part A payment are appropriate, and beneficiaries' concerns about increasingly long stays as outpatients due to hospital uncertainties about payment.

In the FY 2014 IPPS/LTCH PPS final rule, at § 412.3(e)(2), we recognized that if an unforeseen circumstance, such as a beneficiary's death or transfer, results in a shorter beneficiary stay than the physician's expectation of at least 2 midnights, the patient may be considered to be appropriately treated on an inpatient basis and hospital inpatient payment may be made under Medicare Part A. We also clarified, in both the final rule and subsequent subregulatory guidance, that the unforeseen circumstances specified at § 412.3(e)(2) are not all-inclusive and could also include additional circumstances such as unexpected clinical improvement, election of hospice care, or departure against medical advice.

The FY 2014 IPPS/LTCH PPS final rule also indicated that there are exceptions to the 2-midnight benchmark. In other words, we expect there to be cases in which an admitting practitioner expects the beneficiary's length of stay to last less than 2 midnights and yet inpatient admission would still be appropriate. For example, we specified that procedures on the OPPS inpatient only list are always appropriately inpatient, regardless of the actual time expected at the hospital, so long as the procedure is medically necessary and performed pursuant to a physician order and formal admission.

In addition to procedures contained on the OPPS inpatient only list, we noted in the FY 2014 IPPS/LTCH PPS final rule that there may be other rare and unusual circumstances in which a hospital stay expected to last less than 2 midnights would nonetheless be appropriate for inpatient hospital admission and Part A payment. We indicated that we would explore other potential exceptions to the generally applicable benchmark and would detail any such rare and unusual circumstances in subregulatory guidance. As part of this process, throughout the year, we have accepted and considered suggestions from stakeholders on this topic.

In January 2014, we identified medically necessary, newly initiated mechanical ventilation (excluding anticipated intubations related to minor surgical procedures or other treatment) as the first rare and unusual exception to the 2-midnight rule and announced it on the CMS Web site.

We recognize that there could be additional rare and unusual circumstances that we have not identified that justify inpatient admission and Part A payment absent an expectation of care spanning at least 2 midnights and are inviting further feedback on this issue. Suggestions can be sent to CMS via written correspondence or emailed to *SuggestedExceptions@cms.hhs.gov* with ''Suggested Exceptions to the 2-Midnight Benchmark'' in the subject line. We will continue to respond to these suggestions through subregulatory guidance, such as postings on the CMS Web site or manual instruction.

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, FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, § 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 allowable Medicare inpatient hospital capital-related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. 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 Annual Update for FY 2015

The proposed annual update to the capital PPS Federal and Puerto Rico-specific rates, as provided for at § 412.308(c), for FY 2015 is discussed in section III. of the Addendum to this proposed rule.

We note that, in section II.D. of the preamble of this proposed rule, we present a discussion of the MS–DRG documentation and coding adjustment, including previously finalized policies and historical adjustments, as well as the recoupment adjustment to the standardized amounts under section 1886(d) of the Act that we are proposing for FY 2015 in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 631 of the ATRA. Because section 631 of the ATRA requires CMS to make a recoupment adjustment only to the operating IPPS standardized amount, we are not proposing a similar adjustment to the national or Puerto Rico capital IPPS rates (or to the operating IPPS hospital-specific rates or Puerto Rico-specific standardized amount). This approach is consistent with our historical approach regarding the application of the recoupment adjustment authorized by section 7(b)(1)(B) of Public Law 110–90.

In section II.D.7. of the preamble of this proposed rule, we also note our discussion in the FY 2014 IPPS/LTCH PPS final rule of the possibility of applying an additional prospective adjustment to account for the cumulative MS–DRG documentation and coding effect through FY 2010. In that same final rule (78 FR 50515 through 50517 and 50747), we stated that if we were to apply an additional prospective adjustment for the cumulative MS–DRG documentation and coding effect through FY 2010, we believe the most appropriate additional adjustment is −0.55 percent. We did not apply an additional prospective adjustment in FY 2014 for the cumulative MS–DRG documentation and coding effect through FY 2010, consistent with the approach taken for the operating IPPS standardized amount (and hospital-specific rates). We continue to believe that if we were to apply an additional prospective adjustment for the cumulative MS–DRG documentation and coding effect through FY 2010, the most appropriate additional adjustment is −0.55 percent. However, we are not proposing such an adjustment to the capital Federal rate in FY 2015, consistent with the approach taken for the operating IPPS standardized amount (and hospital-specific rates) as discussed in section II.D.7. of the preamble of this proposed rule. We will consider whether such an adjustment to the capital IPPS Federal rate is appropriate in future years' rulemaking.

VI. Proposed Changes for Hospitals Excluded from the IPPS

A. Proposed Rate-of-Increase in Payments to Excluded Hospitals for FY 2015

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting period, the updated target amount is multiplied by total Medicare discharges during that period and applies as an aggregate upper limit (the ceiling as defined in § 413.40(a) of total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, RNHCIs also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed above.

As explained in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50747), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, cancer hospitals, and RNHCIs. Consistent with §§ 412.23(g), 413.40(a)(2)(ii)(A), and 413.40(c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update the target amounts for short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. For the reasons explained in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50747), we are proposing to continue to use the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern

Mariana Islands, and American Samoa for FY 2015 and subsequent fiscal years.

In addition, because we have revised and rebased the IPPS operating market basket to a FY 2010 base year, we are proposing to continue to use the percentage increase in the FY 2010-based IPPS operating market basket to update these target amounts for FY 2015 and subsequent fiscal years. (We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50596 through 50603) for a further discussion of the revision and rebasing of the IPPS operating market to a FY–2010 base year.) Accordingly, for FY 2015, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa would be the FY 2015 percentage increase in the FY 2010-based IPPS operating market basket.

For this proposed rule, based on IHS Global Insight, Inc.'s 2014 first quarter forecast, we estimated that the FY 2010-based IPPS operating market basket update for FY 2015 is 2.7 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 2015.

B. Proposed Updates to the Reasonable Compensation Equivalent (RCE) Limits on Compensation for Physician Services Provided in Providers (§ 415.70)

1. Background

Under section 1848 of the Act and 42 CFR Parts 414 and 415, medical or surgical services furnished by physicians to individual Medicare beneficiaries generally are billed and paid under Medicare Part B on a fee-for-service basis under the Medicare Physician Fee Schedule (MPFS). As required by section 1887(a)(2)(B) of the Act, the amount of allowable compensation for services furnished by physicians to providers that are paid by Medicare on a reasonable cost basis is subject to reasonable compensation equivalent (RCE) limits. Under these limits, Medicare recognizes as reasonable, for purposes of payment to the provider, the lower of the actual cost of the services furnished by the physician to the provider (that is, any form of compensation to the physician) or an RCE. The allowable compensation costs for physicians' services to a provider are described in § 415.55 of the regulations. Under § 415.60(a) of the regulations, for purposes of applying the RCE limits, ''*physician compensation costs* means monetary payments, fringe benefits, deferred compensation, and any other items of value (excluding office space and billing and collection services) that a provider or other organization furnishes a physician in return for the physician's services'' to the provider.

On March 2, 1983, we published a final rule in the **Federal Register** that codified regulations to implement section 1887(a)(2)(B) of the Act (currently at 42 CFR 415.70) and established the first set of RCE limits (48 FR 8902). In accordance with § 415.70(a)(2), RCE limits do not apply to the costs of physician compensation attributable to furnishing inpatient hospital services for which payment is made under the IPPS or to the costs of physician compensation attributable to approved GME programs that are payable under §§ 413.75 through 413.83 of the regulations. In addition, under § 415.70(a)(3), compensation that a physician receives for activities that may not be paid for under either Medicare Part A or Part B is not considered in applying these RCE limits. Furthermore, in accordance with § 413.70, RCE limits are not used in determining the reasonable costs that CAHs incur in compensating physicians for services furnished to the CAH.

The RCE limits apply equally to all physicians' services to providers that are payable on a reasonable cost basis under Medicare. If a physician receives any compensation from one or more providers for his or her services to the provider (that is, those services that benefit patients generally), payment to those providers for the costs of such compensation is subject to the RCE limits. The RCE limits are not applied to payment for services that are identifiable medical or surgical services to individual patients and paid under the MPFS, even if the physician agrees to accept compensation (for example, from a hospital) for those services. Payments to teaching hospitals that have elected to be paid for physicians' services to the provider on a reasonable cost basis in accordance with section 1861(b)(7) of the Act are subject to the limits (68 FR 45458).

2. Overview of the Current RCE Limits

a. Application of the RCE Limits

Currently, we use the RCE limits to compute Medicare payments when a physician is compensated by a provider that is subject to the RCE limits. We also use these limits when the physician is compensated by any other provider-related organization for physician administrative, supervisory, and other services to the provider under Medicare. In applying the RCE limits, we compute the Medicare payments using information submitted on the cost report, and ensure that each compensated physician is assigned to the most appropriate specialty category. The current physician specialty categories for RCE limits are General/Family Practice, Internal Medicine, Surgery, Pediatrics, OB/GYN, Radiology, Psychiatry, Anesthesiology, Pathology, and Total. If there is no specific specialty category (for example, for an emergency room physician), we use the ''Total'' category, for which the RCE limits are calculated based on mean annual income data for all physicians.

If the physician's contractual compensation covers all duties, activities, and services furnished to the provider and, under a reassignment, all physicians' services furnished to individual patients of the provider, and the physician is employed by the provider full time, we use the RCE limit for the appropriate specialty, adjusted by the physician's allocation agreement (which reflects the percentage of total time spent performing services furnished to the provider) to arrive at the Medicare program's share of the provider's allowable physician compensation costs (§ 415.60). In the absence of an allocation agreement, we would assume that 100 percent of the compensation paid to the physician by the provider is related to physicians' services for which payment is made under the MPFS and that there are no allowable physician compensation costs to the provider (§ 415.60(f)(2)).

If a physician's compensation from the provider represents payment only for services that benefit patients generally (that is, the physician bills for all services furnished to individual patients), we use the appropriate specialty RCE limit. If a physician is employed by a provider to furnish services of general benefit to patients on other than a full-time basis, the RCE limit will be adjusted to reflect the hours the physician actually worked, as reported on the provider's cost report, related to a full work year of 2,080 hours.

b. Exceptions to the RCE Limits

Some providers such as small or rural hospitals may be unable to recruit or maintain an adequate number of physicians at a compensation level within the prescribed RCE limits. In accordance with section 1887(a)(2)(C) of the Act and § 415.70(e) of the regulations, if a provider can demonstrate to the MAC its inability to

recruit or maintain physicians at a compensation level allowable under the RCE limits (as documented, for example, by unsuccessful advertising through national medical or health care publications), the MAC may grant the provider an exception to the RCE limits established under these rules. Such exceptions would allow the provider to be paid based on costs for compensation higher than the RCE limit.

c. Methodology for Establishing the RCE Limits

In the March 2, 1983 final rule with comment period (48 FR 8902), we published the initial RCE limits, along with the methodology used to calculate those limits, that were applicable to cost reporting periods beginning during CYs 1982 and 1983. As part of that same rule, we established regulations that outline our general authority to develop, publish, and apply RCE limits (currently at § 415.70). Section 415.70(b) of the regulations specifies that we establish the methodology for determining annual RCE limits, considering, to the extent possible, average physician incomes by specialty and type of location, using the best available data.

The methodology for establishing the initial RCE limits was based on the analysis contained in an internal working paper, ''A Methodology for Determination of Reasonable FTE Compensation for Hospital-Based Physicians.'' [43] (Copies of this working paper are available on the CMS Web site at: *http://www.cms.gov/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.) As outlined in this working paper, our methodology for establishing the initial reasonable levels of compensation includes the following five steps (for additional discussion of this methodology, we refer readers to the March 2, 1983 final rule with comment period (48 FR 8902)):

Step 1: We estimated the national average (mean) income for all physicians using 1979 physician net incomes from the American Medical Association (AMA) Periodic Survey of Physicians (PSP), published by the AMA in its *Profile of Medical Practices,* 1981.

Step 2: We projected physicians' 1979 base net income levels to the appropriate future year to account for changes in net income levels occurring after the period for which we have data using the Consumer Price Index for All Urban Consumers (CPI–U), and projected the results using forecasts of the CPI–U for future years.

Step 3: We determined the relationship between average net income for all physicians (estimated in the first step above) and net income of certain categories of specialist physicians that are commonly compensated by providers for services that generally benefit Medicare beneficiaries resulting in separate specialty adjusters for nine physician specialties as well as the adjuster for the ''Total'' category.

Step 4: We also adjusted each of these specialty (including the ''Total'') adjusters for differences in costs between types of geographic locations using Standard Metropolitan Statistical Areas (SMSAs) as defined by the Office of Management and Budget (OMB).

Step 5: Using the AMA PSP data, we calculated the average hours practiced per year for each specialty and location adjuster combination, which we then related to a standard full-time equivalent (FTE) work year of 2,080 hours. We used these ratios to weight the specialty-location adjusters from the previous step.

This same methodology was used to update the RCE limits published in a notice in the **Federal Register** on May 5, 1997 (62 FR 24483). These updated RCE limits were effective for cost reporting periods beginning on or after May 5, 1997.

For RCE limits established prior to January 1, 1998, we used the CPI–U to update the RCE limits. In a final rule with comment period published in the **Federal Register** on October 31, 1997 (62 FR 59075), we finalized a policy to use the Medicare Economic Index (MEI) to update the RCE limits (rather than the CPI–U), effective for cost reporting periods beginning on or after January 1, 1998. We adopted the MEI as the applicable update factor in order to achieve a measure of consistency in the methodologies used to determine payments to physicians for medical and surgical services furnished to individual patients and reasonable compensation levels for services that are of general benefit to a provider's patients. However, we did not update the RCE limits at that time.

In the FY 2004 IPPS final rule published in the **Federal Register** on August 1, 2003 (68 FR 45458), we published updated RCE limits that were effective for cost reporting periods beginning on or after January 1, 2004. We updated the RCE limits using the CPI–U to adjust the data to 1997, and the MEI to adjust the data from 1998 to 2004. In addition, we continued to adjust the RCE limits to account for differences in salary levels by location, as well as by specialty. For the location adjustment, we continued to base the geographical classifications of the providers on Metropolitan Statistical Areas (MSAs) (the OMB changed the area name to describe metropolitan areas in the 1980's from SMSAs to MSAs, but the definition of MSAs differed only slightly from the previously used SMSAs).

3. Proposed Changes to the RCE Limits

In accordance with § 415.70(b), when establishing the methodology to determine the RCE limits, we consider, to the extent possible, the average physician incomes by specialty and type of location using the best available data. Since the initial RCE limits were developed, we have adjusted the RCE data to account for specialty and location (as discussed earlier in this section). In this proposed rule, we are proposing to use the most recent MEI data to update the RCE limits and to replace the RCE limits that have been in effect since January 1, 2004. We believe that doing so will enhance the accuracy of the RCE limits. In addition, for the reasons discussed below, we are proposing to eliminate the location adjustment to the RCE data, while continuing to adjust the RCE limits by specialty. We are not proposing changes to any of the other existing policies with respect to the application of and exceptions to the RCE limits.

In establishing the initial and subsequently updated RCE limits, we included an adjustment to account for differences in salary levels based on the location of the provider using geographic classifications based on the MSAs as defined by the OMB. We assigned an appropriate MSA designation based on the State/county in which the provider is located. We included a table in each of the previous RCE limit notices and rules, whereby each MSA designation was grouped into one of three categories: Metropolitan areas with a population greater than 1 million, metropolitan areas with a population less than 1 million, and non-metropolitan areas. The MSA designation of the provider is then used to identify the appropriate RCE limit.

To update the current RCE limits by location under the current methodology, we would need to use, as in past updates, the MSA designations that correspond with the update period. However, since 2003, the OMB no longer updates or uses MSAs. We considered continuing to use the MSA designations, as we have in the past, but we would have no way to account for

[43] Cantwell, James R. and Sobaski, William J., *A Methodology for Determination of Reasonable FTE Compensation for Hospital-Based Physicians,* Working Paper No. OR–32, revised December 1982.

shifts in populations among MSAs because the OMB no longer updates geographic classifications based on MSA designations. The OMB regularly updates the geographic definitions, and the counties included in each area, to account for population shifts due to migrations, birth, and death rates but currently the OMB uses Core-Based Statistical Area (CBSA) designations rather than MSAs. If we were to continue to use the MSA designation, providers could potentially be underpaid or overpaid if the population of their MSA changed significantly from 2004. Therefore, we determined that, because the MSA designations are no longer updated, it would not be appropriate to continue using the previous location adjustment methodology. The most recent geographic delineations used by the OMB are CBSAs, a term used to refer to both Metropolitan and Micropolitan Statistical Areas. However, CBSA delineations do not match the MSA definitions that were used to develop the initial and subsequently updated RCE limits. As noted above, we have used the AMA PSP data to develop previous and current RCE limits. The AMA PSP data were collected from 1970 to 1980 and included physicians' income, hours worked, and MSA-based population information. The data that have been used to develop and update the RCE limits were developed using MSAs as the geographic unit. It is not possible to exactly crosswalk the MSA designations to the CBSA designations in order to update the RCE limits using the current location adjustment methodology. Even if it was possible to crosswalk the MSAs to the CBSAs, it would not be appropriate to use the MSA-based AMA PSP data to develop CBSA-based RCE limits. There have been significant changes in the populations of the MSA-based locations contained in the AMA PSP data that could not be translated into CBSAs. As such, that data would no longer be valid as the basis to develop RCE limits based on CBSAs

The OMB has cautioned users about using the new CBSA designations. For instance, in OMB's 2010 ''Standards for Delineating Metropolitan and Micropolitan Statistical Areas (CBSAs)'' published on June 28, 2010 in the **Federal Register** (75 FR 37246), OMB states:

''OMB establishes and maintains these areas solely for statistical purposes. *In reviewing and revising these areas, OMB does not take into account or attempt to anticipate any public or private sector nonstatistical uses that may be made of the delineations. These areas are not designed to serve as a general-purpose geographic framework applicable for nonstatistical activities or for use in program funding formulas.*

''Furthermore, the Metropolitan and Micropolitan Statistical Area Standards do not produce an urban-rural classification, and confusion of these concepts can lead to difficulties in program implementation. Counties included in Metropolitan and Micropolitan Statistical Areas and many other counties may contain both urban and rural territory and populations. . . . OMB urges agencies, organizations, and policy makers to review carefully the goals of nonstatistical programs and policies to ensure that appropriate geographic entities are used to determine eligibility for the allocation of Federal funds.'' (Emphasis in original.)

For CMS to accurately update the location-adjusted RCE limits using the CBSAs, we believe it would be necessary to use a new data source for information on physician salaries, specialties, location, and hours worked; and the data would need to be allocated to different geographic areas based on CBSAs. The AMA PSP collected data from a large sample of office-based physicians. We considered using data that are currently collected and publicly available. We could not find a reliable dataset that contained all of the necessary data elements needed to update the location-adjusted RCE limits based on CBSAs. The most reliable data we could find came from the Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES). The BLS OES data are collected annually, and capture a large and diverse population of physicians and corresponding CBSA. We believe the BLS OES data are the most current, reliable source of income data for physicians. Although, the BLS OES is very reliable and collects data points for physician specialties, salary, and location, it does not collect detailed information for all 10 specialties; the ''Radiology'' and ''Pathology'' specialties are not separately captured. As such, we did not believe it was appropriate to use the BLS OES data to create an updated RCE limit if we would not have data available for two specialties.

We also weighed the benefit of collecting updated information from physicians (through use of a new nationwide survey) in order to obtain the data necessary for application of an appropriate locality adjustment based on CBSAs against the burden placed on such physicians in providing such data. In order to have a dataset that could accurately capture all the necessary information, we would need to collect data from a large population of physicians, including a sufficient sample size for each physician specialty in each CBSA. We weighed the burden that such a nationwide survey would entail for all physicians, including office-based physicians, to be asked to respond to an in-depth survey regarding their salary, specialty, location, hours worked, and other practice information against the benefit of using updated, CBSA-based information to include a location adjustment for the providers that are subject to the RCE limits.

When the RCE limits were developed in 1983, other than inpatient acute care hospitals paid under the IPPS, most provider types were reimbursed on a reasonable cost basis. Since then, providers such as skilled nursing facilities (SNFs), long-term care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), inpatient psychiatric facilities (IPFs), and home health agencies (HHAs) that previously were paid on a reasonable cost basis have transitioned to prospective payment systems and are no longer subject to the RCE limits. As of FY 2011 (the most recent cost report year for which we have complete data), our data show that there were only 59 children's hospitals and cancer hospitals and 46 teaching hospitals (that have elected to be paid for physicians' services to the provider on a reasonable cost basis) that are subject to the RCE limits. As such, we believe the benefit that could be gained by gathering the new data that would be necessary to maintain a location adjustment for the RCE limits is outweighed by the burden of conducting such a comprehensive survey of physicians.

Furthermore, we analyzed how the elimination of the location adjustment would affect the accuracy and appropriateness of the proposed RCE limits. To perform this analysis, we needed a reliable source of physician income data (without a location adjustment) which could be compared to the RCE limits without a location adjustment. We determined that the best available source of physician income data is the mean annual income data for similar RCE physician specialties collected by the BLS OES. As mentioned above, the BLS OES data are collected annually and capture a large and diverse population of physicians. These data are the most current, reliable source of income data by physician specialties. In addition, when comparing salaries, it is important to compare salary amounts that reflect the same number of hours worked per year. Because many physicians do not work

a 2,080 hour work year, their salary may seem higher or lower due to the number of hours actually worked. The RCE limits are based on physicians who worked a 2,080 hour work year. The BLS OES data also are based on a 2,080 hour work year; therefore, we believe that comparing the RCE limits to these BLS OES data is appropriate for purposes of our analysis.

We performed an analysis comparing RCE limits for 2012, calculated without a location adjustment and solely for purposes of the analysis, to the most recently published (at the time of the analysis) BLS OES physician mean annual income data for the same year, to determine whether RCE limits based on the AMA PSP data, but without a location adjustment, would continue to reasonably reflect mean annual physician income data. For 2012, the BLS OES had income information for 8 of the 10 RCE specialties, which include the ''Total'' category; the BLS OES data did not capture the ''Radiology'' and ''Pathology'' specialties. We searched for another reliable data source for ''Radiology'' and ''Pathology'' but we could not find one with sufficient data elements to compare with the RCE limits. We used the MEI to update the RCE limits for these eight specialties to 2012 without including the location factor. We then compared these 2012 RCE limits to the 2012 BLS OES data for these same eight specialties. As shown in the table below, we found that the RCE limits ranged from 10.41 percent above the BLS OES mean annual income data to 3.58 percent below the BLS OES data. Only three of the eight specialties had RCE limits slightly less than the current BLS OES mean annual wages for their specialty. The remaining five specialties had RCE limits above the current BLS OES mean annual wages for the specialties.

ANALYSIS CHART

Specialty	RCE limits updated to 2012*	BLS OES mean 2012 annual wage	Percent difference
Total	$206,300	$184,820	10.41
General/Family Practice	174,600	180,850	−3.58
Internal Medicine	192,700	191,520	0.61
Surgery	240,300	230,540	4.06
Pediatrics	165,500	167,640	−1.29
OB/GYN	231,200	216,760	6.25
Radiology	265,200	N/A	N/A
Psychiatry	176,800	177,520	−0.41
Anesthesiology	233,500	232,820	0.29
Pathology	253,900	N/A	N/A

*These limits were calculated using the proposed methodology only for purposes of this impact analysis.

The RCE amounts updated to 2012 and the BLS OES numbers for 2012 varied only slightly, and in most cases, the RCE limit was higher than the BLS OES mean annual wage. Based on this analysis, we believe that RCE limits calculated using the AMA PSP data, and our proposed elimination of the location adjustment for the updated RCE limits, would result in RCE limits that are a reasonable reflection of mean annual physician income and would continue to ensure that providers subject to the RCE limits are paid in a fair and accurate manner.

Because there are a relatively small number of providers currently affected by the RCE limits and because, as discussed above, we believe the revised RCE limits without a location adjustment would continue to ensure appropriate payment to such providers, we believe that eliminating the location adjustment would have a minimal overall effect on providers subject to the RCE limits and on the industry as a whole.

For the reasons discussed above, we are proposing to eliminate the location adjustment under the RCE limit methodology, and to revise § 415.70(b) of the regulations to remove consideration of the ''type of location'' as part of the methodology used to establish RCE limits.

Set forth below are the proposed updated RCE limits on the amount of allowable compensation for services furnished by physicians to providers for cost reporting periods beginning on or after January 1, 2015. To calculate these proposed RCE limits, we used the same methodology that was used to calculate the original and previous updates to the RCE limits, but did not apply an adjustment based on geographical classification. As noted earlier, this methodology was derived from the 1982 working paper. We used the mean physician income by specialty from that working paper to calculate the RCE limits without adjusting for geographical classification. We then updated these data by the CPI–U (from 1982 to 1997) and then by the MEI (from 1998 to 2015) to compute the proposed updated RCE limits. The proposed RCE limits effective for cost reporting periods beginning on or after January 1, 2015 are shown in the chart below.

PROPOSED CY 2015 RCE LIMITS

Total	$212,100
General/Family Practice	179,500
Internal Medicine	198,100
Surgery	247,100
Pediatrics	170,200
OB/GYN	237,800
Radiology	272,700
Psychiatry	181,800
Anesthesiology	240,100
Pathology	261,100

We are inviting public comments on our proposals to update the RCE limits and to eliminate the location adjustment for the RCE limits for cost reporting periods beginning on or after January 1, 2015. In addition, we are inviting public comments on our proposal to revise § 415.70(b) of the regulations to eliminate consideration of the type of location as part of the methodology to establish RCE limits for cost reporting periods beginning on or after January 1, 2015.

C. Critical Access Hospitals (CAHs)

1. Background

Sections 1820 and 1861(mm) of the Act, as amended by section 4201 of the Balanced Budget Act (BBA) of 1997, replaced the Essential Access Community Hospitals and Rural Primary Care Hospitals (EACH/RPCH) program with the Medicare Rural Hospital Flexibility Program (MRHFP),

under which a qualifying facility can be designated as a CAH. CAHs participating in the MRHFP must meet the conditions for designation by the State and be certified by the Secretary in accordance with section 1820 of the Act. Further, in accordance with section 1820(e)(3) of the Act, a CAH must meet other criteria that the Secretary specifies.

The regulations that govern the conditions of participation (CoPs) for CAHs under the statutory requirements of section 1820 are codified at 42 CFR Part 485, Subpart F.

2. Proposed Changes Related to Reclassification as Rural for CAHs

Under section 1820(c)(2)(B)(i) of the Act, a facility is eligible for designation as a CAH only if it is located in a county or equivalent unit of local government in a rural area (as defined in section 1886(d)(2)(D) of the Act), or is being treated as being located in a rural area in accordance with section 1886(d)(8)(E) of the Act. The regulations implementing this location requirement are located at § 485.610(b). The regulations governing the process for a facility located in an urban area to apply for reclassification as a rural facility under section 1886(d)(8)(E) of the Act are located at § 412.103.

In this proposed rule, we are proposing to implement the most recently published OMB delineations (we refer readers to section III.B. of the preamble of this proposed rule for a discussion of the changes that were announced in OMB Bulletin No. 13–01). As previously stated, a facility must be located in a rural area in order to be eligible for designation as a CAH. Therefore, a new OMB delineation that redesignates an area from rural to urban, affects the status of a facility that is currently a CAH and had met the CAH location requirements prior to the new OMB delineation. A facility that is located in an urban area cannot remain a CAH unless it is reclassified as rural under § 412.103 of the regulations. In both the FY 2005 IPPS final rule (69 FR 49221 and 69 FR 60252) and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43940), we amended the regulations at § 412.103(a) and § 485.610(b) to provide for a transition period during which CAHs that had previously been located in rural areas but, as a result of new OMB delineations, were now located in urban areas, could reclassify as rural under § 412.103. Specifically, in both the FY 2005 IPPS final rule and the FY 2010 IPPS/LTCH PPS final rule, we provided for a 2-year period during which a CAH located in an urban area as a result of the new OMB delineations could continue participating without interruption as a CAH, thereby allowing the CAH sufficient time to reclassify as rural under § 412.103. If the facility did not reclassify as a rural facility by the end of that 2-year period, the CAH would not be able to retain its CAH status beyond that 2-year period. However, under the FY 2005 IPPS final rule and the FY 2010 IPPS/LTCH PPS final rule, the application of the regulation was limited to October 1, 2004 through September 30, 2006, and October 1, 2009 through September 30, 2011, respectively. As a result, in the absence of a new amendment to the regulations each time there are new OMB delineations, a CAH that becomes located in an urban area as a result of those OMB delineations would not be given 2 years to reclassify as rural under § 412.103 of the regulations.

In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43940), we stated that we would consider whether it would be appropriate to propose, in future IPPS rulemaking, to revise § 485.610 and § 412.103 to provide for a transition period any time a CAH that was formerly located in a rural area is designated as being located in an urban area as a result of the redesignation of its county from rural to urban. After further consideration, we believe that it is appropriate to propose to change the regulations to provide for a transition period that is not restricted to a timeframe, but rather can be applied any time a facility that is currently designated as a CAH becomes located in an urban area as a result of a new OMB delineation.

Therefore, we are proposing that, effective October 1, 2014, a CAH that was previously located in a rural area but is now located in an urban area as a result of a new OMB labor market area delineation will continue to be treated as rural for 2 years from the date the OMB delineation is implemented. Accordingly, if the OMB delineations announced in OMB Bulletin No. 13–01 on February 28, 2013 discussed in section III.B. of the preamble of this proposed rule are implemented in the FY 2015 IPPS/LTCH PPS final rule, effective October 1, 2014, any CAH affected by the new OMB delineations in OMB Bulletin No. 13–01 would retain its rural status through September 30, 2016. An affected CAH would be required to reclassify as a rural facility under § 412.103 within that 2-year period in order to continue participating in the Medicare program as a CAH after the 2-year transition period ends. Therefore, taking into consideration the example above, any CAH affected by a new OMB delineation that is implemented in the FY 2015 IPPS/LTCH PPS final rule would be required to reclassify as rural by September 30, 2016, in order to retain its CAH status after September 30, 2016.

To implement this proposed change, we are proposing to revise § 412.103 by adding a new paragraph (a)(6), and to revise § 485.610 by making a conforming change to the introductory text of paragraph (b) and adding a new paragraph (b)(5) to provide for a 2-year transition period that will apply any time a new OMB delineation causes a facility that was previously located in a rural area and is designated as a CAH to be located in an urban area. We believe that this proposal to revise the regulations to automatically provide for a 2-year transition period following the implementation of new OMB delineations is more efficient than providing for a regulatory change limited to a timeframe, and, as a result, will be more effective in reducing any disruption caused by new OMB delineations.

3. Proposed Revision of the Requirements for Physician Certification of CAH Inpatient Services

For inpatient CAH services to be payable under Medicare Part A, section 1814(a)(8) of the Act requires that a physician certify ''that the individual may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the critical access hospital.'' The regulations implementing this statutory requirement are located at 42 CFR 424.15.

Prior to FY 2014, this physician certification was required no later than 1 day before the date on which the claim for payment for the inpatient CAH service is submitted. In the FY 2014 IPPS/LTCH PPS final rule, we revised the CAH regulations concerning the timing requirements for certification of inpatient CAH services. Specifically, we revised § 424.15(b) to state: ''Certification begins with the order for inpatient admission. The certification must be completed, signed, and documented in the medical record prior to discharge'' (78 FR 50970). This change was effective October 1, 2013.

However, in order to provide CAHs with greater flexibility in meeting this certification requirement, we are now proposing to amend the regulations governing the timing of the 96-hour certification requirement at § 424.15(b) such that physician certification is required no later than 1 day before the date on which the claim for payment for the inpatient CAH service is submitted. That is, we are proposing to remove the requirement that certification of the 96-

hour requirement must be completed prior to discharge and are proposing to reinstate the timing requirement that was in place prior to October 1, 2013.

We are proposing to revise § 424.15(b) to remove the phrase ''prior to discharge'' and replace it with ''no later than 1 day before the date on which the claim for payment for the inpatient CAH service is submitted''. In addition, we are proposing to make a conforming amendment to § 424.11(d)(5). Section 424.11(d)(5) states ''[f]or all inpatient hospital or critical access hospital inpatient services, including inpatient psychiatric facility services, a delayed certification may not extend past discharge.'' Because we are proposing to change the timing requirement for physician certification of CAH inpatient services at § 424.15(b), such that the certification could be completed past discharge, we are proposing to revise § 424.11(d)(5) to remove the phrase ''or critical access hospital inpatient''. We are seeking public comment on these proposed changes to the regulations governing the requirement for physician certification of CAH inpatient services.

VII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2015

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act 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 VII. of the preamble of this proposed rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, 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, unless a LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR Part 412, Subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

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 the FY 2014 rulemaking cycle. In addition, in this proposed rule, we discuss the provisions of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), enacted on December 26, 2013, that affect the LTCH PPS. In section VII.I.2. of the preamble of this proposed rule, we discuss the provisions of section 1206(a) of Public Law 113–67, which amended section 1886(m) of the Act by adding paragraph (6) and established, among other things, patient-level criteria for payments under the LTCH PPS for implementation

beginning with FY 2016. In section VII.E. of the preamble of this proposed rule, we discuss the provisions of section 1206(b)(1) of Public Law 113–67, which provide for the retroactive reinstatement and extension, for an additional 4 years, of the moratorium on the full implementation of the 25-percent threshold payment adjustment policy (except for ''grandfathered'' hospitals-within-hospitals (HwHs), which are permanently exempt from this policy). In section VII.G. of the preamble of this proposed rule, we discuss the provisions of section 1206(b)(2) of Public Law 113–67 (as amended by section 112(b) of the Protecting Access to Medicare Act (Pub. L. 113–93), which, subject to certain defined exceptions, provide for statutory moratoria on the establishment of new LTCHs and LTCH satellite facilities and a new statutory moratorium on the increase in the number of hospital beds in LTCHs or LTCH satellite facilities for the period beginning April 1, 2014 and ending September 30, 2017. In section IX.C. of the preamble of this proposed rule, we discuss the provisions of section 1206(c) of Public Law 113–67, which amended the LTCH Quality Reporting Program established under section 1886(m)(5) of the Act by requiring the Secretary to establish a functional status quality measure to evaluate the in mobility among inpatients requiring ventilator support no later than October 1, 2015. In section VII.H. of the preamble of this proposed rule, we discuss the findings of a review of payments to certain LTCHs (that is, LTCHs classified under subclause (II) of section 1886(d)(1)(B)(iv) of the Act) that was conducted in accordance with section 1206(d) of Public Law 113–67, and propose to apply a payment adjustment under the LTCH PPS to ''subclause (II)'' LTCHs beginning in FY 2015 that would result in payments to this type of LTCH resembling payments under the reasonable cost TEFRA payment system model.

2. Criteria for Classification as an LTCH

a. Classification as an LTCH

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv)(I) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. 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, 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 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 under 45 CFR Parts 160 and 162 (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.

The Department of Health and Human Services has a number of initiatives designed to encourage and support the adoption of health information technology and promote nationwide health information exchange to improve health care. The Office of the National Coordinator for Health Information Technology (ONC) leads these efforts in collaboration with other agencies, including CMS and the Office of the Assistant Secretary for Planning and Evaluation (ASPE). Through a number of activities, including several open government initiatives, HHS is promoting the adoption of electronic health record (EHR) technology certified under the ONC Health Information Technology (HIT) Certification Program developed to support secure, interoperable, health information exchange. While certified EHR technology is not yet available for LTCHs and other types of providers that are not eligible for the Medicare and Medicaid EHR Incentive Programs, ONC has requested the HIT Policy Committee (a Federal Advisory Committee) to explore the expansion of EHR

certification under the ONC HIT Certification Program, focusing on EHR certification criteria needed for long-term and postacute care (including LTCHs) and behavioral health care providers. ONC has issued a proposed rule concerning a voluntary 2015 Edition of EHR certification criteria that would more easily accommodate HIT certification for health care settings where individual or institutional health care providers are not typically eligible to qualify for meaningful use incentive payments under Medicare or Medicaid, such as behavioral health or long-term postacute care settings. We believe that the use of certified EHRs by LTCHs (and other types of providers that are ineligible for the Medicare and Medicaid EHR Incentive Programs) can effectively and efficiently help providers improve internal care delivery practices, support the exchange of important information across care partners and during transitions of care, and could enable the reporting of electronically specified clinical quality measures (eCQMs) (as described elsewhere in this rule). More information on the proposed rule concerning a voluntary 2015 Edition of EHR certification criteria, identification of EHR certification criteria and development of standards applicable to LTCHs can be found at:

- *http://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations*;
- *http://www.healthit.gov/facas/FACAS/health-it-policy-committee/hitpc-workgroups/certificationadoption*;
- *http://wiki.siframework.org/LCC+LTPAC+Care+Transition+SWG*; and
- *http://wiki.siframework.org/Longitudinal+Coordination+of+Care*.

B. Proposed Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2015

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, implementation, and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR Part 412, Subpart O applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

The MS–DRGs adopted in FY 2008 represent an increase in the number of DRGs by 207 (that is, from 538 to 745) (72 FR 47171). The MS–DRG classifications are updated annually. There are currently 751 MS–DRG groupings. If we finalize the proposed changes to the MS–DRG groupings described in section II.G. of this preamble, there would be a total of 753 MS–DRG groupings for FY 2015.

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. Below we provide a general summary of our existing methodology for determining the proposed MS–LTC–DRG relative weights.

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 proposed low-volume MS–LTC–DRGs (that is, proposed MS–LTC–DRGs with less than 25 LTCH cases) in determining the proposed 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 proposed relative weights for the large number of proposed 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).) Under our existing methodology, we are proposing to account for adjustments to payments for short-stay outlier (SSO) cases (that is, cases where the covered length of stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay for the MS–LTC–DRG). Furthermore, we are proposing to make adjustments to account for nonmonotonically increasing weights, when necessary. That is, theoretically, cases under the MS–LTC–DRG system that are more severe require greater expenditure of medical care resources and will result in higher average charges such that, in the severity levels within a base MS–LTC–DRG, the proposed relative weights should increase monotonically with severity from the lowest to highest severity level. (We discuss nonmonotonicity in greater detail and our proposed methodology to adjust the proposed MS–LTC–DRG relative weights to account for nonmonotonically increasing proposed 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, EKGs), or minor surgical procedures (for example, a 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 diagnosis and procedure codes 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).

Under HIPAA transactions and code sets regulations at 45 CFR Parts 160 and 162, covered entities must comply with the adopted transaction standards and operating rules specified in Subparts I through S of Part 162. Among other requirements, by January 1, 2012, covered entities were required to use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X233A1 for the health care claims or equivalent encounter information transaction (45 CFR 162.1102).

HIPAA requires covered entities to use the applicable medical data code set requirements when conducting HIPAA transactions (45 CFR 162.1000). Currently, upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the most current version of the Internal Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM). 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 the preamble of this proposed rule for additional information on the annual revisions to the ICD–9–CM codes.)

Providers use the code sets under the ICD–9–CM coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system. We have been discussing the conversion to the ICD–10 coding system for many years. We refer readers to section II.G.1. of the preamble of this proposed rule for additional information on the implementation of the ICD–10 coding system.

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

Medicare administrative contractors (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 relative weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Proposed Changes to the MS–LTC–DRGs for FY 2015

As specified by our regulations at § 412.517(a), which require that the MS–LTC–DRG classifications and relative weights be updated annually, and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, we are proposing to update the MS–LTC–DRG classifications effective October 1, 2014, through September 30, 2015 (FY 2015) consistent with the proposed changes to

specific MS–DRG classifications presented in section II.G. of this preamble (that is, proposed GROUPER Version 32.0). Therefore, the proposed MS–LTC–DRGs for FY 2015 presented in this proposed rule are the same as the proposed MS–DRGs that are being proposed for use under the IPPS for FY 2015. In addition, because the proposed MS–LTC–DRGs for FY 2015 are the same as the proposed MS–DRGs for FY 2015, the other proposed changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under proposed GROUPER Version 32.0 as discussed in section II.G. of the preamble of this proposed rule, including the proposed changes to the MCE software and the ICD–9–CM coding system, also are applicable under the LTCH PPS for FY 2015.

3. Development of the Proposed FY 2015 MS–LTC–DRG Relative Weights

a. General Overview of the Development of the MS–LTC–DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is more costly (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment system rate by the applicable relative weight in determining payment to LTCHs for each case.

The basic methodology used to develop the MS–LTC–DRG relative weights generally continues to be consistent with the general methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991), with the exception of some modifications of our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity resulting from the adoption of the MS–LTC–DRGs. (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550).) Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in a MS–LTC–DRG with a relative weight of 2 will, on average, cost twice as much to treat as cases in a MS–LTC–DRG with a relative weight of 1.

b. Proposed Development of the MS–LTC–DRG Relative Weights for FY 2015

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50755 through 50760), we presented our policies for the development of the MS–LTC–DRG relative weights for FY 2014. The basic methodology we used to develop the FY 2014 MS–LTC–DRG relative weights was the same as the methodology we used to develop the FY 2013 MS–LTC–DRG relative weights in the FY 2013 IPPS/LTCH PPS final rule and was consistent with the general methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). In this FY 2015 IPPS/LTCH PPS proposed rule, we are proposing to continue to apply our established methodology to develop the FY 2015 MS–LTC–DRG relative weights for FY 2015, which includes application of established policies related to the data, the hospital-specific relative value (HSRV) methodology, the treatment of severity levels in the MS–LTC–DRGs, low-volume and no-volume MS–LTC–DRGs, adjustment for nonmonotonicity, and the steps for calculating the MS–LTC–DRG relative weights with a budget neutrality factor. Below we present the methodology that we are proposing to continue to use to determine the MS–LTC–DRG relative weights for FY 2015, which is consistent with the methodology presented in the FY 2014 IPPS/LTCH PPS final rule.

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. We are proposing to continue to apply our established two-step budget neutrality methodology such that the annual update to the MS–LTC–DRG classifications and relative weights for FY 2015 are based on the FY 2014 MS–LTC–DRG classifications and relative weights established in Table 11 listed in section VI. of the Addendum to the FY 2014 IPPS/LTCH PPS final rule (78 FR 51002). (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).)

c. Data

For the FY 2014 IPPS/LTCH PPS final rule (78 FR 50755), to calculate the MS–LTC–DRG relative weights for FY 2014, we obtained total charges from FY 2012 Medicare LTCH bill data from the December 2012 update of the FY 2012 MedPAR file, which were the best available data at that time, and used the finalized Version 31.0 of the GROUPER to classify LTCH cases. Consistent with our historical practice, to calculate the proposed MS–LTC–DRG relative weights for FY 2015 in this proposed rule, we are proposing to obtain total charges from the FY 2013 Medicare LTCH bill data from the December 2013 update of the FY 2013 MedPAR file, which are the best available data at this time, and to use Version 32.0 of the GROUPER to classify LTCH cases.

In this FY 2015 IPPS/LTCH PPS proposed rule and 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 exclude Medicare Advantage (Part C) claims, which are now included in the MedPAR files, in the calculations for the proposed relative weights under the LTCH PPS that are used to determine payments for Medicare fee-for-service claims. Specifically, we are proposing not to use any claims from the MedPAR files that have a GHO Paid indicator value of ''1,'' which effectively removes Medicare Advantage claims from the proposed relative weight calculations. Accordingly, in the development of the proposed FY 2015 MS–LTC–DRG relative weights in this proposed rule, we excluded the data of 12 all-inclusive rate providers and one LTCH that is

paid in accordance with demonstration projects that had claims in the December 2013 update of the FY 2013 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 (MS–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. In this proposed rule, 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 2015. We believe this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this 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 adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for a LTCH is its case-mix, so it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the cases it treats relative to the complexity of the cases treated by all other LTCHs (the average case-mix of all LTCHs).

In accordance with our established methodology, we are proposing to continue to standardize charges for each case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described 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. Treatment of Severity Levels in Developing the Proposed MS–LTC–DRG Relative Weights

For purposes of determining the proposed MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–DRGs based on volume of cases within specific MS–LTC–DRGs. Proposed MS–LTC–DRGs with at least 25 cases are each assigned a unique proposed relative weight; proposed low-volume MS–LTC–DRGs (that is, proposed 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 proposed relative weight of the quintile. Proposed no-volume MS–LTC–DRGs (that is, no cases in the given year's claims data are assigned to those proposed MS–LTC–DRGs) are cross-walked to other proposed MS–LTC–DRGs based on the clinical similarities and assigned the proposed 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 2015. (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 the preamble of this proposed rule.)

Furthermore, in determining the proposed FY 2015 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 2010 LTCH PPS final rule for our rationale for including an adjustment for nonmonotonicity (74 FR 43953 through 43954).

f. Proposed Low-Volume MS–LTC–DRGs

In order to account for proposed MS–LTC–DRGs with low volume (that is, with fewer than 25 LTCH cases), consistent with our existing methodology for purposes of determining the proposed FY 2015 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 2015 MS–LTC–DRG relative weights in this proposed rule, in cases where the initial assignment of a proposed low-volume MS–LTC–DRG to a quintile results 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) of the preamble of this proposed rule.

In this proposed rule, using LTCH cases from the December 2013 update of the FY 2013 MedPAR file (which is currently the best available data), we identified 297 proposed 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 59 proposed MS–LTC–DRGs (297/5 = 59 with two proposed MS–LTC–DRGs as the remainder). We are proposing to assign 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. Based on the data available for this proposed rule, the number of proposed MS–LTC–DRGs with less than 25 cases is not evenly divisible by 5. Therefore, consistent with our historical approach, we are proposing to use the average charge of the low-volume quintile to determine which of the low-volume quintiles contain the additional proposed low-volume MS–LTC–DRG. Specifically for this proposed rule, after organizing the proposed MS–LTC–DRGs by ascending order by average charge, we are proposing to assign the first fifth (1st through 59th) of proposed low-volume MS–LTC–DRGs (with the lowest average charge) into proposed Quintile 1. The proposed MS–LTC–DRGs with the highest average charge cases were assigned into proposed Quintile 5. Because the average charge of the 119th proposed low-volume MS–LTC–DRG in the sorted list was closer to the average charge of the 118th proposed low-volume MS–LTC–DRG (assigned to proposed Quintile 2) than to the average charge of the 120th proposed low-volume MS–LTC–DRG (assigned to proposed Quintile 2), we are proposing to assign it to proposed Quintile 2 (such that proposed Quintile 2 contains 60 proposed low-volume MS– LTC–DRGs before any adjustments for nonmonotonicity, as discussed below). This resulted in 3 of the 5 proposed low-volume quintiles containing 59 proposed MS–LTC–DRGs (proposed Quintiles 1, 3, and 4) and two proposed low-volume quintiles containing 60 proposed MS–LTC–DRGs (Quintiles 2 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 proposed composition of the low-volume quintiles for proposed MS–LTC–DRGs for FY 2015.

Accordingly, in order to determine the proposed FY 2015 relative weights for the proposed MS–LTC–DRGs with low volume, we are proposing to use the five proposed low-volume quintiles described above. We determined a proposed relative weight and (geometric) average length of stay for each of the five proposed low-volume quintiles using the methodology that we are proposing to apply to the proposed MS–LTC–DRGs (25 or more cases), as described below in section VII.B.3.g. of the preamble of this proposed rule. We are proposing to assign the same proposed relative weight and average length of stay to each of the proposed low-volume MS–LTC–DRGs that make up an individual proposed low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of proposed MS–LTC–DRGs with a low volume of LTCH cases will vary in the future.

Furthermore, we note that we will continue to monitor the volume (that is, the number of LTCH cases) in the proposed low-volume quintiles to ensure that our proposed 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 2015 MS–LTC–DRG Relative Weights

In this proposed rule, we are proposing to determine the proposed FY 2015 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 2015 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 proposed MS–LTC–DRG (or proposed low-volume quintile), we are proposing to calculate the FY 2015 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 proposed MS–LTC–DRG (or proposed 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 ''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 2015 MS–LTC–DRG relative weights. We note that, as we discussed in section VII.B.3.c. of the preamble of this proposed rule, 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 2013 update of the FY 2013 MedPAR file.

Step 1—Remove statistical outliers.

The first step in the calculation of the proposed FY 2015 MS–LTC–DRG relative weights is to remove statistical outlier cases. Consistent with our historical relative weight methodology, we are proposing to continue to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each proposed MS–LTC–DRG. These statistical outliers are removed prior to calculating the proposed relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the proposed relative weights could result in an inaccurate proposed 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 2015 MS–LTC–DRG relative weights, the value of many proposed 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 2015 MS–LTC–DRG relative weights, we are proposing to remove 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 were 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 2015 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).

In this proposed rule, 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 MS–LTC–DRG.

Counting SSO cases as full discharges with no adjustment in determining the proposed FY 2015 MS–LTC–DRG relative weights would lower the proposed FY 2015 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 2015 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, we are proposing to calculate the proposed FY 2015 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 was then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. An initial case-mix index value of 1.0 was used for each LTCH.

For each proposed MS–LTC–DRG, we calculated the proposed FY 2015 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) was calculated by dividing the sum of all the LTCH's proposed MS–LTC–DRG relative weights by its total number of cases. The LTCHs' hospital-specific relative charge values (from above) were then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values were then used to calculate a new set of proposed MS–LTC–DRG relative weights across all LTCHs. This iterative process was continued until there was convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 5—Determine a proposed FY 2015 relative weight for proposed MS–LTC–DRGs with no LTCH cases.

As we stated above, we determined the proposed FY 2015 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 2013 update of the FY 2013 MedPAR file for this proposed rule). Using these data, we identified the proposed MS–LTC–DRGs for which there were no LTCH cases in the database, such that no patients who would have been classified to those MS–LTC–DRGs were treated in LTCHs during FY 2013 and, therefore, no charge data were available for these proposed MS–LTC–DRGs. Therefore, in the process of determining the proposed MS–LTC–DRG relative weights, we were unable to calculate proposed relative weights for the proposed MS–LTC–DRGs with no LTCH cases using the methodology described in Steps 1 through 4 above. However, because patients with a number of the diagnoses under these proposed MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we are proposing to assign a proposed relative weight to each of the proposed no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of proposed ''transplant'' MS–LTC–DRGs and proposed ''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 determined proposed FY 2015 relative weights for the proposed MS–LTC–DRGs with no LTCH cases in the December 2013 update of the FY 2013 MedPAR file used in this proposed rule (that is, proposed ''no-volume'' MS–LTC–DRGs) by cross-walking each proposed no-volume MS–LTC–DRG to another proposed MS–LTC–DRG with a calculated proposed relative weight (determined in accordance with the methodology described above). Then, the proposed ''no-volume'' MS–LTC–DRG was assigned the same proposed relative weight (and average length of stay) of the proposed MS–LTC–DRG to which it was cross-walked (as described in greater detail below).

Of the 753 proposed MS–LTC–DRGs for FY 2015, we identified 237 proposed MS–LTC–DRGs for which there are no LTCH cases in the database (including the 8 proposed ''transplant'' MS–LTC–DRGs and 2 proposed ''error'' MS–LTC–DRGs). As stated above, we are proposing to assign proposed relative weights for each of the 237 proposed no-volume MS–LTC–DRGs (with the exception of the 8 proposed ''transplant'' MS–LTC–DRGs and the 2 proposed ''error'' MS–LTC–DRGs, which are discussed below) based on clinical similarity and relative costliness to one of the remaining 516 (753 − 237 = 516) proposed MS–LTC–DRGs for which we were able to determine proposed relative weights based on FY 2013 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 cross-walked one of the 237 proposed ''no volume'' MS–LTC–DRGs, with the exception of the 8 proposed ''transplant'' MS–LTC–DRGs and the 2 proposed ''error'' MS–LTC–DRGs, for purposes of determining a proposed relative weight.) Then, we are proposing to assign 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 are proposing to make adjustments to account for nonmonotonicity.)

For this proposed rule, we cross-walked the proposed no-volume MS–LTC–DRG to a proposed MS–LTC–DRG for which there were LTCH cases in the December 2013 update of the FY 2013 MedPAR file, and to which it was similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. We evaluated the relative costliness in determining the applicable proposed MS–LTC–DRG to which a proposed no-volume MS–LTC–DRG was cross-walked in order to assign an appropriate proposed relative weight for the proposed no-volume MS–LTC–DRGs in FY 2015. (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 2015, 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 then assigned 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 2015. We note that if the proposed cross-walked MS–LTC–DRG had 25 cases or more, its proposed relative weight, which was calculated using the methodology described in Steps 1 through 4 above, was assigned to the proposed no-volume MS–LTC–DRG as well. Similarly, if the proposed MS–LTC–DRG to which the proposed no-volume MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, was designated to one of the proposed low-volume quintiles for purposes of determining the proposed relative weights, we assigned the proposed relative weight of the applicable proposed low-volume quintile to the 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 2015. (As we noted above, in the infrequent case where nonmonotonicity involving a proposed no-volume MS–LTC–DRG resulted, additional adjustments as described in Step 6 were required in order to maintain monotonically increasing proposed relative weights.)

For this proposed rule, a list of the proposed no-volume MS–LTC–DRGs and the proposed MS–LTC–DRGs to which each was cross-walked (that is, the proposed cross-walked MS–LTC–DRGs) for FY 2015 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 proposed FY 2015 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 2015 provided in Table 13B.

Example: There were no cases in the FY 2013 MedPAR file used for this proposed rule for proposed MS–LTC–DRG 61 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC). We determined that proposed MS–LTC–DRG 70 (Nonspecific Cerebrovascular Disorders with MCC) was similar clinically and based on resource use to proposed MS–LTC–DRG 61. Therefore, we assigned the same proposed relative weight of proposed MS–LTC–DRG 70 of 0.8657 for FY 2015 to proposed MS–LTC–DRG 61 (obtained from 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 proposed 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 2015, consistent with our historical relative weight methodology, we are proposing to establish a relative weight of 0.0000 for the following proposed transplant 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 eight proposed transplant MS–LTC–DRGs in the proposed GROUPER program for administrative purposes only. Because we use the same proposed 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 2015 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 secondary diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as ''without CC/MCC.'' When data do not support the creation of three severity levels, the base MS–DRG is subdivided into either two levels or the base MS–DRG is not subdivided. The two-level subdivisions could consist of the MS–DRG with CC/MCC and the MS–DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the MS–DRG with MCC and the MS–DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the ''without CC/MCC'' MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the ''with CC/MCC'' MS–LTC–DRG (in the case of a two-level split) or both the ''with CC'' and the ''with MCC'' MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and 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 proposed 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 proposed 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 proposed MS–LTC–DRG (which are generally expected to have lower resource use and costs). Consequently, in determining the proposed FY 2015 MS–LTC–DRG relative weights in this proposed rule, consistent with our historical methodology, we are proposing to combine 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 was 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 2015 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 2015 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 2015 based on the most recent available LTCH data, and apply a budget neutrality adjustment in determining the proposed FY 2015 MS–LTC–DRG relative weights.

To ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology. In this proposed rule, in the first step of our proposed MS–LTC–DRG budget neutrality methodology, for FY 2015, we are proposing to calculate and apply a normalization factor to the recalibrated proposed relative weights (the result of Steps 1 through 6 above) to ensure that estimated payments were not affected 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 2015 (the first step of our proposed budget neutrality methodology), we are proposing to use the following three steps: (1.a.) we use the most recent available LTCH claims data (FY 2013) and group them using the proposed FY 2015 GROUPER (Version 32.0) and the recalibrated proposed FY 2015 MS–LTC–DRG relative weights (determined in Steps 1 through 6 of the Steps for Determining the Proposed FY 2015 MS–LTC–DRG Relative Weights above) to calculate the average CMI; (1.b.) we group the same LTCH claims data (FY 2013) using the FY 2014 GROUPER (Version 31.0) and FY 2014 MS–LTC–DRG relative weights and calculated the average CMI; and (1.c.) we compute the ratio of these average CMIs by dividing the average CMI for FY 2014 (determined in Step 1.b.) by the average CMI for FY 2015 (determined in Step 1.a.). In determining the proposed MS–LTC–DRG relative weights for FY 2015, each recalibrated proposed MS–LTC–DRG relative weight was multiplied by 1.12619 (determined in Step 1.c.) in the first step of the proposed 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 2015 MS–LTC–DRG classifications and relative weights) are equal to estimated aggregate LTCH PPS payments before reclassification and recalibration (that is, the FY 2014 MS–LTC–DRG classifications and relative weights). Accordingly, consistent with our existing methodology, we are proposing to use FY 2013 discharge data to simulate payments and compared estimated aggregate LTCH PPS payments using the FY 2014 MS–LTC–DRGs and relative weights to estimate aggregate LTCH PPS payments using the proposed FY 2015 MS–LTC–DRGs and relative weights. Specifically, for this proposed rule, as discussed previously in section VII.B.3.c. of this preamble, we are proposing to use LTCH claims data from the December 2013 update of the FY 2013 MedPAR file, as these are the best available data at this time.

For this proposed rule, we are proposing to determine the proposed FY 2015 budget neutrality adjustment factor using the following three steps: (2.a.) we simulate estimated total LTCH PPS payments using the proposed normalized relative weights for FY 2015 and proposed GROUPER Version 32.0 (as described above); (2.b.) we simulate estimated total LTCH PPS payments using the FY 2014 GROUPER (Version 31.0) and the FY 2014 MS–LTC–DRG relative weights in Table 11 of the Addendum to the FY 2014 IPPS/LTCH PPS final rule available on the Internet (78 FR 51002); and (2.c.) we calculate the ratio of these estimated total LTCH PPS payments by dividing the estimated total LTCH PPS payments using the FY 2014 GROUPER (Version 31.0) and the FY 2014 MS–LTC–DRG relative weights (determined in Step 2.b.) by the estimated total LTCH PPS payments using the proposed FY 2015 GROUPER (Version 32.0) and the proposed normalized MS–LTC–DRG relative weights for FY 2015 (determined in Step 2.a.). In determining the proposed FY 2015 MS–LTC–DRG relative weights, each proposed normalized relative weight was multiplied by a proposed budget neutrality factor of 0.995275 (determined in Step 2.c.) in the second step of the proposed budget neutrality methodology to determine the proposed

budget neutral FY 2015 relative weight for each proposed MS–LTC–DRG.

Accordingly, in determining the proposed FY 2015 MS–LTC–DRG relative weights in this proposed rule, consistent with our existing methodology, we are proposing to apply a proposed normalization factor of 1.12619 and a proposed budget neutrality factor of 0.995275 (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 ''IPPS Comparable Thresholds'' (used in determining SSO payments under § 412.529(c)(3)), for FY 2015 (and reflect both the proposed normalization factor of 1.12619 and the proposed budget neutrality factor of 0.995275).

C. Proposed LTCH PPS Payment Rates for FY 2015

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 2015, that is, effective for LTCH discharges occurring on or after October 1, 2014 through September 30, 2015.

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 standard Federal rate as implemented under § 412.523(c)(3), we refer readers to the following final rules: RY 2004 LTCH PPS final rule (68 FR 34134 through 34140); RY 2005 LTCH PPS final rule (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); FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44021 through 44030); FY 2011 IPPS/LTCH PPS final rule (75 FR 50443 through 50444); FY 2012 IPPS/LTCH PPS final rule (76 FR 51769 through 51773); FY 2013 IPPS/LTCH PPS final rule (77 FR 53479 through 53481); and FY 2014 IPPS/LTCH PPS final rule (78 FR 50760 through 50765).

The proposed update to the LTCH PPS standard Federal rate for FY 2015 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 2015 are discussed below, including the reduction to the annual update for LTCHs that fail to submit quality reporting data for fiscal year FY 2015 as required by the statute (as discussed below in section VII.C.2.c. of the preamble of this proposed rule). Furthermore, as discussed below in section VII.C.3. of the preamble of this proposed rule, for FY 2015, in addition to the proposed update factor, under the final year of the 3-year phase-in under the current regulations at § 412.523(d)(3), we are proposing to make a one-time prospective adjustment to the standard Federal rate for FY 2015 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. In addition, 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 changes to the area wage level adjustment for FY 2015 on estimated aggregate LTCH PPS payments, in accordance with § 412.523(d)(4). (We refer readers to the discussion of the reduction to the annual update for LTCHs that fail to submit quality reporting data under section VII.C.2.c. of the preamble of this proposed rule, the proposed application of the one-time prospective adjustment under the final year of the 3-year phase-in under section VII.C.3. of this preamble, and the proposed budget neutrality adjustment for changes in the area wage levels under section V.A. of the Addendum of this proposed rule.)

2. Proposed FY 2015 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 the FY 2013 IPPS/LTCH PPS final rule (77 FR 53468 through 53476), we adopted 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 the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53468) and 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'' (which are discussed in more detail in section VII.C.2.b. of the preamble of this proposed rule.) We note that because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a) 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

b. Proposed 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.

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). Under our methodology, the end of the 10-year moving average of changes in the MFP coincides with the end of the appropriate FY update period. In addition, 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. The MFP adjustment is derived using a projection of MFP that is currently produced by IHS Global Insight, Inc. (For additional details on the development of the MFP adjustment and its application under the LTCH PPS, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51691 through 51692 and 51770 through 51771).)

For FY 2015, we are proposing to continue to use our methodology for calculating and applying the proposed MFP adjustment to determine the annual update to the LTCH PPS standard Federal rate for FY 2015. (For details on the development of the proposed MFP adjustment, 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 Adjustment to the Annual Update to the LTCH PPS Standard Federal Rate Under the Long-Term Care Hospital Quality Reporting (LTCHQR) Program

1. Background

In accordance with section 1886(m)(5) of the Act, as added by section 3004(a) of the Affordable Care Act, the Secretary established the Long-Term Care Hospital Quality Reporting (LTCHQR) Program. (As noted above, although the language of section 3004(a) of the Affordable Care Act refers to years 2011 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 use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.) Under the LTCHQR Program, as required by section 1886(m)(5)(A)(i) of the Act, for FY 2014 and each subsequent year, in the case of an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year, any annual update to a standard Federal rate for discharges for the hospital during the year, and after application of section 1886(m)(3) of the Act, shall be reduced by 2.0 percentage points. Section 1886(m)(5)(A)(ii) of the Act provides that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year. Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved, and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year. For additional information on the history of the LTCHQR Program, including the statutory authority and the selected measures, we refer readers to section IX.C. of the preamble of this proposed rule.

2. Proposed Reduction to the Annual Update to the LTCH PPS Standard Federal Rate Under the LTCHQR Program

Consistent with section 1886(m)(5)(A)(i) of the Act, for FY 2014 and subsequent fiscal years, for LTCHs that do not submit quality reporting data under the LTCHQR Program with respect to such a fiscal year, any annual update to a standard Federal rate for discharges for the LTCH during the fiscal year and after application of the market basket update adjustments required by section 1886(m)(3) of the Act, is further reduced by 2.0 percentage points. That is, in establishing an update to the LTCH PPS standard Federal rate for FY 2014 and subsequent fiscal years, the full LTCH PPS market basket increase estimate, subject to an adjustment based on changes in economy-wide productivity (''the MFP adjustment'') required under section 1886(m)(3)(A)(i) of the Act and an additional reduction required by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act, is further reduced by 2.0 percentage points for LTCHs that fail to submit quality reporting data under the LTCHQR Program. The reduction in the annual update to the LTCH PPS standard Federal rate for failure to report quality data under the LTCHQR Program for FY 2014 and subsequent fiscal years is codified under § 412.523(c)(4) of the regulations.

Specifically, consistent with section 1886(m)(5)(A)(i) of the Act, under § 412.523(c)(4)(i), for an LTCH that does not submit quality reporting data in the form and manner and at the time specified by the Secretary under the LTCHQR Program, the annual update to the standard Federal rate under § 412.523(c)(3) is further reduced by 2.0 percentage points. In addition, consistent with section 1886(m)(5)(A)(ii) of the Act, § 412.523(c)(4)(ii) specifies that any reduction of the annual update to the standard Federal rate under § 412.523(c)(4)(i) will apply only to the fiscal year involved and will not be taken into account in computing the annual update to the standard Federal rate for a subsequent fiscal year. Lastly, consistent with section 1886(m)(5)(B) of the Act, under § 412.523(c)(4)(iii), the application of any reduction of the annual update to the standard Federal rate under § 412.523(c)(4)(i) may result in an annual update that is less than 0.0 percent for a fiscal year, and may result in payment rates for a fiscal year that would be less than such payment rates for the preceding rate year.

We discuss the application of the 2.0 percentage point reduction under § 412.523(c)(4)(i) in our discussion of the proposed annual market basket update to the LTCH PPS standard Federal rate for FY 2015 below in section VII.C.2.e. of the preamble of this proposed rule.

d. Proposed Market Basket Under the LTCH PPS for FY 2015

Under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53468), we adopted a newly created FY 2009-based LTCH-specific market basket for use under the LTCH PPS beginning in FY 2013. The 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. For additional details on the development of the FY 2009-based LTCH-specific market basket, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476).

For FY 2015, we are proposing to continue to use the FY 2009-based LTCH-specific market basket to update

the LTCH PPS for FY 2015. We continue to believe that the FY 2009-based LTCH-specific market basket appropriately reflects the cost structure of LTCHs for the reasons discussed when we adopted the FY 2009-based LTCH-specific market basket for use under the LTCH PPS in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476).

e. Proposed Annual Market Basket Update for LTCHs for FY 2015

Consistent with our historical practice, we are proposing to estimate the market basket update and the proposed MFP adjustment based on IGI's forecast using the most recent available data. Based on IGI's first quarter 2014 forecast, the proposed FY 2015 full market basket estimate for the LTCH PPS using the FY 2009-based LTCH-specific market basket is 2.7 percent. Using our established methodology for determining the MFP adjustment, the current estimate of the proposed MFP adjustment for FY 2015 based on IGI's first quarter 2014 forecast is 0.4 percent, as discussed in section IV.B. of the preamble of this proposed rule. In addition, consistent with our historical practice of using the best available data, we are proposing that if more recent data is available, we would use such data to estimate the market basket update and the MFP adjustment for FY 2015 in the final rule.

For FY 2015, 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 2015 market basket update by the proposed FY 2015 MFP adjustment. To determine the market basket update for LTCHs for FY 2015, as reduced by the MFP adjustment, consistent with our established methodology, we are proposing to subtract the proposed FY 2015 MFP adjustment from the proposed FY 2015 market basket update. Furthermore, sections 1886(m)(3)(A)(ii) and 1886(m)(4)(E) of the Act requires that any annual update to the standard Federal rate for FY 2015 be reduced by the ''other adjustment'' described in paragraph (4), which is 0.2 percentage point for FY 2015. Therefore, following application of the proposed productivity adjustment, we are proposing to reduce the adjusted market basket update (that is, the proposed full market basket increase less the proposed MFP adjustment) by the ''other adjustment'' specified by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act. (For additional details on our established methodology for adjusting the market basket increase by the MFP and the ''other adjustment'' required by the statute, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).)

As discussed previously in section VII.C.2.c. of the preamble of this proposed rule, for FY 2015, section 1886(m)(5) of the Act requires that for LTCHs that do not submit quality reporting data under the LTCHQR Program, any annual update to a standard Federal rate, after application of the adjustments required by section 1886(m)(3) of the Act, is further reduced by 2.0 percentage points. Therefore, the proposed update to the LTCH PPS standard Federal rate for FY 2015 for LTCHs that fail to submit quality reporting data under the LTCHQR Program, the full LTCH PPS market basket increase estimate, subject to an adjustment based on changes in economy-wide productivity (''the MFP adjustment'') as required under section 1886(m)(3)(A)(i) of the Act and an additional reduction required by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act, would also be further reduced by 2.0 percentage points.

In this proposed rule, in accordance with the statute, we are proposing to reduce the proposed FY 2015 full market basket estimate of 2.7 percent (based on IGI's first quarter 2014 forecast of the FY 2009-based LTCH-specific market basket) by the proposed FY 2015 MFP adjustment (that is, the 10-year moving average of MFP for the period ending FY 2015, as described in section IV.B. of the preamble of this proposed rule) of 0.4 percentage point (based on IGI's first quarter 2014 forecast). Following application of the proposed productivity adjustment, the adjusted market basket update of 2.3 percent (2.7 percent minus 0.4 percentage point) would then be reduced by 0.2 percentage point, as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4)(E) 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 2015 of 2.1 percent (that is, the most recent estimate of the LTCH PPS proposed market basket update at this time of 2.7 percent, less the proposed MFP adjustment of 0.4 percentage point, and less the 0.2 percentage point required under section 1886(m)(4)(E) of the Act), provided the LTCH submits quality reporting data in accordance with section 1886(m)(5) of the Act. Accordingly, we are proposing to revise § 412.523(c)(3) by adding a new paragraph (xi), which specifies that the standard Federal rate for FY 2015 would be the standard Federal rate for the previous LTCH PPS year updated by 2.7 percent, and as further adjusted, as appropriate, as described in § 412.523(d). For LTCHs that fail to submit quality reporting data under the LTCHQR Program, under proposed § 412.523(c)(3)(xi) in conjunction with § 412.523(c)(4), we are proposing to further reduce the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points in accordance with section 1886(m)(5) of the Act. Accordingly, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 0.1 percent (that is, 2.1 percent minus 2.0 percentage points) for FY 2015 for LTCHs that fail to submit quality reporting data under the LTCHQR Program. As stated above, consistent with our historical practice of using the best available data, we are proposing that if more recent data is available, we would use such data to establish an annual update to the LTCH PPS standard Federal rate for FY 2015 under § 412.523(c)(3)(xi) in the final rule. (We note that, we also are proposing to adjust the proposed FY 2015 standard Federal rate by applying a one-time prospective adjustment under the final year of the 3-year phase-in under § 412.523(d)(3) (discussed in section VII.C.3. of the preamble of this proposed rule) and by a proposed area wage level budget neutrality factor in accordance with § 412.523(d)(4) (as discussed in section V.B.5. of the Addendum of this proposed rule).)

3. Proposed Adjustment for the Final Year of the Phase-In of the One-Time Prospective Adjustment to the Standard Federal Rate Under § 412.523(d)(3)

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'' in the August 30, 2002 LTCH PPS final rule (67 FR 55954). The statutory budget neutrality requirement means 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 have been made if the LTCH PPS had not been implemented (without accounting for certain statutory provisions that affect the level of payments to LTCHs in years prior to the implementation of the LTCH PPS, as required by the statute).

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 differed 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, under section 123(a)(1) of the BBRA, as amended by section 307(b) of the 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, 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. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53487 through 53488) for a complete discussion of the history of the development of the one-time prospective adjustment to the LTCH PPS standard Federal rate at § 412.523(d)(3).

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53495), we finalized our policy to make a one-time prospective adjustment to the standard Federal rate so that it will be permanently reduced by approximately 3.75 percent to account for the estimated difference between projected aggregate FY 2003 LTCH PPS payments 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. Specifically, using the methodology we adopted in that same final rule, we determined that permanently applying a factor of 0.9625 (that is, a permanent reduction of approximately 3.75 percent) to the standard Federal rate is necessary to ensure estimated total FY 2003 LTCH PPS payments equal estimated total FY 2003 TEFRA payments consistent with our stated policy goal of the one-time prospective adjustment under § 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 refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53487 through 53502) for a complete discussion of the evaluation approach, methodology, and determination of the one-time prospective adjustment to the LTCH PPS standard Federal rate at § 412.523(d)(3).)

Given the magnitude of this adjustment, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53501 through 53502), under § 412.523(d)(3), we established a policy to phase-in the permanent adjustment of 0.9625 to the standard Federal rate over a 3-year period. To achieve a permanent adjustment of 0.9625, under the phase-in of this adjustment, in that same final rule, we explained that we will apply a factor of 0.98734 to the standard Federal rate in each year of the 3-year phase-in, that is, in FY 2013 (which does not apply 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. By applying a permanent factor of 0.98734 to the standard Federal rate in each year for FYs 2013, 2014, and 2015, we will completely account for the entire adjustment by having applied a cumulative factor of 0.9625 (calculated as $0.98734 \times 0.98734 \times 0.98734 = 0.9625$) to the standard Federal rate. Accordingly, under § 412.523(d)(3), we applied a permanent factor of 0.98734 to the standard Federal rate in both FY 2013 and FY 2014 under the established 3-year phase-in of the one-time prospective adjustment.

In this proposed rule, for FY 2015, we are proposing to apply a permanent one-time prospective adjustment factor of 0.98734 to the standard Federal rate for FY 2015 under the last year of the 3-year phase-in of the one-time prospective adjustment, in accordance with the existing regulations under § 412.523(d)(3).

D. Proposed Revision of LTCH PPS Geographic Classifications

1. Background

As discussed in the August 30, 2002 LTCH PPS final rule, which implemented the LTCH PPS (67 FR 56015 through 56019), in establishing an adjustment for area wage levels, the labor-related portion of an LTCH's standard Federal payment rate is adjusted by using an appropriate wage index based on the labor market area in which the LTCH is located. Specifically, the application of the LTCH PPS area wage-level adjustment, which is codified under existing § 412.525(c) of the regulations, is based on the location of the LTCH—either in an ''urban'' area or a ''rural'' area. Currently, under the LTCH PPS, as codified under § 412.503 of the regulations, an ''urban area'' is defined as a Metropolitan Statistical Area (which includes a Metropolitan division, where applicable) as defined by the Executive OMB, and a ''rural area'' is defined as any area outside of an urban area.

In the RY 2006 LTCH PPS final rule (70 FR 24184 through 24185), we revised § 412.525(c) to update the labor market area definitions used under the LTCH PPS, effective for discharges occurring on or after July 1, 2005, based on the Executive OMB's Core-Based Statistical Area (CBSA) designations (''CBSA designations''), which are based on 2000 Census data. We made this revision because we believed that the CBSA designations (geographic classifications) would 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 noted that these were the same CBSA designations implemented for acute care hospitals under the IPPS, which were codified under § 412.64(b) of the regulations, beginning in FY 2005. (For a further discussion of the CBSA-based labor market area designations currently used under the LTCH PPS, we refer readers to the RY 2006 LTCH PPS final rule (70 FR 24182 through 24191).) We have generally updated the LTCH PPS CBSA designations annually since they were adopted for RY 2006 when updates from OMB were available (73 FR 26812 through 26814, 74 FR 44023 through 44204, and 75 FR 50444 through 50445).

In OMB Bulletin No. 10–2, issued on December 1, 2009, OMB announced that the CBSA changes in that bulletin would be the final update prior to the 2010 Census of Population and Housing. We adopted those changes under the

LTCH PPS in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50444 through 50445), effective October 1, 2010. We continued to use these CBSA designations for FYs 2012 and 2013 (76 FR 51808 and 77 FR 53710, respectively). New OMB labor market area delineations (which we refer to in this section as ''new OMB delineations'') based on 2010 standards and the 2010 Decennial Census data were announced by OMB on February 28, 2013. OMB issued Bulletin No. 13–01, which announced revisions to the delineation of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the uses of the delineation of these labor market areas. (For a copy of this bulletin, we refer readers to the following Web site: *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf*. This bulletin specifically provides the delineations of all Metropolitan Statistical Areas (MSAs), Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published in the **Federal Register** on June 28, 2010 (75 FR 37246 through 37252) and 2010 Census data. (We note that, as discussed in section III.B. of the preamble of this proposed rule, consistent with the terminology used in the OMB Bulletin No. 13–01 and the standards published in the **Federal Register** on June 28, 2010, when referencing the new OMB geographic boundaries of Metropolitan Statistical Areas (MSAs) based on 2010 standards, we are using the term ''new OMB delineations'' rather than the term ''CBSA-based labor market area definitions'' that we have used in the past to refer to OMB geographic boundaries of statistical areas (75 FR 37249).)

As discussed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50994 through 50995), in order to implement these changes for the LTCH PPS (as in the case of the IPPS), it is necessary to identify the new OMB delineations for each county and hospital in the country. While the revisions OMB published on February 28, 2013, are not as sweeping as the changes OMB announced in 2003, the February 28, 2013 bulletin does contain a number of significant changes. For example, under the new OMB delineations, there are new CBSAs, urban counties that have become rural, rural counties that have become urban, and existing CBSAs that have been split apart and moved to other CBSAs. Because the update was not issued until February 28, 2013, and it was necessary for the changes made by the update and their ramifications to be extensively reviewed and verified, we were unable to undertake such a lengthy process before publication of the FY 2014 rulemaking cycle. That is, by the time the update was issued, the FY 2014 IPPS/LTCH PPS proposed rule was in the advanced stages of development, and the proposed FY 2014 LTCH PPS wage indexes based on the CBSA designations that are currently used under the LTCH PPS had been developed. Therefore, we did not propose to use the changes to the LTCH PPS CBSA designations for FY 2014 based on the new OMB delineations. Rather, to allow for sufficient time to assess the new changes and their ramifications, we stated that we intended to propose the adoption of the new OMB delineations and the corresponding changes to the wage index based on those delineations under the LTCH PPS for FY 2015 through notice and comment rulemaking, consistent with the approach used under the IPPS (78 FR 50994 through 50995). As discussed below, 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 adopt the new OMB delineations announced in the February 28, 2013 OMB Bulletin No. 13–01, effective for FY 2015 under the LTCH PPS, consistent with the approach proposed for the IPPS as discussed in section III.B. of the preamble of this proposed rule.

2. Proposed Use of the New OMB Labor Market Area Delineations (''New OMB Delineations'')

Historically, Medicare prospective payment systems have utilized labor market area definitions developed by the OMB. As discussed above, the CBSA designations currently used under the LTCH PPS are based on the most recent market area definitions issued by the OMB. The OMB reviews its market area definitions/delineations based on data from the preceding decennial census to reflect more recent population changes. As discussed above and in section III.B. of the preamble of this proposed rule, the new OMB delineations are based on the OMB's latest market area delineations based on the 2010 Decennial Census data. Because we believe that the OMB's latest labor market area delineations are the best available data that reflect the local economies and wage levels of the areas in which hospitals are currently located, we are proposing to adopt the new OMB delineations based on the 2010 Decennial Census data under the LTCH PPS, beginning in FY 2015, for the reasons discussed below (which are consistent with the IPPS proposal discussed in section III.B. of the preamble of this proposed rule).

When we implemented the wage index adjustment under § 412.525(c) for the LTCH PPS, and updated the LTCH PPS labor market area definitions based on the CBSA designations beginning in RY 2006, we explained that the LTCH PPS wage index adjustment was intended to reflect the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. (We refer readers to the RY 2003 LTCH PPS final rule (67 FR 56016) and the RY 2006 LTCH PPS final rule (70 FR 24184).) Because we believe that the new OMB delineations based on 2010 Decennial Census data reflect the most recent available geographic classifications (market area delineations), we are proposing to revise the geographic classifications used under the LTCH PPS based on these new OMB delineations to ensure that the LTCH PPS wage index adjustment continues to most appropriately account for and reflect the relative hospital wage and wage-related costs in the geographic area of the hospital as compared to the national average hospital wage and wage-related costs. Specifically, we are proposing to adopt the new OMB delineations (as discussed in greater detail below), effective for LTCH PPS discharges occurring on or after October 1, 2014 (that is, effective for FY 2015). We note that, because the application of the LTCH PPS area wage-level adjustment under existing § 412.525(c) is made on the basis of the location of the LTCH—either in an ''urban'' area or a ''rural'' area as those terms are defined under existing § 412.503. Under § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area as defined by the Executive OMB. A ''rural area'' is defined as any area outside of an urban area. Therefore, we are not proposing any changes to the existing regulations under this proposal.

As discussed in section III.B. of this preamble, while CMS and other stakeholders have explored potential alternatives to the current CBSA-based labor market system, no consensus has been achieved regarding how best to implement a replacement system. While we recognize that MSAs are not designed specifically to define labor market areas, we believe that they do represent a useful proxy for this purpose. Consistent with the approach taken for the IPPS, we have used MSAs to define labor market areas for

purposes of Medicare wage indices under the LTCH PPS since its implementation in FY 2003. MSAs also are used to define labor market areas for purposes of the wage index for many of the other Medicare payment systems (for example, the IRF PPS, the SNF PPS, the HHA PPS, the OPPS, and the IPF PPS). (We refer readers to the RY 2006 LTCH PPS final rule (70 FR 24184).) Therefore, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to adopt the new OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13–01, effective under the LTCH PPS for FY 2015. In addition, we are proposing to use these new OMB delineations to calculate area wage indexes in a manner that is consistent with the CBSA-based methodologies finalized in the RY 2006 LTCH PPS final rule, as refined in subsequent rulemaking. We also are proposing a wage index transition policy (as discussed in more detail below) for LTCHs that would experience a negative payment impact due to the proposed use of the new OMB delineations. This proposal, including the proposed wage index transition policy, is consistent with the proposal under the IPPS presented in section III.B. of the preamble of this proposed rule. The discussion below is focused on issues related to the proposed use of the new OMB delineations to define labor market areas for purposes of the wage index adjustment under the LTCH PPS, and is consistent with what is being proposed for the IPPS.

a. Micropolitan Statistical Areas

When we adopted the CBSA designations under the LTCH PPS in RY 2006, we discussed CMS' consideration of whether to use Micropolitan Statistical Areas to define the labor market areas for the purpose of the LTCH PPS wage index. OMB defines a ''Micropolitan Statistical Area'' as a Consolidated Metropolitan Statistical Area (CMSA) ''associated with at least one urban cluster that has a population of at least 10,000, but less than 50,000'' (70 FR 24183). We refer to these areas as ''Micropolitan Areas.'' After conducting an extensive impact analysis, we determined that the best course of action would be to treat all hospitals located in ''Micropolitan Areas'' as ''rural,'' and to include these hospitals in the calculation of each State's rural wage index. Because Micropolitian Areas tend to encompass smaller population centers and contain fewer hospitals than MSAs, we determined that if Micropolitan Areas were to be treated as separate labor market areas, the IPPS wage index would include drastically more single-provider labor market areas. This larger number of labor market areas with fewer providers could create instability in year-to-year wage index values for a large number of hospitals; could reduce the averaging effect of the wage index, lessening some of the efficiency incentive inherent in a system based on the average hourly wages for a large number of hospitals; and could arguably create an inequitable system when so many hospitals would have wage indexes based solely on their own wage data while other hospitals' wage indexes would be based on an average hourly wage across many hospitals. For these reasons, we adopted a policy to include Micropolitan Areas in the State's rural wage area, and have continued this policy through the present. (We refer reader to the RY 2006 LTCH PPS final rule (70 FR 24187).)

Based upon the 2010 Decennial Census data, a number of rural and urban counties have joined or have become Micropolitan Areas, while other counties that once were part of a Micropolitan Area under previous OMB CBSA designations, have become either urban or rural under the new OMB delineations. Overall, there are fewer Micropolitan Areas (541) under the new OMB delineations based on 2010 Decennial Census data than existed under the data from the 2000 Census (581). We believe that it is appropriate to continue the policy established in the RY 2006 LTCH PPS final rule, and we are proposing to treat Micropolitan Areas as rural labor market areas under the LTCH PPS. These areas continue to be defined as having relatively small urban cores (populations of 10,000–49,999). We do not believe that it would be appropriate to calculate a separate wage index for areas that typically may include only a few hospitals for the reasons set forth in the RY 2006 LTCH PPS final rule, as discussed above. Therefore, in conjunction with our proposal to use the new OMB labor market area delineations, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, for FY 2015, we are proposing to continue to treat Micropolitan Areas as ''rural,'' and to assign the Micropolitan Area the statewide rural wage index for the State in which the LTCH is located. We also are proposing that, beginning in FY 2015, the wage data for any IPPS hospitals located in the Micropolitan Areas would be included in the calculation of each State's LTCH PPS rural area wage index. (As discussed in section V.B.2. of the Addendum to this proposed rule, the LTCH PPS area wage index values are calculated using the wage data of IPPS hospitals.) We note that this proposal is consistent with the proposal for the IPPS discussed in section III.B.2.a. of the preamble of this proposed rule. We refer readers to section VII.D.2.e. of this preamble for a discussion of our proposals to moderate the impact of our proposed use of the new OMB delineations under the LTCH PPS.

b. Urban Counties That Became Rural Under the New OMB Labor Market Area Delineations

In proposing to use the new OMB delineations, which are based upon 2010 Decennial Census data, for FY 2015, we found that there are a number of counties (or county equivalents) that are defined as ''urban'' under the previous CBSA designations that are now defined as ''rural'' under the new OMB delineations. As discussed in section III.B. of this preamble, an analysis of the new OMB delineations shows that a total of 37 counties (and county equivalents) that were considered to be part of an ''urban'' CBSA are now considered to be located in a ''rural'' area, beginning in FY 2015, based on the new OMB delineations. We refer readers to a table presented in section III.B.2.b. of the preamble of this proposed rule that lists the 37 urban counties that would be defined as rural if we finalize our proposal to use the new OMB delineations. Under our proposal to use the new OMB delineations for the LTCH PPS, we are proposing that LTCHs located in any of the 37 counties listed in the table under section III.B.2.b. of the preamble of this proposed rule would be considered ''rural,'' and would receive their respective State's rural area wage index for FY 2015 under the LTCH PPS. We note that, currently, there are no LTCHs located in any of the 37 counties listed in the table that are currently considered to be part of an ''urban'' CBSA and that would be considered to be located in a ''rural'' area, beginning in FY 2015, if the proposed adoption of the new OMB delineations is finalized. We also proposing that, if finalized, the wage data for any IPPS hospitals located in those 37 counties listed in the table now would be considered ''rural'' when calculating the respective State's LTCH PPS rural area wage index beginning in FY 2015. (As discussed in section V.B.2. of the Addendum to this proposed rule, the LTCH PPS area wage index values are calculated using the area wage data of IPPS hospitals.) We note that this proposal is consistent with the proposal under the IPPS discussed in section

III.B.2.b. of the preamble of this proposed rule. We refer readers to section VII.D.2.e. of the preamble of this proposed rule for a discussion of our proposals to moderate the impact of our proposal to implement the new OMB delineations under the LTCH PPS.

c. Rural Counties That Became Urban Under the New OMB Labor Market Area Delineations

In proposing to use the new OMB labor market area delineations (which are based upon 2010 Decennial Census data) for FY 2015, we found that there are a number of counties (or county equivalents) that are defined as ''rural'' under the previous OMB definitions (that is, CBSA designations) that would be considered ''urban'' if the proposed adoption of the new OMB delineations is finalized. As discussed in section III.B.2.c. of the preamble of this proposed rule, an analysis of the new OMB labor market area delineations shows that a total of 105 counties (and county equivalents) that were previously located in ''rural'' areas now are located in an ''urban'' area under the new OMB delineations. We refer readers to a table in section III.B.2.c. of the preamble of this proposed rule that lists the 105 ''rural'' counties that would be located in an ''urban'' area, if we finalize our proposal to adopt the new OMB delineations presented in section III.B.2.c. of the preamble of this proposed rule. There are currently no LTCHs located in the 105 ''rural'' counties listed in that table.

Under our proposal to adopt the new OMB labor market area delineations, we are proposing that LTCHs located in any of those 105 counties now would be included in their new respective ''urban'' CBSAs and would receive the respective ''urban'' CBSA's area wage index. We also are proposing that, beginning in FY 2015, the wage data for any IPPS hospitals located within those 105 counties now would be included in the calculation of the LTCH PPS area wage index for those hospitals' respective ''urban'' CBSAs. (As discussed in section V.B.2. of the Addendum to this proposed rule, the LTCH PPS area wage index values are calculated using the area wage data of IPPS hospitals.) We note that this proposal is consistent with the proposal for the IPPS discussed in section III.B.2.c. of the preamble of this proposed rule. We refer readers to section VII.D.2.e. of the preamble of this proposed rule for a discussion of our proposals to moderate the impact of our proposal to implement the new OMB delineations under the LTCH PPS.

d. Urban Counties Moved to a Different Urban CBSA Under the New OMB Labor Market Area Delineations

In addition to ''rural'' counties that would become ''urban'' and ''urban'' counties that would become ''rural'' under the new OMB delineations, we found that several urban counties shifted from one urban CBSA to another urban CBSA. In certain cases, the new OMB delineations involved a change only in the CBSA name or code, while the CBSA continued to encompass the same constituent counties. However, in other cases, under the new OMB delineations, some counties are shifted between existing urban CBSAs and new urban CBSAs, changing the constituent makeup of those CBSAs. For example, in some cases, entire CBSA are subsumed by another CBSA. In other cases, some CBSAs have counties that are split off as part of a different urban CBSA, or to form entirely new labor market areas. We refer readers to section III.B.2.d. of the preamble of this proposed rule for additional information, including examples, on urban counties that are moved from one urban CBSA to a different urban CBSA under the new OMB delineations. LTCHs located in these affected counties that would move from one urban CBSA to a different urban CBSA under our proposal to adopt the new OMB delineations would experience both negative and positive impacts in regard to the LTCH's specific area wage index values. We refer readers to section VII.D.2.e. of the preamble of this proposed rule for a discussion of our proposals to moderate the impact imposed upon hospitals because of our proposal to adopt the new OMB labor market area delineations under the LTCH PPS.

e. Proposed Transition Period

As indicated above, overall, we believe that our proposal to adopt the new OMB delineations would result in LTCH PPS wage index values being more representative of the actual costs of labor in a given area. However, we also recognize that some LTCHs would experience decreases in their area wage index values as a result of our proposal. We also realize that many LTCHs would have higher area wage index values under our proposal. To mitigate the impact imposed upon hospitals, we have in the past provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts. While we believe that using the new OMB delineations would create a more accurate payment adjustment for differences in area wage levels, we also recognize that adopting such changes may cause some short-term instability in LTCH PPS payments. Therefore, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing a transition policy for LTCHs that would experience a decrease in their area wage index values due to our proposal to adopt the new OMB delineations under the LTCH PPS. Specifically, for FY 2015, we are proposing to compute a blended area wage index value for any LTCH that would experience a decrease in its area wage index value solely due to the proposed adoption of the new OMB delineations beginning in FY 2015. That is, for purposes of determining an LTCH's area wage index for FY 2015, we are proposing to compute LTCH PPS wage index values using the proposed area wage data discussed above and in section V.B.4. of the Addendum to this proposed rule under both the current (FY 2014) CBSA designations and the proposed (FY 2015) new OMB delineations based on the 2010 OMB Decennial Census data. For each LTCH, we are proposing to compare these two proposed wage indexes. If an LTCH's proposed wage index under the proposed adoption for FY 2015 of the new OMB delineations is lower than the LTCH's proposed wage index under the FY 2014 CBSA designations, we are proposing that, for FY 2015, the LTCH would be paid based on a blended wage index that would be computed as the sum of 50 percent of each of the two proposed wage index values described above (referred to as the proposed 50/50 blended wage index). If an LTCH's proposed wage index under the proposed adoption for FY 2015 of the new OMB delineations is higher than the LTCH's proposed wage index under the FY 2014 CBSA designations, we are proposing that, for FY 2015, the LTCH would be paid based on 100 percent of the proposed wage index under the proposed FY 2015 new OMB delineations (and would not receive the proposed 50/50 blended wage index).

Furthermore, we are proposing that the proposed transitional area wage index policy be used in a budget neutral manner. Under § 412.525(c)(2), any changes to the adjustment for differences in area wage levels are made in a budget neutral manner such that estimated aggregate FY 2015 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 is applied to the standard Federal rate (under § 412.523(d)(4)) to ensure that any changes to the area wage-level adjustments are budget neutral such that any changes to the wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Because our proposed transition policy for LTCHs that would experience a decrease in their area wage index values solely as a result of our finalized policy to adopt the new OMB delineations under the LTCH PPS would result in an increase in estimated aggregate LTCH PPS payments without such changes, we are proposing to include the proposed 50/50 blended wage index in our calculations for the proposed area wage-level adjustment budget neutrality factor that would be applied to the proposed standard Federal rate to ensure that any changes to the area wage-level adjustment are budget neutral. Specifically, consistent with our established methodology, we are proposing to use the following methodology to determine a proposed area wage-level adjustment budget neutrality factor for FY 2015:

- *Proposed Step 1*—We are proposing to simulate estimated aggregate LTCH PPS payments using the FY 2014 wage index values as established in Tables 12A and 12B for the FY 2014 IPPS/LTCH PPS final rule (which is available via the Internet on the CMS Web site) and the FY 2014 labor-related share of 62.537 percent as established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50996).
- *Proposed Step 2*—We are proposing to simulate estimated aggregate LTCH PPS payments using the proposed FY 2015 wage index values as shown in Tables 12A through 12D for this proposed rule (which are available via the Internet on the CMS Web site), including the proposed transitional 50/50 blended wage index values, if applicable (as discussed in section V.B.4. of the Addendum of this proposed rule), and the proposed FY 2015 labor-related share of 62.571 percent (as discussed in section V.B.3. of the Addendum to this proposed rule).
- *Proposed Step 3*—We are proposing to determine the ratio of these estimated total LTCH PPS payments by dividing the estimated total LTCH PPS payments using the FY 2014 area wage-level adjustments (calculated in proposed Step 1) by the estimated total LTCH PPS payments using the proposed FY 2015 area wage-level adjustments (calculated in proposed Step 2) to determine the proposed FY 2015 area wage-level adjustment budget neutrality factor.
- *Proposed Step 4*—We are proposing to then apply the proposed FY 2015 area wage-level adjustment budget neutrality factor from proposed Step 3 to the proposed FY 2015 LTCH PPS standard Federal rate after the application of the proposed FY 2015 annual update as discussed in section V.A.2. of the Addendum to this proposed rule.

As explained above, we are proposing to apply this factor in determining the proposed FY 2015 standard Federal rate to ensure that the proposed updates to the area wage-level adjustment for FY 2015 would be implemented in a budget neutral manner. For this proposed rule, using the steps in the methodology described above, we determined a FY 2015 area wage-level adjustment budget neutrality factor of 1.0002034.

We note that this proposed transitional area wage index policy under our proposal to adopt the new OMB delineations for FY 2015 under the LTCH PPS is consistent with the proposals under the IPPS presented in sections III.B.2.e.(5) and (6) of the preamble of this proposed rule. As noted previously in section VII.D.2.b. of the preamble of this proposed rule, there are currently no LTCHs located in an ''urban'' county that would become ''rural'' under the proposal to adopt the new OMB delineations. Therefore, we are not proposing a transitional area wage index policy that is consistent with the IPPS proposal presented in section III.B.2.e.(2). of the preamble of this proposed rule for hospitals that are currently located in an ''urban'' county that would become ''rural'' under the proposed adoption of the new OMB delineations. We also note that we are not proposing any transitional policies under the LTCH PPS that would be consistent with those presented under the IPPS for hospitals with a reclassification or redesignation as discussed in section III.B.2.e.(3). of the preamble of this proposed rule, or for hospitals deemed urban under section 1886(d)(8)(B) of the Act as discussed in section III.B.2.e.(4) of the preamble of this proposed rule, as those reclassifications, redesignations, and statutory deems are not applicable to LTCHs.

E. Reinstatement and Extension of Certain Payment Rules for LTCH Services—The 25-Percent Threshold Payment Adjustment

1. Background

Section 1206(b)(1)(A) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), enacted on December 26, 2013, provides for the retroactive reinstatement and extension, for an additional 4 years, of the moratorium on the full implementation of the 25-percent threshold payment adjustment (hereinafter referred to as ''the 25-percent policy'') under the LTCH PPS established under section 114(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. In addition, section 1206(b)(1)(B) of Public Law 113–67 provides for a permanent exemption from the application of the 25-percent policy for certain grandfathered co-located LTCHs and LTCH satellite facilities.

Section 1206(b)(1)(C) of Public Law 113–67 also requires that ''. . . [n]ot later than 1 year before the end of the 9-year period referred to in section 114(c)(1) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (42 U.S.C. 1395ww note), as amended by subparagraph (B) [of section 1206 of Pub. L. 113–67], the Secretary of Health and Human Services shall submit to Congress a report on the need for any further extensions (or modifications of the extensions) of the 25 percent rule described in sections 412.534 and 412.536 of title 42, Code of Federal Regulations, particularly taking into account the application of section 1886(m)(6) of the Social Security Act, as added by subsection (a)(1) [of section 1206 of Pub. L. 113–67].'' We refer readers to section VII.I.2. of the preamble of this proposed rule for further discussion of this report.

The 25-percent policy is a payment adjustment under the LTCH PPS, originally established in our regulations at 42 CFR 412.534 for LTCHs and LTCH satellite facilities and their co-located referring hospitals in the FY 2005 IPPS final rule (69 FR 49191), and at 42 CFR 412.536 for all other LTCHs and referring hospitals in the RY 2007 LTCH PPS final rule (72 FR 26870), based on analyses of Medicare discharge data that indicated that patterns of patient shifting appeared to be occurring more for provider financial advantage than for patient benefit. In order to discourage such activity, a payment adjustment was applied for LTCH discharges of patients who were admitted to the LTCH from the same referring hospital in excess of an applicable percentage threshold, which was to transition to a 25-percent threshold after specified phase-in periods. (For rural and single-urban LTCHs and those with MSA-dominant referring hospitals, a 50-percent threshold was applied.). Under this policy, discharges in excess of the threshold are paid at an ''IPPS equivalent'' rate, instead of the much higher LTCH PPS rate. (We refer readers to detailed discussions of the 25-percent

policy for LTCH HwHs and LTCH satellite facilities in the FY 2005 IPPS final rule (69 FR 49191 through 49214) and its application to all other LTCHs in the RY 2008 LTCH PPS final rule (72 FR 26919 through 26944).)

The results of the different rulemaking schedules in effect when §§ 412.534 and 412.536 were implemented (FY 2005 (October 1, 2004) and RY 2007 (July 1, 2006), respectively) are as follows: for co-located LTCHs and LTCH satellite facilities governed under § 412.534, the 25-percent policy was effective for cost reporting periods beginning on or after October 1, 2005 (''October'' LTCHs); for LTCHs and LTCH satellite facilities governed under § 412.536, the 25-percent policy was effective for cost reporting periods beginning on or after July 1, 2007 (''July'' LTCHs). In addition, even though grandfathered LTCH HwHs and LTCH satellite facilities are governed under § 412.534(h), they are ''July'' LTCHs because the 25-percent policy was applied to these facilities in the RY 2008 LTCH PPS final rule.

Section 114(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, provided for a 5-year moratorium on the full application of the 25-percent policy that expired for some LTCHs and LTCH satellite facilities for cost reporting periods beginning on or after October 1, 2012 (''October'' LTCHs) and for other LTCHs and LTCH satellite facilities for cost reporting periods beginning on or after July 1, 2012 (''July'' LTCHs). (For a detailed description of the moratorium on the application of the 25-percent policy, we refer readers to the May 22, 2008 Interim Final Rule with Comment Period (73 FR 29699 through 29704) and the August 27, 2009 Interim Final Rule with Comment Period for the ARRA, which was published in the FY 2010 IPPS final rule and Changes to the LTCH PPS and Rate Years 2010 and 2009 Rates final rule (74 FR 43990 through 43992).

The expiration of the statutory moratorium for both ''July'' and ''October'' LTCHs was delayed because CMS established regulatory extensions in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53483 through 53484), as amended by the FY 2013 IPPS/LTCH PPS correcting amendment (77 FR 63751 through 63753). Specifically, we established a 1-year extension (that is, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013) on the full application of the 25-percent policy for ''October'' LTCHs. For those ''July'' LTCHs that would have been affected by the ''gap'' between the expiration of the statutory moratorium (for cost reporting periods beginning on or after July 1, 2012) and our prospective regulatory relief (for cost reporting periods beginning on or after October 1, 2012), we also provided for an additional moratorium based on LTCH discharges occurring on or after October 1, 2012 and ending at the start of the LTCHs' next cost reporting period. For those ''July'' LTCHs with cost reporting periods beginning on or after October 1, 2012, the regulatory extension of the statutory moratorium, described above, effective for the hospital's first cost reporting period beginning on or after October 1, 2012, resulted in seamless coverage for that group. However, for those ''July'' LTCHs with cost reporting periods beginning on or after July 1, 2012, and before October 1, 2012, that would have otherwise been subject to the ''gap'' between the expiration of the statutory moratorium and the effective date of the regulatory moratoria, we established a second regulatory moratorium effective with discharges occurring beginning October 1, 2012, through the end of the LTCH's cost reporting period (that is, the end of the cost reporting period that began on or after July 1, 2012, and before October 1, 2012). Therefore, by providing for the above described regulatory extension for ''July'' LTCHs, we eliminated the distinction between ''July'' and ''October'' LTCHs, which resulted in the 25-percent policy being applied for all cost reporting periods beginning on or after October 1, 2012, following the expiration of the moratorium. For more details about these moratoria, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53483 through 53484).

Because we did not extend the regulatory moratorium on the 25-percent policy in the FY 2014 IPPS/LTCH PPS final rule, the full application of the payment adjustment policy was effective for all LTCHs (both ''October'' and ''July'' LTCHs) for cost reporting periods beginning on or after October 1, 2013 (78 FR 50772).

2. Proposed Implementation of Section 1206(b)(1) of Public Law 113–67

As stated earlier, section 1206(b)(1)(A) of Public Law 113–67 provides an additional amendment to section 114(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, that extends the ''original'' statutory moratorium on the full implementation of the 25-percent policy to a total of 9 years from the original effective dates established by the MMSEA (July 1 or October 1, 2007, as applicable). As a result, the lapse of the regulatory moratorium on the full implementation of the 25-percent policy is moot. This ''seamless'' statutory moratorium provides relief until cost reporting periods beginning on or after July 1, or October 1, 2016, as applicable. Section 1206(b)(1)(B) provides a permanent exemption from the 25-percent policy for certain grandfathered co-located LTCHs and LTCH satellite facilities.

In this proposed rule, based on the statutory changes made by sections 1206(b)(1)(A) and (b)(1)(B) of Public Law 113–67, we are proposing to make conforming amendments to the regulations governing application of the 25-percent policy. Specifically, we are proposing to revise §§ 412.534(c)(1)(i) and (c)(1)(ii), (c)(2), (c)(3), (d)(1) and (d)(1)(i), (d)(2), (d)(3), (e)(1) and (e)(1)(i), (e)(2), (e)(3), the introductory text of paragraph (h), (h)(4), and (h)(5) and to remove paragraph (h)(6); and removing paragraphs (a)(1)(iii) and (a)(2)(ii), revising (a)(2), and removing paragraph (a)(3) of § 412.536 to reflect the statutory changes.

F. Proposed Changes to the Fixed-Day Thresholds Under the ''Greater Than 3-Day Interruption of Stay'' Policy Under the LTCH PPS

1. Background

The interrupted stay policy is a payment adjustment that was included under the LTCH PPS from the inception; that is, for cost reporting periods beginning on or after October 1, 2002 (FY 2003). In this discussion, we use the terms ''interrupted stay'' and ''interruption of stay'' interchangeably. An ''interruption of stay'' occurs when during the course of an LTCH hospitalization, a patient is discharged to an inpatient acute care hospital, an IRF, or a SNF for treatment or services not available at the LTCH for a specified period followed by a readmittance to the same LTCH. We refer readers to the RY 2003 LTCH PPS final rule (67 FR 56002). When we established this policy, we believed that the readmission to the LTCH represented a continuation of the initial treatment, a stay in which an ''interruption'' occurred, rather than a new admission if the length of stay at the intervening facility was within a specified number of days. If an ''interruption of stay'' occurred, payment for both ''halves'' of the LTCH discharge were then ''bundled,'' and Medicare would make one payment based on the second date of discharge. Specifically, under this policy, we established a fixed-day threshold, which applied to the specified number of days

a Medicare beneficiary spends as an inpatient at an acute care hospital, an IRF, or a SNF. In the RY 2003 LTCH PPS final rule, we explained that we were implementing this policy because we wanted ''. . .to reduce the incentives inherent in a discharged-based prospective payment system of ''shifting'' patients between Medicare-covered sites of care in order to maximize Medicare payments. This policy is particularly appropriate for LTCHs because, as a group, these hospitals differ considerably in the range of services offered such that where some LTCHs may be able to handle certain acute conditions, others will need to transfer their patients to acute care hospitals.

''For instance, some LTCHs are equipped with operating rooms and intensive care units and are capable of performing minor surgeries. However, other LTCHs are unable to provide those services and will need to transfer the beneficiary to an acute care hospital. We believed that our policy also provided for a patient . . . ''who no longer requires hospital-level care, but is not ready to return to the community,'' and who ''. . . could be transferred to a SNF.'' (We refer readers to the RY 2003 LTCH PPS final rule (67 FR 56002).)

Therefore, in the regulations under 42 CFR 412.531, we defined two types of interruptions of stays. Under § 412.531(a)(1), ''[a] 3-day or less interruption of stay'' means a stay at a LTCH during which a Medicare inpatient is discharged from the LTCH to an acute care hospital, IRF, SNF, or the patient's home and readmitted to the same LTCH within 3 days of the discharge from the LTCH. Whereas under the ''3 day or less interruption of stay policy,'' the fixed-day threshold period begins with the calendar date of discharge from the LTCH and ends not later than midnight of the third day, if an LTCH patient's ''interruption'' exceeds this threshold, payment is governed by the ''greater than 3-day interruption of stay'' policy. (We refer readers to the RY 2005 LTCH PPS final rule (69 FR 25690 through 25700), the RY 2006 LTCH PPS final rule (70 FR 24206), and the RY 2007 LTCH PPS final rule (71 FR 27872 through 27875) for detailed discussions of the 3-day or less interruption of stay policy.) We are not proposing to revise the 3-day or less category of interrupted stays, but we make mention of the policy for clarity in making a distinction between the 3-day or less interruption of stay policy and the greater than 3-day interruption of stay policy that we are proposing to revise.

The ''greater than 3-day interruption of stay policy,'' is defined under § 412.531(a)(2) as a stay ''. . . during which a Medicare inpatient is transferred upon discharge to an acute care hospital, an IRF, or a SNF for treatment or services that are not available in the long-term care hospital and returns to the same long-term care hospital within the applicable fixed-day period specified in regulations under § 412.531(a)(2)(i) through (a)(2)(iii).'' For a discharge to an acute care hospital, the applicable fixed-day period is between 4 and 9 consecutive days; the counting of the days begins on the calendar day of discharge from the LTCH and ends on the 9th day when the patient is readmitted to the LTCH. For a discharge to an IRF, the applicable fixed-day period is between 4 and 27 consecutive days; the counting of the days begins on the calendar day of discharge from the LTCH and ends on the 27th day. For a discharge to a SNF, the applicable fixed-day period is between 4 and 45 consecutive days; the counting of the days begins on the calendar day of discharge from the LTCH and ends on the 45th day.

These timeframes reflect our policy of only paying for more than one discharge if the patient's length of stay exceeds one standard deviation from the average length of stay. As we stated in the RY 2003 LTCH PPS final rule, this policy was established with the intent of ''balanc[ing] the payment incentives of both the LTCH and the acute care hospital, IRF, or SNF to which the LTCH patient is discharged before being readmitted to the LTCH,'' and is intended to ensure ''that discharges from LTCHs are based on clinical considerations and not financial incentives'' (67 FR 56002). As we stated at that time, we believed that a threshold of one standard deviation from the average length of stay would address the cost-based disincentives inherent in cases that significantly exceed the average length of stay. Furthermore, the threshold would ''capture the majority of the discharges that are similar to the average length of stay for the respective DRG, combination CMG and comorbidity tier, or for all Medicare SNF cases.'' Specifically, in establishing this policy, we calculated the average length of stay plus one standard deviation for each inpatient setting in which an ''interruption'' could occur in order to determine a fixed-day threshold. This use of a standard deviation as the justification for additional payment is consistent with our use of a standard deviation measure as the measure for paying additional amounts for new technologies under the acute care hospital inpatient prospective payment system. Under that system, ''the cost of a new technology must exceed one standard deviation beyond the mean standardized charge for all cases in the DRG to which the new technology is assigned in order to receive additional payments'' (67 FR 56002).

Therefore, if an LTCH readmission occurs within the fixed-day period both halves of the LTCH discharge are treated as a single discharge for the purposes of payment under the LTCH PPS. In such instances, the beneficiary's readmittance to the LTCH is paid for with a single LTC–DRG payment that covers the initial admission to the LTCH, and the subsequent readmission. That is, a single Medicare payment is made for the entire two-part discharge. Payment to the acute care hospital, the IRF, or the SNF is then made in accordance with the applicable payment policies for those providers when the interruption of stay exceeds 3 days. Therefore, we balanced the payment incentives of both the LTCH and the acute care hospital, IRF, or SNF to which the LTCH patient might be discharged before being readmitted to the LTCH.

As we discussed in the RY 2003 LTCH PPS final rule (67 FR 56007), our concerns about patient shifting were significantly increased in the context of transfers between co-located LTCHS and LTCH satellite facilities, or for LTCH hospital-within-hospital transfers. Collectively, we refer to these arrangements as transfers to ''onsite'' providers. In the regulations under § 412.532(b), we define a facility that is ''co-located or ''on-site'' as ''a hospital, satellite facility, unit, or SNF that occupies space in a building also used by another hospital or unit or in one or more buildings on the same campus, as defined in § 413.65(a)(2) of this subchapter, as buildings used by another hospital or unit.'' Under this LTCH PPS policy, if more than 5 percent of the Medicare patients discharged from an LTCH during a cost reporting period were discharged to an ''onsite'' SNF, IRF, or psychiatric facility, or to an ''onsite'' acute care hospital, and directly readmitted to the same LTCH, the LTCH would be paid one MS–LTC–DRG payment to cover both LTCH discharges, regardless of the length of the interrupted stay. As is the case in regard to the greater than 3-day interruption of stay policy, payment to an acute care hospital, an IRF, or a SNF would not be affected under the 5-percent policy. We refer readers to the RY 2003 LTCH PPS final rule for a

detailed description of the 5-percent policy (67 FR 56007 through 56014).

Our concern about patient shifting among ''onsite'' providers did not originate with the implementation of the LTCH PPS. The LTCH 5-percent policy under § 412.532 was recodified from an earlier regulation under § 413.40(a)(3), which applied a payment adjustment to hospitals paid under the TEFRA payment system, including LTCHs, to address inappropriate discharges of patients to a host hospital paid under the inpatient prospective payment system from an excluded hospital-within-a-hospital (such as a LTCH), that culminated in a readmission to the hospital-within-a-hospital. (We refer readers to the RY 1999 LTCH PPS final rule (64 FR 41353) and the RY 2003 LTCH PPS final rule (67 FR 56007).) In the RY 2003 LTCH PPS final rule, we adopted this payment adjustment under the LTCH PPS to ''address inappropriate shifting of patients among these providers without clinical justification to maximize Medicare payment'' due to inappropriate incentives to prematurely discharge patients to one of these other onsite providers once their lengths of stay at the LTCH exceeded the thresholds established by the short-stay outlier policies.'' Therefore, we sought to ensure that discharges would not be based on ''payment considerations rather than on a clinical basis as an extension of the normal progression of appropriate patient care.''

2. Thresholds Used in Recent Statutory Programs

Two previously implemented Medicare initiatives, the Hospital IQR Program, established by section 501(b) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, and the Readmission Reduction Program, established by section 3025 of the Affordable Care Act, include measures that focus, among other things, on the implied relationships between quality patient care and payment consequences for the Medicare program resulting from patient readmissions. The Hospital IQR Program, which we discuss in detail in section IX.A. of the preamble of this proposed rule, publicly reports, among other things, inpatient outcome measures, including 30-day readmissions for specific medical conditions (acute myocardial infarction, heart failure, pneumonia, total hip/knee arthroplasty, hospital-wide all-cause unplanned, stroke, and COPD). The Hospital Readmissions Reduction Program, which we discuss in section IV.H. of the preamble of this proposed rule, requires CMS to reduce payments to IPPS hospitals with excess readmissions, effective for discharges beginning on October 1, 2012. Under that program, we define a ''readmission'' as an admission to a subsection (d) hospital within 30 days of a discharge from the same or another subsection (d) hospital. As noted in our response to a public comment in the FY 2012 IPPS/LTCH PPS final rule, the ''timeframe of 30 days from the date of the initial discharge from the index hospitalization is the timeframe that has been NQF[National Quality Forum]-endorsed as part of the three readmission measures. The timeframe of 30 days is considered an acceptable standard [for quality measurement] in both the research and measurement communities, as this time period is long enough to capture a substantial proportion of readmissions attributable to an index hospitalization . . . and yet it is short enough that outcomes can be attributed to and influenced by hospital care and the early transition to the outpatient setting. The use of the 30-day timeframe is also a clinically meaningful period for hospitals to collaborate with their communities in an effort to reduce readmissions.'' (We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51669 through 51670).)

In light of the 30-day threshold established for the Hospital IQR Program and the Hospital Readmissions Reduction Program, we conducted an evaluation of our greater than 3-day interruption of stay policy. A review of claims data indicates that interrupted stays at acute care hospitals constitute the vast majority of the intervening stays under the interruption of stay policy. When implementing policies under the Hospital IQR Program and the Hospital Readmissions Reduction Program, we have, in effect, asserted that a second inpatient episode of care that occurs within 30 days of an initial (index) hospitalization is likely linked to the first stay. Under the LTCH PPS, the application of the payment adjustment specified in the ''greater than 3-day interruption of stay'' policy is based on the number of days that elapsed between the initial LTCH discharge and the beneficiary's readmission to the same LTCH. An interruption of stay that does not exceed the fixed-day threshold would result in one ''bundled'' discharge-based payment to cover both LTCH discharges. An interruption of stay that exceeds the fixed-day threshold would currently result in two separate Medicare payments under the LTCH PPS. However, we believe that it would be more appropriate to use a 30-day interval as the fixed-day threshold under the greater than 3-day interruption of stay policy under the LTCH PPS because that is consistent with the intervals used in the Hospital Readmissions Reductions Program and the Hospital Inpatient Quality Reporting Program. As such, we are proposing to revise the fixed-day thresholds under the greater than 3-day interruption of stay policy to provide for a 30-day fixed threshold as an ''acceptable standard'' for determining a linkage between an index discharge and a readmission from an inpatient facility as specified under this policy, that is, an IPPS hospital, an IRF, or a SNF.

3. Proposed Changes to the Greater Than 3-Day Interruption of Stay Policy

We are proposing to adopt a 30-day standard as the fixed-day threshold under the LTCH PPS ''greater than 3-day interruption of stay'' policy. To do so, we are proposing to amend our regulations by revising §§ 412.531(a)(2) and (b)(4) and adding new paragraphs (a)(3) and (b)(5) to reflect this proposed policy change.

Under our proposed policy revision, Medicare payments to LTCHs for patients discharged on or after October 1, 2014, who are treated in an acute care hospital, IRF, or SNF and readmitted to the same LTCH within 30 days of the index LTCH discharge, both discharges from the LTCH would be treated as one episode of care and a single discharge payment would be made to the LTCH. In addition, because we believe that this 30-day fixed-day threshold policy would address ''onsite'' concerns, we are proposing to remove § 412.532, that currently governs discharges from LTCHs to ''onsite'' providers that subsequently readmit the patient to the same LTCH. If we finalize our proposal to adopt the 30-day fixed-day threshold under the LTCH PPS greater than 3-day interruption of stay policy, we no longer believe that the regulatory requirements under § 412.532 are necessary and, therefore, we are proposing to remove that section in its entirety. Furthermore, a determination as to whether an LTCH has exceeded its 5-percent threshold under the LTCH PPS 5-percent policy occurs only upon cost report settlement, and as such, reflects an ''after the fact'' payment adjustment rather than an ''up front'' payment adjustment, such as the payment adjustments that would be applied under our proposed greater than 3-day interruption of stay policy. As such, we believe that the 5-percent policy has a limited impact on provider behavior, and we do not believe that retaining it has significant value to the Medicare program.

In summary, we are proposing to revise the regulations under §§ 412.531(a)(2) and (b)(4) and to add new §§ 412.531(a)(3) and (b)(5) to reflect this proposed payment policy revision. In addition, we are proposing to remove § 412.532 in its entirety and make a conforming change to § 412.525 by removing and reserving paragraph (d)(3), which references payments under § 412.532.

G. Moratoria on the Establishment of LTCHs and LTCH Satellite Facilities and on the Increase in the Number of Beds in Existing LTCHs or LTCH Satellite Facilities

As previously noted, Public Law 113–67 was enacted on December 26, 2013. Section 1206(b)(2) of Public Law 113–67 amended section 114(d) of the MMSEA of 2007, as previously amended by section 4302 of the American Recovery and Reinvestment Act (ARRA) of 2009 (Pub. L. 111–5) and sections 3106(b) and 10312(b) of the Affordable Care Act (Pub. L. 111–148). As further amended by section 112(b) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93), section 114(d) of the MMSEA includes a ''new'' statutory moratoria on the establishment of new LTCHs and LTCH satellite facilities, and on the increase in the number of hospital beds in existing LTCHs and LTCH satellite facilities, ''for the period beginning April 1, 2014 and ending September 30, 2017,'' which mirrors nearly identical provisions of the ''expired'' moratoria under section 114(d)(1) of the MMSEA, as amended by sections 4302 of the ARRA and sections 3106(b) and 10312(b) of the Affordable Care Act. These prior, yet nearly identical, provisions of section 114(d)(1) of the MMSEA, as amended by the ARRA and the Affordable Care Act, expired on December 28, 2012. For clarity and brevity, we will refer to the ''expired'' moratoria or moratorium to reference those that expired on December 28, 2012, and the ''new'' moratoria or moratorium to reference those that began on April 1, 2014, as applicable, throughout this discussion.

The primary difference between the ''expired'' moratoria and the ''new'' moratoria is that, while the ''expired moratoria'' provided for specific exceptions to both the moratorium on the establishment of new LTCHs and LTCH satellite facilities and on increases in the number of beds in existing LTCHs and LTCH satellite facilities, the ''new'' moratoria only provides exceptions to the moratorium on the establishment of new LTCHs and LTCH satellite facilities. No exceptions are provided under the ''new'' moratorium on increases in the number of hospital beds in existing LTCHs and LTCH satellite facilities. (For a detailed description of the ''expired'' moratoria provisions (including the applicable exceptions) that were in effect from December 29, 2007 through December 28, 2012, we refer readers to the May 22, 2008 Interim Final Rule with Comment Period (73 FR 29705 through 29708).

In light of the expiration date of the ''expired'' moratoria on December 28, 2012, and the effective date of the ''new'' moratoria on April 1, 2014, there has been a period of time in which new LTCHs and LTCH satellite facilities have been allowed to be established, and during which time there may have been increases in the number of hospital beds in LTCHs and LTCH satellite facilities. In accordance with section 114(d)(1) of the MMSEA, as amended by section 112(b) of Public Law 113–93, for the period beginning April 1, 2014 through September 30, 2017, CMS will be unable to designate any hospital as an LTCH, unless one of the exceptions (described below) is met.

Additionally, as of April 1, 2014, in accordance with sections 114(d)(6) and (d)(7) of the MMSEA, as amended by section 112(b) of Public Law 113–93, an existing LTCH may not increase the number of its hospital beds. This moratorium will extend through September 30, 2017, and is not subject to any exceptions.

To qualify for an exception under the ''new'' moratorium to establish a new LTCH or LTCH satellite facility during the timeframe between April 1, 2014, and September 30, 2017, a hospital or entity must meet the following criteria:

- The hospital or entity must have begun its qualifying period for payment as an LTCH under 42 CFR 412.23(e).
- The hospital or entity must have a binding written agreement with an outside, unrelated party for the actual construction, renovation, lease, or demolition for an LTCH, and must have expended before April 1, 2014, at least 10 percent of the estimated cost of the project or, if less, $2,500,000.
- The hospital or entity must have obtained an approved certificate of need in a State where one is required.

While this exception only applies to the ''new'' moratorium on the establishment of new LTCHs and LTCH satellite facilities under section 114(d)(7) of the MMSEA, as amended by section 112(b) of Public Law 113–93, the mechanics of the exception are analogous to those established under the ''expired'' moratorium, which ended in 2012. The ''expired'' moratoria were implemented in a May 22, 2008 Interim Final Rule with Comment Period (73 FR 29704 through 29707). As discussed in that rule, some of the terminology in the statutory provision was internally inconsistent. A strictly literal reading of the statutory language under section 114(d)(2) of the MMSEA, as amended by section 4302 of the ARRA and sections 3106(b) and 10312(b) of the Affordable Care Act, presented practical challenges for implementation in light of the established LTCH classification criteria under § 412.23(e) of the regulations. Therefore, we adopted interpretations that we believed would reasonably reconcile seemingly inconsistent provisions and that would result in a logical and workable mandate. Specifically, as drafted, the exception only applies to a hospital or entity when it is already classified as an ''LTCH.'' Such entities would not need an exception to the moratorium on becoming an ''LTCH'' because they would already be an LTCH. As such, we are proposing to interpret this provision under the new exception as we interpreted the exceptions to the ''expired'' moratorium. We discuss our interpretations below.

At the outset of this discussion, we want to clarify which provisions of section 114(d) of the MMSEA, as amended, were subject to the ''expired'' moratoria, and which are subject to the ''new'' moratoria. Sections 114(d)(2) and (3) of the MMSEA, as amended, only address exceptions under the ''expired'' moratoria. Section (d)(6) of the MMSEA, as amended, defines when the exceptions addressed in sections 114(d)(2) and (3) expired. Section (d)(7) of the MMSEA addresses the exception under the ''new'' moratorium on the establishment of new LTCHs and LTCH satellite facilities. There are no exceptions to the ''new'' moratorium on the increases in the number of beds in existing LTCHs and LTCH satellite facilities, as noted above.

Section 114(d)(7)(A) of the MMSEA, as amended, mirrors the expired provisions of section 114(d)(2)(A). Both provisions refer to an LTCH that began its qualifying period for payment as a ''long-term care hospital'' on or before a given date. However, a hospital would not be classified as an LTCH during that qualifying period; the facility or entity would typically be classified as an IPPS hospital. For a full discussion of our rationale for interpreting section 114(d)(2)(A) of the MMSEA to refer to an IPPS hospital meeting the stated requirements, we refer readers to our May 22, 2008 Interim Final Rule with Comment Period (73 FR 20704 through 29707) regarding the implementation of the ''expired'' moratorium. We are proposing to apply the same rationale in

regard to the interpretation of section 114(d)(7)(A), that is, we are proposing to interpret the provision to refer to an acute care hospital meeting the stated requirements as the hospital or entity seeks classification as an LTCH. As we did when interpreting the same language under the ''expired'' moratorium exception under section 114(d)(2)(A) of the MMSEA, as amended by section 4302 of the ARRA and sections 3106(b) and 10312(b) of the Affordable Care Act, we note that the exception under section 114(d)(7)(A) of the MMSEA cannot provide any relief to LTCH satellite facilities because there is no ''qualifying period'' for the establishment of a LTCH satellite facility for payment as a LTCH under § 412.23(e). Therefore, an LTCH satellite facility cannot meet the stated requirements for an exception under section 114(d)(7)(A) of the MMSEA.

Section 114(d)(7)(B) of the MMSEA specifies the conditions for an exception to the moratorium on the establishment of new LTCHs and LTCH satellite facilities having: (1) A binding written agreement with an outside, unrelated party for the actual construction, renovation, lease, or demolition for an LTCH; and (2) expended, before the date of enactment of Public Law 113–93, April 1, 2014, ''at least 10 percent of the estimated cost of the project (or, if less, $2,500,000).'' As drafted, this provision is also problematic. In cases in which a hospital has not yet been built, but there is a binding written agreement for the actual construction of a hospital that intends to be classified as an LTCH, the entity hiring those who would complete the construction would not be classified as an LTCH. Prior to the designation or classification of a hospital or an entity as an LTCH, a hospital must first be established and certified and must then complete the procedures specified under § 412.23(e) in order to qualify as an LTCH, at which point the hospital would be reclassified as an LTCH.

In accordance with our interpretation of section 114(d)(2)(B) of the MMSEA, as amended by section 4302 of the ARRA and sections 3106(b) and 10312(b) of the Affordable Care Act, we are proposing to interpret the contracting and expenditure provisions under section 114(d)(7)(B) of the MMSEA, as added by section 112(b) of Public Law 113–93, to apply to the hospital/entity requesting an exception to the moratorium on the establishment of new LTCHs and LTCH satellite facilities between April 1, 2014, and September 30, 2017—the entity that would be classified as an LTCH if it meets the stated requirements. That entity must have a binding written agreement with an outside unrelated party for the actual construction, renovation, lease, or demolition for converting the hospital to an LTCH, and it must have expended at least 10 percent of the estimated cost of the project (or, if less, $2,500,000) by the date of enactment of Public Law 113–93—April 1, 2014.

Furthermore, with regard to the first prong, as when we implemented the ''expired'' moratoria, we continue to believe that the use of the term ''actual'' in the context of the ''actual construction, renovation, lease, or demolition'' indicates that the provision focuses only on the specific actions cited in the statute, and does not include those actions that are being contemplated or are not yet substantially underway. Although we are aware that a hospital or some other type of entity may enter into binding written agreements regarding services and items (for example, feasibility studies or land purchase) and incur costs for those services and items prior to actual construction, renovation, lease or demolition, we believe that those services or items are not included in what we are permitted to consider under the statutory language of the exception requirements.

With respect to the second prong, the statute specifies that the hospital or entity must have ''expended'' at least 10 percent of the estimated cost of the project (or, if less, $2,500,000) by April 1, 2014. As we did in regard to the interpretation of section 114(d)(2)(B) of the MMSEA, as amended by section 4302 of the ARRA and section 3106(b) and 10312(b) of the Affordable Care Act, we are proposing to interpret the phrase ''cost of the project'' to mean the activities enumerated in the first prong: ''The actual construction, renovation, lease, or demolition for a long-term care hospital.'' That is, the statute requires the hospital or entity to have spent the amount specified in the statute on the actual construction, renovation, lease, or demolition for the contemplated LTCH. Furthermore, as we did previously in regard to the interpretation of section 114(d)(2)(B) of the MMSEA, as amended by section 4302 of the ARRA and sections 3106(b) and 10312(b) of the Affordable Care Act, because the statute uses the phrase ''has expended'' (that is, a past tense phrase), we are proposing to limit funds counting toward the 10 percent or $2,500,000 minimum to those funds that have actually been transferred as payment for the stated aspects of the project prior to April 1, 2014, as opposed to merely obligating capital and posting the cost of the project on its books. We believe that the provision addressed the concept of ''obligate'' in the first prong of the test where the statute specifies ''a binding written agreement . . . for the actual construction, renovation, lease, or demolition of the long-term care hospital . . .'' and there is no reason to believe that the second prong of the test, which requires the ''expenditure'' of 10 percent of the project or, if less, $2,500,000, was intended as a redundancy. The ability to post the expense on the hospital's or entity's books could be satisfied by merely having a binding written agreement under the first prong of section 114(d)(7)(B) of the MMSEA. The fact that a second requirement is included that involves an expenditure indicates that an additional threshold must be met.

Finally, section 114(d)(7)(C) of the MMSEA includes an exception to the moratorium if an LTCH, as of April 1, 2014, has ''obtained an approved certificate of need in a State where one is required.'' As discussed above, we are proposing to apply this exception requirement to the entity that is requesting approval for an exception to the moratorium on the establishment of new LTCHs and LTCH satellite facilities between April 1, 2014, and September 30, 2017—the entity that would be classified as an ''LTCH'' if the stated requirements are met.

However, with that said, we are clarifying what kind of certificate of need we are proposing to accept under the provisions of section 114(d)(7) of the MMSEA. We believe that the certificate of need exception applies to a ''hospital'' or entity that was actively engaged in developing an LTCH, as evidenced by the fact that either an entity that wanted to create a LTCH but did not exist as a hospital as of April 1, 2014, had obtained a certificate of need for a hospital by the date of enactment, or an existing hospital had obtained a certificate of need to convert the hospital into a new LTCH by that date. We are proposing not to apply this exception requirement to a hospital that was already in existence prior to the date of enactment of Public Law 113–93, and that had previously obtained an approved certificate of need for a hospital (other than a LTCH) on or before April 1, 2014. We believe that Congress intended the exception to the moratorium to save those entities that were already actively engaged in becoming an LTCH. The fact that a hospital may have had a certificate of need issued to it years before April 1, 2014, to operate a hospital (other than a LTCH) is not indicative of such active engagement, and, we believe, is outside

of what is contemplated in these LTCH-specific statutory provisions. We are proposing to only apply this exception requirement where the certificate of need was specifically for an LTCH. Because the certificate of need process is controlled at the State level, in determining whether the hospital or entity has obtained an approved certificate of need on or before April 1, 2014, we would consult the applicable State on a case-by-case basis for that determination.

Decisions regarding the application of these moratoria and exceptions provided within the provisions of section 114(d) of the MMSEA will be handled on a case-by-case basis by the applicant's MAC and the CMS Regional Office.

In accordance with these proposals, we also are proposing to revise our regulations under § 412.23(e)(6) and (e)(7) to include a description of the ''new'' moratoria, which is in effect from April 1, 2014, through September 30, 2017, on the establishment of new LTCHs and LTCH satellite facilities (with specific exceptions), and on increasing the number of beds in existing LTCHs and existing LTCH satellite facilities.

H. Evaluation and Proposed Treatment of LTCHs Classified Under Section 1886(d)(1)(B)(iv)(II) of the Act

Section 1206(d) of the Pathway for SGR Reform Act (Pub. L. 113–67) instructs the Secretary to evaluate payments and regulations governing ''hospitals which are classified under subclause (II) of subsection (d)(1)(B)(iv) . . .'' as part of the annual rulemaking for payment rates under subsection (d) of section 1886 of the Act for FY 2015 or FY 2016. (We refer to hospitals ''classified under subclause (II) of subsection (d)(1)(B)(iv) . . .'' as ''subclause (II) LTCHs.'') Based on the results of this evaluation, the Secretary is authorized to adjust the payment rates under section 1886(b)(3) of the Act for this type of hospital (such as by applying a payment adjustment such that the payments resemble those under a ''TEFRA-payment model''). To implement such a payment adjustment, the Secretary would have to propose changes to the existing regulations governing subclause (II) LTCHs.

For this proposed rule, under the requirements of section 1206(d)(1) of Public Law 113–67 to evaluate the payment rates and regulations governing subclause (II) LTCHs, we have reviewed Medicare data from the only hospital meeting the statutory definition of a subclause (II) LTCH. As a result of these analyses, we are proposing to apply a payment adjustment to subclause (II) LTCHs beginning in FY 2015, which would result in payments for this category of LTCHs that resemble a payment based upon a TEFRA payment model (that is, a reasonable cost payment, subject to a ceiling).

Section 4417(b) of the BBA established the meaning of ''subsection (d) hospitals,'' which are paid under the IPPS, and in doing so, excluded two categories of hospitals that experience extended average inpatient length of stays. It also authorized the Secretary to define how an average inpatient length of stay would be calculated for these excluded hospitals. These provisions are included under sections 1886(d)(1)(B)(iv)(I) and (d)(1)(B)(iv)(II) of the Act, and the two categories of hospitals are generally referred to as subclause (I) and subclause (II) LTCHs.

Subclause (I) LTCHs are required to have an average inpatient length of stay that is greater than 25 days. Subclause (II) LTCHs are only required to have an average inpatient length of stay of greater than 20 days. The subclause (II) LTCH definition further limited the classification of a subclause (II) LTCH by including the requirement that the LTCH must have been first excluded from the IPPS in CY 1986, and treated a Medicare inpatient population in which 80 percent of the discharges in the 12-month reporting period ending in Federal FY 1997 had a principal diagnosis that reflected a finding of neoplastic disease. This statutory requirement is implemented under 42 CFR 412.23(e)(2)(ii).

In establishing the category of subclause (II) LTCHs, Congress essentially authorized special treatment of a hospital that, since 1986, had focused on the provision of palliative care to Medicare beneficiaries diagnosed with end-stage cancer. In consideration of the distinction between hospitals qualifying as LTCHs, either as a subclause (I) LTCH or a subclause (II) LTCH, we established different standards for counting the average inpatient length of stay values for these two categories of LTCHs. We calculate the greater than 25-day average length of stay criteria using only Medicare claims data for subclause (I) LTCHs. However, for subclause (II) LTCHs, we calculate the average length of stay based on its entire patient population. We refer readers to the RY 2003 LTCH PPS final rule (67 FR 55974) for a full discussion of our rationale for implementing these average length of stay calculation methodologies.

The theoretical foundations of any PPS are based on a system of averages, where the costs of some cases may exceed the payment, while other cases' costs will be less than the payment, creating an adequate balance in payments. Therefore, it is assumed that a hospital paid under a PPS would be able to maintain a balance of patients that will allow the hospital to achieve fiscal stability. With that said, in developing the LTCH PPS we were aware that a per discharge PPS system that pays the same amount for every case in a specific MS–LTC–DRG could encourage hospitals to make decisions based on financial considerations (such as prematurely discharging patients to reduce the cost of such cases). As per discharge payments under the LTCH PPS are based on the extended lengths of stay that characterize LTCHs, at the outset of the LTCH PPS, we established a short-stay outlier (SSO) policy under which we apply a payment adjustment for LTCH discharges with lengths of stay that do not exceed 5/6 of the geometric average length of stay of the MS–LTC–DRG. Equally, we were aware that there would be exceptionally expensive cases that could create financial disincentives to treat such patients and, therefore, we adopted a high-cost outlier (HCO) policy as well. However, given the nature of a subclause (II) LTCH's patient population, it may not be reasonable to expect a balancing of more and less costly cases, as these LTCHs are generally only treating a subset of very sick patients. As such, we modified our original SSO payment policy for subclause (II) LTCHs, and we exempted this category of LTCHs from additional changes to the SSO policy to account for the extremely high percentage of cases that our data analysis revealed would have been subject to our SSO policy if that policy were to be applied to subclause (II) LTCHs.

In accordance with the requirements of section 1206(d)(1) of Public Law 113–67, we conducted an evaluation of the payment rates and regulations governing subclause (II) LTCHs. We analyzed MedPAR claims data for FY 2010 and estimated Medicare costs incurred by the one LTCH currently classified as a subclause (II) LTCH, a 225-bed LTCH located in New York. We also evaluated the same metrics for two comparison groups of LTCHs, that is, approximately 40 LTCHs located in the same census region (that is, the Northeast Census Region, which includes Connecticut, Maine, New Jersey, and Pennsylvania), and approximately 25 LTCHs with the same bed size category (that is, between 150 and 250 beds) in order to assess the distinctions between a subclause (I) LTCH and a subclause (II) LTCH. For purposes of this analysis, LTCH PPS

payments were calculated from the payment field in the MedPAR claims data, and the estimated costs for those claims were calculated using the covered charges and CCRs in the Provider-Specific File (PSF) that correlate to the discharge date on each claim. We calculated the aggregate average margins (ratio of payment to costs) for the subclause (II) LTCH and for the two sets of comparison groups of LTCHs using the calculated FY 2010 costs and payments. Our analysis found that, under current LTCH PPS payment policy, the subclause (II) LTCH has much lower margins than comparable LTCHs located in the Northeast Census Region or LTCHs with 150–250 beds. Specifically, the subclause (II) LTCH had a negative margin for its Medicare patients paid under LTCH PPS in FY 2010, while both the Northeast Census Region LTCHs and LTCHs with 150–250 beds had positive aggregate margins for its Medicare patients paid under LTCH PPS for the same period.

In our evaluation of subclause (II) LTCHs under the LTCH PPS, in accordance with the requirements of section 1206(d) of Public Law 113–67, we also compared the types of patients treated at subclause (I) and subclause (II) LTCHs. The top five MS–LTC–DRGs for patients treated at the subclause (II) LTCH in FY 2010 account for almost one-third of all of its Medicare discharges. Four of the top five MS–LTC–DRGs for the subclause (II) LTCH involve a neoplastic disease, and its case-mix differs significantly from the subclause (I) LTCHs, which had large proportions of ventilator and respiratory patients. The five most common MS–LTC–DRGs for the subclause (I) LTCHs were: Respiratory system diagnosis with ventilator support 96+ hours (MS–LTC–DRG 207); Pulmonary edema and respiratory failure (MS–LTC–DRG 189); Septicemia or severe sepsis without ventilator support 96+ hours with MCC (MS–LTC–DRG 870); Skin ulcers with MCC (MS–LTC–DRG 592); and Respiratory system diagnosis with ventilator support < 96 hours (MS–LTC–DRG 208). In comparison, for the subclause (II) LTCH, the five most common MS–LTC–DRGs were: Respiratory neoplasms with CC (MS–LTC–DRG 181); Digestive malignancy with CC (MS–LTC–DRG 375); Respiratory neoplasms with MCC (MS–LTC–DRG 180); Organic disturbances & mental retardation (MS–LTC–DRG 884); and Malignancy, female reproductive system w CC (MS–LTC–DRG 755). These data highlight significant differences between a subclause (I) LTCH and a subclause (II) LTCH based on patient-mix and Medicare margins, notwithstanding the considerations that have been made in structuring the current LTCH regulations to acknowledge the uniqueness of an LTCH meeting the statutory definition of a subclause (II) LTCH.

In evaluating ''both the payment rates and regulations governing hospitals which are classified under subclause (II) . . .,'' as required by section 1206(d) of Public Law 113–67, we also analyzed the impacts of upcoming changes to the LTCH PPS under section 1206(a) of Public Law 113–67. In discussing these analyses, we note that, as discussed in section VII.I.2. of the preamble of this proposed rule, we are not proposing any specific policy and payment changes in this proposed rule to implement the provisions of section 1206(a) of Public Law 113–67. We intend to establish policies related to the types of LTCH cases expected to meet the legislative patient-level criteria for the ''standard LTCH PPS payment'' and cases expected to meet the criteria for the ''site neutral'' payments under the LTCH PPS in the FY 2016 rulemaking cycle. Although we are not making any proposals in this proposed rule related to the provisions of section 1206(a) of Public Law 113–67 at this time, we discuss these provisions in this section because they relate to our analysis of the LTCH PPS payment rates and regulations governing subclause (II) LTCHs.

Absent policy proposals for the implementation of section 1206(d) of Public Law 113–67, the payment changes required by section 1206(a) of Public Law 113–67 would apply to subclause (II) LTCHs beginning with discharges occurring in cost reporting periods beginning on or after October 1, 2015 (that is, FY 2016 and beyond). Due to the changes required by the provisions of section 1206(a) of Public Law 113–67 (discussed at greater length under section VII.I. of the preamble of this proposed rule), beginning in FY 2016, only those LTCH discharges meeting specified patient-level clinical criteria will be paid a ''standard LTCH PPS payment amount.'' Discharges not meeting those criteria will be paid based on a ''site neutral'' payment amount (the lesser of the ''IPPS comparable'' amount, as applied under our SSO policy at § 412.529, or 100 percent of the estimated costs of the case). The statutory requirements to be paid the ''standard LTCH PPS payment amount'' are that the LTCH discharge *does not* have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation, and:

- The stay in the LTCH was immediately preceded by a discharge from an acute care hospital that included at least 3 days in an intensive care unit (ICU); or
- The stay in the LTCH was immediately preceded by a discharge from an acute care hospital and the patient's LTCH stay is assigned to an MS–LTC–DRG based on the receipt of ventilator services of at least 96 hours.

Furthermore, section 1206(a)(1)(C)(ii)(II) of Public Law 113–67 specifies that, effective with cost reporting periods beginning on or after FY 2020, any LTCH with an ''LTCH discharge payment percentage'' that demonstrates that more than 50 percent of that LTCH's discharges were paid for based on the ''site neutral'' payment rate will subsequently be paid for all discharges at the rate ''. . . that would apply under subsection (d) for the discharge if the hospital were a subsection (d) hospital.'' We refer readers to section VII.I. of the preamble of this proposed rule for a further discussion of the provisions of section 1206(a) of Public Law 113–67.

In light of these forthcoming statutory changes, we evaluated MedPAR claims data from the only hospital meeting the statutory definition of a subclause (II) LTCH for FY 2010 to project the impact of the revisions to the LTCH PPS made by section 1206(a) of Public Law 113–67. Our simulations included analyses of the potential financial impact of applying the patient-level criteria and ''site neutral'' payment policies to a subclause (II) LTCH, and the financial impact on payments if that LTCH were to be paid for more than 50 percent of its discharges at the ''site neutral'' payment rate. In conducting this analysis in the absence of rules implementing the changes mandated by section 1206(a) of Public Law 113–67, we assumed that there would be no changes in LTCH admission patterns in response to the LTCH PPS payment changes required by section 1206(a) of Public Law 113–67. Furthermore, we used the FY 2010 claims data for the subclause (II) LTCH and the two LTCH comparison groups described above in order to compare the potential effects of the payment changes under the LTCH PPS required by section 1206(a) of Public Law 113–67 between subclause (I) LTCHs and subclause (II) LTCHs. We simulated payments for those discharges that would be expected to meet the legislative patient-level criteria for the ''standard LTCH PPS payment'' and for discharges that would be expected to receive ''site neutral'' payments under the LTCH PPS. Our analysis found that the subclause (II) LTCH would be

expected to have significantly fewer (approximately 5 times fewer) discharges that would be expected meet the legislative patient-level criteria for the ''standard LTCH PPS payment'' than the comparison groups of subclause (I) LTCHs (that is, Northeast Census Region LTCHs and LTCHs with 150–250 beds).

Additionally, we analyzed the potential effects of the ''LTCH discharge payment percentage'' provision under the requirements of section 1206(a)(1)(C)(ii)(II) of Public Law 113–67, as noted above. We evaluated FY 2010 claims data from the subclause (II) LTCH to project the potential impact of this provision. Based on our simulations in which we projected which FY 2010 LTCH claims would be expected to receive ''site neutral'' payments under the LTCH PPS (as described above), and having found a significant number, we project that a significant negative financial impact would be imposed upon the subclause (II) LTCH's payments. Without considerable behavioral changes, the subclause (II) LTCH would be expected to have more than 50 percent of its discharges paid based on a ''site neutral'' payment and, therefore, would receive a payment adjustment under the provisions of section 1206(a)(1)(C)(ii)(II) of Public Law 113–67 for all of its discharges. Furthermore, our analysis revealed that, given the particular medical profile of their patient population, that the ''subsection (d)'' comparable payment amount under the payment adjustment required by section 1206(a)(1)(C)(ii)(II) of Public Law 113–67 would not likely cover the costs for a significant number of their discharges. Consequently, our analysis shows that the subclause (II) LTCH is projected to experience a large negative aggregate average margin for its Medicare discharges under the payment changes required by section 1206(a) of Public Law 113–67.

Based on our findings under our evaluation of payments to subclause (II) LTCHs under the LTCH PPS and consistent with the provisions of section 1206(d) of Public Law 113–67, we evaluated adjustments that could be applied to ensure appropriate payments under the LTCH PPS for a subclause (II) LTCH under the LTCH PPS. This analysis included consideration of a reasonable-cost based model, such as the TEFRA payment system under which certain PPS-excluded hospitals (such as children's and cancer hospitals) are currently paid. The TEFRA payment system, which was established under the provisions of Public Law 97–248, is implemented under the regulations at 42 CFR 413.40.

In addition to governing the current payment of certain PPS-excluded hospitals, the TEFRA payment system was also previously used to pay LTCHs prior to the implementation of the LTCH PPS. As described in the RY 2003 LTCH PPS final rule (67 FR 55957), the TEFRA payment system was ''. . . established [to make] payments based on hospital-specific limits for inpatient operating costs. A ceiling on payments to such hospitals is determined by calculating the product of a facility's base year costs (the year on which its target reimbursement limit is based) per discharge, updated to the current year by a rate-of-increase percentage, and multiplied by the number of total current year discharges.'' (A detailed discussion of target amount payment limits under Public Law 97–248 can be found in the September 1, 1983 final rule published in the **Federal Register** (48 FR 39746).)'' Under the TEFRA payment system, in accordance with section 1886(g) of the Act, Medicare allowable capital costs are paid on a reasonable cost basis.

To evaluate reasonable cost-based payments under a TEFRA-payment model for subclause (II) LTCHs, we estimated operating and capital payments under the TEFRA payment system principles using FY 2010 cost report data for the one LTCH currently classified as a subclause (II) LTCH (the 225-bed LTCH located in New York noted previously). As described above, payments for operating costs under the TEFRA payment system are based on hospital-specific limits (that is, a ceiling). The ceiling on payments is determined as the product of a hospital's base year costs (the year on which its target reimbursement limit is based) per discharge (''target amount per discharge''), updated to the current year by a rate-of-increase percentage, and multiplied by the number of its Medicare discharges for the year. For purposes of this analysis, we determined the subclause (II) LTCH's TEFRA-based target amount per discharge by updating its FY 2000 target amount per discharge (prior to the implementation of the LTCH PPS) using the annual update factors as established under § 413.40(c)(3). We used the FY 2000 target amount per discharge in order to calculate a target amount per discharge that does not include the increased target amounts and caps on the target amounts provided to LTCHs under section 307(a) of the BIPA. Specifically, section 307(a) of the BIPA provided a 2-percent increase to the wage-adjusted 75th percentile cap on the TEFRA target amounts for existing LTCHs for cost reporting periods beginning in FY 2001, and a 25-percent increase to the hospital-specific TEFRA target amounts for LTCHs, subject to the increased 75th percentile cap. These provisions were promulgated prior to the implementation of the LTCH PPS. However, as required by section 307(a)(2) of the BIPA, the 2-percent increase to the 75th percentile cap and the 25-percent increase to the TEFRA target amounts were not to be taken into account in the development and implementation of the LTCH PPS. To ensure that these increases would not be included in the LTCH PPS payments to subclause (II) LTCHs, consistent with the statutory requirement under section 307(a)(2) of the BIPA, for purposes of our analysis, we determined the subclause (II) LTCH's updated target amount by starting with its target amount from the FY 2000 cost report, the year prior to when these increases were effective. Then we updated its FY 2000 target amount per discharge using the annual update factors established under § 413.40. This approach is consistent with the methodology we used to estimate each LTCH's FY 2003 payment per discharge for inpatient operating costs under the TEFRA payment system in determining the one-time prospective adjustment under § 412.523(d)(3) in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53498). For payments for capital-related costs, we used the hospital's capital cost data from Worksheets D, Parts I and II, as reported on their FY 2000 cost report. As described previously, Medicare allowable capital costs are paid on a reasonable cost basis under the TEFRA payment system, in accordance with the regulations under§ 413.40. This approach is also consistent with the methodology we used to estimate each LTCH's FY 2003 payment per discharge for inpatient capital-related costs under the TEFRA payment system in determining the one-time prospective adjustment at § 412.523(d)(3), in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53499). Our analysis of the subclause (II) LTCH's projected payments under a TEFRA-payment model indicated that such payments would reasonably cover the costs for most of their discharges, and consequently, the subclause (II) LTCH is not projected to experience a negative aggregate margin for its Medicare discharges, unlike our projections under both the current LTCH PPS and the forthcoming payment changes to the LTCH PPS required by section 1206(a) of Public Law 113–67.

In the above analyses, we evaluated the current regulations as well as anticipated payment rates under various statutorily mandated policies for FY 2016 on a subclause (II) LTCH under the LTCH PPS based on FY 2010 discharge data, including payments, costs and case-mix. As discussed above, our evaluation indicates that, given the required patient-mix for a subclause (II) LTCH, the forthcoming changes to the LTCH PPS are likely to result in a financial situation that is not sustainable for the subclause (II) LTCH evaluated above. Furthermore, our analysis also shows that current LTCH PPS payments for a subclause (II) LTCH, even with taking into account the considerations that have been made in structuring current LTCH PPS policies to acknowledge the uniqueness of a subclause (II) LTCH, may not be sufficient to cover the costs incurred for the treatment of patients of the particular medical profile of the subclause (II) patient population prescribed by the statute. Furthermore, we believe that in establishing subclause (II) LTCHs, Congress endorsed the support of the unique mission of this particular category of hospital. In fact, while mandating a significant revision to the LTCH PPS under section 1206(a) of Public Law 113–67, under section 1206(d) of the same statute, Congress directed the Secretary to evaluate the impact of the LTCH PPS on subclause (II) LTCHs, and, based on those findings, authorized the Secretary to adjust payment rates and other regulations, as appropriate, for this category of LTCHs.

Accordingly, in recognition of the subclause (II) LTCH's current estimated payment-to-cost ratio under the LTCH PPS and further anticipated losses that would likely otherwise occur under the forthcoming statutory changes to the LTCH PPS, which would render this type of specially recognized facility fiscally untenable, we believe that it is appropriate to exercise the authority under section 1206(d)(2) of Public Law 113–67. Therefore, in this proposed rule, for cost reporting periods beginning on or after October 1, 2014 (FY 2015 and beyond), we are proposing to apply a payment adjustment to subclause (II) LTCH payments under the LTCH PPS such that these LTCH PPS payments would resemble payments made under the reasonable cost-based TEFRA payment system. We believe that it would be appropriate to apply this proposed payment adjustment for a subclause (II) LTCH's first cost reporting period beginning on or after October 1, 2014, rather than discharges occurring on or after October 1, 2014, because it is consistent with the annual update of the hospital-specific limits (ceiling) for inpatient operating costs under the TEFRA payment system (as described below). We are proposing to implement this proposed payment adjustment for subclause (II) LTCHs in the regulations by adding new § 412.526 under 42 CFR Part 412, Subpart O.

Specifically, we are proposing to establish new regulations under § 412.526 that would provide that, for cost reporting periods beginning on or after October 1, 2014, payments to a ''subclause (II)'' LTCH that are made under the LTCH PPS and under Subpart O of Part 412, as adjusted. This adjusted payment amount would generally be equivalent to an amount determined under the reasonable cost-based reimbursement rules for both operating and capital-related costs under 42 CFR Part 413. As described above, Medicare payments for inpatient operating costs under the reasonable-cost based TEFRA payment system are subject to a hospital-specific ceiling on payments that is determined as the product of a hospital's base year costs per discharge (''target amount per discharge''), updated to the current year by a rate-of-increase percentage, and multiplied by the number of its Medicare discharges for the year. Medicare allowable inpatient capital-related costs are paid on a reasonable cost basis, in accordance with section 1886(g) of the Act.

Under this proposed payment adjustment under new § 412.526 for inpatient operating costs, the adjusted payment amount would generally be determined in accordance with the cited provisions of § 413.40. Accordingly, we are proposing to establish a ''target amount'' for a subclause (II) LTCH for purposes of calculating a hospital-specific ceiling on payments for inpatient operating costs under this proposed payment adjustment. We are proposing to determine such a target amount based on the subclause (II) LTCH's target amount that was used to determine its payments for inpatient operating costs under the TEFRA payment system prior to the implementation of the LTCH PPS, updated by the TEFRA payment system rate-of-increase percentages under § 413.40(c)(3). Furthermore, in determining a subclause (II) LTCH's target amount for purposes of this proposed payment adjustment, consistent with the statute (as explained below), we are proposing not to include the increases to LTCHs' TEFRA target amounts and caps provided for by section 307(a) of the BIPA. As discussed previously, prior to the implementation of the LTCH PPS, section 307(a) of the BIPA provided a 2-percent increase to the wage-adjusted 75th percentile cap on the TEFRA target amounts for existing LTCHs for cost reporting periods beginning in FY 2001 and a 25-percent increase to the hospital-specific TEFRA target amounts for LTCHs, subject to the increased 75th percentile cap. Section 307(a)(2) of the BIPA also specifies that the 2-percent increase to the 75th percentile cap and the 25-percent increase to the TEFRA target amounts were not to be taken into account in the development and implementation of the LTCH PPS. Therefore, consistent with the statutory requirement under section 307(a)(2) of the BIPA, under new § 412.526, we are proposing to determine a subclause (II) LTCH's updated target amount based on its FY 2000 TEFRA payment system target amount, the year prior to when the increases under section 307(a) of the BIPA were effective. Using its FY 2000 TEFRA payment system target amount would ensure that the increases provided for by section 307(a) of the BIPA would not be included in the LTCH PPS payments to subclause (II) LTCHs under this proposed LTCH PPS payment adjustment. This approach for excluding those increases to the TEFRA payment system target amounts is consistent with the methodology that was used to develop the one-time prospective adjustment to the standard Federal rate in which we calculated what amount would have been paid under the TEFRA payment system had the LTCH PPS not been implemented (77 FR 53497 through 53500). Therefore, under the proposed payment adjustment for subclause (II) LTCHs under new § 412.526, we are proposing to determine a FY 2015 TEFRA-based target amount by updating the subclause (II) LTCH's FY 2000 TEFRA target amount using the applicable rate-of-increase percentages for FYs 2001 through 2015 established under § 413.40(c)(3).

In addition to payment for inpatient operating costs, the proposed adjusted payment amount for subclause (II) LTCHs that would be equivalent to an amount determined under the reasonable cost-based reimbursement rules under 42 CFR Part 413 would also include payment for inpatient capital-related costs. Under the TEFRA payment system, in accordance with the regulations under 42 CFR Part 413, Medicare allowable capital costs are paid on a reasonable cost basis, consistent with section 1886(g) of the Act. Therefore, we are proposing that

the payment adjustment to subclause (II) LTCHs under new § 412.526 would include reasonable cost-based payments for capital-related costs. Payments under the LTCH PPS encompass both inpatient operating and capital-related costs of furnishing covered inpatient LTCH services, including routine and ancillary costs (67 FR 55983). Accordingly, under new § 412.526, the proposed adjusted payment amount that would be equivalent to an amount determined under the reasonable cost-based reimbursement rules is based only on inpatient operating and capital-related costs incurred by the subclause (II) LTCH for furnishing covered inpatient LTCH services, and does not include any other TEFRA system payment amounts, such as bonus and relief payments, continuous improvement bonus payments, or adjustments to the rate-of-increase limits.

In summary, for cost reporting periods beginning on or after October 1, 2014, we are proposing that payment to a ''subclause (II)'' LTCH be made under the LTCH PPS, as adjusted. The adjusted payment amount would be equivalent to an amount determined under the reasonable cost-based reimbursement rules for both operating and capital-related costs in accordance with the cited portions of Part 413. Under this proposed payment adjustment, Medicare inpatient operating costs would be reimbursed on a reasonable cost basis, subject to a ceiling; that is, an aggregate upper limit on the amount of a hospital's net Medicare inpatient operating costs that would be recognized for payment purposes. For each cost reporting period, the ceiling on payments for Medicare inpatient operating costs would be determined by multiplying the updated target amount for that period by the number of LTCH PPS discharges during that period. For cost reporting periods beginning during FY 2015, the target amount would be equal to the hospital's target amount determined under § 413.40(c)(4) for its cost reporting period beginning during FY 2000, updated by the applicable annual rate-of-increase percentages specified in § 413.40(c)(3) to the subject period (that is, for FYs 2001 through 2015). For subsequent cost reporting periods, the target amount would equal the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period. Payment for Medicare allowable inpatient capital-related costs under this proposed payment adjustment would be paid on a reasonable cost basis, in accordance with the cited portions of 42 CFR Part 413. We are proposing to codify the provisions of this proposed payment adjustment to subclause (II) LTCHs under new § 412.526 of the regulations. In addition, we are proposing to make conforming changes to § 412.521(a)(2) to refer to this proposed payment adjustment under new § 412.526.

I. Description of Statutory Framework for Patient-Level Criteria-Based Payment Adjustment Under the LTCH PPS Under Public Law 113–67

1. Overview

In the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27668 through 27676), we presented a description of our research on the development of patient-level and facility-level criteria for LTCHs and a potential framework for developing changes to the LTCH PPS. The framework was based on the preliminary findings of two projects conducted by Kennell and Associates (Kennell) and its subcontractor, RTI, under the guidance of CMS' Center for Medicare and Medicaid Innovation (the Innovation Center). We stated that we believed that the findings from these projects, in large part, could be used to identify the subpopulation of Medicare beneficiaries that should form the core group of patients under the LTCH PPS (that is, a chronically critical ill/medically ill (CCI/MC) framework for the LTCH PPS). Although this research was not completed at the time of issuance of the FY 2014 IPPS/LTCH PPS proposed rule, we solicited feedback from LTCH stakeholders in the FY 2014 IPPS/LTCH PPS proposed rule on the description of the interim framework, and indicated that any public comments submitted would be evaluated and considered by our contractors with the expectation of formulating a proposal for FY 2015 based on this research (78 FR 27668 through 27676).

Section 1206(a) of Public Law 113–67 amended section 1886(m) of the Act by adding paragraph (6), which establishes patient-level criteria for payments under the LTCH PPS for implementation beginning in FY 2016. Therefore, our prior intention to present a proposal for a CCI/MC framework for the LTCH PPS (as discussed in the FY 2014 IPPS/LTCH PPS proposed and final rules) in this FY 2015 IPPS/LTCH PPS proposed rule has been superseded. Accordingly, we are not proposing revisions to the LTCH PPS based upon the Kennell/RTI framework for FY 2015. Rather, we intend to propose to implement the requirements established by section 1206(a) of Public Law 113–67 in the FY 2016 LTCH PPS rulemaking cycle. (We note that the final report on the CCI/MC framework developed by Kennell/RTI under our research contract is expected to be available later this year and will be made available to the public through a Web site.)

In section VII.I.2. of the preamble of this proposed rule, we summarize the statutory provisions of section 1206(a) of Public Law 113–67, and in section VII.I.3. of the preamble of this proposed rule, we discuss several significant issues arising from these statutory changes to the LTCH PPS, on which we are interested in receiving stakeholder feedback prior to developing our proposals for FY 2016 implementation.

2. Provisions of Section 1206(a) of Public Law 113–67

Section 1206(a) of Public Law 113–67 added a new section 1886(m)(6), which establishes patient-level clinical criteria that must be met in order for a standard LTCH PPS payment to be made and provides that patients stays that do not meet those criteria that will be paid based on an adjusted or ''site neutral'' payment rate. The provisions of section 1206(a) are effective for LTCH discharges occurring during cost reporting periods beginning on or after October 1, 2015 (FY 2016).

Specifically, the patient-level clinical criteria that must be met in order for a standard LTCH PPS payment to be made under section 1886(m)(6) of the Act, as added by section 1206(a) of Public Law 113–67, are that:

- The stay in the LTCH is immediately preceded by a discharge from an acute care hospital that included at least 3 days in an intensive care unit (ICU); or the stay in the LTCH is immediately preceded by a discharge from an acute care hospital and the patient's LTCH stay was assigned to an MS–LTC–DRG based on the receipt of ventilator services of at least 96 hours; and
- The LTCH discharge *does not* have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation.

Section 1886(m)(6)(A) of the Act, as added by section 1206(a) of Public Law 113–67, specifies that payments for LTCH discharges that do not meet the clinical criteria will be made at the applicable ''site neutral payment rate.'' The statute defines ''site neutral payment rate'' as the *lower* of the ''IPPS comparable'' amount or 100 percent of the ''estimated cost'' of the case. The ''IPPS comparable'' amount, which the statute specifies is calculated based on

the methodology applied under the short stay outlier (SSO) policy at 42 CFR 412.529(d)(4), is an amount comparable to the hospital inpatient prospective payment system per diem capped at an amount comparable to the full MS–DRG payment rate, including any applicable outlier payments under § 412.525. We expect to propose calculating the ''cost of the case,'' as specified in the regulations at § 412.529(d)(2), by multiplying the applicable hospital-specific CCR by the Medicare allowable charges for a case, consistent with how we currently estimate the cost of the case under both the SSO and high-cost outlier policies.

Section 1886(m)(6)(B) of the Act also requires a phase-in of this payment policy change under the LTCH PPS over 2 years. Therefore, for LTCH discharges occurring in cost reporting periods during FYs 2016 and 2017 that do not meet the patient level clinical criteria, the total payment amount for LTCH services will be based on one-half of the calculated ''site neutral'' payment rate and one-half of the standard LTCH PPS payment rate. The full payment adjustment based on the requirements of Public Law 113–67 will begin to effect payments to LTCHs and LTCH satellite facilities for discharges beginning with LTCHs' and LTCH satellite facilities' FY 2018 cost reporting period. Therefore, for cost reporting periods beginning during FY 2018, LTCHs will be paid the standard LTCH PPS payment amount only for LTCH discharges that meet the statutory clinical criteria under section 1886(m)(6) of the Act. LTCH discharges that do not meet the clinical criteria will be paid based on the ''site neutral'' payment rate.

Section 1886(m)(6)(C) of the Act, as added by section 1206(a)(1) of Public Law 113–67, also includes a limit on payments for all hospital discharges occurring in cost reporting periods during or after FY 2021 if a hospital fails to meet the applicable LTCH discharge threshold. In anticipation of this limit on payments, section 1886(m)(6)(C)(i) of the Act specifies that, for cost reporting periods beginning on or after October 1, 2015 (FY 2016), the Secretary is required to notify each LTCH of its ''discharge payment percentage,'' which is defined under section 1886(m)(6)(C)(iv) of the Act as the percentage resulting from the ratio of the LTCH's discharges paid based on the standard LTCH PPS payment amount to the LTCH's total discharges for each cost reporting period.

Section 1886(m)(6)(C)(ii) of the Act specifies that, for cost reporting periods during or after FY 2020, the Secretary is required to provide notice to LTCHs with a ''discharge payment percentage'' that indicates that the LTCH does not meet the ''at least 50 percent'' threshold. An LTCH that does not meet the required threshold for a cost reporting period in FY 2020 will be paid for services as if the hospital were an acute care hospital until such time as that facility is reinstated under section 1886(m)(6)(C)(iii) of the Act. Specifically, section 1886(m)(6)(C)(ii) of the Act provides that LTCHs that are determined to be treating a Medicare population with less than 50 percent of patients for whom a standard LTCH PPS payment is made, that is, LTCHs for whom 50 percent or more Medicare beneficiary discharges are paid at the ''site neutral'' payment rate will receive ''. . . the payment amount that would apply under subsection (d) for all discharges as if the hospital were a subsection (d) hospital.'' In other words, LTCHs failing to meet the applicable discharge threshold will be paid an IPPS equivalent payment rate.

Section 1886(m)(6)(C)(iii) of the Act provides that the Secretary is authorized to establish a ''reinstatement'' process through which an LTCH that fails to meet the required discharge threshold percentage can be ''reinstated'' and resume receiving payments under the new payment policy for LTCH services established by section 1206(a)(1) of Public Law 113–67, that is, standard LTCH PPS payments or ''site neutral'' payments, as applicable.

Section 1886(m)(6)(D) of the Act, as added by section 1206(a)(1) of Public Law 113–67, specifies that subsection (d) hospitals in Puerto Rico are deemed to be included in any reference in section 1886(m) of the Act to a subsection (d) hospital.

Section 1206(a)(3) of Public Law 113–67 revised the existing policy for calculating whether an LTCH or LTCH satellite facility meets the greater than 25-day average length of stay requirement in sections 1886(d)(1)(B)(iv)(I) and 1861(ccc)(2) of the Act, which is implemented in the regulations at § 412.23(e)(2) and (e)(3). Specifically, section 1206(a)(3) provides that cases for which Medicare paid the provider under the ''site neutral'' rate, as well as any paid under a Medicare Advantage plan (that is, Medicare Part C) shall be excluded from the calculations of the average length of stay of an LTCH or an LTCH satellite facility. LTCHs that had not attained their LTCH designation by December 10, 2013, are exempt from this statutorily mandated change.

As previously stated, section 1206(a)(1) of Pub. L 113–67 provides for ''site neutral'' payments to an LTCH for certain specified patient discharges effective for discharges occurring in cost reporting periods beginning on or after October 1, 2015. We intend to propose the specific policy and payment changes that will be necessary to implement the Public Law 113–67 provisions for cost reporting periods beginning on or after October 1, 2015, during the FY 2016 rulemaking cycle. Although we are not proposing the changes mandated by section 1206(a)(1) of Public Law 113–67 in this proposed rule, in light of the degree of forthcoming changes, in section VII.I.3. we discuss some of the changes in this proposed rule, and request public feedback to inform our proposals for FY 2016.

3. Additional LTCH PPS Issues

The LTCH PPS was originally established for cost reporting periods beginning on or after October 1, 2002, by section 123(a) of the BBRA (Pub. L. 106–113) and section 307(b) of the BIPA (Pub. L. 106–554). (We also refer readers to section 1886(m) of the Act, as added by section 114(e) of the MMSEA.) Section 307(b) of the BIPA granted the Secretary considerable authority in developing the LTCH PPS, specifying that the Secretary shall ''. . . examine and may provide for appropriate adjustments to the long-term hospital payment system, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment. . . .''

Accordingly, as we evaluate the revisions to the LTCH PPS required by section 1206(a)(1) of Public Law 113–67, we believe that the broad authority permitted by the original statutory mandates continues to grant us the authority to modify, if appropriate, methodologies for our payment determinations under the LTCH PPS. (We refer readers to the RY 2003 LTCH PPS final rule (67 FR 55954), which describes the development and implementation of the LTCH PPS for FY 2003.) Specifically, section 1206(a) of Public Law 113–67 establishes two distinct payment groups for LTCH discharges under the revised system: discharges meeting specified patient-level criteria that will be paid under the ''standard LTCH PPS payment amount'' and all other patient discharges that will be paid under the ''site neutral'' payment rate and methodology (discussed above). In setting the payment rates and factors under the LTCH PPS as required by section 1206(a) of Public Law 113–67 for certain LTCH PPS payment adjustments, such as the MS–LTC–DRG relative weights and high-cost outlier payments, we plan

to evaluate whether it would be appropriate to modify our historical methodology to account for the establishment of the two distinct payment methodologies for LTCHs. For example, we intend to examine whether, beginning in FY 2016, it is still appropriate to include data for *all* LTCH PPS cases, including ''site neutral'' payment cases, in our methodology for setting relative payment weights for MS–LTC–DRGs. We also intend to explore the need for changes to the LTCH PPS high-cost outlier payment policies. Given the fact that, for a number of LTCH patients, payment will be made based on the lower of the ''IPPS comparable'' per diem payment and the estimated cost of the case, we will need to decide whether to maintain a single high-cost outlier ''target'' for all LTCH PPS cases (including ''site neutral'' payment cases) or whether it may be more appropriate to establish separate high-cost outlier ''targets'' for each of the two payment groups under the revised LTCH PPS. Our existing methodology for calculating the MS–LTC–DRG relative weights is discussed during the annual rulemaking cycle and was, most recently, included in the FY 2014 IPPS/LTCH final rule (78 FR 50753 through 50760). Our detailed description of our existing high-cost outlier payment policy, which has remained the same since being implemented, can be found in the RY 2003 LTCH PPS final rule (67 FR 56022 through 56027). (We note that our proposed methodology for calculating the MS–LTC–DRG relative payment weights for FY 2015 can be found in section VII.B.3. of the preamble of this proposed rule, and our proposals under the high-cost outlier payment policy for FY 2015 can be found in section V.D. of the Addendum to this proposed rule.)

We are interested in receiving feedback from LTCH stakeholders on our plans to evaluate whether it would be appropriate to modify any of our historical methodologies as we implement the payment changes to the LTCH PPS under section 1206(a) of Public Law 113–67. In particular, we are interested in public feedback on the issues mentioned earlier (that is, policies relating to establishing the relative payment weights and high-cost outliers) so that we may evaluate various options in preparation for developing proposals to implement the statutory changes beginning in FY 2016.

J. Proposed Technical Change

In this proposed rule, we are proposing to update the legislative basis for the regulations governing the LTCH PPS under Subpart O of Part 412. Specifically, we are proposing to add references under new paragraphs (a)(4), (a)(5), and (a)(6) of § 412.500 of the regulations to the revisions to the Act made by section 4302(a) of Public Law 111–5, sections 3106(a) and 10312(a) of Public Law 111–148, and section 1206 of Public Law 113–67, respectively.

VIII. Appropriate Claims in Provider Cost Reports; Administrative Appeals by Providers and Judicial Review

In this proposed rule, we are proposing to revise the cost reporting regulations in 42 CFR Part 413, Subpart B by requiring a provider to include an appropriate claim for a specific item in its Medicare cost report in order to receive or potentially qualify for Medicare payment for the specific item. If the provider's cost report does not include an appropriate claim for a specific item, payment for the item will not be included in the notice of program reimbursement (NPR) issued by the Medicare Administrative Contractor (MAC) (formerly known as fiscal intermediary and herein referred to as ''contractor'') or in any decision or order issued by a reviewing entity (as defined in 42 CFR 405.1801(a) of the regulations) in an administrative appeal filed by the provider. In addition, we are proposing to revise the appeals regulations in 42 CFR Part 405, Subpart R, by eliminating the requirement that a provider must include an appropriate claim for a specific item in its cost report in order to meet the dissatisfaction requirement for jurisdiction before the Provider Reimbursement Review Board (Board), and by specifying the procedures for Board review of whether the provider's cost report meets the proposed substantive reimbursement requirement of an appropriate cost report claim for a specific item. We also are proposing technical revisions to other Board appeal regulations to conform those regulations to the main revisions (described above) to the cost reporting regulations and the provider appeal regulations, in addition to proposing similar revisions to the Part 405, Subpart R regulations for appeals before the contractor hearing officers. In addition, we are proposing to conform the terminology in Part 405, Subpart R and all subparts of Part 413 from ''intermediary'' or ''fiscal intermediary'' to ''contractor'' pursuant to sections 1816, 1874A and 1878 of the Act. All of these proposed revisions to the cost reporting regulations and the provider appeals regulations would apply to provider cost reporting periods beginning on or after the effective date of the final IPPS annual update rule.

A. Background

1. Payments and Cost Reporting Requirements

For cost reporting years beginning before October 1, 1983, all providers were reimbursed on a reasonable cost basis for Part A (hospital insurance) covered items and services that were furnished to Medicare beneficiaries. Reasonable cost is defined at section 1861(v)(1)(A) of the Act and implementing regulations at 42 CFR Part 413. In the Social Security Amendments of 1983 (Pub. L. 98–21), Congress added section 1886(d) to the Act, which, effective with cost reporting periods beginning on or after October 1, 1983, changed the payment method for inpatient hospital services furnished by short-term acute care hospitals to a prospective payment system (PPS). In accordance with section 1886(d) of the Act and implementing regulations at 42 CFR Part 412, a PPS payment is made at a predetermined specific rate for each hospital discharge (classified according to a list of diagnosis-related groups (DRGs)), excluding certain costs that are paid on a reasonable cost basis.

Later statutory amendments expanded the types of providers and services that are subject to a PPS. The various prospective payment systems for inpatient hospital services are summarized in § 412.1 of the regulations. Other prospective payment systems for different types of providers and services are summarized in §§ 413.170, 413.300, 413.330, and 419.1 of the regulations. As explained in § 413.1(b) of the regulations, if a service is not subject to a PPS when it is furnished, the provider is paid on the basis of reasonable cost. (For ease of reference, we will use the terms ''reimbursement'' and ''payment'' interchangeably unless a particular context calls for the use of one of these terms instead of the other.)

Before October 1, 2005, payments to providers were ordinarily made through private organizations known as fiscal intermediaries, under contracts with the Secretary. After a 6-year transition period (§ 421.400(a)), the claims processing and payment functions of the fiscal intermediaries are now performed by MACs, under contracts with the Secretary.

For covered items and services paid on a reasonable cost basis, the contractor pays a provider during its cost reporting period interim payments that approximate the provider's actual costs. Under a PPS, providers are generally paid for each patient discharge after a bill is submitted.

Sections 1815(a) and 1833(e) of the Act provide that no payments will be made to a provider unless it has furnished the information, requested by the Secretary, needed to determine the amount of payments due the provider under the Medicare program. In general, providers submit this information through annual cost reports that cover a 12-month period of time.

All providers participating in the Medicare program are required under § 413.20(a) to ''maintain sufficient financial records and statistical data for proper determination of costs.'' Moreover, providers must use standardized definitions and follow accounting, statistical, and reporting practices that are widely accepted in the hospital and related fields. Under the provisions of §§ 413.20(b) and 413.24(f), providers are required to submit cost reports annually, with the reporting period based on the provider's accounting year. For cost years beginning on or after October 1, 1989, section 1886(f)(1) of the Act and § 413.24(f)(4) of the regulations require hospitals to submit cost reports in a standardized electronic format, and the same requirement was later imposed for other types of providers. In addition, § 412.52 of the regulations requires all PPS hospitals to meet the recordkeeping and cost reporting requirements of §§ 413.20 and 413.24, which include submitting a cost report for each 12-month period.

2. Administrative Appeals by Providers and Judicial Review

Upon receipt of a provider's cost report, the contractor reviews or audits the cost report, makes any necessary adjustments to the provider's Medicare reimbursement for the cost reporting period, and finally determines the total amount of payment due the provider. This year-end reconciliation of Medicare payment for the provider's cost reporting period constitutes a contractor determination, as defined in § 405.1801(a). Under §§ 405.1801(a)(1), (2) and 405.1803, the contractor must give the provider written notice of the final contractor determination for the cost period in a notice of the total amount of program reimbursement (NPR). The NPR is an appealable determination, and the contractor determination is final and binding unless it is revised on appeal or reopening (§ 405.1807).

Under section 1878(a) of the Act, a provider that has submitted a timely cost report may appeal to the Provider Reimbursement Review Board (the Board) a final determination of program reimbursement made by a contractor, as well as certain final determinations by the Secretary involving payment under the IPPS. The Secretary's delegate, the Administrator of CMS, may review certain Board decisions under section 1878(f)(1) of the Act and § 405.1875 of the regulations. The final decision of the Board or the Administrator is subject to judicial review under section 1878(f)(1) of the Act and § 405.1877 of the regulations. In addition, by regulation, providers are given the right to appeal to the Board or to contractor hearing officers certain other determinations. A CMS reviewing official may review some contractor hearing officer decisions under § 405.1834 of the regulations, but there is no judicial review of decisions by contractor hearing officers or a CMS reviewing official.

Under sections 1878(a)(1)(A), (a)(2), and (a)(3) of the Act, and § 405.1835(a)(1), (a)(2), and (a)(3)(i) of the regulations, a provider may obtain a Board hearing if: (1) the provider is ''dissatisfied'' with a final determination of the contractor [formerly intermediary] or the Secretary; (2) the amount in controversy is at least $10,000; and (3) the provider files a request for a hearing to the Board within 180 days of notice of the final determination of the contractor or the Secretary. The same jurisdictional requirements govern provider appeals to contractor hearing officers under § 405.1811(a)(1), (a)(2), and (a)(3)(i) of the regulations, except that the amount in controversy requirement is at least $1,000 but less than $10,000.

However, the statutory requirements for Board jurisdiction are somewhat different if the provider does not receive a final determination of the contractor on a timely basis. Under sections 1878(a)(1)(B), (a)(2), and (a)(3) of the Act, a provider may obtain a Board hearing if: (1) The provider does not receive a final determination of the contractor on a timely basis, after the provider filed a cost report that complied with the cost reporting regulations; (2) the amount in controversy is at least $10,000; and (3) the provider files a request for a hearing to the Board within 180 days after notice of the contractor's final determination would have been received if such contractor determination had been issued on a timely basis. Moreover, § 405.1835(a)(3)(ii) of the regulations provides that a contractor determination is not timely if it is not issued, through no fault of the provider, within 12 months of the contractor's receipt of the provider's perfected cost report or amended cost report (as specified in § 413.24(f) of the regulations). The same jurisdictional requirements govern provider appeals to contractor hearing officers, based on an untimely contractor determination, under § 405.1811(a), except that the amount in controversy requirement is at least $1,000 but less than $10,000.

3. Appropriate Claims in Provider Cost Reports

Under longstanding Medicare policy as set forth in § 413.24 of the regulations and section 115 of the Provider Reimbursement Manual (PRM), Part 2 (CMS Pub. 15–2), a provider must make an appropriate cost report claim for a specific item in order to be reimbursed for the item, whether through the NPR issued by the contractor or as the result of an administrative appeal or judicial review. For example, as set forth in § 413.24, providers receiving payment on the basis of reimbursable cost are required to provide adequate cost data to the contractor to support payments made for services furnished to beneficiaries. In addition, as set forth in section 115 of the PRM, Part 2, we also require that providers make a specific claim for an item in its cost report, in order to meet the dissatisfaction requirement for Board jurisdiction. The Medicare cost report has always included particular ''lines'' for specific allowable costs such as interest expense and depreciation. If a provider makes a cost report claim for a cost that is allowable, and reimbursement is claimed in accordance with Medicare payment policy, the NPR will include appropriate reimbursement for the cost. (For ease of reference, we will use the terms ''specific item'' or ''item'' to refer to a particular aspect of reasonable cost-based payment or a specific aspect of payment under a prospective payment system unless a particular context calls for the use of more specific terms (for example, the term ''allowable cost'' as used in determining reasonable cost-based payment).)

If the NPR does not include reimbursement for a specific item or if the provider believes it should have received more reimbursement for the item, the provider can request a hearing before the Board or the contractor hearing officers (if the amount in controversy is at least $1,000 but less than $10,000). However, our longstanding policy is that an appropriate cost report claim is a jurisdictional requirement for an appeal to the Board or the contractor hearing officers. As explained above, section 1878(a)(1)(A) of the Act provides for a hearing before the Board if the provider has filed a timely cost report with the

contractor, and the provider is ''dissatisfied'' with a final determination of the contractor or the Secretary. Our view has been that, in order for a provider to be dissatisfied with a specific aspect of the contractor determination, the provider must include an appropriate cost report claim for the specific item so that the contractor can respond to the provider's claim in the NPR and thereby potentially produce a specific reimbursement result about which the provider is dissatisfied.

Under our policy for Board jurisdiction, we required a provider to make a specific claim for an item in its cost report, in order to meet the dissatisfaction requirement for Board jurisdiction. We did not permit a provider to ''self-disallow'' a specific item, even if the Medicare contractor had no discretion to award payment for the item. (In self-disallowing an item, the provider submits a cost report that complies with Medicare policy for the item and then appeals the item to the Board; the contractor's NPR then would not include any disallowance of the item, and therefore the provider would effectively self-disallow the item.) However, the Supreme Court rejected our longstanding policy in *Bethesda Hospital Association* v. *Bowen,* 485 U.S. 399 (1988). The Court held that, despite the providers' failure to claim all the reimbursement they believed should have been made, the plain language of the dissatisfaction requirement in section 1878(a)(1)(A) of the Act supported Board jurisdiction because the contractor had no authority to award reimbursement in excess of a regulation by which it was bound, and thus it would have been futile for the providers to try to persuade the contractor otherwise. The Court also stated in dicta, however, that the dissatisfaction requirement might not be met if providers were to ''bypass a clearly prescribed exhaustion requirement or . . . fail to request from the intermediary reimbursement for all costs to which they are entitled under applicable rules'' (*Bethesda Hosp.,* 485 U.S. at 404–05).

Following the *Bethesda* decision, we no longer required providers to make a cost report claim for reimbursement of items for which the contractor did not have the discretion to award payment due to a regulation or manual provision but, consistent with the dicta in *Bethesda,* we continued to require providers to include cost report claims for allowable costs. However, our policy, as revised in response to *Bethesda,* was also challenged in the courts, and a ''circuit split'' resulted. *Compare Little Co. of Mary Hosp.* v. *Shalala,* 165 F.3d 1162 (7th Cir. 1999) (sustaining our interpretation of the statutory dissatisfaction requirement for Board jurisdiction) *with Loma Linda Univ. Med. Ctr.* v. *Leavitt,* 492 F.3d 1065 (9th Cir. 2007) (rejecting our interpretation of the dissatisfaction requirement); *Maine General Med. Ctr.* v. *Shalala,* 205 F.3d 493 (1st Cir. 2000) (same).

In response to the Supreme Court's *Bethesda* decision and the ensuing circuit split, we then addressed the dissatisfaction requirement in notice and comment rulemaking. In a 2008 final rule, we revised § 405.1811(a)(1) and § 405.1835(a)(1) for contractor and Board hearings, respectively (73 FR 30190, 30195 through 30200, 30244 through 30245, 30249 through 30250 (May 23, 2008)). Under the revised regulations, in order to preserve its appeal rights, a provider must either claim an item in its cost report where it is seeking reimbursement that it believes to be in accordance with Medicare policy, or self-disallow the item if it is seeking reimbursement that it believes may not comport with Medicare policy (for example, where the contractor does not have the discretion to award the reimbursement sought by the provider). In order to self-disallow an item, the provider must follow the applicable procedures for filing a cost report under protest, which are contained currently in section 115 of the PRM, Part 2.

As explained in the preamble to the 2008 final rule, we believe the revised dissatisfaction policy set forth in § 405.1835(a)(1) is a reasonable interpretation of the dissatisfaction requirement for Board jurisdiction in section 1878(a)(1)(A) of the Act (73 FR 30195 through 30200). The dissatisfaction requirement in § 405.1835(a)(1) comports with the Supreme Court's statement (discussed above) that the statutory dissatisfaction requirement might not be met if a provider bypassed a clearly prescribed exhaustion requirement or failed to ask the contractor for reimbursement of all costs to which it is entitled under applicable rules. (*Bethesda Hosp.,* 485 U.S. at 404–05; *Little Co. of Mary,* 165 F.3d 1162 (sustaining our interpretation of the statutory dissatisfaction requirement for Board jurisdiction on the basis of the forgoing statements by the Supreme Court); *Little Co. of Mary Hosp.* v. *Shalala,* 24 F.3d 984 (7th Cir. 1994) (same).

Upon further reflection, however, we believe that the requirement that a provider either claim reimbursement for a specific cost, or expressly self-disallow the cost, in its cost report is more appropriately treated as a cost reporting requirement under sections 1815(a) and 1833(e) of the Act, as the agency cannot make payments to a provider without sufficient information on all claims for which the provider believes it should be paid. Indeed, it is eminently reasonable for the Secretary to require a provider to make an appropriate cost report claim for a specific item if the provider wants to be paid for the item. As we explain in detail in the next section, requiring a cost report claim for full reimbursement or an express self-disallowance of the cost enables the contractor to review and audit the claim, make any adjustments that seem appropriate, and include final payment for the cost as part of the NPR. Accordingly, we are proposing to revise the cost reporting regulations in Part 413, Subpart B by adding the substantive reimbursement requirement that a provider must include an appropriate claim for an item in its cost report. The failure to account appropriately for the item in its cost report will foreclose payment for the item in the NPR issued by the contractor and in any decision, order, or other action by a reviewing entity (as defined in § 405.1801(a) of the regulations) in an administrative appeal filed by the provider.

However, we recognize that the proposed addition to the cost reporting regulations of the substantive reimbursement requirement of an appropriate cost report claim for a specific item would be potentially duplicative of the existing jurisdictional requirement in the Board appeals regulations of an appropriate cost report claim. In order to avoid such duplication, we also are proposing to revise the appeals regulations in Part 405, Subpart R by eliminating the requirement that a provider must include an appropriate claim for an item in its cost report in order to meet the dissatisfaction requirement for Board jurisdiction. Our longstanding requirement of an appropriate cost report claim would be made a substantive reimbursement requirement in the cost reporting regulations and the existing Board jurisdiction requirement of an appropriate cost report claim would be eliminated. These proposed revisions to the cost reporting regulations and the provider appeals regulations would apply on a prospective-only basis, to provider cost reporting periods beginning on or after the effective date of the final IPPS annual update rule.

B. Proposed Changes Regarding the Claims Required in Provider Cost Reports, and for Provider Administrative Appeals

1. Proposed Addition to the Cost Reporting Regulations of the Substantive Reimbursement Requirement of an Appropriate Cost Report Claim

a. Specific Provisions of Proposed Paragraph (j) of § 413.24

We are proposing to add a new paragraph (j) to § 413.24 of the regulations. Proposed paragraph (j)(1) of § 413.24 provides that in order to receive or potentially qualify for payment for a specific item, the provider must include in its cost report an appropriate claim for the specific item. In order to make an appropriate claim for an item in its cost report, the provider must either claim payment for the item in its cost report where it is seeking payment that it believes is consistent with Medicare policy, or self-disallow the item if the provider is seeking payment that it believes may not comport with Medicare policy (for example, where the contractor does not have the authority or discretion to award the payment sought by the provider). In order to self-disallow a specific item, the provider would have to follow the applicable procedures for filing a cost report under protest, which are now contained in section 115 of the PRM, Part 2 and are included in proposed paragraph (j)(2) of § 413.24. Specifically, the provider would have to include an estimated payment amount for each self-disallowed item in the ''protested amount'' line of the cost report, and attach a worksheet explaining why a self-disallowance is necessary (instead of claiming payment for the item in its cost report) and describing how it determined the estimated payment amount for each self-disallowed item.

Proposed paragraph (j)(3) of § 413.24 specifies the procedures for determining whether there is an appropriate cost report claim for a specific item. The default rule is that the question of whether the provider's cost report includes an appropriate claim for the specific item must be determined by reference to the cost report that the provider submits originally to, and is accepted by, the contractor, unless one of three exceptions applies. The first exception is that if the provider submits an amended cost report that is accepted by the contractor, the question of whether there is an appropriate cost report claim for the specific item must be determined by reference to such amended cost report, unless one of the two remaining exceptions applies. The second exception is that if the contractor adjusts the provider's cost report, as submitted originally by the provider and accepted by the contractor or as amended by the provider and accepted by the contractor, whichever is applicable, with respect to the specific item, the question of whether there is an appropriate cost report claim for the specific item must be determined by reference to the provider's cost report, as such cost report is adjusted for the specific item in the contractor's initial determination (as defined in § 405.1801(a)), unless the remaining exception applies. The third exception is that if the contractor reopens either the initial contractor determination for the provider's cost reporting period (pursuant to § 405.1885) or a revised contractor determination for such period (issued pursuant to § 405.1889) and adjusts the provider's cost report with respect to the specific item, the question of whether there is an appropriate cost report claim for the specific item must be determined by reference to the provider's cost report, as such cost report is adjusted for the specific item in the contractor's most recent revised contractor determination for such period.

Providers should make every effort to comply with the default rule set forth in proposed paragraph (j)(3) of § 413.24, even though one of the exceptions to the default rule might come into play later. In order to ensure compliance with the substantive requirement of an appropriate cost report claim for a specific item, the provider should either claim full payment for, or properly self-disallow, the item in the cost report that the provider submits originally to the contractor. However, failure to include an appropriate claim for the specific item in the provider's original ''as submitted'' cost report does not necessarily foreclose any further opportunity to meet the requirement of an appropriate cost report claim for the specific item. Under the first exception to the default rule under proposed paragraph (j)(3), the provider could include an appropriate cost report claim for the specific item in an amended cost report, but the contractor has discretion whether to accept an amended cost report by the provider. Under the second and third exceptions to the default rule under proposed paragraph (j)(3), the requirement of an appropriate cost report claim could be met through the contractor's adjustment of the provider's cost report, either in the contractor's initial determination for the provider's cost reporting period (as defined in § 405.1801(a)) or, if the initial contractor determination is reopened, in the contractor's revised determination. However, in preparing the initial contractor determination for a provider's cost reporting period, the contractor has discretion whether to adjust the provider's cost report with respect to the specific item and, if so, how to adjust the cost report for such item. Similarly, after the initial contractor determination is issued, the contractor has discretion whether to reopen the initial contractor determination and, if the specific item is reopened, whether to adjust the cost report for such item and how to make any such adjustment.

In order to exemplify the workings of proposed paragraph (j)(3) of § 413.24, consider a hospital that seeks a Medicare DSH payment adjustment that, on the provider's view, should be calculated on the basis of 2,000 Medicaid eligible patient days in the numerator of the DSH Medicaid fraction (42 CFR 412.106(b)(4)). If the hospital's as submitted cost report claimed only 1,000 Medicaid eligible patient days for the numerator of the DSH Medicaid fraction, and the number of Medicaid eligible patient days was not changed in an amended cost report by the provider or through adjustments to the cost report by the contractor, the hospital would have made an appropriate cost report claim for only 1,000 Medicaid eligible patient days (instead of 2,000 such days). However, if the provider submitted, and the contractor accepted, an amended cost report that claimed a total of 1,500 Medicaid eligible patient days, the provider would have made a valid cost report claim for 1,500 Medicaid eligible patient days (instead of 2,000 such days). However, if the hospital asked the contractor, during the contractor's review and settlement of the provider's cost report, to count 250 more Medicaid eligible patient days, and the contractor agreed to consider those days in the contractor's initial intermediary determination, the provider would have made a valid cost report claim of 1,750 Medicaid eligible patient days (instead of 2,000 such days). Finally, if the provider next requested, or the contractor initiated on its own motion, the reopening of the initial contractor determination on the specific issue of the number of Medicaid eligible patient days for the DSH Medicaid fraction's numerator, and the contractor did reopen for that specific issue, the provider would have a valid cost report claim of 2,000 Medicaid eligible patient days. At that juncture,

the hospital would have met the requirement of an appropriate cost report claim for all of the 2,000 Medicaid eligible patient days, which is the number of such days that the provider believed from the outset should be used in determining the numerator of the DSH Medicaid fraction.

We believe proposed paragraph (j)(3) of § 413.24 appropriately reflects the usual process in which a cost report claim that is first made in the cost report that is submitted originally to, and accepted by, the contractor, might be altered through an amended cost report by the provider (if the amended cost report is accepted by the contractor) or through adjustments of the provider's cost report claim that are made in the contractor's initial determination or, in the event of a reopening, in the contractor's revised determination. This process enables a provider to ensure compliance with the substantive requirement of an appropriate cost report claim for a specific item, by including in the cost report that the provider submits originally to, and is accepted by, the contractor, either a full claim for payment for a specific item or a proper self-disallowance of the item. In addition, this process gives a provider additional opportunities to meet the requirement of an appropriate cost report claim through an amended cost report by the provider (if the amended cost report is accepted by the contractor) and adjustments to the provider's cost report claim that are included in the contractor's initial contractor determination or, if there is a reopening, in the revised contractor determination. Unlike with the provider's original as submitted cost report, however, the contractor has discretion whether to accept an amended cost report; whether to include particular cost report claim adjustments in the initial contractor determination and, if so, how to determine such adjustments; and whether to reopen a contractor determination and, if there is a reopening, how to determine any cost report claim adjustments that may be included in the revised contractor determination. This ''back and forth'' process between the provider and the contractor, which is reflected in proposed paragraph (j)(3) of § 413.24, facilitates appropriate determinations of program payment and enhances administrative efficiency. Each of the Medicare contractors has substantial experience in reviewing and auditing cost reports and in properly determining payment amounts. The back and forth process between the provider and the contractor eliminates, or minimizes and sharpens, potential disagreements, which obviates the need to file some administrative appeals or narrows the issues in many cases.

In addition, proposed paragraph (j)(4) of § 413.24 provides that, to the extent a provider fails to claim a specific item appropriately in its cost report, the final contractor determination (as defined in § 405.1801(a)) may not include payment for the item. However, if the contractor determines that the provider made an appropriate cost report claim for a specific item but the contractor disagrees with material aspects of the provider's claim for the item, the contractor must make appropriate adjustments to the provider's cost report and include payment for the specific item in the final contractor determination in accordance with the contractor's adjustments to the cost report and to the extent permitted by program policy.

Proposed paragraph (j)(5) of § 413.24 provides that if a party to an administrative appeal questions whether the provider's cost report included an appropriate claim for the specific item under appeal, the reviewing entity (as defined in § 405.1801(a)) must follow the procedures (which we discuss in detail below) that are set forth in proposed § 405.1873 (if the appeal was filed originally with the Board), or the procedures in § 405.1832 (if the appeal was filed initially with the contractor), for review of whether the substantive reimbursement requirement of an appropriate cost report claim for the specific item is satisfied. Those regulations require the reviewing entity to follow the procedures (discussed above) that are set forth in paragraph (j)(3) of this section for determining whether the provider's cost report included an appropriate claim for the specific item under appeal. Also, the reviewing entity may permit payment for the specific item under appeal solely to the extent authorized by § 405.1873(f) (if the appeal was filed originally with the Board) or by § 405.1832(f) (if the appeal was filed initially with the contractor).

b. Statutory and Policy Bases for Proposed Paragraph (j) of § 413.24

We believe the Medicare statute provides ample authority for the above-described proposal to add a new paragraph (j) to § 413.24 of the regulations. This proposal is well within the Secretary's general rulemaking authority under sections 1102 and 1871 of the Act. Moreover, proposed § 413.24(j) is an appropriate exercise of the Secretary's broad authority under sections 1815(a), 1833(e), and 1886(f)(1) of the Act to require providers to furnish the information needed to determine the amount of payment due a provider under the Medicare program. As described above, we have relied on these particular statutory provisions in adopting regulations that require providers to submit annual cost reports; specify the requisite contents of cost reports; and impose various procedural requirements for cost reports (such as time periods for timely submission of cost reports and certification requirements for cost reports). Moreover, we have invoked the same statutory provisions in requiring providers to report other specific information as a condition for Medicare payment (we refer readers to, for example, *Community Hosp. of Monterey Peninsula* v. *Thompson,* 323 F.3d 782, 790, 795–800 (9th Cir. 2003) (sustaining Medicare's policy that providers must bill ''crossover bad debts'' to the State Medicaid agency because 42 U.S.C. 1395g(a) (that is, section 1815(a) of the Act) ''specifically granted the Secretary broad discretion as to what information to require as a condition of payment to providers under the Medicare program''). Indeed, as explained above, the Secretary's broad discretion with respect to cost reporting requirements is also reflected in the Board appeals provisions of section 1878(a) of the Act, which makes provider compliance with cost reporting requirements a prerequisite of Board jurisdiction.

In addition to the plainly sufficient statutory authority for proposed § 413.24(j), we believe there are sound policy reasons for requiring a provider to include an appropriate claim for an item in its cost report by either claiming payment for the item (where the provider believes such claim would comport with Medicare policy), or by self-disallowing the item (if the provider is seeking payment that it believes may not be consistent with Medicare policy). This proposal has three main parts, each of which we address separately.

First, we believe that if a cost is allowable and the provider does not disagree with how Medicare determines payment for the cost, the provider's cost report should include a claim for full payment of the cost in accordance with the program's payment policy. In such cases, a cost report claim for full payment of the cost enables the contractor to review the claim, make any adjustments that seem appropriate, and include final payment for the cost as part of the NPR. Requiring a cost report claim for full payment of allowable costs (where the provider

does not disagree with how Medicare determines payment for the cost) facilitates the contractor's discharge of some of its principal responsibilities, which include using the contractor's expertise and experience to review and audit payment claims, make any necessary adjustments, and include final payment for the cost in the NPR. Absent some misstep by the contractor in reviewing such a cost report claim and determining final payment for the item, there would be no need for the provider to later request reopening or to file an administrative appeal regarding the item. Even if the provider disagreed with some aspect of the contractor's payment determination for the specific item, any such disagreement would be narrowed and delineated more precisely because our proposal, to require a full cost report claim for payment of allowable costs, will give the contractor an opportunity to review and audit the claim and determine the extent to which (if at all) to include payment for the claim in the NPR. Therefore, the interests of administrative finality and efficiency will be advanced if providers are required to include a cost report claim for full payment of allowable costs.

Proposed § 413.24(j)'s requirement of a cost report claim for full payment of allowable cost also comports with the division of responsibilities between the contractors and the Board and the other reviewing entities (as defined in § 405.1801(a)). At present, there are 12 contractors, each of which has a fairly large staff with substantial experience and expertise in reviewing and auditing cost reports and determining final payment in accordance with Medicare policy. By contrast, the Board has only five members and a relatively small staff. We believe it is a waste of scarce resources and very inefficient for a provider to first raise a clearly allowable cost in an appeal to the Board when the contractor could have reviewed and finally determined payment for such an allowable cost in the NPR, if the provider had simply made a timely cost report claim for full payment of the allowable cost. As indicated by the very name of the Provider Reimbursement Review Board, it is a ''Review Board'' or administrative appeals tribunal, not the Medicare program's front line auditors charged with making the initial determination of program reimbursement for such allowable costs.

Second, there are also sound policy reasons for proposing, under a new paragraph (j) in § 413.24, that a provider must self-disallow a specific item if it is seeking payment that it believes may not comport with Medicare policy (for example, because the provider believes the contractor does not have the discretion to make the payment sought by the provider), by following the applicable procedures for filing a cost report under protest (procedures that, as explained above, are now contained in section 115 of the PRM, Part 2 and would be set forth in proposed paragraph (j)(2) of § 413.24). When a provider self-disallows an item by accounting for it appropriately in the ''protested amount'' line of the cost report (instead of claiming payment for the item), the contractor has an opportunity to correct any misconceptions that the provider may have had about the item. For example, the contractor could determine, contrary to the provider's apparent understanding in self-disallowing a specific item, that the item in question is actually an allowable cost that is reimbursable in accordance with program policy. Another example: the contractor might determine, despite the provider's understanding of Medicare policy and its concomitant self-disallowance, that program policy has changed and the item is now an allowable cost or a new payment policy now applies that permits the payment methodology used by the provider in support of its self-disallowance of the item (for example, 75 FR 50042; 50275 through 50286 (August 16, 2010) (discussing CMS Ruling 1498–R, which revised Medicare disproportionate share hospital (DSH) payment policy in response to adverse judicial precedent, and made such revisions applicable to open cost reports and certain pending administrative appeals). In such cases, the contractor's deep expertise and experience and its resources can be brought to bear in reviewing self-disallowed items, making any necessary corrections, and finally allowing payment for corrected items in the NPR. Indeed, these kinds of contractor actions comport with section 1874A(a)(4) of the Act and § 413.20(b) of the regulations, which require the contractors to furnish providers with consultative services, education, training, information and instructions, and technical assistance regarding the interpretation and application of payment principles and other program policies; be available to address provider questions and problems on a daily basis; and facilitate communication between the agency and providers. Accordingly, we believe our proposed addition of a self-disallowance requirement to the cost reporting regulations will facilitate exhaustion of administrative remedies through the contractor's review and final settlement of the provider's cost report, and when the contractor corrects errors in a provider's self-disallowance, the erstwhile need to appeal to the Board or request reopening could be obviated (we refer readers to *Little Co. of Mary Hosp.* v. *Shalala,* 165 F.3d 1162, 1165 (7th Cir. 1999) (the Secretary's requirement of an appropriate cost report claim for an item ensures that the contractor will have the ''first shot'' at determining any reimbursement for the item, before any appeal to the Board need be filed).

By requiring the self-disallowance of items that providers believe may not comport with Medicare policy, proposed § 413.24(j) would also contribute importantly to other aspects of program administration. For example, this proposal would facilitate provider compliance with the existing requirements in § 413.24(f) that each provider submit a complete, accurate, and timely cost report, and that the provider's administrator or chief financial officer certify that the submitted cost report is complete and accurate. Our proposed self-disallowance requirement would also enhance CMS' ability to accurately estimate the program's potential liabilities (for example, for purposes of the agency's preparation of required financial statements). Similarly, this proposal would improve the contractors' ability to establish audit and other workload priorities. The proposed addition of a self-disallowance requirement (for items that providers believe may not comport with Medicare policy) to the cost reporting regulations would also enable us to better monitor Medicare policy and potentially adjust our policies in response to a pattern of provider self-disallowances of a given item. Indeed, the importance of requiring complete and accurate cost report information is highlighted by the fact that we use cost report data for a wide variety of purposes such as setting and refining prospective payment rates; establishing hospital market basket weights; calculating Medicare and total facility margins; determining payment for graduate medical education (GME) and indirect medical education (IME); creating projections for the President's annual budget and for the annual Medicare Trustees Report; for various research projects; and for responding to requests from the public, the Congress, the Executive Office of Management and Budget (EOMB), and other parts of the Administration.

Third, we believe there also are sound reasons for our proposal that, under a new § 413.24(j), if a provider fails to account appropriately for an item in its cost report (by making a full claim for

payment for the item or self-disallowing the item if the provider believes a payment claim would not comport with Medicare policy), the NPR issued by the contractor may not include payment for the item and payment also may not be permitted in any decision, order, or other action by a reviewing entity (as defined in § 405.1801(a)) in an administrative appeal filed by the provider. Under existing §§ 405.1835(a)(1) and 405.1840(b)(3), the consequence of not making an appropriate cost report claim for an item is that the Board would not have jurisdiction over the provider's appeal of the item. (Similarly, under §§ 405.1811(a)(1) and 405.1814(b)(3), the contractor hearing officers would lack jurisdiction for an item if the provider did not make an appropriate cost report claim for the item.) As explained below, however, we are proposing to eliminate the jurisdictional requirement of an appropriate cost report claim in existing §§ 405.1835(a)(1) and 405.1840(b)(3) for Board appeals (and the corresponding jurisdictional requirement in §§ 405.1811(a)(1) and 405.1814(b)(3) for contractor hearing officer appeals), because we believe it is a requirement more appropriately placed in the cost reporting regulations. Given that our longstanding policy of requiring an appropriate cost report claim for an item would be added to the cost reporting regulations, in proposed paragraph (j) of § 413.24, this provision is a natural place to spell out the consequences of not abiding by this cost reporting requirement. In this regard, we note that the proposed addition of a new paragraph (j) to § 413.24 is like the existing paragraph (e) in § 413.20, which provides for the suspension of Medicare payments if a provider fails to maintain the records necessary for proper determination of Medicare reimbursement. Similarly, if a provider fails to include an appropriate claim for an item in its cost report, the NPR issued by the contractor will not include payment for the item and payment also will not be permitted in any decision, order, or other action by a reviewing entity (as defined in § 405.1801(a)) in an administrative appeal filed by the provider.

2. Proposed Revisions to the Provider Reimbursement Appeal Regulations

a. Elimination of the Jurisdictional Requirement of an Appropriate Cost Report Claim

In this proposed rule, we are proposing to eliminate the requirement in existing §§ 405.1835(a)(1) and 405.1840(b)(3) of the regulations that a provider must include an appropriate claim for an item in its cost report in order to meet the dissatisfaction requirement for Board jurisdiction. We believe there is a sound basis in law and policy for this proposal. Our proposal to eliminate an appropriate cost report claim as a requirement for Board jurisdiction is well within the Secretary's general rulemaking authority under sections 1102 and 1871 of the Act. Moreover, this specific proposal is a reasonable interpretation of the ''dissatisfied'' provision in section 1878(a)(1)(A) of the Act. In our view, this statutory provision is ambiguous and the interpretation in the existing appeal regulations, which requires providers to make appropriate cost report claims in order to meet the dissatisfaction prerequisite of Board jurisdiction with respect to a specific item, is a permissible interpretation of the statute. As described above, however, providers have challenged our interpretation of the statutory dissatisfaction provision in litigation spanning more than 30 years, and in public comments on current §§ 405.1835(a)(1) and 405.1840(b)(3) of the regulations which were adopted in the FY 2008 IPPS final rule (73 FR 30195 through 30200; CMS' response to public comments on the current Board appeals regulations that are based on our interpretation of the statutory dissatisfaction provision). Providers have maintained throughout this litigation and in the referenced public comments that the statutory dissatisfaction provision does not support our policy of requiring an appropriate cost report claim as a prerequisite of Board jurisdiction. We continue to disagree with this view of the statute, and still believe that the existing Board appeals regulations are based on a permissible interpretation of the statutory dissatisfaction provision. As explained above, existing § 405.1835(a)(1) comports with the Supreme Court's statement that the statutory dissatisfaction requirement might not be met if a provider bypassed a clearly prescribed exhaustion requirement or failed to ask the contractor for payment of all costs to which it is entitled under applicable rules (*Bethesda Hosp.,* 485 U.S. at 404–05). Furthermore, the U.S. Court of Appeals for the Seventh Circuit has twice sustained our interpretation of the statutory dissatisfaction provision, on the basis of the forgoing statements by the Supreme Court (*Little Co. of Mary,* 165 F.3d 1162; *Little Co. of Mary,* 24 F.3d 984). Nonetheless, we believe our proposal, to eliminate § 405.1835(a)(1)'s jurisdictional requirement of an appropriate cost report claim certainly does not conflict with the ''dissatisfied'' provision in section 1878(a)(1)(A) of the Act.

This particular proposal is supported by section 1878(a)(1)(B) of the Act, which authorizes certain Board appeals if the provider does not receive a final contractor determination on a timely basis. (Section 405.1835(a)(3)(ii) of the regulations specifies the time period and other conditions for Board appeals where the provider does not receive a final contractor determination on a timely basis.) Section 1878(a)(1)(B) of the Act does not include an express dissatisfaction provision. Thus, our proposal, to eliminate existing § 405.1835(a)(1)'s dissatisfaction jurisdictional requirement of an appropriate cost report claim, would result in Board appeals regulations that more closely track the express terms of section 1878(a)(1)(B) of the Act.

In addition to the sufficient statutory authority for our proposed elimination of an appropriate cost report claim as a requirement for Board jurisdiction, there are sound policy reasons for this proposal. As explained above, we believe that, by requiring appropriate cost report claims in proposed § 413.24(j), complete and accurate determinations of provider reimbursement will be facilitated as will the many other important aspects of program administration. Thus, because we would require an appropriate cost report claim in proposed § 413.24(j), it is reasonable to eliminate the Board jurisdiction requirement in existing §§ 405.1835(a)(1) and 405.1840(b)(3) of an appropriate cost report claim. We note that once this amendment to the Board appeals regulations becomes effective, this proposal will facilitate an orderly end to any litigation regarding the Board jurisdiction requirement of an appropriate cost report claim.

As explained above, our proposed revisions to the cost reporting regulations and the provider appeals regulations would apply on a prospective-only basis, to provider cost reporting periods beginning on or after the effective date of the final IPPS annual update rule. Until these proposed regulations take effect, however, the requirement of an appropriate cost report claim in §§ 405.1835(a)(1) and 405.1840(b)(3) of the regulations will continue to be a requirement for Board jurisdiction. Thus, until these proposed regulations become effective, the Board and the Administrator of CMS will continue to determine Board jurisdiction by

reference to the appropriate cost report claim requirements of §§ 405.1835(a)(1) and 405.1840(b)(3), along with other applicable jurisdictional provisions of section 1878 of the Act and §§ 405.1835 and 405.1840 of the regulations. We believe that, because it is essential to require appropriate cost report claims for the various reasons that we discussed above, it is necessary and proper to continue to require an appropriate cost report claim as a prerequisite of Board jurisdiction under §§ 405.1835(a)(1) and 405.1840(b)(3) until the proposed addition to the cost reporting regulations, of the substantive reimbursement requirement of an appropriate cost report claim, takes effect.

b. Proposed Addition of § 405.1873 Regarding Board Review of Compliance with Cost Report Claim Requirements in Proposed § 413.24(j)

We are proposing to add a new § 405.1873 to the Board appeal regulations, which will address how the Board should proceed when any party to an appeal questions whether a provider made an appropriate cost report claim (as required by proposed § 413.24(j)) for a specific item under appeal. We believe this new regulation is necessary to forestall potential confusion about how the substantive reimbursement requirement in proposed § 413.24(j) of an appropriate cost report claim for a specific item will pertain to Board appeals of the same item.

Under paragraph (b)(1) of proposed new § 405.1873, the Board will consider timely submitted factual evidence and legal argument on, and then prepare written specific findings of fact and conclusions of law regarding, the question of whether the provider's cost report complied with proposed § 413.24(j). The Board will give these written specific factual findings and legal conclusions to each party to the appeal, and they must be included in the record of administrative proceedings for the appeal. Paragraph (b)(2) of proposed § 405.1873 provides that, upon giving the parties to the appeal the Board's written factual findings and legal conclusions on the question of whether the provider's cost report included an appropriate cost claim for the specific item under appeal, the Board then must proceed to issue one of four types of overall decisions with respect to such item. As discussed below, paragraph (d) of proposed § 405.1873 provides that, if the Board issues either of two types of overall Board decisions regarding the specific item under appeal (that is, a hearing decision or an expedited judicial review (EJR) decision where EJR is granted), the Board's written specific factual findings and legal conclusions (reached under proposed § 405.1873(b)) about whether there was an appropriate cost report claim for the item, must be included in such overall Board decision regarding the specific item, along with the other matters that are already required for a Board hearing decision or a Board EJR decision where EJR is granted. However, under paragraph (e) of proposed § 405.1873, if the Board issues either of two other types of overall Board decisions regarding the specific item under appeal (that is, a jurisdictional dismissal decision or an EJR decision where EJR is denied), the Board's written specific factual findings and legal conclusions (pursuant to proposed § 405.1873(b)) must not be included in the overall Board decision regarding the specific item. In any event, the Board's factual findings and legal conclusions about whether there was an appropriate cost report claim for the item must be included in the record of administrative proceedings for the appeal in accordance with § 405.1865 of the regulations.

We believe that, in order to ensure full and appropriate implementation of both the addition of the substantive reimbursement requirement of an appropriate cost report claim (in proposed § 413.24(j)) and the elimination of the Board jurisdiction requirement of an appropriate cost report claim (in existing §§ 405.1835(a)(1) and 405.1840(b)(3)), it is necessary to foreclose certain types of Board decisions, orders, and other actions. Accordingly, in order to give full force and effect to our proposed elimination of the Board jurisdiction requirement of an appropriate cost report claim, paragraph (c)(1) of new § 405.1873 would prohibit a denial of jurisdiction, a declination to exercise jurisdiction, the imposition of a sanction, and various other actions by the Board, if any such jurisdictional decision, order, sanction, or other specified action is based on (in whole or in part) the Board's determination that the provider's cost report did not meet proposed § 413.24(j)'s substantive reimbursement requirement of an appropriate cost report claim for the specific item.

In some cases, the Board jurisdiction requirement of an appropriate cost report claim has been addressed in different but related terms. For example, Board jurisdiction has been denied based on the absence, in the final contractor determination or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal. Another example: Board jurisdiction has also been denied due to the lack of a particular determination by the contractor or the Secretary regarding the specific item under appeal, in the final contractor determination or Secretary determination under appeal. We believe that, in order to give full force and effect to the proposed elimination of the Board jurisdiction requirement of an appropriate cost report claim, it is also necessary to address related terms such as the absence of specific adjustments and the lack of particular determinations regarding the specific item under appeal. Accordingly, paragraph (c)(2) of proposed new § 405.1873 would prohibit a denial of jurisdiction, a declination to exercise jurisdiction, the imposition of a sanction, and various other actions by the Board, if any such jurisdictional decision, sanction, or other specified action is based on (in whole or in part) the absence, in the final contractor determination or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item in the final contractor determination or Secretary determination under appeal. However, paragraph (c)(2)(i)(A) of proposed new § 405.1873 would provide for an important exception: if the provider's appeal of the specific item is based on the reopening of such item (pursuant to § 405.1885 of the regulations) where the specific item is not revised, adjusted, corrected, or otherwise changed in a revised final contractor determination or Secretary determination, the Board must deny jurisdiction over the specific item under appeal (as prescribed in §§ 405.1887(d) and 405.1889(b) of the regulations). The reopening regulations are an exercise of the Secretary's general rulemaking authority under sections 1102 and 1872 of the Act, and this exception (in proposed § 405.1873(c)(2)(i)(A)) is necessary to ensure consistency with the above-referenced reopening regulations, our longstanding ''issue specific'' interpretation of the reopening regulations, and the interests of administrative finality and efficiency (we refer readers, for example, to *HCA Health Servs. of Okla.* v. *Shalala,* 27 F.3d 614 (D.C. Cir. 1994) (the reopening regulations are based on the Secretary's general rulemaking authority, and the issue specific interpretation of the reopening rules is reasonable and supportive of administrative finality).

Under paragraph (d) of proposed § 405.1873, there are two types of Board decisions that must include any specific findings of fact and conclusions of law by the Board (reached under paragraph (b) of proposed § 405.1873), on the question of whether the provider's cost report included an appropriate claim for the specific item under appeal. First, paragraph (d)(1) of proposed § 405.1873 provides that, if the Board issues a hearing decision on the specific item under appeal (pursuant to § 405.1871 of the regulations), the Board's specific findings of fact and conclusions of law about whether there was an appropriate cost report claim for the specific item, must be included in such a hearing decision along with the other matters prescribed in existing § 405.1871(a). A Board hearing decision addresses whether the provider has established that it should receive relief on the matter at issue (as specified in § 405.1871(a)(3)). Under proposed § 413.24(j), the requirement of an appropriate cost report claim is a substantive prerequisite of any payment for the specific item, which applies in addition to other payment requirements for the particular item (for example, the specific requirements for payment of interest expense under § 413.153 of the regulations). We believe that, because a Board hearing decision addresses whether the provider has established that it meets the substantive requirements for payment of the item under appeal whereas an appropriate cost report claim is a substantive prerequisite of any payment for the specific item (under proposed § 413.24(j)), any factual findings and legal conclusions about whether there was an appropriate cost report claim should be included in any hearing decision that might be issued by the Board regarding the specific item. In addition, we note that if the Board elects to issue a hearing decision that also includes factual findings and legal conclusions about whether the other payment requirements for the specific item were satisfied (in addition to the Board's findings and conclusions about whether there was an appropriate cost report claim for the item), such a hearing decision (addressing all the substantive reimbursement requirements for the specific item) will safeguard against piecemeal proceedings before the Board and potentially before the Administrator of CMS and a Federal court. However, paragraph (d)(1)(ii) of proposed § 405.1873 provides that, if the Board determines that the provider's cost report did not include an appropriate claim for the specific item under appeal, the Board has discretion whether or not to address in its hearing decision whether the other substantive reimbursement requirements for the specific item are also satisfied.

Second, paragraph (d)(2) of proposed § 405.1873 provides that, if the Board issues an expedited judicial review (EJR) decision where EJR is granted regarding the specific item under appeal (pursuant to § 405.1842(f)(1) of the regulations), any specific findings of fact and conclusions of law by the Board (reached under paragraph (b) of proposed § 405.1873) about whether there was an appropriate cost report claim for the specific item, must be included in such an EJR decision. Section 1878(f)(1) of the Act and § 405.1842 of the regulations authorize EJR if the requirements for Board jurisdiction over a specific item are satisfied, and the Board determines that it lacks the authority to decide a legal question that is relevant to the specific item under appeal. The Administrator of CMS may review the Board's determination as to whether there is Board jurisdiction over the specific item, but the Administrator may not review the Board's determination as to whether it has the authority to decide a relevant legal question. We believe that paragraph (d)(2) of proposed § 405.1873 will also safeguard against piecemeal proceedings before the Board, the Administrator of CMS, and a Federal court. By requiring a Board EJR decision that grants EJR to include any factual findings and legal conclusions (reached under proposed § 405.1873(b)) about whether there was an appropriate cost report claim for the specific item under appeal, along with the Board's determinations that the two requirements for EJR were satisfied (that is, a finding of Board jurisdiction plus the Board's determination that it lacks the authority to decide a legal question relevant to the specific item under appeal), piecemeal proceedings would be minimized or eliminated because the Board EJR decision will encompass both the question of whether there was an appropriate cost report claim for the specific item and the relevant legal question for which EJR was granted (and for which the Board determined that it has no authority to decide such legal question). Piecemeal proceedings before the Administrator of CMS would also be minimized or eliminated because, under proposed § 405.1875(a)(2)(v) (which we discuss separately below), if the Administrator reviews and issues an EJR decision on the question of whether there is Board jurisdiction over the specific item under appeal, the Administrator will also review, and any decision will address, the Board's specific findings of fact and conclusions of law about whether there was an appropriate cost report claim for the specific item. In turn, our proposal to require an EJR decision that grants EJR to include any specific factual findings and legal conclusions under proposed § 405.1873(b) would ensure that when a Federal court exercises its EJR authority under section 1878(f)(1) of the Act and § 405.1842 of the regulations by reviewing a relevant legal question (for which the Board determined it has no decisional authority), the court's review can also potentially encompass the final specific findings of fact and conclusions of law by the Board or the Administrator, as applicable, about whether there was an appropriate cost report claim for the specific item. If it is determined, in a final EJR decision that grants EJR, that there was an appropriate cost report claim for the specific item under appeal, the court may have no occasion to review the final specific findings of fact and conclusions of law on the question of whether there was an appropriate cost report claim for the specific item. However, if it is instead determined, in a final EJR decision that grants EJR, that the provider's cost report did not include an appropriate claim for the specific item under appeal, the court can potentially review in one proceeding the final specific findings of fact and conclusions of law about whether there was an appropriate cost report claim for the specific item, along with the relevant legal question for which EJR was granted (and for which the Board determined that it has no authority to decide such legal question).

However, paragraph (e) of proposed new § 405.1873 would provide that there are two other types of Board decisions that must not include any specific findings of fact and conclusions of law by the Board (reached under proposed § 405.1873(b)), on the question of whether the provider's cost report included an appropriate claim for the specific item under appeal. On the one hand, paragraph (e)(1) of proposed new § 405.1873 would provide that if the Board issues a jurisdictional dismissal decision on the specific item under appeal (pursuant to § 405.1840(c)), the Board's specific findings of fact and conclusions of law about whether there was an appropriate cost report claim for the specific item must not be included in such a jurisdictional dismissal decision. When the Board issues a jurisdictional dismissal decision on a specific item under appeal, the Board's

denial of jurisdiction obviates any need to address the question of whether the substantive reimbursement requirements that are specific to the particular item (for example, the specific requirements for payment for certain depreciation under § 413.134) are satisfied. Because the requirement of an appropriate cost report claim for each specific item is also a substantive prerequisite of any payment for the specific item (as prescribed in proposed § 413.24(j)), a denial of jurisdiction over the specific item also obviates any need to address the substantive reimbursement requirement of an appropriate cost report claim in the Board's jurisdictional dismissal decision.

Similarly, under paragraph (e)(2) of proposed new § 405.1873, if the Board issues an EJR decision where EJR is denied on the specific item under appeal (pursuant to § 405.1842(f)(2)), the Board's specific findings of fact and conclusions of law (reached under paragraph (b) of proposed new § 405.1873) about whether there was an appropriate cost report claim for the specific item, must not be included in such an EJR decision. If EJR is denied solely because the Board determines that it does have the authority to decide the legal question relevant to the specific item under appeal, the Board would conduct further proceedings and issue another decision (as specified in § 405.1842(h)(2)(i)). If such further decision is a hearing decision, under proposed § 405.1873(d)(1), the Board's factual findings and legal conclusions (under proposed § 405.1873(b)) about whether there was an appropriate cost report claim must be included in the Board's hearing decision; if the Board elects to also include in the hearing decision its factual findings and legal conclusions about whether the other reimbursement requirements for the specific item are satisfied, piecemeal proceedings before the Board and potentially before the Administrator of CMS and a Federal court would be minimized or eliminated. However, if EJR is denied because the Board lacked jurisdiction over the specific item under appeal, the Board's factual findings and legal conclusions about whether there was an appropriate cost report claim must not be included in such an EJR decision; as explained above regarding Board jurisdictional dismissal decisions, the denial of Board jurisdiction in such an EJR decision obviates the need to address the substantive reimbursement requirement of an appropriate cost report claim, just as there is no need to consider other payment requirements for the particular item under appeal.

Paragraph (f) of proposed new § 405.1873 addresses the various effects of the Board's factual findings and legal conclusions (reached under paragraph (b) of proposed § 405.1873) regarding whether there was an appropriate cost report claim in the two types of Board decisions where such factual findings and legal conclusions must be included: Board hearing decisions, and Board EJR decisions where EJR is granted. An appropriate cost report claim for a specific item is a necessary, but not sufficient, condition for Medicare payment for the specific item. This is because the requirement of an appropriate cost report claim for each specific item is a substantive prerequisite of any payment for the specific item (as prescribed in proposed § 413.24(j)), but all other payment requirements (for example, the particular requirements for payment for certain bad debts under § 413.89) also must be satisfied. Accordingly, under paragraph (f)(1) of proposed new § 405.1873, if the Board determines, as part of a final hearing decision, that the provider's cost report included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j)), payment for the specific item is made in accordance with Medicare policy, but only if the Board further determines in such hearing decision that all the other substantive reimbursement requirements for the specific item are also satisfied. Conversely, if the Board determines, in a final hearing decision, that the cost report lacked an appropriate claim for the specific item under appeal, payment for the specific item is not made, regardless of whether the Board further determines in such hearing decision that the other substantive reimbursement requirements for the specific item are satisfied.

Similarly, paragraph (f)(2) of proposed new § 405.1873 provides that, if the Board or the Administrator of CMS (as applicable) determines, as part of a final EJR decision where EJR is granted, the provider's cost report included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j)), payment for the specific item is made in accordance with Medicare policy, but only to the extent permitted by the final decision of a Federal court pursuant to the EJR provisions of section 1878(f)(1) of the Act (see also §§ 405.1842 and 405.1877) regarding the legal question that is relevant to the specific item (but for which the Board determined it has no decisional authority). By contrast, if the Board or the Administrator of CMS (as applicable) determines, in a final EJR decision where EJR is granted, that the cost report lacked an appropriate claim for the specific item under appeal, payment for the specific item is not made unless: (i) The specific factual findings and legal conclusions by the Board or the Administrator of CMS, as applicable, about whether there was an appropriate cost report claim for the specific item are reversed or modified by the final decision of a Federal court (pursuant to section 1878(f)(1) of the Act and § 405.1877 of the regulations)); and (ii) only to the extent permitted by the final decision of a Federal court pursuant to the EJR provisions of section 1878(f)(1) of the Act (see also §§ 405.1842 and 405.1877 of the regulations) regarding the legal question that is relevant to the specific item (but for which the Board determined it has no decisional authority).

c. Related Proposed Revisions to § 405.1875 Regarding Administrator Review

We are proposing two revisions to § 405.1875 of the regulations, which provides for review by the Administrator of CMS of certain Board decisions, orders, and other actions. We believe these revisions will facilitate the full and appropriate implementation of our proposals (discussed above) to add the substantive reimbursement requirement of an appropriate cost report claim (in proposed § 413.24(j)), eliminate the Board jurisdiction requirement of an appropriate cost report claim (in existing §§ 405.1835(a)(1) and 405.1840(b)(3)), and to add specific procedures for Board review of questions about compliance with the substantive reimbursement requirement of an appropriate cost report claim (in proposed new § 405.1873).

First, under existing § 405.1875(a)(2) of the regulations, the Administrator may review a Board hearing decision, a Board dismissal decision, the Board's jurisdictional determination in an EJR decision (but not the Board's determination, in an EJR decision, of whether it has the authority to decide a relevant legal question), and any other Board decision or action deemed to be final by the Administrator. We are proposing to add a new paragraph (a)(2)(v) to § 405.1875, which would provide that if the Administrator reviews a Board hearing decision, or the jurisdictional component of a Board EJR decision where EJR is granted, regarding a specific item, the Administrator's review of such a hearing decision or such an EJR decision, as applicable, will

include, and any decision issued by the Administrator under § 405.1875(e) of the regulations will address, the Board's specific findings of fact and conclusions of law in such hearing decision or EJR decision (as prescribed in proposed § 405.1873(b) and (d)) on the question of whether the provider's cost report included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j)). We believe this proposed revision to § 405.1875(a)(2) is an important additional safeguard against piecemeal administrative appeal proceedings and potentially before a Federal court. As explained above with respect to proposed § 405.1873(d)(1), if the Board elects to issue a hearing decision that also includes factual findings and legal conclusions about whether the other payment requirements for the specific item were satisfied (in addition to the Board's findings and conclusions about whether there was an appropriate cost report claim for the item), all of the payment requirements for the specific item will be presented in one Board hearing decision for purposes of any review by the Administrator under proposed § 405.1875(a)(2)(v) and a Federal court. Moreover, for the specific reasons set forth above regarding proposed § 405.1873(d)(2), our proposal to require that the Board's factual findings and legal conclusions about whether there was an appropriate cost report claim for the item be included in an EJR decision where EJR is granted will also minimize or eliminate piecemeal proceedings before the Board and, given the proposed addition of § 405.1875(a)(2)(v), before the Administrator of CMS and a Federal court.

Second, existing § 405.1875(a) requires the Board to promptly send copies of hearing decisions and EJR decisions to the Office of the Attorney Advisor. Although the Board often (perhaps typically) sends copies of dismissal decisions to the Office of the Attorney Advisor, the Board is not required to so. We are proposing to amend the last sentence of paragraph (a) of § 405.1875 by requiring the Board to promptly send copies of dismissal decisions to the Office of the Attorney Advisor. This revision will facilitate the Administrator's exercise of her discretion under § 405.1875(a)(2)(ii) as to whether to review specific Board dismissal decisions. Also, given our proposals to eliminate the Board jurisdiction requirement of an appropriate cost report claim (in existing §§ 405.1835(a)(1) and 405.1840(b)(3)) and to add procedures for Board review of compliance with the substantive reimbursement requirement of an appropriate cost report claim (in proposed § 405.1873)), our further proposal to require the Board to promptly send copies of dismissal decisions to the Office of the Attorney Advisor will enhance the Administrator's ability to ensure full and appropriate implementation of our proposed revisions to the Board appeal regulations.

C. Proposed Conforming Changes to the Board Appeal Regulations and Corresponding Revisions to the Contractor Hearing Regulations

We are proposing technical revisions to several other Board appeal regulations. We believe these other technical revisions are necessary and appropriate to maintain consistency with our principal proposals (discussed above) to add the substantive reimbursement requirement of an appropriate cost report claim (in proposed § 413.24(j)); eliminate the Board jurisdiction requirement of an appropriate cost report claim (in existing §§ 405.1835(a)(1) and 405.1840(b)(3)); and add procedures for Board review of compliance with the substantive reimbursement requirement of an appropriate cost report claim (in proposed § 405.1873)). Finally, we are proposing similar revisions to the existing regulations for appeals to the contractor hearing officers. Specifically, we are proposing to eliminate an appropriate cost report claim as a jurisdictional requirement for contractor hearing officer appeals (in existing §§ 405.1811(a)(1) and 405.1814(b)(3)); add a new § 405.1832 that (like new § 405.1873 for Board appeals) will detail the procedures for contractor hearing officer review of compliance with the substantive reimbursement requirement of an appropriate cost report claim (as prescribed in proposed § 413.24(j)). These proposed revisions to the existing regulations for appeals to the contractor hearing officers comport with our usual practice of adopting similar regulations for both Board appeals and for contractor hearing officer appeals unless there is a sufficient reason to do otherwise.

1. Technical Corrections and Conforming Changes to §§ 405.1801 and 405.1803

We are proposing to revise the definition of ''intermediary determination'' in § 405.1801(a) to clarify that the determination is final as set forth in 1878(a) of the Act and to reflect the conforming technical correction to ''contractor determination''. We are proposing to revise § 405.1801(b) to more appropriately refer to § 413.24 generally (following the proposed addition of paragraph (j) to § 413.24). We are proposing to revise § 405.1803 to refer to the final contractor (instead of intermediary) determination as set forth in § 405.1801 and to appropriately cross-reference the proposed newly revised § 405.1835(a).

2. Technical Corrections and Conforming Changes to §§ 405.1811, 405.1813, and 405.1814

As we are proposing to eliminate the jurisdictional requirement of an appropriate cost report claim in existing §§ 405.1835(a)(1) and 405.1840(b)(3) for Board appeals, we are similarly proposing to eliminate the corresponding jurisdictional requirement in §§ 405.1811(a)(1) and 405.1814(b)(3) for contractor hearing officer appeals. Specifically, we are proposing to eliminate an appropriate cost report claim as a jurisdictional requirement for contractor hearing officer appeals. In addition, we are proposing to revise § 405.1813 to add an appropriate cross-reference to § 405.1811, pursuant to the proposed technical correction in § 405.1811. We are proposing technical corrections to §§ 405.1836 and 405.1837 in conformance with the proposed revision to § 405.1835(a)(1) to eliminate the reference to the jurisdictional requirement of an appropriate cost report claim.

3. Proposed New § 405.1832

We are proposing to add new § 405.1832 which will detail the procedures for contractor hearing officer review of compliance with the substantive reimbursement requirement of an appropriate cost report claim (as prescribed in proposed § 413.24(j)) in appeals first filed with contractor hearing officers.

4. Proposed Revisions to § 405.1834

We are proposing to amend § 405.1834, which provides for review of contractor hearing officer decisions by the CMS reviewing official, by adding a new paragraph (b)(2)(iii). Under proposed § 405.1834(b)(2)(iii), the CMS reviewing official will review, and address in any decision, the specific factual findings and legal conclusions of contractor hearing officers regarding compliance with the substantive requirement of an appropriate cost report claim (as prescribed in proposed § 413.24(j)), as part of the CMS reviewing official's review of a contractor hearing decision.

5. Technical Corrections and Conforming Changes to §§ 405.1836, 405.1837, and 405.1839

We are proposing technical and conforming changes to §§ 405.1836, 405.1837, and 405.1839 to comport and maintain consistency with the principal proposed regulation changes discussed above.

6. Technical Corrections to 42 CFR Part 405, Subpart R and All Subparts of 42 CFR part 413

We are proposing to conform the terminology in 42 CFR part 405 Subpart R and all subparts of 42 CFR part 413 by replacing the term ''intermediary'' and its various deviations to ''contractor'', and its various deviations, pursuant to sections 1816, 1874A, and 1878 of the Act.

IX. Proposed Quality Data Reporting Requirements for Specific Providers and Suppliers

We seek to promote higher quality and more efficient health care for Medicare beneficiaries. This effort is supported by the adoption of widely agreed-upon quality measures. We have worked with relevant stakeholders to define quality measures 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.

We have implemented quality reporting programs for multiple care settings, including:

- Hospital inpatient services under the Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program);
- Hospital outpatient services under the Hospital Outpatient Quality Reporting (OQR) Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP));
- Care furnished by physicians and other eligible professionals under the Physician Quality Reporting System (PQRS, formerly referred to as the Physician Quality Reporting Program Initiative (PQRI));
- Inpatient rehabilitation facilities under the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP);
- Long-term care hospitals under the Long-Term Care Hospital Quality Reporting (LTCHQR) Program;
- PPS-exempt cancer hospitals under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program;
- Ambulatory surgical centers under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program;
- Inpatient psychiatric facilities under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program;
- Home health agencies under the home health quality reporting program (HH QRP); and,
- Hospice facilities under the Hospice Quality Reporting Program.

We have also implemented the End-Stage Renal Disease Quality Incentive Program and Hospital Value-Based Purchasing Program (described further below) that link 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 reporting burden on providers will be reduced. As appropriate, we will consider the adoption of clinical quality 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 adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. However, once these activities are accomplished, 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 reporting burden to hospitals. We believe that in the near future, 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 hospitals will be able to switch primarily to EHR-based data reporting for many measures that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

We also have 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 most recently adopted additional policies for the Hospital VBP Program in section XIV. of the CY 2014 OPPS/ASC final rule with comment period (78 FR 75120 through 75121). We are proposing additional policies for this program in section IV.I. of the preamble of this proposed rule. Under the Hospital VBP Program, hospitals will receive value-based incentive payments based on their quality performance with respect to performance standards 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 we have described for the Hospital VBP Program. The Hospital IQR Program is linked with the Hospital VBP Program because many of the measures and the reporting infrastructure for the programs overlap. We view the Hospital VBP Program as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare from a passive payer of claims into an active purchaser of quality 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.

We also view the Hospital-Acquired Condition (HAC) payment adjustment program authorized by section 1886(p) of the Act, as added by section 3008 of the Affordable Care Act, and the Hospital VBP Program, as related but separate efforts to reduce HACs. The Hospital VBP Program is an incentive program that awards payments to hospitals based on quality performance on a wide variety of measures, while the HAC Reduction Program creates a payment adjustment resulting in payment reductions for the lowest performing hospitals based on their rates of HACs. Proposed policies for the Hospital VBP Program are included in section IV.I. of the preamble of this proposed rule. Proposed policies for the HAC Reduction Program are included in section IV.J. of the preamble of this proposed rule.

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 the preamble of this proposed rule, we are proposing changes to the following Medicare quality reporting systems:

- In section IX.A., the Hospital IQR Program.
- In section IX.B., the PCHQR Program.
- In section IX.C., the LTCHQR Program.

In addition, in section IX.D. of the preamble of this proposed rule, we are proposing changes to the Medicare EHR Incentive Program.

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background

a. History of 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 to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50789 through 50807) for the measures we have adopted for the Hospital IQR measure set through the FY 2016 payment determination and subsequent years.

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 QualityNet Web site at *http://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). 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 with 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.

The NQF regularly maintains its endorsed measures through annual and triennial reviews, which may result in the NQF making updates to the measures. We believe that it is important to have in place a subregulatory process to incorporate nonsubstantive updates made by the NQF into the measure specifications we have adopted for the Hospital IQR Program so that these measures remain up-to-date. We also recognize that some changes the NQF might make to its endorsed measures are substantive in nature and might not be appropriate for adoption using a subregulatory process.

Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505), we finalized a policy under which we use a subregulatory process to make nonsubstantive updates to measures used for the Hospital IQR Program. With respect to what constitutes substantive versus nonsubstantive changes, we expect to make this determination on a case-by-case basis. Examples of nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures). We believe that nonsubstantive changes may include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based.

We will continue to use rulemaking to adopt substantive updates made to measures we have adopted for the Hospital IQR Program. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example: Changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice. These policies regarding what is considered substantive versus nonsubstantive would apply to all measures in the Hospital IQR Program. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process.

We believe this policy adequately balances our need to incorporate updates to 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.

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 this proposed rule, we are not proposing to change our current policy 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.medicare.gov/hospitalcompare*) and/or the interactive *https://data.medicare.gov* Web site, after a 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. For more information on measures reported to *Hospital Compare,* please see *http://www.medicare.gov/hospitalcompare*. Other information not reported to *Hospital Compare* may be made

available on other CMS Web sites such as *http://www.cms.hhs.gov/HospitalQualityInits/* or *https://data.medicare.gov*.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50777 through 50778) we responded to public comments on what additional quality measures and information featured on *Hospital Compare* may be highly relevant to patients and other consumers of health care, and how we may better display this information on the *Hospital Compare* Web site.

2. Removal and Suspension of Hospital IQR Program Measures

a. Considerations in Removing Quality Measures From the Hospital IQR Program

As discussed further below, we generally retain measures from the previous year's Hospital IQR Program measure set for subsequent years' measure sets except when we specifically propose to remove or replace them. 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 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. We also take into account the views of the Measure Applications Partnership (MAP) when determining when a measure should be removed, and we strive to eliminate redundancy of similar measures (77 FR 53505 through 53506).

In this proposed rule, we are proposing to change the criteria for determining when a measure is ''topped-out.'' A measure is ''topped-out'' when measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures) (77 FR 53505 through 53506). We do not believe that measuring hospital performance on ''topped-out'' measures provides meaningful information on the quality of care provided by hospitals. We further believe that quality measures, once ''topped out,'' represent care standards that have been widely adopted by hospitals. We believe such measures should be considered for removal from the Hospital IQR Program because their associated reporting burden may outweigh the value of the quality information they provide.

In order to determine ''topped out'' status, we are proposing to apply the following two criteria, the first of which was previously adopted by the HVBP Program in the Hospital Inpatient VBP Program final rule (76 FR 26496 through 26497), to Hospital IQR measures. The second criterion is a modified version of what was previously adopted by the Hospital VBP Program in the above mentioned final rule, with the change from the ''less than'' operator (<) to the ''less than or equal to'' operator (≤):

- Statistically indistinguishable performance at the 75th and 90th percentiles; and
- Truncated coefficient of variation ≤ 0.10.

The coefficient of variation (CV) is a common statistic that expresses the standard deviation as a percentage of the sample mean in a way that is independent of the units of observation. Applied to this analysis, a large CV would indicate a broad distribution of individual hospital scores, with large and presumably meaningful differences between hospitals in relative performance. A small CV would indicate that the distribution of individual hospital scores is clustered tightly around the mean value, suggesting that it is not useful to draw distinctions among individual hospitals' measure performance. By adopting ''less than or equal to'' in our ''topped out'' test, we are clarifying the interpretation of the CV when a tie at 0.1 occurs due to rounding. We believe that the proposed criteria distinguish measures with significant variation in performance among hospitals.

In the Hospital VBP Program context, we used a modified version of the CV, namely a truncated CV, for each measure, in which the 5 percent of hospitals with the lowest scores, and the 5 percent of hospitals with highest scores were first truncated (set aside) before calculating the CV. This was done to avoid undue effects of the highest and lowest outlier hospitals, which if included, would tend to greatly widen the dispersion of the distribution and make the measure appear to be more reliable or discerning.

We welcome public comments on this proposal.

b. Proposed Removal of Hospital IQR Program Measures for the FY 2017 Payment Determination and Subsequent Years

As we continue moving towards including more clinical outcomes measures as opposed to process-of-care measures in the Hospital IQR Program measure set, we have considered removing additional measures using our previously-adopted removal criteria. We are proposing to remove five measures from the Hospital IQR Program for the FY 2017 payment determination and subsequent years, which begins in the CY 2015 reporting period: (1) AMI–1 Aspirin at arrival (NQF #0132); (2) AMI–3 ACEI/ARB for left ventricular systolic dysfunction (NQF #0137); (3) AMI–5 Beta-blocker prescribed at discharge (NQF #0160); (4) SCIP INF–6 Appropriate Hair Removal; and (5) Participation in a systematic database for cardiac surgery (NQF #0113).

We are proposing to remove the first four process measures because they were previously determined to be ''topped out'' and suspended (77 FR 53509). We are proposing to remove the fifth measure because the MAP recommended the measure's removal in its MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs, which is available at: *http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx*. The MAP report states that the measure's NQF endorsement has been placed on reserve status because the measure is ''topped-out.'' The purpose of reserve status is to retain endorsement of reliable and valid quality performance measures that have overall high levels of performance with little variability so that performance could be monitored in the future if necessary to ensure that performance does not decline. This status would apply only to highly credible, reliable, and valid measures that have high levels of performance due to quality improvement actions (often facilitated or motivated through public reporting and other accountability programs). More information about NQF reserve status is available at: *https://www.qualityforum.org/docs/Reserve_Endorsement_Status.aspx*.

By removing these measures, we would alleviate the maintenance costs and administrative burden to hospitals

associated with retaining them. Should we determine that hospital adherence to these practices has unacceptably declined, we would propose to resume data collection in future rulemaking. In addition, we would comply with any requirements imposed by the Paperwork Reduction Act before re-proposing these measures.

We also analyzed the remainder of the Hospital IQR measure set for other potential ''topped out'' measures using the previously adopted criteria. The analysis was based on the most recent two quarters of clinical process of care data available in the CMS Clinical Data Warehouse for IPPS eligible hospitals, which covers a measurement period from 01/01/2013 to 06/30/2013 (Q1 2013–Q2 2013). Based on this analysis and using the previously adopted criteria, we believe that an additional 15 chart-abstracted measures are ''topped out,'' and we are proposing to remove them from the measure set for the FY 2017 payment determination and subsequent years. However, we are proposing to retain the electronic clinical quality measure version of 10 of these chart-abstracted measures for Hospital IQR Program reporting as discussed further in section IX.A.7.f. of the preamble of this proposed rule. We believe that retaining ''topped out'' measures under certain circumstances enables us to continue monitoring the clinical topic covered by the measure to ensure that hospitals continue to maintain high levels of performance. Further, we believe the additional reporting burden associated with retaining these measures is mitigated by retaining electronic versions of those measures, which are more easily reported by hospitals. These 10 measures are denoted in the chart below by an asterisk.

''TOPPED OUT'' CHART-ABSTRACTED MEASURES PROPOSED FOR REMOVAL FOR THE FY 2017 PAYMENT DETERMINATION

- AMI–1: Aspirin at Arrival (previously suspended).
- AMI–3: ACEI or ARB for left ventricular systolic dysfunction—Acute Myocardial Infarction (AMI) Patients (previously suspended) (NQF #0137).
- AMI–5: Beta-Blocker Prescribed at Discharge for AMI (previously suspended) (NQF #0160).
- AMI–8a: Primary PCI received within 90 minutes of hospital arrival * (NQF #0163).
- HF–2: Evaluation of left ventricular systolic function (NQF #0135).
- PN–6: Initial antibiotic selection for community-acquired pneumonia (CAP) in immunocompetent patients* (NQF #0147).
- SCIP–Inf–1: Prophylactic antibiotic received within one hour prior to surgical incision* (NQF #0527).
- SCIP–Inf–2: Prophylactic antibiotic selection for surgical patients* (NQF #0528).
- SCIP–Inf–3: Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery) (NQF #0529).
- SCIP–Inf–4: Cardiac surgery patients with controlled postoperative blood glucose (NQF #0300).
- SCIP–Inf–6: Surgery patients with appropriate hair removal (previously suspended) (NQF #0301).
- SCIP–Inf–9: Urinary catheter removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with day of surgery being day zero.* (NQF #0453).
- SCIP–Card–2: Surgery patients on beta blocker therapy prior to arrival who received a beta blocker during the perioperative period (NQF #0284).
- SCIP–VTE–2: *Surgery Patients Who Received Appropriate Venous Thromboembolism (VTE) Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery* (NQF #0218).
- STK–2: Discharged on antithrombotic therapy * (NQF #0435).
- STK–3: Anticoagulation therapy for atrial fibrillation/flutter* (NQF #0436).
- STK–5: Antithrombotic therapy by the end of hospital day two* (NQF #0438).
- STK–10: Assessed for rehabilitation* (NQF #0441).
- VTE–4: Patients receiving un-fractionated Heparin with doses/labs monitored by protocol*.
- Participation in a systematic database for cardiac surgery (NQF #0113).

* Proposed to be retained as an electronic clinical quality measure.

We welcome public comments on our proposal to remove these measures.

3. Process for Retaining Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53513), for our finalized measure retention policy. When we adopt measures for the Hospital IQR Program beginning with a particular payment determination, these measures are automatically adopted for all subsequent payment determinations unless we propose to remove, suspend, or replace the measures.

We are not proposing any changes to our policy for retaining previously adopted measures for subsequent payment determinations.

4. Additional Considerations in Expanding and Updating Quality Measures Under the Hospital IQR Program

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for a discussion of the considerations we use to expand and update quality measures under the Hospital IQR Program. We are not proposing any changes to the considerations in expanding or updating quality measures.

5. Previously Adopted Hospital IQR Program Measures for the FY 2016 Payment Determination and Subsequent Years

For currently adopted and future condition-specific, claims-based measures, beginning with the FY 2017 payment determination and subsequent years, we would like to propose to use 3 years of data to calculate measures unless otherwise specified. In other words, this reporting period would apply to all future calculations of condition specific measures already adopted in the Hospital IQR Program and any condition-specific measures that may be subsequently adopted in future years. The currently adopted, applicable measures are:

- Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute myocardial infarction (AMI) hospitalization for patients 18 and older (NQF #0230)
- Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following heart failure (HF) hospitalization for patients 18 and older (NQF #0229)
- Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following pneumonia hospitalization (NQF #0468)
- Stroke 30-day mortality rate
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR)

following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1893)

- 30-day all-cause, Acute Myocardial Infarction (AMI) 30-day risk standardized readmission rate (RSMR) following Acute Myocardial Infarction (AMI) hospitalization (NQF #0505)
- 30-day all-cause, risk standardized readmission rate (RSMR) following Heart Failure (HF) hospitalization (NQF #0330)
- 30-day all-cause, risk standardized readmission rate (RSMR) following Pneumonia (PN) hospitalization (NQF #0506)
- 30-day risk standardized readmission rate (RSMR) following Total Hip/Total Knee Arthroplasty (NQF #1551)
- 30-day risk standardized readmission rate (RSMR) following Stroke hospitalization
- 30-day risk standardized readmission rate (RSMR) following COPD hospitalization (NQF #1891)
- Hip/Knee Complication: Hospital-level Risk-Standardized Complication Rate (RSCR) following Elective Primary Total Hip Arthroplasty (NQF #1550)

We welcome public comments on our proposal to use 3 years of data to calculate current and future condition-specific, claims-based measures.

The Influenza Vaccination Coverage Among Healthcare Personnel (HCP) (NQF #0431) was finalized for the Hospital IQR program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51633) and the Hospital Outpatient Quality Reporting (HOQR) in the CY 2014 OPPS/ASC final rule (78 FR 75099). We received public comments regarding the burden of separately collecting and reporting HCP influenza vaccination statuses for both the inpatient and outpatient settings. In response to these concerns, we clarified that beginning with the 2014–2015 influenza season (CY 2014 reporting period and FY 2016 payment determination), facilities should collect and report a single vaccination count for each healthcare facility by CMS Certification Number (CCN), instead of separately by inpatient or outpatient setting, in order to reduce burden. We announced this clarification regarding how to designate HCP for this measure in an Operational Guidance document which can be found on our on our Web page at: *http://origin.glb.cdc.gov/nhsn/PDFs/HCP/Operational-Guidance-ACH–HCP-Flu.pdf*. Using the CCN will allow healthcare facilities with multiple care settings to simplify data collection and submit a single count applicable across the inpatient and outpatient settings. We will then publicly report the percentage of HCP who received an influenza vaccination per CCN. This single count per CCN will inform the public of the percentage of vaccinated HCP at a particular healthcare facility, which would still provide meaningful data and help to improve the quality of care. Specific details on data submission for this measure can be found at: *http://www.cdc.gov/nhsn/acute-care-hospital/hcp-vaccination/* and at *http://www.cdc.gov/nhsn/acute-care-hospital/index.html*.

The following table shows measures currently adopted for the Hospital IQR Program, including suspended measures.

Topic	Hospital IQR program measures previously adopted for the FY 2016 payment determination and subsequent years
Acute Myocardial Infarction (AMI) Measures	
	• AMI–1: Aspirin at Arrival (previously suspended). • AMI–3: ACEI or ARB for left ventricular systolic dysfunction—Acute Myocardial Infarction (AMI) Patients (previously suspended) (NQF #0137). • AMI–5: Beta-Blocker Prescribed at Discharge for AMI (previously suspended) (NQF #0160). • AMI–7a Fibrinolytic therapy received within 30 minutes of hospital arrival (NQF #0164). • AMI–8a: Primary PCI received within 90 minutes of hospital arrival (NQF #0163) *.
Heart Failure (HF) Measure	
	• HF–2 Evaluation of left ventricular systolic function (NQF #0135) *.
Stroke (STK) Measure Set	
	• STK–1 Venous thromboembolism (VTE) prophylaxis (NQF #0434). • STK–2 Discharged on antithrombotic therapy (NQF #0435) *. • STK–3 Anticoagulation therapy for atrial fibrillation/flutter (NQF #0436) *. • STK–4 Thrombolytic therapy (NQF #0437). • STK–5 Antithrombotic therapy by the end of hospital day two (NQF #0438). • STK–6 Discharged on statin medication (NQF #0439). • STK–8 Stroke education. • STK–10 Assessed for rehabilitation (NQF #0441).
Venous Thromboembolism (VTE) Measure Set	
	• VTE–1 Venous thromboembolism prophylaxis (NQF #0371). • VTE–2 Intensive care unit venous thromboembolism prophylaxis (NQF #0372). • VTE–3 Venous thromboembolism patients with anticoagulation overlap therapy (NQF #0373). • 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) Measure	
	• PN–6 Initial antibiotic selection for community-acquired pneumonia (CAP) in immunocompetent patients (NQF #0147).
Surgical Care Improvement Project (SCIP) Measures	
	• SCIP INF–1 Prophylactic antibiotic received within one hour prior to surgical incision (NQF #0527) *. • SCIP INF–2 Prophylactic antibiotic selection for surgical patients (NQF #0528).

Topic	Hospital IQR program measures previously adopted for the FY 2016 payment determination and subsequent years
	• SCIP INF–3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery) (NQF #0529). • SCIP INF–4 Cardiac surgery patients with controlled postoperative blood glucose (NQF #0300). • SCIP INF–9 Urinary catheter removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with day of surgery being day zero (NQF #0453). • SCIP Card-2 Surgery patients on beta blocker therapy prior to arrival who received a beta blocker during the perioperative period (NQF #0284). • SCIP–VTE-2 *Surgery Patients Who Received Appropriate Venous Thromboembolism (VTE) Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery* (NQF #0218).
Mortality Measures	
	• Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute myocardial infarction (AMI) hospitalization for patients 18 and older (NQF #0230). • Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following heart failure (HF) hospitalization for patients 18 and older (NQF #0229). • Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following pneumonia hospitalization (NQF #0468). • Stroke 30-day mortality rate. • Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1893).
Patient Experience of Care Measure	
	• HCAHPS survey (NQF #0166) (expanded to include two new ''About You'' items and the 3-item Care Transition Measure) (NQF #0228).
Readmission Measures	
	• Hospital 30-day all-cause risk-standardized readmission rate (RSRR) following acute myocardial infarction (AMI) hospitalization (NQF #0505). • Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following heart failure hospitalization (NQF #0330). • Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following pneumonia hospitalization (NQF #0506). • Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551). • Hospital-Wide All-Cause Unplanned Readmission (HWR) (NQF #1789). • 30-day risk standardized readmission rate (RSMR) following Stroke hospitalization. • Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891).
AHRQ Patient Safety Indicators (PSIs) Composite Measure	
	• PSI–90 Patient safety for selected indicators (composite) (NQF #0531).
AHRQ PSI and Nursing Sensitive Care Measure	
	• PSI–4 Death among surgical inpatients with serious treatable complications (NQF #0351).
Structural Measures	
	• Participation in a Systematic Database for Cardiac Surgery (NQF #0113). • Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care. • Participation in a Systematic Clinical Database Registry for General Surgery. • Safe Surgery Checklist Use.
Healthcare-Associated Infections (HAI) Measures	
	• National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139). • American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753). —SSI following Colon Surgery. —SSI following Abdominal Hysterectomy. • National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138). • *National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure* (NQF #1716). • National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717). • Influenza vaccination coverage among healthcare personnel (HCP) (NQF #0431).
Surgical Complications Measures	

Topic	Hospital IQR program measures previously adopted for the FY 2016 payment determination and subsequent years
	• Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550).
Emergency Department (ED) Throughput Measures	
	• ED–1 Median time from ED arrival to ED departure for admitted ED patients (NQF #0495). • ED–2 Admit Decision Time to ED Departure Time for Admitted Patients (NQF #0497).
Prevention: Global Immunization (IMM) Measures	
	• IMM–1 Pneumococcal Immunization (previously suspended) (NQF #1653). • IMM–2 Influenza Immunization (NQF #1659).
Cost Efficiency Measures	
	• Payment-Standardized Medicare Spending Per Beneficiary (MSPB) (NQF #2158). • AMI Payment per Episode of Care.
Perinatal Care (PC) Measure	
	• PC–01 Elective delivery (NQF #0469)

* Measures proposed for removal for the FY 2016 payment determination and subsequent years.

6. Proposed Refinements to Existing Measures in the Hospital IQR Program

We are proposing to incorporate refinements for several measures that were previously adopted in the Hospital IQR Program. These refinements have either arisen out of the NQF endorsement maintenance process, or during our internal efforts to harmonize measure approaches. The measure refinements include the following: (1) Refining the planned readmission algorithm for all seven readmission measures included in the Hospital IQR Program; (2) modifying the hip/knee readmission and complication measure cohorts to exclude index admissions with a secondary fracture diagnosis; and (3) modifying the hip/knee complication measure to not count as complications coded as ''present on admission'' (POA) during the index admission.

a. Proposed Refinement of Planned Readmission Algorithm for 30-Day Readmission Measures

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50785 through 50787) we adopted the CMS Planned Readmission Algorithm Version 2.1 (the Algorithm) for the Hospital IQR Program. In the same final rule (78 FR 50785 through 50787, 50790 through 50792, and 50794 through 50798), we also finalized the use of the CMS Planned Readmission Algorithm Version 2.1 in the AMI, HF, PN, THA/TKA, HWR, and COPD measures. This algorithm identifies readmissions that are planned and occur within 30 days of discharge from the hospital. A complete description of the Algorithm, which includes lists of planned diagnoses and procedures, is available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html in the ''Planned Readmission'' folder.* NQF has endorsed the use of the Algorithm for these measures.

In that final rule (78 FR 50652), in response to comments, we agreed to continually review the Algorithm and make updates as needed. Since its development, we have identified and made improvements. As a result, we are now proposing to use an updated, revised version, the CMS Planned Readmission Algorithm Version 3.0, for the AMI, HF, PN, THA/TKA, HWR, COPD, and Stroke readmission measures for the FY 2015 payment determination and subsequent years. As discussed further below, we are also proposing to use Version 3.0 of this algorithm for the CABG readmission measure that we are proposing to include in the Hospital IQR Program starting in FY 2017, proposed in section IX.A.7.a. of the preamble of this proposed rule.

Version 3.0 incorporates improvements made based on a validation study of the algorithm. Researchers reviewed 634 patients' charts at 7 hospitals, classified readmission as planned or unplanned based on the chart review, and compared the results to the claims-based algorithm's classification of the readmissions. The findings suggested the algorithm was working well but could be improved.

Specifically, the study suggested the need to make small changes to the tables of procedures and conditions used in the algorithm to classify readmission as planned or unplanned. The algorithm uses the Agency for Healthcare Research and Quality's (AHRQ's) Clinical Classification Software (CCS) to group thousands of procedure and diagnosis codes into fewer categories of related procedures or diagnoses. The algorithm then uses four tables of procedures and diagnoses categories and a flow diagram to classify tables as planned or unplanned. Additional information on this software is available at: *http://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccs.jsp*. For all measures, the first table identifies procedures that, if present in a readmission, classify the readmission as planned. The second table identifies primary discharge diagnoses that always classify readmissions as planned. Because almost all planned admissions are for procedures or surgeries, a third table identifies procedures for which patients are typically admitted; if any of these procedures is coded in the readmission, we classify a readmission as planned as long as that readmission does not have an acute (unplanned) primary discharge diagnosis. The fourth table lists the acute (unplanned) primary discharge diagnoses that disqualify readmissions that include one or more of the potentially planned procedure in the third table as planned. These tables are structured the same across all measures but the specific procedure and conditions they contain vary slightly for certain measures based on clinical considerations for each cohort. The current tables for each measure can be found in the measure methodology reports at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Version 3.0 modifies two of these tables by removing or adding procedures or conditions to improve the accuracy of the algorithm. First, the validation study revealed that the algorithm could be improved by removing two procedure CCS categories from the third table, the potentially planned procedure table: CCS 211—Therapeutic Radiation and CCS 224—Cancer Chemotherapy. Typically, patients do not require admission for scheduled Therapeutic Radiation treatments (CCS 211). The study found that readmissions that were classified as planned because they included Therapeutic Radiation were largely unplanned.

The algorithm was also more accurate when CCS 224—Cancer Chemotherapy was removed from the potentially planned procedure table. The second table of the algorithm classifies all readmissions with a *principal diagnosis* of Maintenance Chemotherapy as planned. Most patients who receive cancer chemotherapy have both a code for Cancer Chemotherapy (CCS 224) and a principal discharge diagnosis of Maintenance Chemotherapy (CCS 45). In the validation study, the readmissions for patients who received Cancer Chemotherapy (CCS 224) but who did not have a principal diagnosis of Maintenance Chemotherapy were largely unplanned, therefore removing CCS 224 from the potentially planned procedure table improved the algorithm's accuracy. Therefore, Version 3.0 removes CCS 211 and CCS 224 from the list of potentially planned procedures to improve the accuracy of algorithm.

As noted above, the algorithm uses a table of acute principal discharge diagnoses to help identify unplanned readmissions. Readmissions that have a principal diagnosis listed in the table are classified as unplanned, regardless of whether they include a procedure in the potentially planned procedure table. The validation study identified one diagnosis CCS that should be added to the table of acute diagnoses to more accurately identify truly unplanned admissions as unplanned: Hypertension with Complications (CCS 99). Hypertension with complications is a diagnosis that is rarely associated with planned readmissions.

In addition, the validation study identified a subset of ICD–9 diagnosis codes within two CCS diagnosis categories that should be added to the acute diagnosis table to improve the algorithm. CCS 149, Pancreatic Disorders, includes the code for acute pancreatitis; clinically there is no situation in which a patient with this acute condition would be admitted for a planned procedure. Therefore, Version 3.0 adds the ICD–9 code for acute pancreatitis, 577.0, to the acute primary diagnosis table to better identify unplanned readmissions. Finally, CCS 149, Biliary Tract Disease, is a mix of acute and non-acute diagnoses. Adding the subset of ICD–9 codes within this CCS group that are for acute diagnoses to the list of acute conditions improves the accuracy of the algorithm for these acute conditions while still ensuring that readmissions for planned procedures, like cholecystectomies, are counted accurately as planned. For more detailed information on how the algorithm is structured and the use of tables to identify planned procedures and diagnoses, we refer readers to CMS's Planned Readmission Algorithm Version 2.1: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. As noted above, readers can find the specific Version 3.0 tables for each measure in the measure updates and specifications reports at the above link.

We invite public comment on our proposal to use the CMS Planned Readmission Algorithm Version 3.0, for the AMI, HF, PN, THA/TKA, HWR, COPD, and Stroke readmission measures for the FY 2015 payment determination and subsequent years.

b. Proposed Refinement of Total Hip Arthroplasty and Total Knee Arthroplasty (THA/TKA) 30-Day Complication and Readmission Measures

In this proposed rule, for the FY 2015 payment determination and subsequent years, we are proposing to refine: (1) The measure outcome and cohort for the Elective Primary THA/TKA All-Cause 30-Day Risk-Standardized Complication Measure (NQF #1550); and (2) the measure cohort for the Elective Primary THA/TKA All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (NQF #1551).

As part of measure implementation, CMS conducted a dry run for both the THA/TKA readmission and complication measures in September/October of 2012. More information on the dry run is available at: *https://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228889945763&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3DDryRun_HWR-HK_SummRept_122112.pdf&blobcol=urldata&blobtable=MungoBlobs*.

During the dry run, several commenters suggested CMS evaluate the use of Present on Admission (POA) codes for both the hip/knee readmission and complication measures. We agreed with the suggestion and have been monitoring POA data collection and testing its readiness for use in claims-based measures. We also noted our intent to evaluate the use of POA codes in Hospital IQR Program measures, such as the stroke mortality rate measure, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50801). We have since tested the use of the POA codes and propose to incorporate POA codes into the hip/knee complication measure for FY 2015 payment determination and subsequent years in order to prevent identifying a condition as a complication of care if it was present during admission.

In addition, currently, the THA/TKA Readmission Measure (NQF #1551) adopted for the Hospital IQR Program is intended to only include patients who have an elective THA or TKA. Currently, this measure excludes patients who have a principal discharge diagnosis of femur, hip, or pelvic fracture on their index admission since hip replacement for hip fracture is not an elective procedure. However, after hospitals reviewed their hospital-specific THA/TKA Readmission Measure data during the national dry-run, CMS learned that hospitals code hip fractures that occur during the same admission as a THA as not only a principal diagnosis, but also alternatively, a secondary diagnosis, instead of just a principal diagnosis as currently specified by the measure. According to feedback received from hospitals participating in the dry-run, the measure methodology failed to identify, and, appropriately exclude, a small number of patients (that is, 0.42 percent of patients in 2009–2010 data) with a hip fracture that had non-elective total hip arthroplasty as captured by these secondary diagnoses.

Therefore, to ensure that all such non-elective hip fracture patients are excluded from the measure, we are proposing to refine the measure to exclude patients with hip fractures coded as either a principal or secondary diagnosis during the index admission beginning with the FY 2015 payment determination and subsequent years. We believe this refinement is responsive to comments from hospitals (78 FR 50709) and will allow us to accurately exclude patients who were initially admitted for a hip fracture and who then subsequently underwent total hip

arthroplasty, making their procedure non-elective.

We invite public comment on these proposed refinements.

c. Anticipated Effect of Proposed Refinements to Existing Measures

Based on our analyses of discharges between July 2009 and June 2012, our proposal to use the Planned Readmission Algorithm Version 3.0 would have the following effects on measures had these changes been applied for the FY 2014 payment determination as an example. We are sharing this information to provide the public with a sense of the extent to which these refinements to the measures will change the measure scores. As the results show, while the refinements improve the accuracy of the measures, the changes in actual scores are very slight.

The proposed 30-day readmission rate (excluding the planned readmissions) would increase by 0.1 percentage points for AMI; 0.2 percentage points for HF; 0.1 percentage points for PN; 0.1 percentage points for COPD; 0.0 percentage points for hip/knee; 0.1 percentage points for HWR; and 0.0 percentage points for stroke.

The new national measure (unplanned) rate for each condition would have been 18.4 percent for AMI; 23.2 percent for HF; 17.7 percent for PN; 21.1 percent for COPD; 5.4 percent for hip/knee; 16.1 percent for HWR; and 13.8 percent for stroke.

The number of readmissions considered planned (and, therefore, not counted as a readmission) would decrease by 334 for AMI; 1,375 for HF; 981 for PN, 574 for COPD; 309 for hip/knee; 7,417 for HWR; and 242 for stroke.

COMPARISON OF PLANNED READMISSION ALGORITHMS V 2.1 AND 3.0 FOR AMI/HF/PN/COPD/HK/HWR/STROKE READMISSION MEASURES (BASED ON 2009–2012 DISCHARGES)

	AMI		HF		PN		COPD		Hip/Knee		HWR		Stroke	
	V 3.0	V 2.1	V 3.0	V 2.1	V 3.0	V 2.1	V 3.0	V 2.1	V 3.0	V 2.1	V 3.0	V 2.1	V 3.0	V 2.1
Number of Discharges	513,331	513,331	1,262,826	1,262,826	1,089,758	1,089,758	989,381	989,381	879,641	879,641	6,918,467	6,918,467	502,376	502,376
Number of Unplanned Readmissions	94,453	93,940	292,976	290,450	192,887	191,797	208,759	207,770	47,236	47,236	1,112,885	1,105,378	69,323	69,081
Readmission Rate	18.4%	18.3%	23.2%	23.0%	17.7%	17.6%	21.1%	21.0%	5.4%	5.4%	16.1%	16.0%	13.8%	13.8%
Number of Planned Readmissions	11,947	12,281	16,230	17,605	6,545	7,526	6,447	7,021	2,326	2,635	85,673	93,180	5,750	5,992
Planned Readmission Rate	2.3%	2.4%	1.3%	1.4%	0.6%	0.7%	0.7%	0.7%	0.3%	0.3%	1.2%	1.3%	1.1%	1.2%
% of Readmissions that are Planned	11.2%	11.6%	5.3%	5.7%	3.3%	3.8%	3.0%	3.3%	4.7%	5.3%	7.1%	7.8%	7.7%	8.0%

7. Proposed Additional Hospital IQR Program Measures for the FY 2017 Payment Determination and Subsequent Years

For purposes of the Hospital IQR Program, section 1886(b)(3)(B)(IX)(aa) 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. However, the statutory requirements under section 1886(b)(3)(B)(IX)(bb) 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.

We are proposing to add a total of eleven measures to measure set for the FY 2017 payment determination and subsequent years. The first nine new measures are: (1) Hospital 30-day, all-cause, unplanned, risk-standardized readmission rate (RSRR) following coronary artery bypass graft (CABG) surgery (claims-based); (2) Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following coronary artery bypass graft (CABG) surgery (claims-based); (3) Hospital-level, risk-standardized 30-day episode-of-care payment measure for pneumonia (claims-based); (4) Hospital-level, risk-standardized 30-day episode-of-care payment measure for heart failure (claims-based); (5) Severe Sepsis and Septic Shock: Management Bundle (NQF #0500) (chart-abstracted); (6) EHDI–1a Hearing Screening Prior to Hospital Discharge (NQF #1354) (electronic health record-based); (7) PC–05 Exclusive Breast Milk Feeding and the subset measure PC–05a Exclusive Breast Milk Feeding Considering Mother's Choice (NQF #0480) (electronic health record-based); (8) CAC–3 Home Management Plan of Care (HMPC) Document Given to Patient/Caregiver (electronic health record-based); and, (9) Healthy Term Newborn (NQF #0716) (electronic health record-based).

In addition, to align the Hospital IQR Program with the Medicare EHR Incentive Program for Eligible Hospitals and Critical Access Hospitals and allow hospitals as many measure options as possible that overlap both programs, we are proposing to readopt two measures previously removed from the Hospital IQR Program as voluntary electronic clinical quality measures: (10) AMI–2 Aspirin Prescribed at Discharge for AMI (NQF #0142) (electronic clinical quality measure); and (11) AMI–10 Statin Prescribed at Discharge (NQF #0639) (electronic clinical quality measure). These two measures are part of the Stage 2 Medicare EHR Incentive Program measure set for eligible hospitals and CAHs.

The four proposed claims-based measures (1–4, above) were included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2013'' in compliance with section 1890A(a)(2) of the Act, and they were reviewed by the MAP in its MAP 2014 Recommendations on Measures for More Than 20 Federal Programs final report, available at: *http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx.*

The proposed chart-abstracted measure (5 above) Severe Sepsis and Septic Shock: Management Bundle (NQF #0500) was included in the MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS final report, available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738.*

The proposed measures 6–9 above were included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2012'' in compliance with section 1890A(a)(2) of the Act, and they were reviewed by the MAP in its MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS final report, available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738*.

Measures 10 and 11 were included on a publicly available document entitled ''Measures Under Consideration for Calendar Year 2012'' in compliance with section 1890A(a)(2) of the Act, and they were reviewed by the MAP in its Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking available at *https://www.qualityforum.org/Publications/2012/02/MAP_Pre-Rulemaking_Report__Input_on_Measures_Under_Consideration_by_HHS_for_2012_Rulemaking.aspx.*

a. Proposed Hospital 30-day, All-cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery

(1) Background

CABG is a priority area for outcomes measure development, because it is a common procedure associated with considerable morbidity, mortality, and health care spending. In 2007, there were 114,028 hospitalizations for CABG surgery and 137,721 hospitalizations for combined surgeries for CABG and valve procedures (''CABG plus valve'' surgeries) in the U.S.[44]

Readmission rates following CABG surgery are high and vary across hospitals. For example, in 2009 Medicare fee-for-service (FFS) data, the median hospital-level risk-standardized readmission rate after CABG was 17.2 percent and ranged from 13.9 percent to 22.1 percent.[45] This is consistent with published data as the average 30-day all-cause, hospital-level readmission rate in New York state was 16.5 percent and ranged from 8.3 percent to 21.1 percent among all patients who underwent CABG surgery between January 1, 2005 and November 30, 2007.[46] Among patients readmitted within 30 days, 87.3 percent of readmissions were for reasons related to CABG surgery, with a 30-day rate of readmissions due to complications of CABG surgery of 14.4 percent. Patients readmitted within 30 days also experienced a 2.8 percent in-hospital mortality rate during their readmission(s), three-fold higher than the 30-day mortality rate for patients without readmissions.[47] Hence, addressing the causes of readmission will improve outcomes for patients.

Readmissions after CABG also impose significant health care costs. In 2007, the Medicare Payment Advisory Committee (MedPAC) published a report to Congress in which it identified the seven conditions associated with the most costly potentially preventable

[44] Drye E, Krumholz H, Vellanky S, Wang Y. Probing New Conditions and Procedures for New Measure Development: Yale New Haven Health Systems Corporation; Center for Outcomes Research and Evaluation.; 2009:1–7.

[45] Suter L.G., Wang, C., Vellanky S., Potteiger J., Curtis J., Lin Z., Geary L.L., Krumholz H.M., Drye E.D. Hospital-level 30-day All-Cause Unplanned Readmission Following Coronary Artery Bypass Graft Surgery: Report prepared for the Centers for Medicare & Medicaid Services. 2012.

[46] Hannan EL, Zhong Y, Lahey SJ, et al. 30-day readmissions after coronary artery bypass graft surgery in New York State. *JACC Cardiovasc Interv.* 2011;4(5):569–576.

[47] Ibid.

readmissions in the U.S.[48] Among these seven, CABG ranked as having the highest potentially preventable readmission rate within 15 days following discharge (13.5 percent) and the second highest average Medicare payment per readmission ($8,136).[49] The annual cost to Medicare for potentially preventable CABG readmissions was estimated at $151 million.

High readmission rates and wide variation in these rates suggest that there is room for improvement. Reducing readmissions after CABG surgery has been identified as a target for quality measurement. An all-cause readmission measure for patients who undergo CABG surgery will provide hospitals with an incentive to reduce readmissions through prevention and/or early recognition and treatment of postoperative complications, and improved coordination of peri-operative care and discharge planning.

The specifics of the measure methodology are included in the measure methodology report we have posted on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. We refer readers to the report for further details on the risk-adjustment statistical model.

We are proposing to include this non-NQF-endorsed measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section IX.A.7. of the preamble of this proposed rule. Although the proposed measure is not currently NQF-endorsed, we considered available measures that have been endorsed or adopted by the NQF. We also are not aware of any other 30-day, all-cause, unplanned, risk-standardized readmission rate (RSRR) following coronary artery bypass graft (CABG) surgery measures that have been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on this topic. The measure has been reviewed by the MAP and was conditionally supported pending NQF endorsement as detailed in its Pre-Rulemaking 2014 Map Recommendations Report available at: *https://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*. This measure was submitted to NQF on February 5, 2014 and is currently under review.

[48] Medicare Payment Advisory Committee. Report to the Congress: Promoting Greater Efficiency in Medicare, 2007.

[49] Ibid.

(2) Overview of Measure

The CABG readmission measure assesses hospitals' 30-day, all-cause risk-standardized rate of unplanned readmission following admission for a CABG procedure. In general, the measure uses the same approach to risk adjustment and hierarchical logistic modeling (HLM) methodology that is specified for CMS's other readmission measures previously adopted for this program. Information on how the measure employs HLM can be found in the 2012 CABG Readmission Measure Methodology Report (available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(3) Data Sources

The proposed measure is claims-based. It uses Medicare administrative data from hospitalizations for Medicare FFS beneficiaries hospitalized for a CABG procedure.

(4) Outcome

The outcome for this measure is 30-day, all-cause readmission, defined as an unplanned subsequent inpatient admission to any applicable acute care facility for any cause within 30 days of the date of discharge from the index hospitalization. This outcome period is consistent with other NQF-endorsed publicly reported readmission measures (AMI, HF, PN, COPD, HWR and, THA/TKA).

The measure assesses all-cause unplanned readmissions (excluding planned readmissions) rather than readmissions for CABG only for several reasons. First, from the patient perspective, a readmission for any reason is likely to be an undesirable outcome of care, even though not all readmissions are preventable. Second, limiting the measure to CABG-related readmissions may limit the effort focus too narrowly rather than encouraging broader initiatives aimed at improving the overall care within the hospital and transitions from the hospital setting. Moreover, it is often hard to exclude quality issues and accountability based on the documented cause of readmission. For example, a patient who underwent a CABG surgery and develops a hospital-acquired infection may ultimately be readmitted for sepsis. It would be inappropriate to consider such a readmission to be unrelated to the care the patient received for their CABG surgery. Finally, while the measure does not presume that each readmission is preventable, interventions generally have shown reductions in all types of readmissions.[50] [51]

The measure does not count planned readmissions as readmissions. Planned readmissions would be identified in claims data using the CMS Planned Readmission Algorithm Version 3.0 that detects planned readmissions that may occur within 30 days of discharge from the hospital. Version 2.1 of the algorithm was finalized for use in the current Hospital IQR Program readmission measures in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50785 through 50787, 50790 through 50792 and 50794 through 50798). However, we are proposing to update the algorithm to version 3.0, and details on the updates to this algorithm can be found in section IX.A.6.a. of the preamble of this proposed rule. The proposed CABG readmission measure uses the planned readmission algorithm tailored for CABG patients. We adapted the algorithm for this group of patients with input from CABG surgeons and other experts, narrowing the types of readmissions considered planned since planned readmissions following CABG are less common and less varied than among patients discharged from the hospital following a medical admission. More detailed information on how the CABG measure incorporates the Planned Readmission Algorithm Version 3.0 can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. Once at the Web site go to the Coronary Artery Bypass Graft (CABG) Readmission zip file. Open the file labeled, ''Version10_Readmission_CABG_Measure_Methodology_Report_3 19 2014'' and refer to Section 2.3.3. For the CABG measure, unplanned readmissions that fall within the 30-day post-discharge timeframe from the index admission would not be counted as readmissions for the index admission if they were preceded by a planned readmission.

(5) Cohort

The cohort includes patients aged 65 years and older who received a qualifying CABG procedure at an acute care facility. Patients are eligible for

[50] Gulshan Sharma, Kou Yong-Fang, Freeman Jean L, Zhang Dong D, Goodwin James S.: Outpatient Follow-up Visit and 30-Day Emergency Department Visit and Readmission in Patients Hospitalized for Chronic Obstructive Pulmonary Disease. *Arch Intern Med*. Oct. 2010;170:1664–1670.

[51] Nelson EA, Maruish ME, Axler JL.: Effects of Discharge Planning and Compliance with Outpatient Appointments on Readmission Rates. *Psychiatr Serv*. July 1 2000;51(7):885–889.

inclusion if they had a qualifying CABG procedure and continuous enrollment in Medicare FFS one year prior to the first day of the index hospital stay and through 30 days post-discharge. The index stay is the stay that triggers the 30-day measurement period.

In order to include a clinically-coherent set of patients in the measure, we sought input from clinical experts regarding the inclusion of other concomitant cardiac and non-cardiac procedures, such as valve replacement and carotid endarterectomy. Adverse clinical outcomes following such procedures are higher than those following ''isolated'' CABG procedures, that is, CABG procedures performed without concomitant high-risk cardiac and non-cardiac procedures.[52] Limiting the measure cohort to ''isolated'' CABG patients is consistent with published reports of CABG outcomes; [9] therefore, the measure cohort considers only patients undergoing isolated CABG as eligible for inclusion in the measure. We defined isolated CABG patients as those undergoing CABG procedures without concomitant valve or other major cardiac, vascular or thoracic procedures. In addition, our clinical experts, consultants, and Technical Expert Panel (TEP) members agreed that an isolated CABG cohort is a clinically coherent cohort for quality measurement. For detailed information on the cohort definition, we refer readers to the 2012 CABG Readmission Measure Methodology Report on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(6) Inclusion and Exclusion Criteria

The measure includes hospitalizations for patients who are 65 years of age or older at the time of index admission and for whom there was a complete 12 months of Medicare FFS enrollment to allow for adequate risk adjustment. The measure excludes the following admissions from the measure cohort: (1) Admissions for patients who are discharged against medical advice (excluded because providers do not have the opportunity to deliver full care and prepare the patient for discharge); (2) admissions for patients who die during the initial hospitalization (these patients are not eligible for readmission); (3) admissions for patients with subsequent qualifying CABG procedures during the measurement period (a repeat CABG procedure during the measurement period very likely represents a complication of the original CABG procedure and is a clinically more complex and higher risk surgery, therefore we select the first CABG admission for inclusion in the measure and exclude subsequent CABG admissions from the cohort); and (4) admissions for patients without at least 30 days post-discharge enrollment in Medicare FFS (excluded because the 30-day readmission outcome cannot be assessed in this group).

(7) Risk-Adjustment

The measure adjusts for differences across hospitals in how at risk their patients are for readmission relative to patients cared for by other hospitals. The measure uses claims data to identify patient clinical conditions and comorbidities to adjust patient risk for readmission across hospitals, but does not adjust for potential complications of care. The model does not adjust for socioeconomic status or race because risk adjusting for these characteristics would hold hospitals with a large proportion of minority or low socioeconomic status patients to a different standard of care than other hospitals. One goal of this measure is to illuminate quality differences that such risk adjustment would obscure.

(8) Calculating the Risk-Standardized Readmission Ratio (RSRR)

The measure is calculated using hierarchical logistic modeling (HLM). This approach appropriately accounts for the types of patients a hospital treats (that is, hospital case mix), the number of patients it treats, and the quality of care it provides. The HLM is an appropriate statistical approach to measuring quality based on patient outcomes when the patients are clustered within hospitals (and therefore the patients' outcomes are not statistically independent) and the number of eligible patients for the measure varies from hospital to hospital. As noted above, the measure methodology defines hospital case mix based on the clinical diagnoses provided in the hospital claims for their patients' inpatient and outpatient visits for the 12 months prior to the CABG hospitalization, as well as those present in the claims for care at admission. The methodology, however, specifically does not account for diagnoses present in the index admission that may indicate complications rather than patient comorbidities.

The RSRR is calculated as the ratio of the number of predicted readmissions to the number of expected readmissions and then the ratio is multiplied by the national unadjusted readmission rate. The ratio is greater than one for hospitals that have more readmissions that would be expected for an average hospital with similar cases and less than one if the hospital has fewer readmissions than would be expected for an average hospital with similar cases. This approach is analogous to a ratio of ''observed'' or ''crude'' rate to an ''expected'' or risk-adjusted rate used in other similar types of statistical analyses.

The RSRR is a point estimate—the best estimate of a hospital's readmission rate based on the hospital's case mix. For displaying the measure for the Hospital IQR Program, we computed an interval estimate, which is similar to the concept of a confidence interval, to characterize the level of uncertainty around the point estimate. We use the point estimate and interval estimate to determine hospital performance (for example, higher than expected, as expected, or lower than expected). For more detailed information on the calculation methodology, we refer readers to our Web site at: *http://cms.gov/Medicare/QualityInitiativesPatientAssessmentInstruments/HospitalQualityInits/Measure-Methodology.html*.

We invite public comment on this proposal.

b. Proposed Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery [53]

(1) Background

CABG is a priority area for outcomes measure development because it is a common procedure associated with considerable morbidity, mortality, and health care spending. In 2007, there were 114,028 hospitalizations for CABG surgery and 137,721 hospitalizations for combined surgeries for CABG and valve procedures (''CABG plus valve'' surgeries) among Medicare FFS patients in the U.S.[54]

CABG surgeries are costly procedures that account for the majority of major cardiac surgeries performed nationally. In FY 2009, isolated CABG surgeries accounted for almost half (47.6 percent) of all cardiac surgery hospital

[52] Hannan EL, Zhong Y, Lahey SJ, et al. 30-day readmissions after coronary artery bypass graft surgery in New York State. *JACC Cardiovasc Interv.* 2011;4(5):569–576.

[53] Krumholz H. CABG Mortality Measure Methodology Report Section 1, Subtask 3.1, Deliverable #49a: Yale New Haven Systems Corporation; Center for Outcomes Research and Evaluation; 2012.

[54] Drye E, Krumholz H, Vellanky S, Wang Y. Probing New Conditions and Procedures for New Measure Development: Yale New Haven Systems Corporation; Center for Outcomes Research and Evaluation; 2009:7.

admissions in Massachusetts.[55] This provides an example of the frequency in which a CABG Is performed for a patient admitted for cardiac surgery. In 2008, the average Medicare payment was $30,546 for CABG without valve and $47,669 for CABG plus valve surgeries.[56]

Mortality rates following CABG surgery are not insignificant and vary across hospitals. For example, in 2009 Medicare FFS data indicated that the median hospital-level, risk-standardized mortality rate after CABG was 3.0 percent and ranged from 1.5 percent to 7.9 percent.[57] Even within a single state, the observed in-hospital, 30-day all-cause, hospital-level mortality rate was 1.81 percent and ranged from 0.0 percent to 5.6 percent among patients who were discharged after CABG surgery (without any other major heart surgery earlier in the hospital stay) in New York in 2008. The risk-adjusted mortality rate ranged from 0.0 percent to 8.2 percent.[58]

Variation in these rates suggests that there is room for improvement. An all-cause mortality measure for patients who undergo CABG surgery will provide hospitals with an incentive to reduce mortality through improved coordination of perioperative care and discharge planning. This is further supported by the success of registry-based mortality measures in reducing CABG mortality rates. For example, California reports that CABG mortality in that state has steadily declined from 2.9 percent in 2003, the first year of mandatory reporting of their state registry measure, to 2.2 percent in 2008.[59]

The specifics of the measure methodology are included in the measure methodology report we have posted on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. We refer readers to the report for further details on the risk-adjustment statistical model.

We are proposing to include this non-NQF-endorsed measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section IX.A.7. of the preamble of this proposed rule. Although the proposed measure is not currently NQF-endorsed, we considered available measures that have been endorsed or adopted by the NQF, and we were unable to identify any measures that assess hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following coronary artery bypass graft (CABG) surgery. We also are not aware of any other 30-day, all-cause, RSMR measures that have been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on this topic. The measure has been reviewed by the MAP and was conditionally supported pending NQF endorsement as detailed in its Pre-Rulemaking 2014 Map Recommendations Report available at: *https://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx*. This measure was submitted to NQF on March 17, 2014 and is currently under review.

(2) Overview of Measure

The CABG mortality measure assesses hospitals' 30-day, all-cause risk-standardized rate of mortality following admission for a CABG procedure. In general, the measure uses the same approach to risk adjustment and hierarchical logistic modeling (HLM) methodology that is specified for CMS's other mortality measures previously adopted for this program. Information on how the measure employs HLM can be found in the 2012 CABG Mortality Measure Methodology Report (available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(3) Data Sources

The proposed measure is claims-based. It uses Medicare administrative data from hospitalizations for Medicare FFS beneficiaries hospitalized for a CABG procedure.

(4) Outcome

The outcome for this measure is 30-day, all-cause mortality, defined as death for any cause within 30 days of the date of the index procedure date. We use a standard period of assessment so that the outcome for each patient is measured consistently. Without a standard period, variation in length of stay would have an undue influence on mortality rates, and institutions would have an incentive to adopt strategies to shift deaths out of the hospital without improving quality. The measure differs from the timeframe used in the other 30-day mortality measures in the Hospital IQR Program by starting the outcome window from the procedure date rather than the admission date. Data from 2009 Medicare FFS patients demonstrates that 25 percent of CABG procedures occurred more than 3 days after the admission date. Therefore, dating the measurement period from admission would potentially underestimate the period of risk for a substantial number of hospitals.

We chose 30-day mortality because it is an outcome that can be strongly influenced by hospital care and the early transition to the outpatient setting. Clinical experts concur that a 30-day timeframe is clinically sensible for measuring outcomes following CABG surgery.

The measure assesses all-cause mortality rather than CABG-specific mortality for several reasons. First, limiting the measure to CABG-related mortalities may limit the focus of efforts to improve care to a narrow set of approaches as opposed to encouraging broader initiatives aimed at improving the overall in-hospital care. Second, cause of death may be unreliably recorded and it is often not possible to exclude quality issues and accountability based on the documented cause of mortality. Finally, from a patient perspective, death due to any cause is the outcome that matters.

(5) Cohort

The cohort includes patients aged 65 years and older who received a qualifying CABG procedure at an acute care facility. Patients are eligible for inclusion if they had a qualifying CABG procedure and continuous enrollment in Medicare FFS one year prior to the first day of the index hospital stay and through 30 days post-procedure.

In order to include a clinically-coherent set of patients in the measure, we sought input from clinical experts regarding the inclusion of other concomitant cardiac and non-cardiac procedures, such as valve replacement and carotid endarterectomy. Adverse clinical outcomes following such procedures are higher than those following ''isolated'' CABG procedures, that is, CABG procedures performed without concomitant high-risk cardiac and non-cardiac procedures.[60] Limiting

[55] Massachusetts Data Analysis Center. Adult Coronary Artery Bypass Graft Surgery in the Commonwealth of Massachusetts: Hospital and Surgeons Risk-Standardized 30-Day Mortality Rates. In: *Health MDoP*, ed. Boston; 2009:77.

[56] Pennsylvania Health Care Cost Containment Council. Cardiac Surgery in Pennsylvania 2008–2009. Harrisburg; 2011:60.

[57] Ibid.

[58] New York State Department of Health. Adult Cardiac Surgery in New York State 2006–2008; 2010:54.

[59] California CABG Outcomes Reporting Program. The California Report on Coronary Artery Bypass Graft Surgery: 2007–2008 Hospital and Surgeon Data. 2011:119.

[60] Hannan EL, Zhong Y, Lahey SJ, et al. 30-day readmissions after coronary artery bypass graft surgery in New York State. JACC Cardiovasc Interv. 2011;4(5):569–576.

the measure cohort to ''isolated'' CABG patients is consistent with published reports of CABG outcomes; [61] therefore, the measure cohort considers only patients undergoing isolated CABG as eligible for inclusion in the measure. We defined isolated CABG patients as those undergoing CABG procedures without concomitant valve or other major cardiac, vascular or thoracic procedures. In addition, our clinical experts, consultants, and Technical Expert Panel (TEP) members agreed that an isolated CABG cohort is a clinically coherent cohort for quality measurement. For detailed information on the cohort definition, we refer readers to the 2012 CABG Mortality Measure Methodology Report on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

(6) Inclusion and Exclusion Criteria

The measure includes hospitalizations for patients who are 65 years of age or older at the time of index admission and for whom there was a complete 12 months of Medicare FFS enrollment to allow for adequate risk adjustment. The measure excludes the following admissions from the measure cohort: (1) Admissions for patients who leave hospital against medical advice excluded because providers do not have the opportunity to deliver full care and prepare the patient for discharge); and (2) admissions for patients with subsequent qualifying CABG procedures during the measurement period (a repeat CABG procedure during the measurement period very likely represents a complication of the original CABG procedure and is a clinically more complex and higher risk surgery, therefore we select the first CABG admission for inclusion in the measure and exclude subsequent CABG admissions from the cohort).

(7) Risk-Adjustment

The measure adjusts for differences across hospitals in how at risk their patients are for death relative to patients cared for by other hospitals. The measure uses claims data to identify patient clinical conditions and comorbidities to adjust patient risk for readmission across hospitals, but does not adjust for potential complications of care. Consistent with NQF guidelines, the model does not adjust for socioeconomic status or race because risk adjusting for these characteristics would hold hospitals with a large proportion of minority or low socioeconomic status patients to a different standard of care than other hospitals. One goal of this measure is to illuminate quality differences that such risk adjustment would obscure.

(8) Calculating the Risk-Standardized Mortality Ratio (RSMR)

The measure is calculated using hierarchical logistic modeling (HLM). This approach appropriately accounts for the types of patients a hospital treats (that is, hospital case mix), the number of patients it treats, and the quality of care it provides. The HLM is an appropriate statistical approach to measuring quality based on patient outcomes when the patients are clustered within hospitals (and therefore the patients' outcomes are not statistically independent) and the number of eligible patients for the measure varies from hospital to hospital. As noted above, the measure methodology defines hospital case mix based on the clinical diagnoses provided in the hospital claims for their patients' inpatient and outpatient visits for the 12 months prior to the CABG hospitalization, as well as those present in the claims for care at admission. The methodology, however, specifically does not account for diagnoses present in the index admission that may indicate complications rather than patient comorbidities.

The RSMR is calculated as the ratio of the number of predicted deaths to the number of expected deaths and then the ratio is multiplied by the national unadjusted mortality rate. The ratio is greater than one for hospitals that have more deaths than would be expected for an average hospital with similar cases and less than one if the hospital has fewer deaths than would be expected for an average hospital with similar cases. This approach is analogous to a ratio of ''observed'' or ''crude'' rate to an ''expected'' or risk-adjusted rate used in other similar types of statistical analyses.

The RSMR is a point estimate—the best estimate of a hospital's mortality rate based on the hospital's case mix. For displaying the measure for the Hospital IQR Program, we computed an interval estimate, which is similar to the concept of a confidence interval, to characterize the level of uncertainty around the point estimate. We use the point estimate and interval estimate to determine hospital performance (for example, higher than expected, as expected, or lower than expected). For more detailed information on the calculation methodology, we refer readers to our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

We invite public comment on this proposal.

c. Proposed Hospital-Level, Risk-Standardized 30-Day Episode-of-Care Payment Measure for Pneumonia

(1) Background

Providing high-value care is an essential part of our mission to provide better health care for individuals, better health for populations, and lower costs for health care. In order to incentivize innovation that promotes high-quality care at high value it is critical to examine measures of payment and patient outcomes concurrently. There is evidence of variation in payments at hospitals for pneumonia patients; mean 30-day risk-standardized payment among Medicare FFS patients aged 65 or older hospitalized for pneumonia in 2008–2009 was $13,237, and ranged from $8,281 to $27,975 across 4,155 hospitals. However, high or low payments to hospitals are difficult to interpret in isolation. Some high payment hospitals may have better clinical outcomes when compared with low payment hospitals while other high payment hospitals may not have better outcomes. For this reason, the value of hospital care is more clearly assessed when pairing hospital payments with hospital quality. Therefore, we are proposing to include this non-NQF-endorsed measure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section IX.A.7. of the preamble of this proposed rule. Although the proposed measure is not currently NQF-endorsed, we considered available measures that have been endorsed or adopted by the NQF, and we were unable to identify any measures that assess hospital risk-standardized payment associated with a 30-day episode-of-care for pneumonia. We also are not aware of any other 30-day episode-of-care pneumonia measures that have been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on this topic. The MAP supports this measure but reiterated the need for this measure to be submitted for NQF-endorsement: *https://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*. This measure was submitted to the NQF for endorsement on April 18, 2014.

We believe it is important to adopt this measure as pneumonia is one of the leading causes of hospitalization for

[61] Ibid.

Americans 65 and over, and pneumonia patients incur roughly $10 billion in aggregate health care costs.[62] Furthermore, because 30-day all-cause mortality and readmission measures for pneumonia are already publicly reported, pneumonia serves as a model condition for assessing relative value for an episode of care that begins with an acute hospitalization because including this measure in the Hospital IQR Program and publicly reporting it on *Hospital Compare* will allow stakeholders to assess information about a hospital's quality and cost of care for pneumonia. The measure reflects differences in the management of care for patients with pneumonia both during hospitalization and immediately post-discharge. By focusing on one specific condition, value assessments may provide actionable feedback to hospitals and incentivize targeted improvements in care.

(2) Overview of Measure and Rationale for Examining Payments for a 30-Day Episode-of-Care

The pneumonia payment measure assesses hospital risk-standardized payment associated with a 30-day episode-of-care for pneumonia for any hospital participating in the Hospital IQR Program. The measure includes Medicare FFS patients aged 65 or older admitted for pneumonia and calculates payments for these patients over a 30-day episode-of-care beginning with the index admission. In general, the measure uses the same approach to risk-adjustment as our 30-day outcome measures previously adopted for the Hospital IQR Program. We refer readers to our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

When examining variation in payments, consideration of the episode-of-care triggered by admission is meaningful for several reasons. First, hospitalizations represent a brief period of illness that requires ongoing management post-discharge and decisions made at the admitting hospital affect payments for care in the immediate post-discharge period. Second, attributing payments for a continuous episode-of-care to admitting hospitals may reveal practice variations in the full care of the illness that can result in increased payments. Third, a 30-day preset window provides a standard observation period by which to compare all hospitals. Lastly, the pneumonia payment measure is intended to be paired with our 30-day pneumonia mortality and readmission measures and capture payments for Medicare patients across care settings, services, and supplies, except for Medicare Part D (that is, inpatient, outpatient, skilled nursing facility, home health, hospice, physician/clinical laboratory/ambulance services, supplier Part B items, and durable medical equipment, prosthetics/orthotics, and supplies).

We have posted the measure methodology report on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. We refer readers to the report for further details on the risk adjustment statistical model as well as the model results.

(3) Data Sources

The proposed measure is claims-based and uses Medicare administrative data that contain hospitalizations and payments for Medicare FFS beneficiaries hospitalized with pneumonia.

(4) Outcome

The primary outcome of the pneumonia payment measure is the hospital-level risk-standardized payment for a pneumonia episode-of-care. The measure captures payments for Medicare patients across all care settings, services, and supplies, except Part D. By risk-standardizing the payment measure, we are able to adjust for case-mix at any given hospital and compare a specific hospital's pneumonia payment to other hospitals with the same case-mix. The analytic time frame for the pneumonia payment measure begins with the index admission for pneumonia and ends 30 days post-admission.

In order to isolate payment variation that reflects practice patterns rather than CMS payment adjustments, the pneumonia payment measure excludes policy and geography payment adjustments unrelated to clinical care decisions. We achieve this by ''stripping'' or ''standardizing'' payments for each care setting. Stripping refers to removing geographic differences and policy adjustments in payment rates for individual services from the total payment for that service. Standardizing refers to averaging payments across geographic areas for those services where geographic differences in payment cannot be stripped. Stripping and standardizing the payment amounts allows for a fair comparison across hospitals based solely on payments for decisions related to clinical care of pneumonia.

(5) Cohort

We created the pneumonia payment measure cohort to be aligned with the publicly reported pneumonia mortality measure cohort. Consistent with these measures, the pneumonia payment measure includes hospitalizations with a principal hospital discharge diagnosis of pneumonia using the International Classification of Diseases, Ninth revision, Clinical Modification (ICD–9–CM). These measures will use data from July 2010–Jun 2013 which does not yet include the period for which ICD–10 codes are mandatory. ICD–10 will officially be implemented on October 1, 2015. A full list of ICD–9–CM codes included in the final cohort can be found in Appendix B of the technical report on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. The measure includes only those hospitalizations from short-stay acute care hospitals in the index cohort and restricts the cohort to patients enrolled in FFS Medicare Parts A and B (with no Medicare Advantage coverage).

(6) Inclusion and Exclusion Criteria

The pneumonia payment measure includes hospitalizations for patients 65 years or older at the time of index admission and for whom there was a complete 12 months of FFS enrollment to allow for adequate risk adjustment. An index admission/hospitalization is the initial pneumonia admission that triggers the 30-day episode-of-care for this payment calculation. The measure excludes the following admissions from the measure cohort: (1) Admissions for patients with fewer than 30 days of post-admission enrollment in Medicare because this is necessary in order to identify the outcome (payments) in the sample over the analytic period; (2) admissions for patients having a principal diagnosis of pneumonia during the index hospitalization who were transferred from another acute care facility are excluded, because the hospital where the patient was initially admitted made the critical acute care decisions (including the decision to transfer and where to transfer); (3) admissions for pneumonia patients who were discharged on the same or next day as the index admission and did not die or get transferred are excluded, because it is unlikely these patients

[62] Lindenauer PK, Lagu T, Shieh M, Pekow PS, Rothberg MB. Association of diagnostic coding with trends in hospitalizations and mortality of patients with pneumonia, 2003–2009. JAMA: The Journal of the American Medical Association. 2012;307(13):1405–1413.

suffered a clinically significant pneumonia; (4) admissions for patients enrolled in the Medicare Hospice program any time in the 12 months prior to the index hospitalization, including the first date of the index admission are excluded, because it is likely that these patients are continuing to seek comfort care and their goal may not be survival; (5) admissions for patients who are discharged alive and against medical advice are excluded because providers did not have the opportunity to deliver full care and prepare the patient for discharge; (6) admissions for patients transferred to or from federal or Veterans Administration hospitals are excluded, because we do not have claims data for these hospitals; thus, including these patients would systematically underestimate payments; and (7) admissions without a DRG or DRG weight for the index hospitalization are excluded, because we cannot calculate a payment for these patients' index admission using the IPPS; this would underestimate payments for the entire episode-of-care. There are two portions of the DRG system that determine how much a provider is reimbursed. The first is the DRG itself which indicates the reason a patient was admitted. The second is the DRG weight which determines the severity of the admission. Without either of these, we were unable to calculate the payment for the index admission.

(7) Risk Adjustment

The measure adjusts for differences across hospitals in how payments are affected by patient comorbidities relative to patients cared for by other hospitals. Consistent with NQF guidelines, the model does not adjust for socioeconomic status or race, because risk-adjusting for these characteristics would hold hospitals with a large proportion of minority or low socioeconomic status patients to a different standard of care than other hospitals. One goal of this measure is to illuminate quality differences that such risk-adjustment would obscure.

(8) Calculating the Risk-Standardized Payment (RSP)

The measure is calculated using a hierarchical generalized linear model with a log link and a Poisson error distribution. This is a widely accepted statistical method that enables fair evaluation of relative hospital performance by taking into account patient risk factors as well as the number of patients that a hospital treats. This statistical model accounts for the structure of the data (patients clustered within hospitals) and calculates: (1) How much variation in hospital payment overall is accounted for by patients' individual risk factors (such as age and other medical conditions); and (2) how much variation is accounted for by hospital-specific performance. This approach appropriately models a positive, continuous, right-skewed outcome like payment and also accounts for the types of patients a hospital treats (that is, hospital case mix), the number of patients it treats, and the quality of care it provides. The hierarchical generalized linear model is an appropriate statistical approach to measuring quality based on patient outcomes when the patients are clustered within hospitals and sample sizes vary across hospitals. Clustered patients are within the same hospital, and the quality of care of the hospital affects all patients, so the outcomes for each hospital's patients are not fully independent (that is, completely unrelated) as is assumed by many statistical models. As noted above, the measure methodology defines hospital case mix based on the clinical diagnoses provided in the hospital claims for their patients' inpatient and outpatient visits for the 12 months prior to the pneumonia hospitalization, as well as those present in the claims for care at admission. This methodology specifically does not, however, account for diagnoses present in the index admission that may indicate complications rather than patient comorbidities.

The RSP is calculated as the ratio of predicted payments to expected payments and then the ratio is multiplied by the national unadjusted average payment for an episode of care. The ratio is greater than one for hospitals that have higher payments than would be expected for an average hospital with similar cases and less than one if the hospital has lower payments than would be expected for an average hospital with similar cases. This approach is analogous to a ratio of ''observed'' or ''crude'' rate to an ''expected'' or ''risk-adjusted'' rate used in other similar types of statistical analyses.

The RSP is a point estimate—the best estimate of a hospital's payment based on the hospital's case mix. To calculate the measure for the Hospital IQR Program, we computed an interval estimate, which is similar to the concept of a confidence interval, to characterize the level of uncertainty around the point estimate, we use the point estimate and interval estimate to determine hospital performance (for example, higher than expected, as expected, or lower than expected). The interval estimate indicates that the true value of the payment ratio lies between the lower limit and the upper limit of the interval. For more detailed information on the calculation methodology, we refer readers to our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

This measure is meant to be paired with our 30-day pneumonia mortality and/or readmission measure in order for us to gain a better understanding of the value of care for a hospital's patients and the nation as a whole.

We invite public comment on this proposal.

d. Proposed Hospital-Level, Risk-Standardized 30-day Episode-of-Care Payment Measure for Heart Failure

(1) Background

There is evidence of variation in payments at hospitals for heart failure patients; mean 30-day risk-standardized payment among Medicare FFS patients aged 65 or older hospitalized for heart failure in 2008–2009 was $13,922, and ranged from $9,630 to $20,646 across 3,714 hospitals. However, high or low payments to hospitals are difficult to interpret in isolation. Some high payment hospitals may have better clinical outcomes when compared with low payment hospitals while other high payment hospitals may not have better outcomes. For this reason, the value of hospital care is more clearly assessed when pairing hospital payments with hospital quality. Therefore, we are proposing to include this non-NQF-endorsed measure: hospital risk-standardized payment associated with a 30-day episode-of-care for heart failure in the Hospital IQR Program under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section IX.A.7. of the preamble of this proposed rule. Although the proposed measure is not currently NQF-endorsed, we considered available measures that have been endorsed or adopted by the NQF, and we were unable to identify any measures that assess hospital risk-standardized payment associated with a 30-day episode-of-care for heart failure. We also are not aware of any other 30-day episode-of-care heart failure measures that have been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on this topic. The MAP supports this measure but reiterated the need for this measure to be submitted for NQF-endorsement:

https://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx. The HF measure was submitted to NQF and is currently under review as part of the cost and resource use project.

We believe it is important to adopt this measure as heart failure is one of the leading causes of hospitalization for Americans 65 and over and costs roughly $34 billion annually.[63] [64] Furthermore, because 30-day all-cause mortality and readmission measures for heart failure are already publicly reported, heart failure serves as a model condition for assessing relative value for an episode of care that begins with an acute hospitalization. Including this measure in the Hospital IQR Program and publicly reporting it on *Hospital Compare* will allow stakeholders to assess information about a hospital's quality and cost of care for heart failure. The measure reflects differences in the management of care for patients with heart failure both during hospitalization and immediately post-discharge. By focusing on one specific condition, value assessments may provide actionable feedback to hospitals and incentivize targeted improvements in care.

(2) Overview of Measure and Rationale for Examining Payments for a 30-Day Episode-of-Care

The heart failure payment measure assesses hospital risk-standardized payment associated with a 30-day episode-of-care for heart failure for any hospital participating in the Hospital IQR Program. The measure includes Medicare FFS patients aged 65 or older admitted for heart failure and calculates payments for these patients over a 30-day episode-of-care beginning with the index admission. In general, the measure uses the same approach to risk-adjustment as our 30-day outcome measures previously adopted for the Hospital IQR Program. We refer readers to the measure methodology report on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

When examining variation in payments, consideration of the episode-of-care triggered by admission is meaningful for several reasons. First, hospitalizations represent brief periods of illness that require ongoing management post-discharge; and decisions made at the admitting hospital affect payments for care in the immediate post-discharge period. Second, attributing payments for a continuous episode-of-care to admitting hospitals may reveal practice variations in the full care of the illness that can result in increased payments. Third, a 30-day preset window provides a standard observation period by which to compare all hospitals. The term preset window means that every admission will be tracked 30 days post admission in order to apply a standardized measurement window. In order to compare payments across providers it is important that the comparison window is identical for each admission at each hospital. Lastly, the heart failure payment measure is intended to be paired with our 30-day heart failure mortality and readmission measures and capture payments for Medicare patients across all care settings, services, and supplies, except for Medicare Part D (that is, inpatient, outpatient, skilled nursing facility, home health, hospice, physician/clinical laboratory/ambulance services, supplier Part B items, and durable medical equipment, prosthetics/orthotics, and supplies).

We have posted the measure methodology report on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. We refer readers to the report for further details on the risk adjustment statistical model as well as the model results.

(3) Data Sources

The proposed measure is claims-based and uses Medicare administrative data that contain hospitalizations and payments for Medicare FFS beneficiaries hospitalized with heart failure.

(4) Outcome

The primary outcome of the heart failure payment measure is the hospital-level risk-standardized payment for a heart failure episode-of-care. The measure captures payments for Medicare patients across all care settings, services, and supplies, except Part D. By risk-standardizing the payment measure, we are able to adjust for case-mix at any given hospital and compare a specific hospital's heart failure payment to other hospitals with the same case-mix. The analytic time frame for the heart failure payment measure begins with the index admission for heart failure and ends 30 days post-admission. The index admission is any admission included in the measure calculation that begins the 30-day AMI episode of care.

In order to isolate payment variation that reflects practice patterns rather than CMS payment adjustments, the heart failure payment measure excludes policy and geography payment adjustments unrelated to clinical care decisions. We achieve this by ''stripping'' or ''standardizing'' payments for each care setting. These concepts were also discussed previously in the proposed hospital-level, risk-standardized 30-day episode-of-care payment measure for pneumonia measure in section IX.A.7.c.(4) of the preamble of this proposed rule.

(5) Cohort

We created the heart failure payment measure cohort to be aligned with the publicly reported heart failure mortality measure cohort. Consistent with these measures, the heart failure payment measure includes hospitalizations with a principal hospital discharge diagnosis of heart failure using ICD–9–CM codes included in the final cohort can be found in Appendix B of the technical report on our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. The measure will be using data from July 2010–Jun 2013 which does not yet include the period where ICD–10 codes are mandatory. ICD–10–CM/PCS will officially be implemented on October 1, 2015; therefore, the measure will not include ICD–10 data for another three reporting periods. An index admission/hospitalization is the initial heart failure admission that triggers the 30-day episode-of-care for this payment calculation. The measure includes only those hospitalizations from short-stay acute care hospitals in the index cohort and restricts the cohort to patients enrolled in FFS Medicare Parts A and B (with no Medicare Advantage coverage). These hospitalizations are the admissions which were included in the measure after applying all inclusion/exclusion criteria.

(6) Inclusion and Exclusion Criteria

The heart failure payment measure includes hospitalizations for patients 65 years or older at the time of index admission and for whom there was a complete 12 months of FFS enrollment to allow for adequate risk adjustment. The measure excludes the following admissions from the measure cohort: (1) Admissions for patients with fewer than 30 days of post-admission enrollment in

[63] Russo CA, Elixhauser, A. Hospitalizations in the Elderly Population, 2003. Agency for Healthcare Research and Quality. 2006.

[64] Heidenriech PA, Trogdon JG, Khavjou OA, Butler J, Dracup K, Ezekowitz MD, et al. Forecasting the future of cardiovascular disease in the United States: a policy statement from the American Heart Association. Circulation. 2011;123(8):933–44.

Medicare because this is necessary in order to identify the outcome (payments) in the sample over the analytic period; (2) admissions for patients having a principal diagnosis of heart failure during the index hospitalization who were transferred from another acute care facility are excluded, because the hospital where the patient was initially admitted made the critical acute care decisions (including the decision to transfer and where to transfer); (3) admissions for heart failure patients who were discharged on the same or next day as the index admission and did not die or get transferred are excluded, because it is unlikely these patients suffered a clinically significant heart failure; (4) admissions for patients enrolled in the Medicare Hospice program any time in the 12 months prior to the index hospitalization, including the first date of the index admission are excluded, because it is likely that these patients are continuing to seek comfort care and their goal may not be survival; (5) admissions for patients who are discharged alive and against medical advice are excluded because providers did not have the opportunity to deliver full care and prepare the patient for discharge; (6) admissions for patients transferred to or from federal or Veterans Administration hospitals are excluded, because we do not have claims data for these hospitals; thus, including these patients would systematically underestimate payments; (7) admissions without a DRG or DRG weight for the index hospitalization are excluded, because we cannot calculate a payment for these patients' index admission using the IPPS; this would underestimate payments for the entire episode-of-care; and (8) admissions for patients who receive a heart transplant or LVAD during the index admissions or episode of care because these patients are clinically distinct, generally very high payment cases, and not representative of the typical heart failure patient that this measure aims to capture.

(7) Risk Adjustment

The measure adjusts for differences across hospitals in how payments are affected by patient comorbidities relative to patients cared for by other hospitals. The model does not adjust for socioeconomic status or race, because risk-adjusting for these characteristics would hold hospitals with a large proportion of minority or low socioeconomic status patients to a different standard of care than other hospitals. One goal of this measure is to illuminate quality differences that such risk-adjustment would obscure.

(8) Calculating the Risk-Standardized Payment (RSP)

The measure is calculated using hierarchical generalized linear statistical models with a log link and a Gamma error distribution. This approach appropriately models a positive, continuous, right-skewed outcome like payment and also accounts for the types of patients a hospital treats (that is, hospital case-mix), the number of patients it treats, and the quality of care it provides. The hierarchical generalized linear model is an appropriate statistical approach to measuring quality based on patient outcomes when the patients are clustered within hospitals (and therefore the patients' outcomes are not statistically independent) and sample sizes vary across hospitals. As noted above, the measure methodology defines hospital case mix based on the clinical diagnoses provided in the hospital claims for their patients' inpatient and outpatient visits for the 12 months prior to the heart failure hospitalization, as well as those present in the claims for care at admission. This methodology specifically does not, however, account for diagnoses present in the index admission that may indicate complications rather than patient comorbidities.

The RSP is calculated as the ratio of predicted payments to expected payments and then the ratio is multiplied by the national unadjusted average payment for an episode of care. The ratio is greater than one for hospitals that have higher payments than would be expected for an average hospital with similar cases and less than one if the hospital has lower payments than would be expected for an average hospital with similar cases. This approach is analogous to a ratio of ''observed'' or ''crude'' rate to an ''expected'' or ''risk-adjusted'' rate used in other similar types of statistical analyses.

The RSP is a point estimate—the best estimate of a hospital's payment based on the hospital's case mix. For displaying the measure for the Hospital IQR Program, we computed an interval estimate, which is similar to the concept of a confidence interval, to characterize the level of uncertainty around the point estimate, we use the point estimate and interval estimate to determine hospital performance (for example, higher than expected, as expected, or lower than expected). For more detailed information on the calculation methodology, we refer readers to our Web site at: *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

This measure is meant to be paired with our 30-day heart failure mortality and/or readmission measure in order for us to gain a better understanding of the value of care for a hospital's patients and the nation as a whole.

We invite public comment on this proposal.

e. Proposed Severe Sepsis and Septic Shock: Management Bundle Measure (NQF #0500)

(1) Background

Sepsis, severe sepsis, and septic shock can arise from a simple infection, such as pneumonia or urinary tract infection. Although it can affect anyone at any age, it is more common in infants, the elderly, and patients with chronic health conditions such as diabetes and immunosuppressive disorders seen in transplant patients. Information for this measure comes from the NQF Measure Information-Composite for the severe sepsis and septic shock: management bundle (NQF #0500).[65] More information on this issue is available from the Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2012.[66] Sepsis is associated with mortality rates of over 16 to 49 percent, which is more than 8 times higher than the rate for inpatient stays for other hospital admissions. Findings from the National Hospital Discharge Survey indicate that the number of hospital stays for septicemia more than doubled between the years of 2000 and 2008, and patients with this condition were more severely ill than patients hospitalized for other conditions. Severe sepsis and septic shock are frequent causes of re-hospitalizations, especially during the first year after the initial hospitalization.

Based on national discharge data reported by the Agency for Healthcare Research and Quality (AHRQ), sepsis was the sixth most common principal reason for hospitalization in the United States in 2009, accounting for 836,000 hospital stays. There were an additional 829,500 stays with a secondary diagnosis of sepsis for a total of 1,665,400 inpatient stays and 258,000

[65] National Quality Forum (NQF). Measure Information-Composite. #500 Severe Sepsis and Septic Shock: Management Bundle. Updated 2014 Jan 2. NQF: Washington, DC *http://www.qualityforum.org/Home.aspx*.

[66] Dellinger RP, Levy MM, Rhodes A, Annane D, et al. Surviving Sepsis Campaign: international guidelines for management of severe sepsis and septic shock: 2012. Crit Care Med. 2013 Feb; 41(2):580–637.

deaths. From 1993 to 2009, sepsis-related hospital stays increased by 153 percent, with an average annual increase of 6 percent. Medicare was the predominant payer for sepsis-related hospital stays, covering 58.1 percent of patients. Sepsis cases and sepsis-related deaths are expected to continue to increase with the aging of the population.

In a landmark study by Rivers et al.,[67] it has been shown that an absolute and relative reduction in mortality from sepsis can be reduced 16 percent and 30 percent, respectively, when aggressive care is provided within 6 hours of hospital arrival. Furthermore, a recent study of the 2008 Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample[68] determined that patients admitted through the Emergency Department had a 17 percent lower likelihood of dying from sepsis than when directly admitted.

The severe sepsis and septic shock: management bundle measure (NQF #0500) is NQF endorsed and is conditionally supported by the MAP in its Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS, available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738*. The MAP noted the measure addresses an NQS priority not adequately addressed in the program measure set, but conditionally supported this measure stating, ''Not ready for implementation; measure concept is promising but requires modification or further development.'' In addition, ''MAP noted the need for continued development of electronic specifications for NQF #0500 Severe Sepsis and Septic Shock: Management Bundle. We are recommending this measure because we believe severe sepsis and septic shock are important conditions to monitor. While some workgroup members challenged the feasibility and evidence behind this measure, MAP deferred to the recent endorsement review of this measure and conditionally supported it for the Meaningful Use Program. Public comment from Edwards Lifesciences supports MAP's conclusion.''

(2) Overview of Measure

The purpose of the proposed severe sepsis and septic shock: management bundle measure is to support the efficient, effective, and timely delivery of high quality sepsis care in support of the Institute of Medicine's (IOM) aims for quality improvement. This is consistent with the Department of Health and Human Service National Quality Strategy's priorities directed at one of the leading causes of mortality. By providing timely, patient-centered care, and making sepsis care more affordable through early intervention, reduced resource use and complication rates can result. The severe sepsis and septic shock early management bundle provides a standard operating procedure for the early risk stratification and management of a patient with severe infection. Through applying this standard operating procedure, a clinically and statistically significant decrease in organ failure, mortality, and the utilization of health care resources has been demonstrated for over 10 years. Additional information about this measure is available on the NQF's Web site at *http://www.qualityforum.org/QPS/0500*.

(3) Data Sources

The proposed measure is chart-abstracted data of patients presenting with septic shock who received treatment detailed in the *Calculations* section below.

(4) Outcome

The outcome criteria for this measure consists of: measure lactate; blood cultures; timely antibiotics; fluid resuscitation; lactate clearance; vasopressors, central venous pressure (CVP), central venous oxygen saturation (ScvO2); and overall bundle compliance. These are discussed in more detail below:

- Measure Lactate

Measurement of lactate levels is specifically associated with improved outcomes in sepsis, and an elevated lactate value identifies patients at higher risk for poor outcomes. Up to 10 percent of in-hospital cardiac arrest in the United States per year is secondary to sepsis (pneumonia). These patients are often misdiagnosed and sent to the medical floors only to suffer acute hemodynamic deterioration. These outcomes could be potentially avoided with lactate measurement upon admission providing risk stratification triggering alternative dispositions.

Levy et al. (2010) conducted an international, multisite ''Surviving Sepsis Campaign'' (SSC) initiative (Levy et al. SSC initiative) to determine the rate of change at which the sites reached the SSC guideline targets. In the first quarter of this initiative, only 61.0 percent of patients had lactate values measured consistent with guidelines. In addition, prior studies have shown that care prompted by measurement of lactate levels in sepsis patients reduced resource utilization and cost. This leads to lower likelihood of hospital-acquired conditions. This performance measure has been previously used as a core component of multicenter and national quality improvement initiatives. Formalizing it as a national performance measure will provide direct targets for intervention that are closely linked with improvements in mortality and cost.

- Blood Cultures

In the first quarter of the Levy et al. SSC initiative, only 64.5 percent of patients had blood cultures collected prior to antibiotic administration. Collecting blood cultures prior to antibiotic administration is specifically associated with improved outcomes in sepsis, and pathogens identified by blood cultures allow for customized therapy. As a result, blood cultures continue as a recommendation of the current Surviving Sepsis Guidelines.

By obtaining blood cultures, antibiotic regimens can be customized to treat the specific infecting organism. This will result in less unnecessary exposure to antibiotics, reducing complications associated with antibiotic use, including drug reactions, allergies and adverse events, the development of drug-resistant organisms, and the occurrence of *Clostridium difficile* colitis. The performance measure for collecting blood cultures for suspected sepsis has been previously used and continues as a core component of the SSC guidelines.

- Timely Antibiotics

Kumar et al.[69] found the median time to appropriate antibiotics was 6 hours after shock. In the first quarter of the Levy et al.[70] SSC initiative, only 60.4 percent of patients received timely antibiotics. Multiple studies, for example, have demonstrated that delays in administration of appropriate antibiotics in patients with sepsis and other severe infections are associated with longer lengths of stay, higher costs,

[67] Rivers E, Nguyen B, Havstad S et al. Early goal-directed therapy in the treatment of severe sepsis and septic shock. N Engl J Med. 2001; 345: 1368–77.

[68] HCUP Nationwide Inpatient Sample (NIS). Healthcare Cost and Utilization Project (HCUP). 2007–2009. Agency for Healthcare Research and Quality, Rockville, MD. *http://www.hcup-us.ahrq.gov/nisoverview.jsp*.

[69] Kumar A, Roberts D, Wood K, Light B, et al. Duration of Hypotension before Initiation of Effective Antimicrobial Therapy is the Critical Determinant of Survival in Human Septic Shock. Crit Care Med. 2006;34 (6):1589–96.

[70] Levy MM, Dellinger RP, et al.; Surviving Sepsis Campaign. The Surviving Sepsis Campaign: results of an international guideline based performance improvement program targeting severe sepsis. Crit Care Med. 2010 Feb;38(2):367–74.

and higher mortality. In septic shock, the Kumar et al. study demonstrated that every hour in delay of appropriate antibiotics was associated with a 7.6 percent higher mortality. The timely administration of broad-spectrum antibiotics was associated with significantly higher risk adjusted survival. Based on a preponderance of data, the current recommendations in the international guidelines for the management of severe sepsis and septic shock includes the administration of broad-spectrum antibiotic therapy within 1 hour of diagnosis of septic shock and severe sepsis.

• Fluid Resuscitation

A common finding in patients with septic shock, manifested by low blood pressure and/or other signs of organ hypoperfusion, such as elevated serum lactate levels, is intravascular volume depletion. The degree of the intravascular volume deficit in sepsis varies, yet nearly all patients require initial volume resuscitation and many patients require continuing fluid resuscitation over the first 24 hours.

Early fluid resuscitation is associated with improved outcomes for patients with acute lung injury due to septic shock. International guidelines recommend that patients with suspected hypovolemia be initially treated with at least 30 mL/kg of crystalloid (for example, Ringer's solution) to determine clinical response. In the first quarter of the Levy et al.[71] SSC initiative, only 59.8 percent of patients received fluid resuscitation consistent with guidelines. Timely fluid resuscitation avoids an error of omission in which indicated therapy is delayed or omitted. By improving outcomes, length of stay is reduced. This leads to lower likelihood of hospital-acquired conditions. This performance measure has been previously used as a core component and continues as a core component of the SSC guidelines. Formalizing it as a national performance measure will provide direct targets for intervention that are closely linked with improvements in mortality and cost.

• Lactate Clearance

Elevated lactate levels prompt the consideration of specific care practices toward hemodynamic optimization guided by either central venous oxygen saturation or lactate clearance. International guidelines recommend that patients with sepsis and continued elevated lactate values have additional therapies until lactate levels are normalized. However, normal lactate levels can be seen in septic shock, especially in children.

• Vasopressors, Central Venous Pressure (CVP), and Central Venous Oxygen Saturation (ScvO2)

Performance gaps in individual bundle elements can range from 79 percent (Confidence Interval (CI) (69–89 percent) for vasopressors, to 27 percent (CI 18–36 percent) for Central Venous Pressure (CVP) measurement, and as low as 15 percent (CI 7–23 percent) for Central Venous Oxygen Saturation (ScvO2) in some community emergency departments. These numbers increase (50–75 percent) in larger hospital settings. CVP has been shown to have a significant association with mortality [72] and multiple studies and meta-analysis have shown a significant association with reaching an ScvO2 of 70 percent and improved mortality.

• Overall Bundle Compliance

Multiple initiatives promoting bundles of care for severe sepsis and septic shock were associated with improved guideline compliance and lower hospital mortality. Even with compliance rates of less than 30 percent, absolute reductions in mortality of 4–6 percent have been noted. Coba et al.[73] found that when all bundle elements were completed within 18 hours and compared with patients who did not have bundle completion, the mortality difference was 10.2 percent. Thus, there is a direct association between bundle compliance and improved mortality. Additionally, a continuous quality improvement (CQI) initiative, can improve compliance rates. CQI is a quality management process that encourages continually assessing performance and whether improvements can be made.[74] Multiple studies have shown that standardized order sets, enhanced bedside monitor display, telemedicine and comprehensive CQI feedback is feasible, modifies clinician behavior and is associated with decreased hospital mortality.

(5) Cohort

This measure will focus on patients aged 18 years and older who present with symptoms of severe sepsis or septic shock. These patients will be eligible for the 3 hour (severe sepsis) and/or 6 hour (septic shock) early management measures.

(6) Inclusion and Exclusion Criteria

Numerator Statement: the numerator is: Patients from the denominator who received all the following: Step 1, Step 2, and Step 3 within 3 hours of time of presentation, and if septic shock is present (as either defined as hypotension or lactate >=4 mmol/L), who also received Step 4, Step 5, Step 6, and Step 7 within 6 hours of time of presentation. The steps are described in detail below.

Step 1: Measure lactate level
Step 2: Obtain blood cultures prior to antibiotics
Step 3: Administer broad spectrum antibiotics
Step 4: Administer 30 ml/kg crystalloid for hypotension or lactate >= 4 mmol/L
Step 5: Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation to maintain a mean arterial pressure >= 65)
Step 6: In the event of persistent arterial hypotension despite volume resuscitation (septic shock) or initial lactate >= 4 mmol/L (36 mg/dl), measure central venous pressure and central venous oxygen saturation
Step 7: Re-measure lactate if initial lactate is elevated

Denominator: The denominator is the number of patients presenting with severe sepsis or septic shock. The following patients presenting with severe sepsis or septic shock will be excluded from the denominator:

• Patients with advanced directives for comfort care;
• Patients with clinical conditions that preclude total measure completion;
• Patients for whom a central line is clinically contraindicated;
• Patients for whom a central line was attempted but could not be successfully inserted;
• A patient or a surrogate decision maker declines or is unwilling to consent to such therapies or central line placement; and
• Patients who are transferred to an acute care facility from another acute care facility.

(7) Calculations

In calculating this measure, the denominator is the number of patients presenting with severe sepsis or septic shock. The numerator in this measure is patients from the denominator who had their lactate levels measured, had blood cultures obtained prior to receiving

[71] Ibid.

[72] Varpula M, Tallgren M, Saukkonen K, Voipio-Pulkki LM, Pettila V. Hemodynamic variables related to outcome in septic shock. *Intensive Care Med.* Jun 23 2005;31:1066–1071.

[73] Coba V, Whitmill M, Mooney R, et al. Resuscitation Bundle Compliance in Severe Sepsis and Septic Shock: Improves Survival, Is Better Late than Never. J Intensive Care Med. Jan 10 2011.

[74] Edwards PJ, et al. Maximizing your investment in EHR: Utilizing EHRs to inform continuous quality improvement. JHIM 2008;22(1):32–7.

antibiotics, and who received broad spectrum antibiotics within 3 hours of presentation. If septic shock is present, the patients also must receive 30 ml/kg crystalloid for hypotension or lactate >=4 mmol/L, apply vasopressors (for hypotension that does not respond to initial fluid resuscitation to maintain a mean arterial pressure >= 65), in the event of persistent arterial hypotension despite volume resuscitation (septic shock) or initial lactate >=4 mmol/L (36mg/dl) measure central venous pressure and central venous oxygen saturation, and the patient's lactate level must be re-measured if the initial lactate level is elevated.

We invite public comment on this proposal.

f. Electronic Health Record-Based Voluntary Measures

(1) Overview of New Electronic Health Record-Based Voluntary Measures

We are proposing four new voluntary electronic health record-based measures to be submitted as electronically specified measures: (1) Hearing Screening Prior to Hospital Discharge (NQF #1354); (2) PC–05 Exclusive Breast Milk Feeding and the Subset Measure PC–05a Exclusive Breast Milk Feeding Considering Mother's Choice (Collectively Referred to as NQF #0480); (3) Home Management Plan of Care (HMPC) Document Given to Patient/Caregiver (measure de-endorsed therefore not appropriate to associate with an NQF #); (4) and Healthy Term Newborn (NQF #0716). The four proposed electronic health record-based measures were included on a publicly available document entitled ''List of Measures Under Consideration for December 1, 2012'' in compliance with section 1890A(a)(2) of the Act, and they were reviewed by the MAP in its MAP Pre Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS. The final MAP report is available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72746*. We considered the input and recommendations provided by the MAP in selecting measures to propose for the Hospital IQR Program.

The specifications for the electronic clinical quality measures for eligible hospitals are found at: *http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html.*

(2) Proposed Voluntary Electronically Specified Measure: Hearing Screening Prior to Hospital Discharge (NQF #1354)

The Hearing Screening Prior to Hospital Discharge (NQF #1354) measure assesses the proportion of all live births born at a hospital that have been screened for hearing loss before hospital discharge. The Joint Committee on Infant Hearing encourages early screening and intervention in infants with hearing loss to maximize linguistic competence and literacy development in children with hearing loss or who are hard of hearing. Early intervention improves developmental and social outcomes for children. The States and CDC have collected this measure as a population-based measure for more than 10 years.

This measure is NQF-endorsed and was supported by the MAP in their Pre Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS, available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738*. The MAP noted that the measure addresses a high-impact condition not adequately addressed in the program measure set.

The numerator is all live births during the measurement period born at a facility and screened for hearing loss prior to discharge, or screened but still not discharged, or not screened due to medical reasons or a medical exclusion.

The denominator includes all live births during the measurement period born at a facility and discharged without being screened, or screened prior to discharge, or screened but still not discharged.

The measure excludes any patient deceased prior to discharge and has not received hearing screening.

(3) Proposed Voluntary Measure: PC–05 Exclusive Breast Milk Feeding and the Subset Measure PC–05a Exclusive Breast Milk Feeding Considering Mother's Choice (Collectively Referred to as NQF #0480)

Exclusive breast milk feeding for the first 6 months of neonatal life has long been the expressed goal of World Health Organization (WHO), HHS, American Academy of Pediatrics (AAP) and American College of Obstetricians and Gynecologists (ACOG).

The PC–05 Exclusive Breast Milk Feeding measure and the subset measure PC–05a Exclusive Breast Milk Feeding Considering Mother's Choice (NQF #0480) is endorsed by the NQF and supported by the MAP in its Pre Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS, available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738*. The MAP noted that the measure addresses a high-impact condition not adequately addressed in the program measure set.

This measure assesses the number of newborns exclusively fed breast milk during the newborn's entire hospitalization; and the subset measure only includes those newborns whose mothers chose to exclusively feed breast milk.

The numerator is the same for both the measure and subset measure—newborns that were fed breast milk only since birth. However, the denominators differ. For PC–05, the denominator is defined as single term liveborn newborns discharged alive from the hospital with ICD–9–CM Principal Diagnosis Code for single liveborn newborn. The denominator for the subset measure, PC–05a, is defined as single term newborns discharged alive from the hospital excluding those whose mothers chose not to breast feed with ICD–9–CM Principal Diagnosis Code for single liveborn newborn. The ICD–9–CM Principal Diagnosis Codes for single liveborn newborns are found in Appendix A, Table 11.20.1: Single Live Newborn in the Specifications Manual for Joint Commission National Quality Measures available at: *http://manual.jointcommission.org/releases/TJC2013A/AppendixATJC.html.*

Excluded populations:

- Admitted to the Neonatal Intensive Care Unit (NICU) at this hospital during the hospitalization.
- ICD–9–CM Other Diagnosis Codes for galactosemia as defined in Appendix A, Table 11.21 in the Specifications Manual for Joint Commission National Quality Measures found at: *http://manual.jointcommission.org/releases/TJC2013A/AppendixATJC.html.*
- ICD–9–CM Principal Procedure Code or ICD–9–CM Other Procedure Codes for parenteral infusion as defined in Appendix A, Table 11.22 in the Specifications Manual for Joint Commission National Quality Measures found at: *http://manual.jointcommission.org/releases/TJC2013A/AppendixATJC.html.*
- Experienced death.
- Length of Stay >120 days.
- Enrolled in clinical trials.
- Patients transferred to another hospital.
- ICD–9–CM Other Diagnosis Codes for premature newborns as defined in Appendix A, Table 11.23 in the Specifications Manual for Joint Commission National Quality Measures found at: *http://manual.joint*

commission.org/releases/TJC2013A/AppendixATJC.html.

• Documented Reason for Not Exclusively Feeding Breast Milk.

The maternal reasons for not exclusively breastfeeding are limited to the following situations:

• HIV infection;

• Human t-lymphotrophic virus type I or II;

• Substance abuse and/or alcohol abuse;

• Active, untreated tuberculosis;

• Taking certain medications, that is, prescribed cancer chemotherapy, radioactive isotopes, antimetabolites, antiretroviral medications and other medications where the risk of morbidity outweighs the benefits of breast milk feeding;

• Undergoing radiation therapy;

• Active, untreated varicella;

• Active herpes simplex virus with breast lesions; and

• Admission to Intensive Care Unit (ICU) post-partum.

We invite public comments on this proposal.

(4) Proposed Voluntary Measure CAC–3: Home Management Plan of Care (HMPC) Document Given to Patient/Caregiver

Asthma is the most common chronic disease in children and a major cause of morbidity and health care costs nationally. For children, asthma is one of the most frequent reasons for admission to hospitals. There were approximately 157,000 admissions for childhood asthma in the United States in 2009. Under-treatment and/or inappropriate treatment of asthma are recognized as major contributors to asthma morbidity and mortality. Guidelines developed by the National Asthma Education and Prevention Program (NAEPP) of the National Heart, Lung and Blood Institute (NHLBI), as well as by the American Academy of Pediatrics (AAP) for the diagnosis and management of asthma in children, recommend establishing a plan for maintaining control of asthma and for establishing plans for managing exacerbations.

The CAC–3: Home Management Plan of Care (HMPC) Document Given to Patient/Caregiver measure is no longer endorsed by the NQF and was not supported by the MAP in its Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738,* because the measure no longer meets the NQF endorsement criteria. However, based on the prevalence of asthma among children, as well as the risks associated with under-treatment or over-treatment described above, we believe the measure is appropriate for voluntary collection. Because asthma is a serious, and potentially life-threatening disease, we believe that it is important to allow hospitals to voluntarily report this data, which may help inform our policy.

This measure assesses the proportion of pediatric asthma patients (aged 2–17 years) discharged from an inpatient hospital stay with a HMPC document in place. The numerator is the number of pediatric asthma inpatients with documentation that they or their caregivers were given a written HMPC document that addresses: (1) arrangements for follow-up care, (2) environmental control and control of other triggers, (3) method and timing of rescue actions, (4) use of controllers, and (5) use of relievers.

The denominator is the number of pediatric asthma inpatients (age 2 years through 17 years) discharged with a principal diagnosis of asthma.

The measure excludes: (1) Patients with an age less than 2 years or 18 years or greater; (2) patients who have a length of stay greater than 120 days; and (3) patients enrolled in clinical trials.

We invite public comments on this proposal.

(5) Proposed Voluntary Measure: Healthy Term Newborn (NQF #0716)

This measure assesses the optimal outcome of pregnancy and childbirth, specifically a healthy term newborn. It evaluates the impact of any changes in the management or intervention on the positive outcome for the newborn.

The measure is NQF endorsed. The MAP recommended removal of this measure in its Pre Rulemaking Report: 2013 Recommendations on Measures under Consideration by HHS available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738*, because the measure required modification or further development. However, the MAP strongly supported the measure concept for inclusion once technical issues were resolved. Given its endorsement by NQF, as well as the MAP's strong support for the measure concept, we believe the measure is appropriate for voluntary reporting.

The result of the measure calculation is the percentage of term singleton live births (excluding those with diagnoses originating in the fetal period) that do not have significant complications during birth or the nursery care.[75]

The numerator of this measure is the absence of conditions or procedures reflecting morbidity that happened during birth and nursery care to an otherwise normal infant.

The denominator is composed of singleton, term (>=37 weeks), inborn, live births in their birth admission. The denominator further has eliminated fetal conditions likely to be present before labor. Maternal and obstetrical conditions (for example, hypertension, prior cesarean, malpresentation) are not excluded unless there is evidence of fetal effect prior to labor (for example, Intrauterine Growth Restriction (IUGR)/Small for Gestational Age (SGA)).

This measure excludes: (1) Multiple gestations; (2) preterm, congenital anomalies; and, (3) fetuses affected by selected maternal conditions.

We invite public comments on this proposal.

g. Proposed Readoption of Measures as Voluntarily Reported Electronic Clinical Quality Measures

In order to align with the EHR Incentive Program for eligible hospitals (EHs) and critical access hospitals (CAHs), we are proposing to re-adopt two measures previously removed from the Hospital IQR Program; (a) AMI–2 Aspirin Prescribed at Discharge for AMI (acute myocardial infarction) (NQF #0142) (electronic clinical quality measure); and (b) AMI–10 Statin Prescribed at Discharge (NQF #0639) (electronic clinical quality measure). We are proposing to add these measures to the list of voluntarily reported electronic clinical quality measures as described in section IX.A.7.f. of the preamble of this proposed rule. We believe we should continue aligning the Hospital IQR Program and the EHR Incentive Program in order to minimize reporting burden and continue the transition to reporting of electronic clinical quality measures, and we believe voluntary adoption of these measures will further that aim. Further, allowing hospitals the option to electronically report topped-out measures will provide hospitals with an opportunity to test the accuracy of their electronic health record reporting systems.

We welcome public comments on this proposal.

(1) Proposed Readoption of AMI–2 Aspirin Prescribed at Discharge (NQF #0142)

The AMI–2 Aspirin Prescribed at Discharge (NQF #0142) assesses the

[75] National Quality Forum. National Voluntary Consensus Standards for Patient Outcomes 2009. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=67546.*

percentage of acute myocardial infarction (AMI) patients who are prescribed aspirin at hospital discharge.

The measure is NQF endorsed, but has been placed in reserve status, as the performance on this measure is topped out. The MAP recommended the measure should be suspended and phased out in its Pre-Rulemaking Report: 2013 Recommendations on Measures under Consideration by HHS available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738*. However, as stated above, we intend to continue aligning the Hospital IQR Program and EHR Incentive Program, and we believe collecting this measure on a voluntary basis enables us to continue collecting quality data on this topic while working to minimize reporting burden on participating hospitals. Further, allowing hospitals the option to electronically report topped-out measures will provide hospitals with an opportunity to test the accuracy of their electronic health record reporting systems.

The numerator includes AMI patients in the denominator who are prescribed aspirin at hospital discharge. The denominator includes patients with the following ICD–9–CM principal diagnosis codes of AMI: 410.00, 410.01, 410.10, 410.11, 410.20, 410.21, 410.30, 410.31, 410.40, 410.41, 410.50, 410.51, 410.60, 410.61, 410.70, 410.71, 410.80, 410.81, 410.90, and 410.91.

The following patients are excluded from this measure:

- Patients less than 18 years of age;
- Patients who have a length of stay greater than 120 days;
- Patients enrolled in clinical trials;
- Patients who were discharged to another hospital;
- Patients who expired;
- Patients who left the hospital against medical advice;
- Patients who were discharged to home for hospice care;
- Patients who were discharged to a health care facility for hospice care;
- Patients with comfort measures only documented; and
- Patients with a documented reason for no aspirin at discharge.

We invite public comments on this proposal.

(2) Proposed Readoption of AMI–10 AMI-Statin Prescribed at Discharge (NQF #0639)

AMI–10 AMI-Statin Prescribed at Discharge (NQF #0639) assesses the percent of acute myocardial infarction (AMI) patients who are prescribed a statin at hospital discharge.

The measure is NQF endorsed. The MAP recommended phased removal in its Pre-Rulemaking Report: 2013 Recommendations on Measures under Consideration by HHS available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738* because the performance on this measure is likely topped out. However, as stated above, we intend to continue aligning the Hospital IQR Program and EHR Incentive Program, and we believe collecting this measure on a voluntary basis enables us to continue collecting quality data on this topic while working to minimize reporting burden on participating hospitals. Further, allowing hospitals the option to electronically report topped-out measures will provide hospitals with an opportunity to test the accuracy of their electronic health record reporting systems.

The numerator includes AMI patients in the denominator who are prescribed a statin medication at hospital discharge. The denominator includes patients with the following ICD–9–CM principal diagnosis codes of AMI: 410.00, 410.01, 410.10, 410.11, 410.20, 410.21, 410.30, 410.31, 410.40, 410.41, 410.50, 410.51, 410.60, 410.61, 410.70, 410.71, 410.80, 410.81, 410.90, and 410.91.

The following patients are excluded from this measure:

- Patients less than 18 years of age;
- Patients who have a length of stay greater than 120 days;
- Patients with comfort measures only documented;
- Patients enrolled in clinical trials;
- Patients who were discharged to another hospital;
- Patients who left the hospital against medical advice;
- Patients who expired;
- Patients who were discharged to their home for hospice care;
- Patients who were discharged to a health care facility for hospice care;
- Patients with low-density lipoprotein less than 100 mg/dL within the first 24 hours after hospital arrival or 30 days prior to hospital arrival and not discharged on a statin; and
- Patients with a reason for not prescribing statin medication at discharge.

We invite public comments on this proposal.

In summary, for FY 2017 payment determination and subsequent years, we are proposing to: (1) Adopt 11 total measures—9 new measures (4 of which are voluntary electronic clinical quality measures) and 2 previously removed measures re-adopted as voluntary electronic clinical quality measures, and (2) remove 10 measures (4 of which were previously suspended). If finalized, this would give a total of 62 measures (46 required and 16 voluntary electronic clinical quality measures) in the Hospital IQR Program measure set.

Set out below is a table showing both the previously adopted and the proposed quality measures for the FY 2017 payment determination and subsequent years. Please note that this table does not include suspended measures or measures proposed for removal.

Topic	Previously adopted hospital IQR program measures and measures proposed in this proposed rule for the FY 2017 payment determination and subsequent years
Acute Myocardial Infarction (AMI) Measures.	• AMI–2 Aspirin Prescribed at Discharge for AMI */□/† (NQF #0142). • AMI–7a Fibrinolytic therapy received within 30 minutes of hospital arrival □ (NQF #0164). • AMI–8a Primary PCI received within 90 minutes of hospital arrival □/† (NQF #0163). • AMI–10 Statin Prescribed at Discharge */□/† (NQF #0639).
Stroke Measure (STK) Set	• STK–1 Venous thromboembolism (VTE) prophylaxis (NQF #0434). • STK–2 Discharged on antithrombotic therapy □/† (NQF #0435). • STK–3 Anticoagulation therapy for atrial fibrillation/flutter □/† (NQF #0436). • STK–4 Thrombolytic therapy □ (NQF #0437). • STK–5 Antithrombotic therapy by the end of hospital day two □/† (NQF #0438). • STK–6 Discharged on statin medication □ (NQF #0439). • STK–8 Stroke education □. • STK–10 Assessed for rehabilitation □/† (NQF #0441).
Venous Thromboembolism (VTE) Measure Set.	• VTE–1 Venous thromboembolism prophylaxis □ (NQF #0371). • VTE–2 Intensive care unit venous thromboembolism prophylaxis □ (NQF #0372). • VTE–3 Venous thromboembolism patients with anticoagulation overlap therapy □ (NQF #0373).

Topic	Previously adopted hospital IQR program measures and measures proposed in this proposed rule for the FY 2017 payment determination and subsequent years
	• 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 □ (NQF #0376).
Sepsis Measure	• Severe sepsis and septic shock: management bundle * (NQF #0500).
Pneumonia (PN) Measure	• PN–6 Initial Antibiotic Selection for community-acquired pneumonia (CAP) in Immunocompetent Patients □/† (NQF #0147).
Surgical Care Improvement Project (SCIP) Measures.	• SCIP INF–1 Prophylactic antibiotic received within one hour prior to surgical incision □/† (NQF #0527). • SCIP INF–2 Prophylactic antibiotic selection for surgical patients □/† (NQF #0528). • SCIP INF–9 Urinary catheter removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with day of surgery being day zero □/† (NQF #0453).
Mortality Measures	• Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute myocardial infarction (AMI) hospitalization for patients 18 and older (NQF #0230). • Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following heart failure (HF) hospitalization for patients 18 and older (NQF #0229). • Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following pneumonia hospitalization (NQF #0468). • Stroke 30-day mortality rate. • Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1893). • Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following coronary artery bypass graft (CABG) surgery (NQF #1893).*
Patient Experience of Care Measure.	• HCAHPS survey (NQF #0166) (expanded to include two new ''About You'' items and the 3-item Care Transition Measure) (NQF #0228).
Readmission Measures	• Hospital 30-day all-cause risk-standardized readmission rate (RSRR) following acute myocardial infarction (AMI) hospitalization (NQF #0505). • Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following heart failure hospitalization (NQF #0330). • Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following pneumonia hospitalization (NQF #0506). • Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551). • Hospital-Wide All-Cause Unplanned Readmission (HWR) (NQF #1789). • Stroke 30-day Risk Standardized Readmission. • Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891). • Hospital 30-day, all-cause, unplanned, risk-standardized readmission rate (RSRR) following coronary artery bypass graft (CABG) surgery.*
AHRQ Patient Safety Indicators (PSIs) Composite Measure.	• PSI–90 Patient safety for selected indicators (composite) (NQF #0531).
AHRQ PSI and Nursing Sensitive Care.	• PSI–4 Death among surgical inpatients with serious treatable complications (NQF #0351).
Structural Measures	• Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care (NQF #0113). • Participation in a Systematic Clinical Database Registry for General Surgery (NQF #0493). • Safe Surgery Checklist Use.
Healthcare-Associated Infections (HAI) Measures.	• National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139). • American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753). —SSI following Colon Surgery. —SSI following Abdominal Hysterectomy. • National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138). • *National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure* (NQF #1716). • National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717). • Influenza vaccination coverage among healthcare personnel (HCP) (NQF #0431).
Surgical Complications	• Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550).
Emergency Department (ED) Throughput Measures.	• ED–1 Median time from ED arrival to ED departure for admitted ED patients (NQF #0495). □ • ED–2 Admit Decision Time to ED Departure Time for Admitted Patients (NQF #0497). □
Prevention: Global Immunization (IMM) Measure.	• Influenza Immunization (NQF #1659).
Cost Efficiency	• Payment-Standardized Medicare Spending Per Beneficiary (MSPB) (NQF #2158). • AMI Payment per Episode of Care. • Hospital-level, risk-standardized 30-day episode-of-care payment measure for heart failure.* • Hospital-level, risk-standardized 30-day episode-of-care payment measure for pneumonia.*

Topic	Previously adopted hospital IQR program measures and measures proposed in this proposed rule for the FY 2017 payment determination and subsequent years
Perinatal Care (PC)	• PC–01 Elective delivery □ (NQF #0469). • PC–05 Exclusive Breast Milk Feeding and the subset measure PC–05a Exclusive Breast Milk Feeding Considering Mother's Choice (NQF #0480). */□/† • Children's Asthma Care-3 Home Management Plan of Care (HMPC) document given to patient/caregiver. */□/† • Healthy Term Newborn (NQF #0716). */□/† • Hearing Screening Prior to Hospital Discharge (NQF #1354). */□/†

* New or expanded measures for FY 2017 payment determination and subsequent years.
□ Electronic clinical quality measure.
† Voluntary measure.

PREVIOUSLY ADOPTED VOLUNTARY ELECTRONIC CLINICAL QUALITY MEASURES AND PROPOSED VOLUNTARY ELECTRONIC CLINICAL QUALITY MEASURES FOR THE FY 2017 PAYMENT DETERMINATION AND ASSOCIATED NQF DOMAINS

Short name	Measure name	NQF #	Domain as assigned in Stage 2 final rule [76]
ED–1	Emergency Department Throughput—Median time from ED arrival to ED departure for admitted ED patients.	0495	Patient and Family Engagement.
ED–2	Emergency Department Throughput—admitted patients—Admit decision time to ED departure time for admitted patients.	0497	Patient and Family Engagement.
STK–2	Discharged on antithrombotic therapy	0435	Clinical Process/Effectiveness.
STK–3	Anticoagulation therapy for atrial fibrillation/flutter	0436	Clinical Process/Effectiveness.
STK–4	Thrombolytic Therapy	0437	Clinical Process/Effectiveness.
STK–5	Antithrombotic therapy by end of hospital day two	0438	Clinical Process/Effectiveness.
STK–6	Discharged on Statin Medication	0439	Clinical Process/Effectiveness.
STK–8	Stroke education	N/A	Patient and Family Engagement.
STK–10	Assessed for rehabilitation	0441	Care Coordination.
VTE–1	Venous thromboembolism prophylaxis	0371	Patient Safety.
VTE–2	Intensive care unit venous thromboembolism prophylaxis	0372	Patient Safety.
VTE–3	Venous thromboembolism patients with anticoagulation overlap therapy	0373	Clinical Process/Effectiveness.
VTE–4	Patients receiving un-fractionated Heparin with doses/labs monitored by protocol.	N/A	Clinical Process/Effectiveness.
VTE–5	VTE discharge instructions	N/A	Patient and Family Engagement.
VTE–6	Incidence of potentially preventable VTE	0376	Patient Safety.
PC–01	Elective Delivery	0469	Clinical Process/Effectiveness.
PC–05	Exclusive Breast Milk Feeding and the subset measure PC–05a Exclusive Breast Milk Feeding Considering Mother´s Choice.*	0480	Clinical Process/Effectiveness.
EHDI–1a	Hearing screening prior to hospital discharge*	1354	Clinical Process/Effectiveness.
	Healthy Term Newborn*	0716	Patient Safety.
CAC–3	Home Management Plan of Care (HMPC) Document Given to Patient/Caregiver.	N/A	Patient and Family Engagement.
AMI–2	Aspirin Prescribed at Discharge for AMI*	0142	Clinical Process/Effectiveness.
AMI–7a	Fibrinolytic Therapy Received Within 30 minutes of Hospital Arrival	0164	Clinical Process/Effectiveness.
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0163	Clinical Process/Effectiveness.
AMI–10	Statin Prescribed at Discharge*	0639	Clinical Process/Effectiveness.
PN–6	Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients.	0147	Efficient Use of Healthcare Resources.
SCIP–Inf–1a	Prophylactic Antibiotic Received within one Hour Prior to Surgical Incision.	0527	Patient Safety.
SCIP–Inf–2a	Prophylactic Antibiotic Selection for Surgical Patients	0528	Efficient Use of Healthcare Resources.
SCIP–Inf–9	Urinary catheter removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with day of surgery being day zero.	0453	Patient Safety.

* Measure proposed for adoption or readoption in Hospital IQR Program.

h. Electronic Clinical Quality Measures

(1) Data Submission Requirements for Quality Measures That May Be Voluntarily Electronically Reported for the FY 2017 Payment Determination

We believe that collection and reporting of data through health information technology will greatly simplify and streamline reporting for many CMS quality reporting programs. Through electronic reporting, hospitals will be able to leverage EHRs to capture, calculate, and electronically submit quality data that is currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program. As we noted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51614), we recognize the need to align and harmonize measures across CMS quality reporting programs to minimize the reporting burden imposed on hospitals. In the Medicare EHR Incentive Program Stage 2 final rule (77 FR 54083 through 54087), we finalized a total of 29 clinical quality measures from which hospitals must select at least 16 measures covering three National Quality Strategy (NQS) domains to report beginning in FY 2014. We anticipate that, as health information technology evolves and infrastructure is

[76] Medicare EHR Incentive Program Stage 2 final rule (77 FR 54083 through 54087).

expanded, we will have the capacity to accept electronic reporting of many of the chart-abstracted measures that are currently part of the Hospital IQR Program.

In the FY 2014 IPPS/LTCH PPS final rule, for the STK (with the exception of STK–1), VTE, ED, and PC measure sets, we allowed hospitals to either: (1) electronically report at least one quarter of CY 2014 (Q1, Q2, or Q3) quality measure data for each measure in one or more of those four measure sets; or (2) continue reporting all measures in those four measure sets using chart-abstracted data for all four quarters of CY 2014 (78 FR 50818).

For the FY 2017 payment determination, we are proposing to expand this policy, such that providers may select to voluntarily report any 16 of the 28 Hospital IQR Program electronic clinical quality measures that align with the Medicare EHR Incentive Program as long as those 16 measures span three different NQS domains. The 28 measures are listed in the table below. Only 28 of the 29 measures adopted in the Medicare EHR Incentive Program are applicable for the Hospital IQR Program, because the measure ED–3 Median time from ED arrival to ED departure for discharged ED patients (NQF #0496) is an outpatient setting measure. We expect eligible hospitals to select measures that best apply to their patient mix.

For the FY 2017 payment determination, we also are proposing to expand the reporting requirement of electronic clinical quality measures to require a full year's data collection and submission instead of a minimum of one quarter. In addition, for the FY 2017 payment determination, we are proposing to require data submission within approximately 60 days after the end of a calendar year quarter. We have listed the proposed submission deadlines in the table below. We also refer readers to section IX.D.2. of the preamble of this proposed rule for a description of the electronic clinical quality measures data reporting periods and proposed submission deadlines.

CY 2015/FY 2017 Electronic Clinical Quality Measures Data Reporting Periods and Proposed Submission Deadlines

CY 2015 quarter	Reporting period (2015)	Proposed submission deadline (2015)
1	January 1–March 31	May 30.
2	April 1–June 30	Aug 30.
3	July 1–September 30	Nov 30.
4	October 1–December 31	Feb 28.

As an incentive for hospitals to voluntarily submit electronically-specified clinical quality measures, we are proposing that for the FY 2017 payment determination, hospitals successfully submitting electronic clinical quality measures according to our procedures will not have to validate those electronic clinical quality measures by submitting chart-abstracted data to validate the accuracy of the measure data submitted electronically.

By proposing these changes, we would further align the Hospital IQR Program and the Medicare EHR Incentive Program and promote greater electronic clinical quality measure data reporting for hospitals. In addition, we believe that these changes would ease hospitals' administrative burden, as they will be able to report the same clinical quality measures once to partially satisfy both the Hospital IQR and Medicare EHR Incentive Programs' requirements.

(2) Public Reporting of Electronic Clinical Quality Measures

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50813 through 50818), we adopted a policy under which we would only publicly report electronic clinical quality measure data under the Hospital IQR Program if we determined that the data are accurate enough to be reported. However, we noted that the majority of public commenters had opposed our proposal to withhold the electronically reported data from publication on *Hospital Compare,* and instead urged us to publicly display it (78 FR 50815). Therefore, for electronic clinical quality measure data submitted for the FY 2016 payment determination, we will publically report the data as previously finalized. However, for the FY 2017 payment determination, we now propose to provide hospitals that voluntarily report one year of electronic clinical quality measure data (as proposed above) an option to have their data reported on *Hospital Compare* with *a preview period prior to public reporting.* We also propose to add a footnote next to that publically reported data indicating that it is a result of electronically-specified measures.

We welcome public comments on these proposals.

8. Possible New Quality Measures and Measure Topics for Future Years

a. Mandatory Electronic Clinical Quality Measure Reporting for FY 2018 Payment Determination

We anticipate that, as EHR technology changes and improves, hospitals will electronically report all clinical process-of-care and HAI measures, which are currently part of the Hospital IQR Program or which have been proposed for adoption into the Program. As stated above, we intend for the future direction of electronic quality measure reporting to significantly reduce administrative burden on hospitals under the Hospital IQR Program. We will continue to work with measure stewards and developers to develop new measure concepts, and conduct pilot, reliability, and validity testing. We believe that this voluntary reporting option will provide hospitals and CMS with the ability to test systems in CY 2015 for future quality program proposals that, if finalized, will make electronic reporting a requirement instead of voluntary. 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.

We intend to propose to require reporting of electronic clinical quality measures for the Hospital IQR Program beginning for the CY 2016 reporting period or FY 2018 payment determination. We considered proposing to require hospitals to electronically report some Hospital IQR Program quality measures in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27695). After considering public comments, we made electronic reporting voluntary in CY 2014 in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50813 through 50814). However, after two years, we believe that hospitals

are more prepared and should be required to report Hospital IQR Program measures as electronic clinical quality measures beginning in CY 2016. We intend to propose this policy in future rulemaking, but request comments on this intention here.

b. Possible Future Electronic Clinical Quality Measures

We intend to continue to support the following measure domains in the Hospital IQR Program measure set: effective clinical care (for example, the AMI, PN, STK, and VTE measures), communication and care coordination (for example, the readmission measures), patient safety (for example, the HAI measures), person and caregiver-centered experience (for example, the HCAHPS measure), community/population health (for example, the global immunization measure), and efficiency and cost reduction (for example, the Medicare Spending per Beneficiary measure). This approach will enhance better patient care while aligning the Hospital IQR Program with our other established quality reporting and pay-for-performance programs, such as the Hospital VBP Program.

Based on the above approach, we intend to propose to adopt the following electronic clinical quality measures with data collection beginning with October 1, 2016 discharges (or, as described further above, January 1, 2017, if the proposal to align reporting under the Hospital IQR Program and Medicare EHR Incentive Program is finalized) to coincide with EHR Incentive Program Stage 3 collection:

• Hepatitis B Vaccine Coverage Among All Live Newborn Infants Prior to Hospital or Birthing Facility Discharge NQF #0475

The Hepatitis B Vaccine Coverage Among All Live Newborn Infants Prior to Hospital or Birthing Facility Discharge NQF #0475 measure is NQF-endorsed, supported by the MAP and conditionally supported by the MAP as an electronic clinical quality measure for the EHR Incentive Program by the MAP in its 2014 Recommendations on Measures for More Than 20 Federal Programs final report available at: *http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx*. However, the MAP recommends a review of the electronic specifications of this measure through the NQF endorsement process.

This measure requires each hospital/birthing facility to measure its administration of a dose of hepatitis B vaccine to all infants born in their hospital/birthing facility prior to discharge for a specific time period (for example, one calendar year). Hospitals are required to assess infants whose parents refused vaccination for exclusion from the coverage estimate.

• PC–02 Cesarean Section NQF #0471

The PC–02 Cesarean Section NQF #0471 is NQF-endorsed and supported by the MAP in its 2014 Recommendations on Measures for More Than 20 Federal Programs final report available at: *http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx*. The MAP noted that there is an important public education piece to the reporting of PC–02 and recommended that CMS work with others to ensure consumers understand what the results mean and why the measure is important.

This measure assesses the number of nulliparous women with a term, singleton baby in a vertex position delivered by cesarean section.

• Adverse Drug Events—Hyperglycemia

Adverse Drug Events—Hyperglycemia is conditionally supported by the MAP in its 2014 Recommendations on Measures for More Than 20 Federal Programs final report available at: *http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx*. Use of this measure would address a very common condition. The MAP expressed concerns over the feasibility of using this measure in the Hospital IQR Program as it has been tested using electronic data and stated that the NQF endorsement process should resolve this issue.

This measure assesses the average percentage of hyperglycemic hospital days for individuals with a diagnosis of diabetes mellitus, anti-diabetic drugs (except metformin) administered, or at least one elevated glucose level during the hospital stay. The measure's numerator is the sum of the percentage of hospital days in hyperglycemia for all admissions in the denominator. The measure's denominator is the total number of admissions with a diagnosis of diabetes mellitus, at least one administration of insulin or any oral anti-diabetic medication except metformin, or at least one elevated blood glucose value (>200 mg/dL [11.1 mmol/L]) at any time during the entire hospital stay.

Exclusions include: (1) Admissions with a diagnosis of diabetic ketoacidosis (DKA) or hyperglycemic hyperosmolar syndrome (HHS); (2) admissions without any hospital days included in the analysis; (3) admissions with lengths of stay greater than 120 days.

• Adverse Drug Events—Hypoglycemia

Adverse Drug Events—Hypoglycemia is conditionally supported by the MAP in its 2014 Recommendations on Measures for More Than 20 Federal Programs final report, which is available at: *http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx*. Use of this measure would address a common condition that is very dangerous to patients. The MAP expressed concerns over the feasibility of using this measure in the Hospital IQR Program as it has been tested using electronic data and that the NQF endorsement process should resolve this issue.

This measure assesses the rate of hypoglycemic events following the administration of an anti-diabetic agent. The measure's numerator is the total number of hypoglycemic events (<40 mg/dL) that were preceded by administration of a short/rapid-acting insulin within 12 hours or an anti-diabetic agent other than a short/rapid-acting insulin within 24 hours, were not followed by another glucose value greater than 80 mg/dL within 5 minutes, and were at least 20 hours apart. The measure's denominator is total number of hospital days with at least one anti-diabetic agent administered. Exclusions include admissions with length of stay greater than 120 days.

We request comments on these possible future measures.

9. 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, to the Secretary in accordance with this clause and in a

form and manner, and at a time, specified by the Secretary, data required to be submitted on measures selected under this clause with respect to such a fiscal year. We note that, in accordance with this section, the FY 2015 payment determination begins the first year that the Hospital IQR Program will reduce the applicable percentage increase by one-quarter of such applicable percentage increase. In order to participate in the Hospital IQR Program, hospitals must meet specific procedural requirements.

Hospitals choosing to participate in the Hospital IQR Program must also meet specific data collection, submission, and validation requirements. For each Hospital IQR Program year, we require that hospitals submit data on each measure in accordance with the measure's specifications for a particular period of time. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/*.

Hospitals submit quality data through the secure portion of the QualityNet Web site. This Web site meets or exceeds all current Health Insurance Portability and Accountability Act requirements for security of protected health information.

In order to participate in the Hospital IQR Program, hospitals must meet specific procedural requirements. Hospitals choosing to participate in the Hospital IQR Program must also meet specific data collection, submission, and validation requirements.

b. Procedural Requirements for the FY 2017 Payment Determination and Subsequent Years

The Hospital IQR Program procedural requirements are codified in regulation at 42 CFR 412.140. We refer readers to the codified regulations for participation requirements, as further explained by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50810 through 50811).

c. Data Submission Requirements for Chart-Abstracted Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536 through 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures.

We are not proposing any changes to data submission requirements for chart-abstracted measures at this time.

d. Alignment of the EHR Incentive Program Reporting and Submission Timelines for Clinical Quality Measures With Hospital IQR Program Reporting and Submission Timelines

The Hospital IQR Program and the EHR Incentive Program have different reporting and submission periods for clinical quality measures, with hospitals reporting data to the Hospital IQR Program based on calendar year deadlines while the EHR Incentive Program is based on fiscal year deadlines. In addition, the Hospital IQR Program generally requires quarterly reporting and submission of data for chart-abstracted measures while the EHR Incentive Program requires annual submission of clinical process of care measure data.

As a result of the different and incongruent Hospital IQR and Medicare EHR Incentive Programs' schedules, hospitals reporting and submitting measure data to both programs would have to do so multiple times in a calendar year. This discrepancy may create confusion and additional burden for hospitals attempting to report data to both programs. To alleviate this possible confusion and reduce provider burden, beginning with the CY 2015 reporting period/FY 2017 payment determination, we are proposing to incrementally align the data reporting and submission periods for clinical quality measures for the Medicare EHR Incentive Program and the Hospital IQR Program on a calendar year basis.

This proposed change also would also move us closer to meeting our commitment to align quality measurement and reporting among our programs, as we described in the Electronic Health Record Incentive Program –Stage 2 final rule (77 FR 54049 through 54051), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53502 and 53534), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811 through 50819 and 78 FR 50903 through 50904).

In order to ease the transition and prevent the delay of Medicare EHR Incentive Program payments, we are proposing to incrementally shift the Medicare EHR Incentive Program reporting and submission periods for clinical quality measures to align with that of the Hospital IQR Program. We refer readers to section IX.E.2. of the preamble of this proposed rule for a detailed discussion of this proposal in the EHR Incentive Program. Specifically, for the CYs 2015 and 2016, we are proposing in the EHR Incentive Program to require CY reporting, but only for the first three calendar quarters (that is, January through September). This proposal will allow us to align data reporting and submission periods without shifting the EHR incentive payments.

We note that for the Hospital IQR Program, for the FY 2017 payment determination, we are proposing to change the November 30th submission deadline to require data submission within approximately 60 days of the close of a quarter. We refer readers to section IX.A.7.h.(1) of the preamble of this proposed rule where this proposal is made. We are also proposing this change in the Medicare EHR Incentive Program in order to align the two programs. We refer readers to section IX.D.2. of the preamble of this proposed rule where this proposal is made. In summary, we are proposing to align the reporting and submission periods of the Medicare EHR Incentive Program clinical quality measures with that of the Hospital IQR Program for CYs 2015 and 2016.

PROPOSED REPORTING TIMELINE TO ALIGN THE EHR INCENTIVE PROGRAM WITH PROPOSED HOSPITAL IQR PROGRAM SUBMISSION PERIODS

	CY	EHR incentive program reporting requirements*	Hospital IQR program reporting requirements	Submission period**
2015 Reporting Period	Q1	January 1—March 31, 2015.	January 1—March 31, 2015.	Data must be submitted by May 31, 2015.
	Q2	April 1—June 30, 2015	April 1—June 30, 2015	Data must be submitted by August 31, 2015.
	Q3	July 1—September 30, 2015.	July 1—September 30, 2015.	Data must be submitted by November 30, 2015.

PROPOSED REPORTING TIMELINE TO ALIGN THE EHR INCENTIVE PROGRAM WITH PROPOSED HOSPITAL IQR PROGRAM SUBMISSION PERIODS—Continued

	CY	EHR incentive program reporting requirements*	Hospital IQR program reporting requirements	Submission period**
	Q4 ...	N/A for EHR Incentive Program.	October 1—December 31, 2015.	For Hospital IQR Program, Data must be submitted by February 28, 2016.
2016 Reporting Period	Q1 ...	January 1—March 31, 2016.	January 1—March 31, 2016.	Data must be submitted by May 31, 2016.
	Q2 ...	April 1—June 30, 2016	April 1—June 30, 2016	Data must be submitted by August 31, 2016.
	Q3 ...	July 1—September 30, 2016.	July 1—September 30, 2016.	Data must be submitted by November 30, 2016.
	Q4 ...	N/A for EHR Incentive Program.	October 1—December 31, 2016.	For Hospital IQR Program, Data must be submitted by February 28, 2017.

* Calendar year alignment and quarterly reporting for 2015 and 2016 would apply for electronically reported CQM data only.
** Proposed EHR Incentive Program and Hospital IQR submission period would allow data submission on an ongoing basis starting January 2 of the reporting year, and ending approximately 60 days after the end of the quarter.

The Medicare EHR Incentive Program also clarifies case threshold denominator and reporting zero denominators are included in the Medicare EHR Incentive Program at sections IX.D.5. and IX.D.6. of the preamble of this proposed rule.

We invite public comments on these proposals.

e. Sampling and Case Thresholds for the FY 2017 Payment Determination and Subsequent Years

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (75 FR 50230), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years.

We are not proposing any changes to sampling or case thresholds.

f. HCAHPS Requirements for the FY 2017 Payment Determination and Subsequent Years

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), the FY 2014 IPPS/LTCH PPS final rule and (78 FR 50819 through 50820) for details on HCAHPS requirements.

We are not proposing any changes to HCAHPS requirements at this time.

Hospitals and HCAHPS survey vendors should, however, regularly check the official HCAHPS Web site at *http://www.hcahpsonline.org* for new information and program updates regarding the HCAHPS Survey, its administration, oversight and data adjustments.

g. Data Submission Requirements for Structural Measures for the FY 2017 Payment Determination and Subsequent Years

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 through 51644), and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53538 through 53539) for details on the data submission requirements for structural measures.

We are not proposing any changes to data submission requirements for structural measures at this time.

h. Data Submission and Reporting Requirements for Healthcare-Associated Infection (HAI) Measures Reported via NHSN

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51631 through 51633; 51644 through 51645), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50820 through 50822) for details on the data submission and reporting requirements for healthcare-associated infection (HAI) measures reported via the CDC's National Healthcare Support Network (NHSN) Web site. The data submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/*.

We are not proposing any changes to data submission and reporting requirements for healthcare-associated infection measures reported via the NHSN.

10. Submission and Access of HAI Measures Data Through the CDC's NHSN Web site

As finalized in the FY 2014 Hospital IPPS/LTCH PPS final rule (78 FR 50805 through 50807), the Hospital IQR Program requires hospitals to report data via the CDC's NHSN Web site for the following HAI measures: (1) CLABSI (NQF #0139); (2) CAUTI (NQF #0138); (3) SSI following colon surgery; (4) SSI following abdominal hysterectomy; (5) laboratory-identified MRSA *bacteremi*a infection (NQF #1716); (6) laboratory-identified *Clostridium difficile* infection (NQF #1717); and, (7) healthcare personnel vaccination (NQF #0413). 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 specific HAI measures to NHSN.

For the FY 2016 payment determination and subsequent years, for the Hospital IQR program, we are clarifying our data reporting and submission requirements for the above stated HAI measures. By adopting the data reporting and submission procedures set forth by the CDC, we intended that hospitals report, through the existing NHSN process, any and all data elements at the patient-level that are designated as ''required'' on NHSN forms (such as, the ''primary bloodstream infection'' or ''annual facility survey'' forms). Some examples of these ''required'' patient-level data elements include: patient identifier, date of birth, and gender; detailed event data, such as specific symptoms identified to meet case definitions and laboratory results; and risk factor data used to calculate the hospital-level measures. Hospitals may find a comprehensive list of required forms and data elements on the NHSN Web site (*http://www.cdc.gov/nhsn/acute-care-hospital/index.html*).

We further wish to clarify that the NHSN required data collected by the CDC will be shared with CMS for Hospital IQR Program and Hospital VBP Program administration, monitoring and evaluation activities, including validation, appeals review, program impact evaluation, and development of quality measure specifications. CMS routinely uses submitted quality measure data for these types of program administration, monitoring and evaluation activities.

In addition, we are proposing that we will also receive access from the CDC to voluntarily submitted name and race identifying information with respect to Hospital IQR Program required measures. These data will also be used for Hospital IQR Program and Hospital VBP Program administration, monitoring and evaluation activities, including validation, appeals review, program impact evaluation, and development of quality measure specifications. More specifically, for Hospital IQR Program validation, we propose to use these data to ensure accurate matching between patient charts submitted for HAI validation that cannot be matched to NHSN using Medicare beneficiary identification numbers. We also propose to use these data as appropriate for program evaluation.

We invite public comment on this proposal.

11. Proposed Modifications to the Existing Processes for Validation of Chart-Abstracted Hospital IQR Program Data

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), we finalized the processes and procedures for validation of chart-abstracted measures in the Hospital IQR Program for the FY 2015 payment determination and subsequent years; this rule also contained a comprehensive summary of all procedures finalized in previous years and still in effect. Several modifications to these processes were finalized for the FY 2016 and FY 2017 payment determinations in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50835). For the FY 2017 payment determination and subsequent years, we are proposing additional modifications to these processes. Proposed changes fall into the following categories: (a) Eligibility criteria for hospitals selected for validation; (b) number of charts to be submitted per hospital for validation; (c) combining scores for HAI and clinical process-of-care measures; (d) processes to submit medical records for chart-abstracted measures; and (e) plans to validate electronic clinical quality measure data.

a. Eligibility Criteria for Hospitals Selected for Validation

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50833 through 50834), for the FY 2016 payment determination and subsequent years, we finalized our process to draw a random sample of 400 hospitals and an additional sample of up to 200 hospitals meeting specific targeting criteria for purposes of validation. For the FY 2017 payment determination and subsequent years, we are proposing one minor change to this process. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50227), we defined hospitals eligible for validation as the subset of subsection (d) hospitals that successfully submitted ''at least one case for the third calendar quarter of the year two years prior to the year to which validation applies.''

For the FY 2017 payment determination and subsequent years, we are proposing to change the definition of validation-eligible hospitals to be the subset of subsection (d) hospitals that successfully submitted at least one case to the Hospital IQR Clinical Data Warehouse during the quarter containing the most recently available data. The quarter containing the most recently available data will be defined based on when the random sample is drawn. For example, for the FY 2017 payment determination, we intend to draw this sample in November or December of 2014. The second quarter (Q2) of 2014 ends in June 2014, but hospitals participating in the Hospital IQR Program may submit quality data from this quarter until November 15, 2014 (see *www.qualitynet.org* for submission deadlines). If CMS draws its sample early in November 2014, before all the second quarter hospital data are submitted and processed by the Clinical Data Warehouse, the ''quarter containing the most recently available data'' will be first quarter (Q1) of 2014. On the other hand, if CMS draws its sample late November or early December 2014 after the second quarter 2014 hospital data are processed, the second quarter of 2014 will contain the most recently available data.

We are proposing this change because, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50825), for the FY 2017 annual payment determination and subsequent years, we changed the timing of quarters for validation of HAI measures, as illustrated in the three graphs (78 FR 50824). To align with this change for HAI measures and to give hospitals more time to complete HAI validation template requirements once selected, we intend to draw the validation sample several months sooner than we have historically drawn it. Historically, we drew the sample early in each calendar year. This proposal provides us with greater flexibility for when we can sample hospital data and allows CMS to use the most recent data available to select hospitals.

We invite public comment on this proposal.

b. Number of Charts To Be Submitted per Hospital for Validation

(1) Background

In the sections that follow, we are proposing to: (1) Change the number of charts hospitals must submit for validation; (2) change the measure-specific sample sizes for HAI validation; and (3) change the topic areas and sample design for clinical process-of-care measures. We are proposing these changes because Section 1886(o) of the Act requires the Hospital VBP Program to use a subset of Hospital IQR Program measures and there is a declining number of measures and chart-abstracted measure topic areas available to the Hospital VBP Program. Our proposals also will direct more resources to measures and topic areas that also overlap with the Hospital VBP Program. Finally, our proposals will ensure that all chart-abstracted measure topic areas containing required measures within the Hospital IQR Program are included in validation. A more detailed rationale accompanies each proposal.

As described in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), the Hospital IQR Program validates chart-abstracted data submitted to two different systems: clinical process-of-care data submitted to the Hospital IQR Program Clinical Data Warehouse and HAI data submitted to the NHSN. Different validation approaches are used for the data submitted to each of the systems. The process for selecting and validating HAI data was first introduced in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51646 through 51648) and has evolved annually in each successive IPPS/LTCH PPS rule. In contrast, validation of the clinical process of care measures, which involves separate samples for each topic area, has not substantively changed since it was first finalized for the FY 2012 payment determination in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43884 through 43889).

(2) Proposed Number of Charts to be Submitted for Validation

(A) Total Number of Charts Required for Validation

Our current policy requires hospitals to submit 96 charts for validation (60 charts for clinical process-of-care measures and 36 charts for HAIs) (78 FR 50825 through 50834). For the FY 2017 payment determination and subsequent years, we are proposing to require hospitals selected for Hospital IQR Program validation to submit 18 patient charts per quarter for a total of 72 charts per year. A sample size of 72 charts is statistically estimated to be the number of charts needed to determine whether an individual hospital clearly passed validation and to assess hospital performance across both types of measures (HAIs and clinical process-of-care) combined. As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53551), hospitals may fall into three validation categories: (1) Hospitals pass validation with a lower bound of the confidence interval greater than or equal to 75 percent; (2) hospitals fail validation with an upper bound for a hospital's confidence interval lower than 75 percent; and (3) hospitals neither pass nor fail validation with a 90 percent confidence interval that includes values above and below 75 percent. Hospitals in the third category that neither pass nor fail validation receive their annual payment update, but may be randomly sampled for inclusion in the targeted validation in the following year.

We estimate that a sample of 72 charts will be sufficient to estimate a reliability of 75 percent +/- 10 percent with 90 percent confidence, assuming a design effect no greater than 1.4. Historical data suggests that most hospitals in the Hospital IQR Program pass validation and validated data have a high level of accuracy. For example, for the FY 2013 payment determination, approximately 95 percent of hospitals validated had data reliability of 85 percent or higher. With a sample of 72 charts and an expected mean data reliability well above 85 percent, we should be able to identify most hospitals that pass validation. Of the remaining hospitals, we will use the same conservative approach to identify hospitals failing validation that we have used since the inception of the Hospital IQR Program.

(B) Number of Charts Required for HAI and Clinical Process-of-Care Measures

As finalized in the FY 2014 IPPS/LTCH PPS final rule for the FY 2017 payment determination and future years, we require hospitals to submit 9 charts for HAI measures per quarter (78 FR 50831) and for the FY 2016 payment determination and future years, we require hospitals to submit 15 charts for clinical process-of-care measures per quarter for validation (78 FR 50830). For the FY 2017 payment determination and subsequent years, we are proposing that of the 18 charts proposed to be submitted per quarter (above), 10 charts would be submitted to validate HAI measures and 8 charts would be submitted to validate clinical process-of-care measures. This would equal 72 charts per year with a mix of 40 HAI and 32 clinical process-of-care measure charts. We are proposing to require more HAI charts than clinical process-of-care measure charts because HAI measures now, as proposed, have a greater impact on the Hospital VBP and the Hospital-Acquired Condition (HAC) Reduction Programs. Considering only the relative importance of HAIs and clinical process-of-care charts to the Hospital VBP Program, which is about 4 times as great, CMS might choose a ratio larger than 10 HAI charts for every 8 clinical process-of-care charts. However, we estimate that CMS spends about 4 times as much money per chart to validate HAIs than clinical process-of-care measures. Moreover, the clinical process of care measures are still a critical part of the Hospital IQR Program. Therefore, CMS proposed this mix of 40 HAI and 32 clinical process of care charts per year because we believe it to be optimal after considering both the relative importance of the two types of charts to the Hospital IQR Program and related payment incentive programs and the relative cost of validation for the two types of charts.

We invite public comment on these proposals.

(3) HAI Validation: Measures and Measure-Specific Sample Sizes

In the FY 2014 IPPS/LTCH final rule (78 FR 50828 through 50832) for the FY 2016 payment determination and subsequent years, we finalized the HAI measures to be included in validation, the processes for completing validation, and the specific sample sizes for each. To validate HAI data, hospitals must use Validation Templates to provide supplemental data to CMS. These supplemental data provide CMS with a set of candidate infections for each HAI. As finalized previously, hospitals sampled for validation will be randomly assigned to provide two Validation Templates, either: (1) CLABSI and CAUTI, or 2) MRSA and CDI. Consequently, up to 300 hospitals will provide data on each of these 4 measures. We also previously finalized a decision to validate a smaller number of patient charts for SSI from twice as many hospitals because of the smaller number of candidate SSIs expected per hospital per quarter. We are not proposing to change the process for validating individual measures.

However, above in this section, we are proposing to increase the total HAI sample size by 1 chart per quarter for a total of 4 more charts per year. As explained below in this section, HAI measures have greater relative scoring weights in the Hospital VBP and HAC Reduction Programs than clinical process-of-care measures. Therefore, in order to align the Hospital IQR Program with the Hospital VBP and HAC Reduction Programs, we are proposing to increase measure-specific sample size targets to support this 1 chart per quarter increase in the Hospital IQR Program for the FY 2017 payment determination and subsequent years. Specifically, the total number of charts for CLABSI, CAUTI, MRSA, and CDI would increase by 1 from 15 to 16; and the total number of charts for SSI would increase by 2 from 6 to 8. The previously finalized and proposed specific sample-size charts are detailed in the tables below.

PREVIOUSLY FINALIZED NUMBER OF CHARTS REQUIRED FOR HAI VALIDATION FOR THE FY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

HAI	Number of hospitals	Number of quarters	Charts/quarter/hospital	Number of charts per hospital
Previously Finalized:				
Central line associated bloodstream infections (CLABSI)	Up to 300	4	*3.75	15
Catheter-associated urinary tract infections (CAUTI)	Up to 300	4	*3.75	15
MRSA	Up to 300	4	*3.75	15

PREVIOUSLY FINALIZED NUMBER OF CHARTS REQUIRED FOR HAI VALIDATION FOR THE FY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

HAI	Number of hospitals	Number of quarters	Charts/quarter/ hospital	Number of charts per hospital
CDI	Up to 300	4	*3.75	15
SSI	Up to 600	4	*1.5	6

*As previously finalized, within each hospital, quarterly targets are 3, 3, and 1 respectively for CLABSI, CAUTI, and SSI, and 3, 3, and 1 respectively for MRSA, CDI, and SSI. As finalized, 2 additional charts per quarter per hospital were to be randomized to meet the fractional case targets on average.

PROPOSED NUMBER OF CHARTS TO BE SUBMITTED FOR HAI VALIDATION FOR THE FY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

HAI	Number of hospitals	Number of quarters	Charts/quarter/ hospital	Number of charts per hospital
Proposed:				
Central line associated bloodstream infections (CLABSI)	Up to 300	4	4	16
Catheter-associated urinary tract infections (CAUTI)	Up to 300	4	4	16
MRSA	Up to 300	4	4	16
CDI	Up to 300	4	4	16
SSI	Up to 600	4	2	8

We invite public comment on this proposal.

(4) Clinical Process of Care Measures: Topic Areas and Sample Design

As discussed above in this section, we are proposing to sample 8 total patient charts for clinical process-of-care measures per quarter per hospital included in validation for the Hospital IQR Program for the FY 2017 payment determination and subsequent years. Those 8 charts are discussed in greater detail below.

As shown in the table below, two other Hospital IQR Program clinical process-of-care topic areas overlap with measures proposed for inclusion in the FY 2017 Hospital VBP Program. Regardless, we are not proposing to target those topic areas for the following reasons. One of these measures, PC–01, Elective delivery prior to 39 completed weeks of gestation, is reported in aggregate. We cannot use the same mechanism to validate PC–01 as we use for measures reported at the patient level, but we hope to include it in our validation program in the future should reporting PC–01 as an electronic clinical quality measure becomes a requirement. The second measure is AMI–7a. AMI–7a describes a process of care only performed in small rural hospitals. Of the approximately 3,300 hospitals participating in the Hospital IQR Program for the FY 2015 payment determination, only 113 submitted cases for this measure in the first two quarters of CY 2013. Therefore, targeting hospitals that report the AMI–7a measure would unduly single out small rural hospitals that disproportionately report relatively high AMI–7a measure denominator counts for validation, and would be inequitable.

NUMBER OF CHART-ABSTRACTED CLINICAL PROCESS-OF-CARE MEASURES PER TOPIC AREA PROPOSED TO BE REPORTED IN THE HOSPITAL IQR PROGRAM IN THE CY 2014 AND CY 2015 DATA COLLECTION PERIODS *

Topic area	Number of required measures reported in CY 2014 for FY 2016 hospital IQR program	Number of required measures proposed for CY 2015 for FY 2017 hospital IQR program	Proposed to include in the Hospital VBP program for FY 2017
Acute Myocardial Infarction (AMI)	2	1	Yes.
Heart Failure (HF)	1	0	No.
Pneumonia (PN)	1	0	No.
Surgical Care Improvement Project (SCIP)	7	0	No.
Venous thromboembolism (VTE)	6	5	No.
Stroke (STK)	8	4	No.
Emergency department throughput (ED)	2	2	No.
Prevention—global immunization (IMM)	1	1	Yes.
Sepsis	0	1	No.
Perinatal Care (PC) **	1	1	Yes.

*Data validated for the FY 2017 payment determination are Quarter 3, CY 2014, Quarter 4, CY 2014 Quarter 1, CY 2015 and Quarter 2, CY 2015 (78 FR 50824).

**Not reported at the patient level and not proposed for inclusion in validation.

For the FY 2017 payment determination and subsequent years, we are proposing that the remaining 5 of the 8 clinical process-of-care charts be drawn from a systematic random sample of charts across all topic areas

containing required measures other aside from those in the immunization and perinatal care topic areas. Across all hospitals included in validation, we believe this approach will ensure adequate numbers of patient charts are sampled for each topic area. Under this proposal, the pool of clinical process-of-care topic areas sampled for validation will include: STK, VTE, ED, and sepsis, as well as all other IQR required topic areas such as AMI. We received many comments in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50807 through 50810; 78 FR 50825) regarding the importance of validating VTE, STK, and ED measures not included in validation for the FY 2016 payment determination. With this proposal, STK, VTE, ED, and sepsis measures would be included in the pool of clinical process-of-care measures for validation. The systematic random sample of topic areas from this pool would ensure that charts are sampled proportionate to the number of charts submitted for each topic. Thus, a sample of 20 charts per year would not be limited to only one topic area by random occurrence. In addition, across all hospitals included in validation, we believe this approach will ensure adequate numbers of patient charts are sampled for each topic area.[77]

This proposal simultaneously simplifies the sampling plan for clinical process-of-care measures and gives us the flexibility of introducing or removing new topic areas into validation each year without having to redesign and propose a new sampling strategy. Using a random sample ensures that new topic areas are not excluded from the validation sample and we can more easily adjust as the topic areas change over the years. If this proposal is finalized, every time a new required topic area is added to the Hospital IQR Program, it will automatically be added to validation, and every time a topic is removed from the Hospital IQR Program, it will automatically be excluded from validation.

We invite public comment on these proposals.

(5) Immunization Measure Validation

We are proposing for the Hospital IQR Program for the FY 2017 payment determination and subsequent years, that 3 of the 8 total patient charts each quarter be targeted from the Immunization topic area. Currently, this topic area only includes the Immunization for Influenza (NQF #1659) measure, which overlaps with the Hospital VBP Program. We want to ensure that every hospital included in validation is validated for this topic area because of the overlap.

c. Combining Scores for HAI and Clinical Process of Care Topic Areas

We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43885) for the process of scoring clinical process-of-care measures, the FY 2014 IPPS/LTCH PPS final rule (78 FR 50832 through 50833) for the process of scoring HAI measures, and FY 2014 IPPS/LTCH PPS final rule (78 FR 50833) for the process to be used to compute the confidence interval. We are not proposing any changes to those established policies.

However, for the FY 2017 payment determination and subsequent years, we are proposing to modify our approach to weighting the scores for each of the HAI, IMM and ''other topic areas'' with two proposals.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50226) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53548 through 53553), we established a process to combine the HAI and clinical process-of-care measure scores by weighting them proportionate to the number of measures included in validation. For example, in section IX.A.11.b.4. of the preamble of this proposed rule, our proposal to validate all clinical process of care measures required by the Hospital IQR Program for the FY 2017 payment determination would yield 14 clinical process-of-care measures in validation in CY 2015 and only 5 HAI measures in validation. Using the previously finalized weights, the clinical process of care measures score would contribute 14/19 and the HAI score would contribute only 5/19 to the combined score. This weighting does not reflect either the relative importance of HAIs to clinical process of care measures in the Hospital VBP Program nor the resources proposed to devote to their validation.

In sections IV.I. and IV.J. of the preamble of this proposed rule (the Hospital VBP Program and the HAC Reduction Program, respectively), we are proposing to weight the patient safety domain (of which the HAI measures are part) more heavily in the Hospital VBP Program (20 percent for the patient safety domain versus 5 percent for the clinical process of care measures) and to use the HAI measures for the HAC Reduction Program. In this section, we are proposing to weight the HAI measures more heavily than the clinical process of care scores to align with these proposals in sections IV.I and IV.J. For the FY 2017 payment determination and subsequent years, we are proposing to weight the HAI score 66.7 percent (or 2/3) of the total score and the clinical process-of-care measures to weight 33.3 percent (or 1/3) of the total score. Further justification is provided after the second proposal.

In addition, we are proposing to weight the IMM measures more heavily than other chart-abstracted clinical process-of-care measures validated in the Hospital IQR Program to align with the Hospital VBP Program. We are changing the process currently established to calculate the clinical process-of-care score, which is based on application of the formulas for the variance of a stratified single-stage cluster sample with unequal cluster sizes and the variance of a proportion in a stratified random sample (see reference to Cochran's ''Sampling Techniques'' at 75 FR 50226 and 78 FR 53550). We have previously applied this formula without consideration for the relative importance of different measures. When so applied, each topic area is weighted proportionate to the amount of data submitted to the warehouse for that topic area.

However, we are proposing to modify the formulas as previously applied to weight the IMM topic area more heavily because of the overlap with the Hospital VBP Program. For the FY 2017 payment determination and subsequent years, we are proposing to weight the ''IMM'' clinical topic area as 66.7 percent (2/3) and all other topic areas combined 33.3 percent (1/3) of the clinical process-of-care score. The weights reflect our policy preference to place greater relative weight on Hospital VBP Program included measures to better ensure accurate scores and payment. Emphasizing chart-abstracted clinical process of care measures validated in the Hospital IQR Program to align with the Hospital VBP Program will address the need to validate Hospital IQR Program data not currently included in Hospital VBP Program for public reporting and validation feedback to hospitals.

The table below shows the effect of the two proposals combined (the first to weight the HAI score more heavily than the clinical process-of-care score and the second to weight IMM data more heavily than other clinical process-of-care topic areas). The HAI topic area will count 3 times as much as the IMM

[77] We used data submitted to the Clinical Data Warehouse for the Hospital IQR Program from quarters 1 and 2 of 2013 to estimate that at least 400 cases per topic area would be validated per year (across all hospitals).

topic area and 6 times as much as all other topic areas combined.

PROPOSED WEIGHTING TO COMBINE SCORES ACROSS CHART-ABSTRACTED TOPIC AREAS INCLUDED IN VALIDATION FOR THE FY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Topic area	Weight (percent)
Health care associated infection (HAI)	66.7
Immunization (IMM)	22.2
Other (AMI, ED, sepsis, STK, VTE)	11.1
Total	100

Previously, the clinical process of care measures accounted for 20 percent of the Hospital VBP Program score, whereas the HAI measures were a subset of the outcome measures weighted 30 percent (FR 53605 through 53606). The proposed relative weights for the HAI (66 percent) and IMM (22 percent) topic areas better reflect the strong emphasis we are proposing for the HAI measures.

These proposals will require adjustments to the formulas applied to compute the confidence intervals. As we have done in the past, we intend to post the specific formulas used to compute the confidence interval on the QualityNet Web site at least one year prior to final computation (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1138115987129*). These formulas will continue to account appropriately for the manner in which patient charts were sampled and data were abstracted.

We invite public comment on these proposals.

d. Processes To Submit Patient Medical Records for Chart-abstracted Measures

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50834 through 50835), we finalized a process for the FY 2016 payment determination and subsequent years that allows hospitals to submit patient charts for validation via: (1) Paper patient medical records; or (2) secure transmission of electronic versions of patient information. The process previously finalized restricts electronic submission of patient information to digital images of patient medical records submitted using encrypted CD–ROMs, DVDs, or flash drives.

We are proposing for the FY 2017 payment determination and subsequent years to expand the options for secure transmission of electronic versions of patient medical records. Specifically, we are proposing to allow hospitals to submit digital images (PDFs) of patient charts using a Secure File Transfer Portal on the QualityNet Web site. This portal would allow hospitals to transfer files through either a Web-based portal or directly from a client application using a secure file transfer protocol. The system provides a mechanism for securely exchanging documents containing sensitive information such as Protected Health Information (PHI) or Personally Identifiable Information (PII). Detailed instructions on how to use this system are available in the Secure File Transfer 1.0 User Manual available on QualityNet at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1228773343598*. After July 2014, hospitals can submit all Hospital IQR Program validation data using this portal. This proposal responds to many commenters from the FY 2014 IPPS/LTCH PPS rulemaking that were concerned that encrypted CD–ROMs were cumbersome and requested viable alternatives. We believe that the burden associated with using this portal will be similar to or less than that involved with submitting patient medical records via portable electronic media (that is, encrypted CD–ROMS, DVDs, or flash drives). Therefore, we intend to reimburse hospitals according to the rate established for submitting patient medical records via portable electronic media (78 FR 50956).

We invite public comment on this proposal.

e. Plans To Validate Electronic Clinical Quality Measure Data

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50807 through 50810), we finalized a voluntary process allowing hospitals to partially meet Hospital IQR Program requirements for the FY 2014 payment determination by submitting electronic clinical quality measure data via certified electronic health record technology. Many commenters expressed concern that we did not have an adequate methodology to validate these data.

To respond to these concerns as well as to ensure that Hospital IQR Program data are accurate and reliable, we conducted an environmental scan, including review of prior public comments to CMS proposed rules and requests for information, review of the technical and academic literatures, numerous listening sessions, and interviews with nine hospitals. From these activities, we identified three key categories of threats to data accuracy: (1) The design of the EHR product, including both the manufacturer-provided EHR product and the hospital's customizations of that EHR product to support the hospital's specific workflows and processes, (2) hospital and provider documentation practice, and (3) EHR and electronic clinical quality measure standards and specifications. We understand the potential threats to validity in each of these categories. To respond to these concerns, we are currently conducting a small scale test of a remote real-time validation strategy for electronic clinical quality measures in approximately 9 hospitals.

We are not proposing any requirements for validation of electronic clinical quality measures for the FY 2017 payment determination. However, we intend to conduct a larger scale pilot test of validation activities in FY 2015. The pilot test will engage up to 100 volunteer hospitals in a highly interactive test abstraction of their EHR systems using a secure remote access, real-time abstraction technology that meets the HIPAA Privacy and Security Rules' requirements. Hospitals that volunteer to participate must meet the EHR Incentive Program Stage 2 criteria (77 FR 53968 through54162) and be able to produce QRDA Category 1 Revision 2 extracted data (individual patient data) for at least 6 of the 16 measures in the STK, VTE, ED, and PC topic areas. The Office of the National Coordinator for Health Information Technology (ONC) adopted QRDA as the standard to support both QRDA Category I

(individual patient) and QRDA Category III (aggregate) data submission approaches for meaningful use Stage 2 in the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology rule (77 FR 54163 through 54292). Interested hospitals will be invited to attend a 30-minute pre-briefing session where they will be provided with detailed instructions about the process and a demonstration explaining how to install needed software and have any concerns about security or systems requirements addressed. The software to be installed, Bomgar, is approved by CMS and meets our security requirements allowing CDAC to remotely view isolated records in real-time under hospital supervision, comparing all abstracted data with QRDA Category 1 file data and summarizing the results after the real-time session.

We implemented Bomgar software, a commercial product, in a CMS data center to allow for the review of medical records securely over the Internet. The product will allow the CDAC staff and Hospital medical record staff to easily set up remote support sessions for reviewing Hospital IQR Program-related EHR records under hospital supervision. The software was tested and passed our strict security standards. The electronic sessions do not require changes to a hospital's firewall or network because both the CDAC computer and the hospital computer connect to the product through secure outbound connections. The product will log and record every session and all session data will be safe-guarded by federal government approved encryption.

While CDAC has limited, remote viewing access, hospitals will be asked to:

- Generate separate lists of patients eligible for measures in each of the four topic areas (STK, VTE, ED, and PC);
- Generate QRDA Category 1 files extracted automatically from an EHR for all applicable measures for up to 3 records within each of the 4 topic areas (for a total of 12 records) as selected by CDAC; and
- Show selected records, such as laboratory records, and patient medical history, navigating through the EHR system as directed by CDAC.

During this remote real-time session, CDAC will:

- Follow the specifications for the electronic measure to abstract relevant information related to each data element from up to 10 different sources, for example, medication administration records, laboratory reports, and patient history, (including structured and unstructured fields) within each patient medical record.

After concluding the real-time session with a hospital, CDAC will:

- Compare all abstracted data with QRDA Category 1 file data; and
- Summarize results identifying patterns of concern.

Based on these results, CMS and our contractors will:

- Work with measure stewards to refine measure specifications based on conflicting findings;
- Share conflicting findings with individual hospitals to support improvement;
- Publicize de-identified patterns of conflicting findings that allow vendors to develop automated checks;
- Determine reliability (agreement) between QRDA Category 1 extracted and abstracted data; and
- Produce descriptive statistics to estimate sample size requirements for future validation.

To address the burden associated with this test, we intend to reimburse hospitals for the burden associated with their participation. Details about reimbursement are included in section XIII.B.6. of the preamble of this proposed rule. We will post on QualityNet a detailed draft of the operational procedures that volunteer hospitals will be expected to follow during the public comment period. We developed this process to attempt to meet all of our goals for validity, as further explained in the table below.

ELECTRONIC CLINICAL QUALITY MEASURE VALIDATION STRATEGY SUMMARY FOR THE HOSPITAL IQR PROGRAM

Desired Attributes of Validation Strategy
• Assesses accuracy including reliability and population representativeness. • Employs a standardized process conducted by an objective third party. • Minimizes burden to hospitals. • Minimizes costs to CMS by being performed at a central location. • Leverages the dynamic qualities of an EHR, including query functions. • May ultimately integrate with validation of other IQR measures.
Goals of Test
• Assess the accuracy and completeness of electronic clinical quality measure data. • Assess Hospital IQR Program readiness for electronic clinical quality measure reporting requirements. • Identify the needs for and implement updates to measure specifications and standards. • Plan future validation requirements, including detailed operational instructions and sample size.
Planned Process Overview
Hospitals will: • Allow CMS' Clinical Data Abstraction Contractor (CDAC) to remotely view records in real-time. • Generate separate lists of patients eligible for measures to be validated. • Generate QRDA Category 1 extract files for all applicable measures for up to 12 records selected by CDAC. • Show selected records, navigating through the EHR system as directed by CDAC. CDAC will: • Abstract data following the specifications for the electronic measure and relevant information related to each data element from up to 10 different sources (including structured and unstructured fields) within each medical record. • Compare all abstracted data with QRDA Category 1 file data. • Assess and refine operational processes. CMS and its contractors will: • Determine reliability (agreement) between extracted and abstracted measures. • Work with measure stewards to refine measure specifications based on conflicting findings. • Share conflicting findings with individual hospitals to support improvement.

ELECTRONIC CLINICAL QUALITY MEASURE VALIDATION STRATEGY SUMMARY FOR THE HOSPITAL IQR PROGRAM—Continued

- Publicize de-identified common patterns of conflicting findings that allow vendors to develop automated checks.
- Produce descriptive statistics to estimate sample size requirements for future validation.
- Reimburse hospitals for burden associated with participation in test.

We invite public comment on this voluntary pilot test for validation.

We also considered other validation approaches including one that supplements the current procedures and compares quality data manually abstracted by the hospitals with QRDA Category 1 extracts from their EHRs. Although we are making no specific proposals related to these alternatives at this time, we invite comments on whether we should develop or identify existing computerized applications to assist hospitals in self-validation and on the specific functionalities that may be useful for self-validation. For example, as part of the validation process, should CMS develop or identify an existing application that would use natural language processing, to identify potential threats to validity that human abstractors might then review more closely. An example of such an application might be one that searches the unstructured fields for contraindications to VTE prophylaxis, even if such contraindications were not noted in a structured field within an EHR. We also invite comments any other types of applications that would be useful for self-validation.

12. Data Accuracy and Completeness Acknowledgement Requirements for the FY 2017 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for information for details on DACA requirements for the FY 2017 payment determination and subsequent years.

We are not proposing any changes to DACA form requirements at this time.

13. Public Display Requirements for the FY 2017 Payment Determination and Subsequent Years

We refer readers to the FY 2008 IPPS final rule (72 FR 47360), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836) for details on public display requirements for the FY 2017 payment determination and subsequent years.

The Hospital IQR Program quality measures are typically reported on the *Hospital Compare* Web site at: *http://www.medicare.gov/hospitalcompare*, but on occasion are reported on other CMS Web sites such as *http://www.cms.gov* and/or *https://data.medicare.gov*.

We are not proposing any changes to public display requirements at this time.

14. Reconsideration and Appeal Procedures for the FY 2017 Payment Determination and Subsequent Years

We refer readers to the FY 2012 IPPS/LTCH final rule (76 FR 51650 through 51651), the FY 2014 IPPS/LTCH final rule (78 FR 50836), and at 42 CFR § 412.140(e) for details on reconsideration and appeal procedures for the FY 2017 payment determination and subsequent years.

We are not proposing any changes to the reconsideration and appeals procedures at this time.

15. Hospital IQR Program Extraordinary Circumstances Extensions or Exemptions

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651 through 51652), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836 through 50837), and 42 CFR 412.140(c)(2) for details on the Hospital IQR Program extraordinary circumstances extensions or waivers. We are not proposing any substantive changes to these policies or the processes. However, in the future, we will refer to the process as the Extraordinary Circumstances Extensions or Exemptions process. We are currently in the process of revising the Extraordinary Circumstances/Disaster Extension or Waiver Request form, previously approved under OMB control number 0938–1171.

In addition, we are proposing to make a conforming change from the phrase ''extension or waiver'' to the phrase ''extension or exemption'' in 42 CFR 412.140(c)(2). Section 412.140(c)(2) currently states, ''*Exception.* Upon request by a hospital, CMS may grant an extension or waiver of one or more data submission deadlines in the event of extraordinary circumstances beyond the control of the hospital. Specific requirements for submission of a request for an extension or waiver are available on QualityNet.org.'' We are proposing to revise this language to state, ''*Exception.* Upon request by a hospital, CMS may grant an extension or exemption of one or more data submission deadlines in the event of extraordinary circumstances beyond the control of the hospital. Specific requirements for submission of a request for an extension or exemption are available on QualityNet.org.''

B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Statutory Authority

Section 3005 of the Affordable Care Act added new sections 1866(a)(1)(W) and (k) to the Act. Section 1866(k) establishes a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as a ''PPS-Exempt Cancer Hospital'' or ''PCH''). Section 1866(k)(1) of the Act states that, for FY 2014 and each subsequent fiscal year, a PCH must submit data to the Secretary in accordance with section 1866(k)(2) of the Act with respect to such 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 must 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 was required to 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 PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Such procedures must ensure that a PCH has the opportunity to review the data that are to be made public with respect to the PCH prior to such data being made public. 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 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 rule covers only those PPS-excluded cancer hospitals meeting eligibility criteria specified in 42 CFR 412.23(f).

3. Previously Finalized PCHQR Program Quality Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561), we finalized five quality measures for the FY 2014 program and subsequent years. Specifically, we finalized two of the CDC NHSN-based HAI quality measures (outcome measures): (1) CLABSI; and (2) CAUTI. We also finalized three cancer-specific 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 the American Joint Committee on Cancer (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. We also discussed the collection requirements and submission timeframes for these measures in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563 through 53566).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50838 through 50840), we finalized one new quality measure for the FY 2015 program and subsequent years. Specifically, we finalized the CDC's NHSN HAI measure of Surgical Site Infection (SSI). We did not remove or replace any of the previously finalized measures from the PCHQR Program for the FY 2015 program and subsequent years.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50840 through 50846), we finalized 12 new quality measures for the FY 2016 program and subsequent years. Specifically, we finalized six new SCIP measures, five new clinical process/oncology care measures and the HCAHPS Survey for reporting beginning with the FY 2016 program and subsequent years. We did not remove or replace any of the previously finalized measures from the PCHQR Program for the FY 2016 program and subsequent years. We also discussed the collection requirements and submission timeframes for these measures in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50850 through 50853).

We are not proposing to remove or replace any of the previously finalized measures from the PCHQR Program for the FY 2017 program and subsequent years.

4. Proposed Update to the Clinical Process/Oncology Care Measures Beginning With the FY 2016 Program

Beginning with the FY 2016 program, we are proposing to update the specifications for each of the five clinical process/oncology care measures so that for each measure, PCHs must report all-patient data. We believe that the delivery of high quality care in the PCH setting is critically important and that collecting data on all patients will enable us to ensure that high quality care is delivered to Medicare beneficiaries in this setting. In addition, all-patient data increases transparency in the health care system, aligns with State and federal initiatives,[78] and improves research efforts. Our proposal to require PCHs to collect all-patient data provides us with the data to inform the public with the most robust and accurate reflection of the quality of care and patient outcomes in the PCH setting. In addition, this proposal will align the specifications of the clinical process/oncology care measures with those of the SCIP PCHQR measures, for which all-patient data are required for submission.

We welcome public comments on this proposal for the clinical process/oncology care measures for the FY 2016 program and subsequent years.

5. Proposed New Quality Measure Beginning With the FY 2017 Program

a. Considerations in the Selection of Quality Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556) and in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50837 through 50838), we indicated that we have taken a number of principles into consideration when developing and selecting measures for the PCHQR Program, and that many of these principles are modeled on those we use for measure development and selection under 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 cancer hospitals that reflects the level of care and the most important areas of service furnished by those hospitals. The measures should address gaps in the quality of cancer care.
- We also consider input solicited from the public through rulemaking and public listening sessions.
- We consider suggestions and input from a PCH Technical Expert Panel (TEP), convened by a CMS measure development contractor, which rated potential PCH quality measures for importance, scientific soundness, usability, and feasibility. The TEP membership includes health care providers specializing in the treatment of cancer, cancer researchers, consumer and patient advocates, disparities experts, and representatives from payer organizations.

Like the Hospital IQR Program, the PCHQR Program supports the National Quality Strategy (NQS), national priorities, HHS Strategic Plans and Initiatives, the CMS Quality Strategy, and strives for burden reduction whenever possible. The PCHQR Program also takes into consideration the recommendations of the Measure Applications Partnership (MAP). The MAP is a multi-stakeholder body convened by the NQF for the purpose of providing input to HHS on the selection of measures.

b. Proposed New Quality Measure Beginning With the FY 2017 Program

We are proposing to adopt one new clinical effectiveness measure for the FY 2017 program and subsequent years:

[78] All-Payer Claims Database (APCD) Fact Sheet; available at: *http://www.apcdcouncil.org/issue-briefs-and-fact-sheets.*

External Beam Radiotherapy for Bone Metastases (NQF #1822). The proposed clinical effectiveness measure was included on a publicly available document entitled ''List of Measures under Consideration for December 1, 2013,'' a list of quality and efficiency measures being considered for use in various Medicare programs. The proposed measure was submitted to the MAP Hospital Workgroup for review. The MAP supported the inclusion of this measure in the PCHQR Program. The MAP's conclusions can be found in the ''MAP Pre-Rulemaking Report: 2014 Recommendations on Measures Under Consideration by HHS,'' which is available at: *https://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx*. We considered the MAP's input and recommendations for this proposed measure for the PCHQR Program, and specifically, we note that the proposed measure addresses the MAP priority of palliative care for cancer patients. In addition, the proposed measure addresses the NQS domain of effective clinical care.

We believe that this NQF-endorsed measure developed by the American Society for Radiation Oncology (ASTRO) meets the requirement under section 1866(k)(3)(A) of the Act that measures specified for the PCHQR generally be endorsed by the entity with a contract under section 1890(a) of the Act (currently the NQF). This measure assesses the percentage of patients (both Medicare and non-Medicare) with painful bone metastases and no history of previous radiation who receive EBRT with an acceptable dosing schedule. The measure numerator includes all patients with painful bone metastases, and no previous radiation to the same site, who receive EBRT with any of the following recommended fractionation schemes: 30Gy/10fxns, 24Gy/6fxns, 20Gy/5fxns, or 8Gy/1fxn. The measure denominator includes all patients with painful bones metastases and no previous radiation to the same site, who receive EBRT. The following patients are excluded from the denominator: Patients who have had previous radiation to the same site; patients with femoral axis cortical involvement greater than 3 cm in length; patients who have undergone a surgical stabilization procedure; and patients with spinal cord compression, cauda equina compression, or radicular pain. For the reasons explained more fully below, we believe that this measure will reduce the rate of EBRT services overuse, support our commitment to promoting patient safety, and support the NQS domains.

Bone metastases are a common manifestation of malignancy. Some cancer types have a bone metastasis prevalence as high as 70 to 95 percent.[79] EBRT can provide significant pain relief in 50 to 80 percent of patients with painful bone metastases.

In October 2009, ASTRO organized a Task Force to perform an assessment of existing recommendations in order to address a lack of palliative radiotherapy guidelines. Based on a review of the literature, the Task Force recommended the following EBRT dosing schedules for patients with previously un-irradiated painful bone metastases: 30 Gy over the course of 10 fractions, 24 Gy over the course of 6 fractions, 20 Gy over the course of 5 fractions, and a single 8 Gy fraction.[80] Despite the recommendations, the actual doses applied for EBRT continue to include dosing schedules as high as 25 fractions.[81] Other studies support the conclusion that shorter EBRT schedules produce similar pain relief outcomes when compared to longer EBRT schedules, and that patients prefer shorter EBRT schedules because of their convenience, increased tolerability, and reduced side effects.[82]

In addition, the ASTRO Task Force found that the frequency and severity of side effects associated with a single fraction were the same or less than those associated with multiple fraction regimens, indicating that shorter treatment schedules may be preferable.[83] The proposed External Beam Radiotherapy for Bone Metastases measure seeks to address the performance gap in treatment variation, ensure appropriate use of EBRT, and prevent the overuse of radiation therapy. We believe that this measure is necessary to support patient preferences for shorter EBRT schedules as well as to ensure patient safety, given that shorter treatment courses show similar or fewer side effects while producing similar clinical outcomes.

We believe the proposed measure is applicable to the PCH setting because it addresses cancer care associated with radiation therapy. The adoption of measures that apply to multiple health care settings is one of our objectives in promoting quality care consistently across all health care settings. Detailed specifications for this proposed measure can be found at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=70374*.

In summary, in addition to the 18 measures that we previously finalized for the PCHQR Program, we are proposing one new measure for reporting beginning with the FY 2017 program. The proposed policies regarding the form, manner, and timing of data collection for this measure are discussed in later sections. The table below lists all previously adopted measures as well as the proposed new measure for the PCHQR Program for the FY 2017 program and subsequent years. We welcome public comment on this proposal.

Topic	PCHQR program measures for the FY 2017 program and subsequent years (including proposed new measure)
	Safety and Healthcare-Associated Infection—HAI
	• (NQF #0139) NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure*. • (NQF #0138) NHSN Catheter-Associated Urinary Tract Infections (CAUTI) Outcome Measure*. • (NQF #0753) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure* (currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery).
	Clinical Process/Cancer-Specific Treatments
	• (NQF #0223) 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*.

[79] Coleman RE. Metastatic bone disease: Clinical features, pathophysiology and treatment strategies. Cancer Treat Rev. 2001;27:165–176.

[80] Lutz S, Berk L, Chang E, et al. Palliative radiotherapy for bone metastases: An ASTRO evidence-based guideline. Int J Radiat Oncol Biol Phys. 2011;79(4):965–976.

[81] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=70374*.

[82] Lutz S, Berk L, Chang E, et al. Palliative radiotherapy for bone metastases: An ASTRO evidence-based guideline. Int J Radiat Oncol Biol Phys. 2011;79(4):965–976.

[83] FY 2013 IPPS/LTCH PPS final rule 77 FR 53561 (NQF# 0223, 0559, and 0220).

Topic	PCHQR program measures for the FY 2017 program and subsequent years (including proposed new measure)
	• (NQF #0559) 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 #0220) Adjuvant Hormonal Therapy*.
SCIP	
	• (NQF #0218) Surgery Patients who Received Appropriate VTE Prophylaxis within 24 Hrs Prior to Surgery to 24 Hrs After Surgery End Time*. • (NQF #0453) Urinary Catheter Removed on Post-Operative Day 1 or Post-Operative Day 2 with Day of Surgery Being Day Zero*. • (NQF #0527) Prophylactic Antibiotic Received Within 1 Hr Prior to Surgical Incision*. • (NQF #0528) Prophylactic Antibiotic Selection for Surgical Patients*. • (NQF #0529) Prophylactic Antibiotic Discontinued Within 24 Hrs After Surgery End Time*. • (NQF #0284) Surgery Patients on Beta Blocker Therapy Prior to Admission who Received a Beta Blocker During the Perioperative Period*.
Clinical Process/Oncology Care Measures	
	• (NQF #0382) Oncology-Radiation Dose Limits to Normal Tissues*. • (NQF #0383) Oncology: Plan of Care for Pain*. • (NQF #0384) Oncology: Pain Intensity Quantified*. • (NQF #0390) Prostate Cancer-Adjuvant Hormonal Therapy for High-Risk Patients*. • (NQF #0389) Prostate Cancer-Avoidance of Overuse Measure-Bone Scan for Staging Low-Risk Patients*.
Patient Engagement/Experience of Care	
	• (NQF #0166) HCAHPS*.
Clinical Effectiveness Measure	
	• (NQF #1822) External Beam Radiotherapy for Bone Metastases**.

* Previously finalized measures.
** Proposed for the FY 2017 program and subsequent years in this proposed rule.

6. Possible New Quality Measure Topics for Future Years

We seek to develop a comprehensive set of quality measures for widespread use for informed decision-making and quality improvement in the PCH setting. Therefore, in future rulemaking, we intend to propose to adopt new or updated measures, such as measures that assess the safety and efficiency of the diagnosis and treatment of cancer, measures that take into account novel diagnostic and treatment modalities, measures that assess symptoms and functional status, and measures of appropriate disease management. Additional measure topics to be considered include patient centered care planning and care coordination, shared decision making, measures of quality of life outcomes, and measures of admissions for complications of cancer and treatment for cancer. We believe that such measures will 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 quality of care information.

We welcome public comment and specific suggestions for measure topics for the following measure domains: outcomes, quality of life, clinical quality of care, care coordination, patient safety, patient and caregiver experience of care, population/community health, and efficiency. These domains align with those of the NQS, and we believe that selecting measures to address these domains will promote better cancer care while aligning the PCHQR Program with other established quality reporting and pay for performance programs such as the Hospital IQR Program, the Hospital OQR Program and the Hospital VBP Program.

Generally, we retain measures from the previous years' PCHQR Program measure sets for subsequent years. However, in future years we will consider developing criteria to determine whether or not to remove or replace measures from the PCHQR Program measure set. In developing removal criteria, we will consider those criteria used by other CMS quality reporting programs in order to align the PCHQR Program with those programs.

We welcome public comments on the criteria for removal or replacement of measures from the PCHQR Program.

In an effort to reduce the reporting burden for PCHs, in future years, we will consider proposing to require PCHs to report electronically specified clinical quality measures for the PCHQR Program. We believe that the collection and reporting of data through health information technology would greatly simplify and streamline reporting for many CMS quality reporting programs, including the PCHQR Program. Through electronic reporting, PCHs would be able to leverage EHRs to capture, calculate, and electronically submit quality data that is currently manually chart-abstracted and submitted to CMS for the PCHQR Program. In developing future proposals for electronic clinical quality measures adoption, we will consider the need to align and harmonize measures across various quality reporting programs to minimize the reporting burden imposed on PCHs.

We welcome public comments on the development of electronic clinical quality measure reporting criteria for future years.

7. Maintenance of Technical Specifications for Quality Measures

We maintain technical specifications for the PCHQR Program measures, and we periodically update those specifications. The specifications can be found on the QualityNet Web site at: *https://qualitynet.org/dcs/ContentServer?cid=1228772356060&pagename=QnetPublic%2FPage%2FQnetTier2&c=Page*.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505), we finalized a policy under which we use

a subregulatory process to make nonsubstantive updates to measures used for the Hospital IQR Program. We also adopted this process for all measures adopted for the PCHQR Program. With respect to what constitutes substantive versus non-substantive changes, we expect to make this determination on a case-by-case basis. Examples of nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure. We believe that nonsubstantive changes may include updates to measures based upon changes to guidelines upon which the measures are based.

We will continue to use rulemaking to adopt substantive updates to the measures we have adopted for the PCHQR Program. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example: Changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice. We also note that to the extent a PCHQR measure is endorsed by the NQF, the NQF measure maintenance process incorporates an opportunity for public comment and engagement.

We believe the endorsement processes, as well as our treatment of substantive versus nonsubstantive measure changes, adequately balances our need to incorporate updates to PCHQR 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.

8. Public Display Requirements Beginning With the FY 2014 Program

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 must ensure that a PCH has the opportunity to review the data that is to be made public with respect to the PCH prior to such data being made public. Section 1866(k)(4) of the Act also provides that the Secretary must report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospital on the CMS Web site.

In order to meet these requirements, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53562 through 53563), we finalized our policy to publicly display the submitted data on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) and established a preview period of 30 days prior to making such data public.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50847 through 50848), we finalized our proposal to display publicly in 2014 and subsequent years the data for the measures listed below:

- 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); and
- 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 year we are proposing to publicly display in 2015 and subsequent years the data for the Adjuvant Hormonal Therapy measure (NQF #0220).

We are also proposing to publicly display no later than 2017 and for subsequent years the data for the measures listed below:

- NHSN Catheter-Associated Urinary Tract Infections (CAUTI) Outcome Measure (NQF #0138); and
- NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139).

At present, all PCHs are reporting CLABSI and CAUTI data to the NHSN under the PCHQR Program. However, due to the low volume of data produced and reported by the small number of facilities (in fewer than 2 years), the CDC is unable to calculate reasonable and reliable baseline estimates, or expected rates, which are needed for the purpose of calculating these measure rates. Therefore, we estimate that the first public posting of the CLABSI and CAUTI PCHQR Program data reported to the NHSN from the PCHs will be no later than 2017.

We invite public comment on these proposals.

9. Form, Manner, and Timing of Data Submission Beginning With the FY 2017 Program

a. Background

Section 1866(k)(2) of the Act requires that, beginning with the FY 2014 PCHQR Program, each PCH must submit to the Secretary data on quality measures specified under section 1866(k)(3) of the Act in a form and manner, and at a time as specified by the Secretary.

Data submission requirements and deadlines for the PCHQR Program are generally posted on the QualityNet Web site at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772864228*.

b. Proposed Reporting Requirements for the Proposed New Measure: External Beam Radiotherapy for Bone Metastases (NQF #1822) Beginning With the FY 2017 Program

We are proposing that PCHs report the proposed External Beam Radiotherapy for Bone Metastases (NQF #1822) measure beginning with January 1, 2015 discharges and for subsequent years. We are proposing that PCHs would report this measure to CMS via a CMS Web-based Measures Tool on an annual basis (July 1—August 15 of each respective year). This approach is consistent with the data submission deadlines finalized for the clinical process/oncology care measures (78 FR 50850 through 50851) and PCHs are already preparing to begin submitting PCHQR data using this timeline. We also believe that annual data submission of once per year (as opposed to quarterly data submission of four times per year) will reduce PCH cost and burden. We believe that these proposed dates will provide enough advance notice for PCHs to prepare to report the measure.

We are proposing to collect the EBRT for Bone Metastases measure rates for the FY 2017 program and subsequent years using all-patient (both Medicare and non-Medicare) data from the four quarters (Q1, Q2, Q3, and Q4) of CY 2015, and that PCHs must submit aggregated data for the measure for each of these quarters during a data submission window that would be open from July 1 through August 15, 2016. For the FY 2017 program and subsequent years, we refer readers to the reporting periods and data submission window outlined in the table below in this section.

For data collection, we are proposing that PCHs submit aggregate-level data through the CMS Web-based Measures Tool or submit an aggregate data file through a vendor (via QualityNet infrastructure). We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50850 through 50851) for more information on the CMS Web-based aggregated data collection tool.

We welcome public comment on the proposed reporting periods, data submission timeframes, and data collection methods/modes for the proposed measure for the FY 2017 program and subsequent years.

PROPOSED EXTERNAL BEAM RADIOTHERAPY FOR BONE METASTASES (NQF #1822) MEASURE-REPORTING PERIODS AND SUBMISSION TIMEFRAMES FOR THE FY 2017 PROGRAM AND SUBSEQUENT YEARS

Program year (FY)	Reporting periods (CY)	Data submission deadlines
2017	Q1 2015 discharges (January 1, 2015–March 31, 2015) Q2 2015 discharges (April 1, 2015–June 30, 2015) Q3 2015 discharges (July 1, 2015–September 30, 2015) Q4 2015 discharges (October 1, 2015–December 31, 2015)	July 1, 2016–August 15, 2016.
2018	Q1 2016 discharges (January 1, 2016–March 31, 2016) Q2 2016 discharges (April 1, 2016–June 30, 2016) Q3 2016 discharges (July 1, 2016–September 30, 2016) Q4 2016 discharges (October 1, 2016–December 31, 2016)	July 1, 2017–August 15, 2017.
Subsequent Years	Q1 discharges (January 1–March 31 of each year 2 years before the program year). Q2 discharges (April 1–June 30 of each year 2 years before the program year) Q3 discharges (July 1–September 30 of each year 2 years before the program year) Q4 discharges (October 1–December 31 of each year 2 years before the program year)	July 1–August 15 of each year before the program year.

c. Proposed Reporting Options for the Clinical Process/Cancer Specific Treatment Measures Beginning with the FY 2015 Program and the SCIP and Clinical Process/Oncology Care Measures Beginning With the FY 2016 Program

We are proposing to modify the data submission requirements for the three clinical process/cancer specific treatment measures [84] that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53564), and the six SCIP measures and five clinical process/oncology care measures that we adopted in the FY 2014 IPPS/LTCH final rule (78 FR 50846). Under those requirements, PCHs submit aggregate-level clinical process/cancer specific treatment measure data to a CMS contractor, aggregate-level clinical process/oncology care measure data through the CMS Web-based Measures Tool, and patient-level SCIP measure data through the QualityNet infrastructure. We are now proposing to allow PCHs to report the clinical process/cancer specific treatment, SCIP, and clinical process/oncology care data to CMS using one of two mechanisms. Under the first option, which is newly proposed for the SCIP and clinical process/oncology care measure sets, PCHs or their authorized vendors can enter aggregate numerator and denominator data into a CMS Web page located on the secure part of the CMS QualityNet infrastructure. Under the second option, which is newly proposed for the clinical process/cancer specific treatment, SCIP, and clinical process/oncology care measures, PCHs or their authorized vendors can submit an aggregate data file through a CMS secure QualityNet file exchange process. We are proposing these options in order to decrease the reporting burden for PCHs.

We believe that the newly proposed submission option, which is further described below for the SCIP measures, will result in a considerable burden reduction for PCHs, as it includes once annually, rather than once quarterly, submission deadlines and submission of aggregate data as opposed to patient level data for the SCIP measures. We are proposing this update to the SCIP measures submission requirements in anticipation of a possible change to the Hospital IQR Program IT infrastructure to discontinue patient level SCIP data collection. This IT infrastructure change is due to the proposed removal of SCIP measures from the Hospital IQR Program, which we are proposing in section IX.A.2.b. of the preamble of this proposed rule. We believe that providing PCHs with a choice regarding how they submit data on these measures will result in a considerable burden reduction for PCHs because under both options, PCHs will be able to submit the data once annually and in an aggregate form.

We are proposing that PCHs submit an annual data file stratified by four quarters for each of the SCIP measures. We believe that this proposal provides the public with sufficiently reliable quality measure information while reducing PCH burden through providing two data collection options. We will provide detailed technical file format specifications on the public QualityNet Web site (*www.qualitynet.org*) following publication of this year's final rule. The newly proposed submission deadlines for the SCIP measures are outlined in the table below.

These proposed requirements would replace, for the purposes of the PCHQR Program, the update to the SCIP timeline and IT infrastructure that we finalized for the PCHQR Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50851 through 50852).

PROPOSED UPDATE TO THE SIX SCIP MEASURES-REPORTING PERIODS AND SUBMISSION TIMEFRAMES FOR THE FY 2016 PROGRAM AND SUBSEQUENT YEARS

Program year (FY)	Reporting periods (CY)	Data submission deadlines
2016	Q1 2015 discharges (January 1, 2015–March 31, 2015)	July 1, 2015–August 15, 2015.
2017	Q2 2015 discharges (April 1, 2015–June 30, 2015)	July 1, 2016–August 15, 2016.

[84] FY 2013 IPPS/LTCH PPS final rule; 77 FR 53561 (NQF# 0223, 0559, and 0220).

PROPOSED UPDATE TO THE SIX SCIP MEASURES-REPORTING PERIODS AND SUBMISSION TIMEFRAMES FOR THE FY 2016 PROGRAM AND SUBSEQUENT YEARS—Continued

Program year (FY)	Reporting periods (CY)	Data submission deadlines
Subsequent Years	Q3 2015 discharges (July 1, 2015–September 30, 2015) Q4 2015 discharges (October 1, 2015–December 31, 2015) Q1 discharges (January 1–March 31 of each year two years before the program year). Q2 discharges (April 1–June 30 of each year two years before the program year) Q3 discharges (July 1–September 30 of each year two years before the program year) Q4 discharges (October 1–December 31 of each year two years before the program year)	July 1–August 15 of each year before the program year.

We invite public comment on the proposed new reporting mechanism that would apply to the three clinical process/cancer specific treatment measures, five clinical process/oncology care treatment measures, and six SCIP measures.

We are not proposing any changes to the previously finalized procedural requirements, Notice of Participation (NOP) requirements, or Data Accuracy and Completeness Acknowledgement (DACA) requirements. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563 through 53567) for more information on these requirements.

d. Proposed New Sampling Methodology for the Clinical Process/Oncology Care Measures Beginning With the FY 2016 Program

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50842), we adopted a policy under which PCHs could report the five clinical process/oncology care measures finalized for the FY 2016 program and subsequent years using the same sampling methodology that we allow for the reporting of those measures under the PQRS. We are proposing to replace the previously adopted sampling methodology with a sampling methodology similar to the one we have allowed hospitals to use to report the SCIP measures under the Hospital IQR Program. The sampling methodology specified in the PQRS Specifications Manual is specific to the physician office setting. We believe that the methodology we are proposing in this proposed rule is more applicable to PCHs because it was developed for hospital level reporting.

The proposed methodology will allow for different numbers of cases to be reported based on each PCH's cancer patient population size. This is necessary for the PCHQR Program because bed size varies among PCHs from 20 to >250 beds.[85] The proposed sampling methodology for the clinical process/oncology care measures is shown below, and we believe it will decrease the reporting burden on PCHs while producing reliable measure rates.

Average quarterly initial population size "N"	Minimum required sample size "N"
>125	25.
51–125	20 percent of the initial patient population.
10–50	10.
<10	No sampling; 100 percent of the initial patient population.

We are also proposing that PCHs report population and sample size counts (by measure) for Medicare and non-Medicare discharges by quarter for the five clinical process/oncology care measures for the FY 2016 program and subsequent years.

We are proposing these requirements in order to support our effort to align with existing reporting requirements used in other CMS quality reporting programs, such as the Hospital IQR Program, which requires participating hospitals to submit population and sample size counts for certain measures in addition to the all payer data needed to calculate measure rates. We view it as vital for PCHs to accurately determine their aggregate population and appropriate sample size data in order for CMS to assess PCHs' data reporting accuracy and completeness for their total population of cases, including both Medicare and non-Medicare patients.

We welcome public comments on these proposals for the clinical process/oncology care measures for the FY 2016 program and subsequent years.

[85] American Hospital Directory: *http://www.ahd.com/freesearch.php.*

10. Exceptions From Program Requirements

In our experience with other quality reporting and 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). We do not wish to unduly increase their burden during these times. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50848), we finalized our policy that, for the FY 2014 program and subsequent years, PCHs may request and we may grant exceptions (formerly referred to as waivers) with respect to the reporting of required quality data when extraordinary circumstances beyond the control of the PCH warrant. When exceptions are granted, we will notify the respective PCH. We are in the process of revising the Extraordinary Circumstances/Disaster Extension or Waiver Request form (CMS–10432), approved under OMB control number 0938–1171.

We are not proposing any substantive changes to this PCHQR exception process.

C. Long-Term Care Hospital Quality Reporting (LTCHQR) Program

1. Background

In accordance with section 1886(m)(5) of the Act, as added by section 3004(a) of the Affordable Care Act, the Secretary established the Long-Term Care Hospital Quality Reporting (LTCHQR) Program. Under section 1886(m)(5)(A)(i) of the Act, for the rate year 2014 and each subsequent rate year, 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 (which we also refer to as a ''payment determination'') 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. As we discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51744), for the purposes of the LTCH PPS, the term ''rate year'' and the term ''fiscal year'' both refer to the time period beginning October 1 and ending September 30. In order to eliminate any possible confusion, we will use the term ''fiscal year'' rather than ''rate year'' in our discussion of the LTCHQR Program.

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 section 1886(m)(5)(D)(ii) of the Act applies. This contract is currently held by NQF. Additional information regarding NQF and its measure review processes is available at: *http://www.qualityforum.org/Measuring_Performance/Measuring_Performance.aspx.*

While as a general matter the Secretary must select endorsed measures for the LTCHQR Program, 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 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 the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756).

2. General Considerations Used for Selection of Quality Measures for the LTCHQR Program

We seek to promote higher quality and more efficient health care for the beneficiaries we serve. Quality reporting programs, including public reporting of quality information, advance such quality improvement efforts. Quality measurement remains the key tool to the success of these programs. Therefore, the selection of only the highest caliber of measures is a priority for CMS.

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.qualityforum.org/Setting_Priorities/NPP/National_Priorities_Partnership.aspx*), the HHS Strategic Plan (*http://www.hhs.gov/secretary/about/priorities/priorities.html*), the National Quality Strategy (NQS) (*http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm*), and the CMS Quality Strategy (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html*).

We also must consider input from the NQF MAP when selecting measures under the LTCHQR Program. The MAP is composed of multi-stakeholder groups convened by the NQF, our current contractor under section 1890 of the Act. The NQF must convene these stakeholders and provide us with the stakeholders' input on the selection of certain categories of quality and efficiency measures as part of a pre-rulemaking process described in section 1890A of the Act. We, in turn, must take this input into consideration in selecting those categories of measures. The NQF MAP met in December 2013 and January 2014 and provided input to CMS as required under section 1890A(a)(3) of the Act. This input appears in the MAP's January 2014 Pre-Rulemaking Report available for download at: *http://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report__2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx.* Measures proposed for the LTCHQR Program in this proposed rule are measures CMS included under the List of Measures under Consideration (MUC List) for December 1, 2013,[86] a list that the Secretary must make available to the public by December 1 of each year, as part of the pre-rulemaking process, as described in section 1890A(a)(2) of the Act. The measures we are proposing in this rule for the LTCHQR Program are discussed in the MAP Pre-Rulemaking Report (pp. 192–193). The MAP reviewed each measure proposed in this rule. We refer readers to the following sections of the preamble of this proposed rule for more information on the MAP's recommendations: IX.C.7.a.(1), Functional Status Quality Measure: Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function; IX.C.7.a.(2), Functional Status Quality Measure: Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support; and IX.C.7.b., Proposed Quality Measure: National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure.

After due consideration to any measures that may have been endorsed or adopted by a consensus organization, including the NQF, for the LTCH setting, we are proposing measures that are either fully supported by the MAP for the LTCHQR Program, or that we believe most closely align with the national priorities discussed in this section of the proposed rule. In the absence of the MAP's full support, in some cases we are proposing measures for which there is MAP conditional support and that meet the exception criteria in section 1886(m)(5)(D)(ii) of the Act. Further discussion of why each proposed measure is a high priority in the LTCH setting is included below.

3. Policy for Retention of LTCHQR Program Measures Adopted for Previous Payment Determinations

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53615), for the LTCHQR Program, we adopted a policy that once a quality measure is adopted, it will be retained for use in subsequent years, unless otherwise stated. For the purpose of streamlining the rulemaking process, when we initially adopt a measure for the LTCHQR Program for a payment determination, this measure will be automatically adopted for all subsequent years or until we propose to remove, suspend, or replace the measure. For further information on how measures are considered for removal, suspension, or replacement, we refer readers to the FY 2013 IPPS/LTCH PPS final rule.

We are not proposing any changes to this policy for retaining LTCHQR Program measures adopted for previous payment determinations.

4. Policy for Adopting Changes to LTCHQR Program Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616), we adopted our policy that if the NQF updates an endorsed measure that we have adopted for the LTCHQR Program in a manner that we consider to not substantively change the nature of the measure, we will use a subregulatory process to incorporate those updates to the measure specifications that apply to the LTCHQR Program. With respect to

[86] Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=74245.*

what constitutes a substantive versus a nonsubstantive change, we expect to make this determination on a measure-by-measure basis. Examples of such nonsubstantive changes might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and changes to exclusions for a measure. The subregulatory process for nonsubstantive changes will include revision of the LTCHQR Program Manual and posting of updates on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html*. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent, such as changes in acceptable timing of medication, procedure/process, test administration, or expansion of the measure to a new setting.

We are not proposing any changes to this policy for adopting changes to LTCHQR Program measures.

5. Previously Adopted Quality Measures

a. Previously Adopted Quality Measures for the FY 2015 and FY 2016 Payment Determinations and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53636), we retained the application of Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay) (NQF #0678) to the LTCH setting (initially adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51745 through 51750)) for the FY 2015 payment determination and subsequent years, and adopted updated versions of National Health Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) and NHSN Central Line-Associated Blood Stream Infection (CLABSI) Outcome Measure (NQF #0139), for the FY 2014 payment determination and subsequent years. We also adopted two new quality measures for the LTCHQR Program for the FY 2016 payment determination and subsequent years, in addition to the three previously adopted measures (the CAUTI measure, CLABSI measure, and Pressure Ulcer measure): (1) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680); and (2) Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) (77 FR 53624 through 53636).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50861 through 50863), we adopted the NQF-endorsed version of the Pressure Ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678), for the LTCHQR Program for the FY 2015 payment determination and subsequent years.

Set out below are the quality measures, both previously adopted measures retained in the LTCHQR Program and measures adopted in FY 2013 and FY 2014 IPPS/LTCH PPS final rules, for the FY 2015 and FY 2016 payment determinations and subsequent years.

LTCHQR Program Quality Measures Adopted for the FY 2015 and FY 2016 Payment Determinations and Subsequent Years

NQF Measure ID	Measure title	Payment determination
NQF #0138	National Health Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure*.	FY 2015 and Subsequent FYs.
NQF #0139	National Health Safety Network (NHSN) Central Line-Associated Blood Stream Infection (CLABSI) Outcome Measure*.	FY 2015 and Subsequent FYs.
NQF #0678	Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay)*.	FY 2015 and Subsequent FYs.
NQF #0680	Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay)**.	FY 2016 and Subsequent FYs.
NQF #0431	Influenza Vaccination Coverage among Healthcare Personnel**	FY 2016 and Subsequent FYs.

b. Previously Adopted Quality Measures for the FY 2017 and FY 2018 Payment Determinations and Subsequent Years

In the FY 2014 IPPS/LTCH PPS final rule, we adopted three additional measures for the FY 2017 payment determination and subsequent years (78 FR 50863 through 50874) and one additional measure for the FY 2018 payment determination and subsequent years (78 FR 50874 through 50877). These measures are set out in the table below.

LTCHQR Program Quality Measures Previously Adopted for the FY 2017 and FY 2018 Payment Determinations and Subsequent Years

NQF Measure ID	Measure title	Payment determination
NQF #1716	National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	FY 2017 and Subsequent Years.
NQF #1717	National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure.	FY 2017 and Subsequent Years.
NQF Review Pending (NQF #2512).	All-cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals.	FY 2017 and Subsequent Years.
Application of NQF #0674.	Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) ...	FY 2017 and Subsequent Years.

6. Proposed Revisions to Data Collection Timelines and Submission Deadlines for Previously Adopted Quality Measures

We are proposing, for the FY 2016 payment determination and subsequent years, to revise data collection timelines and submission deadlines for a measure that we previously adopted for the LTCHQR Program: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680). We are also reproposing, for the FY 2018 payment determination only, revised data collection timelines and submission deadlines for the Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (Application of NQF #0674) measure. For all subsequent years (FY 2019 and beyond), data collection for this measure would begin on January 1 and continue through December 31.

a. Proposed Revisions to Data Collection Timelines and Submission Deadlines for Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680)

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50858 through 50861), we revised the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure for the FY 2016 payment determination and subsequent years. Specifically, we finalized that for the FY 2016 payment determination, LTCHs must collect data for any patient admitted or discharged during the influenza vaccination season, from October 1, 2014, through April 30, 2015, and submit data for these patients by May 15, 2015.

We are seeking to better align the data collection timelines and submission deadlines of the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure with the data collection timelines and submission deadlines of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure because both measures are reported using the same data collection instrument, the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set. Therefore, for the FY 2016 payment determination and subsequent years, we are proposing to revise the data collection timelines and submission deadlines for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure. Specifically, we are proposing that the first data collection timeline would take place during the fourth quarter of the CY preceding the applicable FY (for example, October 2014 through December 2014 for the FY 2016 payment determination), with data submission by February 15, 2015 and the second data collection timeline would take place during the first quarter of the CY preceding the applicable FY (for example, January 2015 through March 2015 for the FY 2016 payment determination), with data submission by May 15, 2015. The proposed changes are illustrated below for the FY 2016 and FY 2017 payment determinations only, but similar collection timelines and submission deadlines would also apply to subsequent years. By taking into account the influenza vaccination season, these proposed changes would align data collection and submission for this measure (NQF #0680) with the rest of the LTCH CARE Data Set.

PROPOSED DATA COLLECTION TIMELINES AND SUBMISSION DEADLINES FOR LTCHQR PROGRAM QUALITY DATA FOR THE FY 2016 AND FY 2017 PAYMENT DETERMINATIONS: PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE (SHORT-STAY) (NQF #0680)

Data collection timelines	Submission deadlines	Payment determination
October 1, 2014–December 31, 2014	February 15, 2015	FY 2016.
January 1, 2015–March 31, 2015	May 15, 2015.	
October 1, 2015–December 31, 2015	February 15, 2016	FY 2017.
January 1, 2016–March 31, 2016	May 15, 2016.	

We note that these proposed changes would only apply to the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) for the LTCHQR Program, and would not be applicable to any other LTCHQR Program measures, proposed or adopted, unless explicitly stated.

We invite public comments on our proposal to revise the data collection timelines and submission deadlines for this patient influenza vaccination measure (NQF #0680) for the FY 2016 payment determination and subsequent years.

b. Proposed Revisions to Data Collection Timelines and Submission Deadlines for the Application of Percent of Residents Experiencing One or More Falls With Major Injury (Long-Stay) (NQF #0674)

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877), we adopted this measure for the FY 2018 payment determination. We further finalized that LTCHs should begin to collect and submit data on this measure using the LTCH CARE Data Set starting January 1, 2016.

To ensure the successful implementation of new and updated versions of LTCH CARE Data Set, we will be following an implementation cycle beginning April 1, 2016, which will allow for a predictable future release schedule. We believe that adherence to a predictable future release schedule that takes into account both the changes that must be made to the LTCH CARE Data Set, as well as requirements that are managed by LTCHs for such changes, will help ensure successful implementation. Therefore, we will be adhering to a date of April 1 of any given year, when releasing future iterations of the LTCH CARE Data Set. This change will effectively delay the implementation of the January 1, 2016, release by three months, allowing LTCHs additional time to become familiar with and to participate in trainings related to the revised LTCH CARE Data Set, as well as time to incorporate given changes into their existing IT infrastructure.

Therefore, we are proposing that for the FY 2018 payment determination, data collection for this measure would begin on April 1, 2016. For all

subsequent years, data collection for this measure would begin on January 1 and continue through December 31. The proposed changes are illustrated below for the FY 2018 and FY 2019 payment determinations.

PROPOSED DATA COLLECTION TIMELINES AND SUBMISSION DEADLINES FOR LTCHQR PROGRAM QUALITY DATA FOR THE FY 2018 AND FY 2019 PAYMENT DETERMINATIONS: APPLICATION OF PERCENT OF RESIDENTS EXPERIENCING ONE OR MORE FALLS WITH MAJOR INJURY (LONG-STAY) (NQF #0674)

Data collection timelines	Submission deadlines	Payment determination
April 1, 2016–June 30, 2016	August 15, 2016	FY 2018.
July 1, 2016–September 30, 2016	November 15, 2016..	
October 1, 2016–December 31, 2016	February 15, 2017..	
January 1, 2017–March 31, 2017	May 15, 2017	FY 2019
April 1, 2017–June 30, 2017	August 15, 2017.	
July 1, 2017–September 30, 2017	November 15, 2017.	
October 1, 2017–December 31, 2017	February 15, 2018.	

We note that these proposed changes would be applicable only to the Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674) measure, and not applicable to any other LTCHQR Program measures, proposed or adopted, unless specifically proposed for such measures.

We invite public comments on these proposals.

7. Proposed New LTCHQR Program Quality Measures for the FY 2018 Payment Determination and Subsequent Years

We are proposing three new quality measures for the FY 2018 payment determination and subsequent years. Two of these are related to functional status, and one measure is related to ventilator-associated events (VAE). One of the proposed functional status quality measures is Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function. The second proposed functional status quality measure is Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support. The quality measures are described in more detail below.

a. Proposed New LTCHQR Program Functional Status Quality Measures for the FY 2018 Payment Determination and Subsequent Years

Patients in LTCHs present with clinically complex conditions. In addition to having complex medical care needs for an extended period of time, LTCH patients often have functional limitations due to the nature of their conditions, as well as deconditioning due to prolonged bed rest and treatment requirements (for example, ventilator use). These patients are therefore at high risk for functional decline during the LTCH stay that is both condition-related and iatrogenic.

The National Committee on Vital and Health Statistics, Subcommittee on Health,[87] noted: ''[i]nformation on functional status is becoming increasingly essential for fostering healthy people and a healthy population. Achieving optimal health and well-being for Americans requires an understanding across the life span of the effects of people's health conditions on their ability to do basic activities and participate in life situations in other words, their functional status.''

The functional assessment items included in the two functional status quality measures were originally developed and tested as part of the Post-Acute Care Payment Reform Demonstration version of the CARE Item Set, which was designed to standardize assessment of patients' status across acute and post-acute settings, including LTCHs, IRFs, SNFs, and HHAs. The functional status items on the CARE Item Set are daily activities that clinicians typically assess at the time of admission and/or discharge in order to determine patients' needs, evaluate patient progress and prepare patients and families for a transition to home or to another setting.

The development of the CARE Item Set and a description and rationale for each item is described in a report entitled ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set: Volume 1 of 3.'' [88] Reliability and validity testing were conducted as part of CMS' Post-Acute Care Payment Reform Demonstration, and we concluded that the functional status items have acceptable reliability and validity. A description of the testing methodology and results are available in several reports, including the report entitled ''The Development and Testing of the Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report On Reliability Testing: Volume 2 of 3'' [89] and the report entitled ''The Development and Testing of The Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report on Care Item Set and Current Assessment Comparisons: Volume 3 of 3.'' [90] The reports are available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html*.

(1) Proposed Functional Status Quality Measure: Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function

The first functional status quality measure we are proposing for the FY 2018 payment determination and subsequent years is a process quality measure entitled Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function. This quality measure reports the percent of LTCH patients with both an admission and a discharge functional assessment and a care plan that addresses function.

This process measure requires the collection of admission and discharge functional status data by trained clinicians using standardized clinical assessment items, or data elements, that assess specific functional activities (that

[87] Subcommittee on Health National Committee on Vital and Health Statistics, ''Classifying and Reporting Functional Status'' (2001).

[88] Barbara Gage et al., ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set'' (RTI International, 2012).

[89] Ibid.

[90] Ibid.

is, self-care, mobility, cognition, communication, and bladder continence). The self-care and mobility function items are coded using a 6-level rating scale that indicates the patient's level of independence with the activity; higher scores indicate more independence. The codes for rating the cognition, communication and bladder items range from 2 to 7 levels. For this quality measure, inclusion of function in the patient's care plan is determined based on whether a functional goal is recorded at admission for at least one of the standardized self-care or mobility function items using the 6-level rating scale.

An increasing body of reported evidence has supported the safety and feasibility of early mobilization and rehabilitation of critically ill but stable patients, with minimal adverse events and risk to the patient.[91] [92] [93] [94] [95] [96] Early mobility and rehabilitation in these settings have been associated with improved patient outcomes. Therefore, this quality measure addresses the importance of: (1) Conducting a functional assessment at the time of admission addressing self-care, mobility, cognition, communication, and bladder continence; (2) incorporating the functional assessment findings made at the time of admission into the patients' care plan and setting at least one discharge self-care or mobility functional status goal; and (3) conducting a functional assessment at the time of discharge addressing self-care, mobility, cognition, communication, and bladder continence.

Functional limitations following critical illness are becoming increasingly prevalent as a result of improving critical care medicine and survival rates.[97] Short-term and long-term adverse consequences among critically ill and chronically, critically ill patients in LTCH and Intensive Care Unit (ICU) settings include severe weakness,[98] [99] [100] [101] muscle atrophy,[102] connective-tissue shortening,[103] loss of bone mass,[104] increased risk for blood clots,[105] increased risk for pressure ulcers,[106] deconditioning,[107] [108] deficits in self-care and ambulation,[109] and functional impairment,[110] fatigue,[111] as well as cognitive impairment, including profound and persistent deficits in memory, attention/concentration, and executive function,[112] [113] [114] and the inability to return to work one year after hospital discharge.[115] [116] Cognitive impairment in survivors of critical illness has been associated with anxiety and depression, inability to return to work, and inability of older persons to return home.[117] To mitigate these adverse consequences, traditional practices of bed rest and immobility have been challenged in recent years, and early mobility and rehabilitation have been increasingly recognized as important to improve patients' long-term functional outcomes,[118] [119] [120] with recovery of function being described as both desirable and possible.[121] The lack of early mobility initiation in ICU settings has also been described as a strong predictor of patient outcomes.[122]

The clinical practice guideline *Rehabilitation after Critical Illness* [123] from the National Institute for Health and Clinical Excellence (NICE) recommends performing clinical assessment to determine the patient's risk of developing physical and nonphysical morbidity during the critical care stay as early as clinically possible, identifying current rehabilitation needs for patients at risk of morbidity, establishing short-term and medium-term rehabilitation goals based on the clinical assessment, starting an individualized structured rehabilitation program as early as possible, and performing clinical reassessment before discharge.

The importance of standardized functional assessment in LTCH settings is also supported by the high prevalence of therapy services provided in this setting, as well as the need for care coordination for patients returning home and receiving follow-up care in the community and patients receiving additional institutional healthcare services after discharge from an LTCH. A study [124] of 1,419 ventilator-dependent patients from 23 LTCHs reported that physical, occupational, and speech therapy were the most commonly provided services among a comprehensive list of 34 procedures, services, and treatments provided during the LTCH stay. The high frequency of physical (84.8 percent), occupational (81.5 percent), and speech (79.7 percent) therapy reflects use of the rehabilitative model of care adopted by many post-ICU ventilator weaning programs, which is important in restoration of function. This high utilization of therapy services supports the need for standardized functional

[91] J. Adler and D. Malone, ''Early mobilization in the intensive care unit: a systematic review,'' *Cardiopulm Phys Ther J* 23, no. 1 (2012).

[92] J.P. Kress, ''Clinical trials of early mobilization of critically ill patients,'' *Crit Care Med* 37, no. 10 Suppl (2009).

[93] W.D. Schweickert and J.P. Kress, ''Implementing early mobilization interventions in mechanically ventilated patients in the ICU,'' *Chest* 140, no. 6 (2011).

[94] W.D. Schweickert et al., ''Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomised controlled trial,'' *Lancet* 373, no. 9678 (2009).

[95] J.M. Zanni et al., ''Rehabilitation therapy and outcomes in acute respiratory failure: an observational pilot project,'' *J Crit Care* 25, no. 2 (2010).

[96] A. Drolet et al., ''Move to improve: the feasibility of using an early mobility protocol to increase ambulation in the intensive and intermediate care settings,'' *Phys Ther* 93, no. 2 (2013).

[97] Adler and Malone, ''Early mobilization in the intensive care unit: a systematic review.''

[98] Ibid.

[99] S.L. Dang, ''ABCDEs of ICU: Early mobility,'' *Crit Care Nurs Q* 36, no. 2 (2013).

[100] E.H. Skinner et al., ''Development of a physical function outcome measure (PFIT) and a pilot exercise training protocol for use in intensive care,'' *Crit Care Resusc* 11, no. 2 (2009).

[101] Centre for Clinical Practice at NICE (UK), ''Rehabilitation after critical illness [Internet].'' National Institute for Health and Clinical Excellence (NICE), *http://www.nice.org.uk/nicemedia/live/12137/43564/43564.pdf.*

[102] Zanni et al., ''Rehabilitation therapy and outcomes in acute respiratory failure: an observational pilot project.''

[103] Ibid.

[104] Dang, ''ABCDEs of ICU: Early mobility.''

[105] Ibid.

[106] Ibid.

[107] Schweickert and Kress, ''Implementing early mobilization interventions in mechanically ventilated patients in the ICU.''

[108] Zanni et al., ''Rehabilitation therapy and outcomes in acute respiratory failure: an observational pilot project.''

[109] Adler and Malone, ''Early mobilization in the intensive care unit: a systematic review.''

[110] Skinner et al., ''Development of a physical function outcome measure (PFIT) and a pilot exercise training protocol for use in intensive care.''

[111] Centre for Clinical Practice at NICE (UK), ''Rehabilitation after critical illness [Internet].''

[112] Ibid.

[113] M.E. Wilcox et al., ''Cognitive dysfunction in ICU patients: risk factors, predictors, and rehabilitation interventions,'' *Crit Care Med* 41, no. 9 Suppl 1 (2013).

[114] N.E. Brummel et al., ''A combined early cognitive and physical rehabilitation program for people who are critically ill: the activity and cognitive therapy in the intensive care unit (ACT–ICU) trial,'' *Phys Ther* 92, no. 12 (2012).

[115] Dang, ''ABCDEs of ICU: Early mobility.''

[116] H.J. Engel et al., ''ICU early mobilization: from recommendation to implementation at three medical centers,'' *Crit Care Med* 41, no. 9 Suppl 1 (2013).

[117] Wilcox et al., ''Cognitive dysfunction in ICU patients: risk factors, predictors, and rehabilitation interventions.''

[118] Drolet et al., ''Move to improve: the feasibility of using an early mobility protocol to increase ambulation in the intensive and intermediate care settings.''

[119] Dang, ''ABCDEs of ICU: Early mobility.''

[120] Z. Li et al., ''Active mobilization for mechanically ventilated patients: a systematic review,'' *Arch Phys Med Rehabil* 94, no. 3 (2013).

[121] C.L. Rochester, ''Rehabilitation in the intensive care unit,'' *Semin Respir Crit Care Med* 30, no. 6 (2009).

[122] Dang, ''ABCDEs of ICU: Early mobility.''

[123] Centre for Clinical Practice at NICE (UK), ''Rehabilitation after critical illness [Internet].''

[124] D.J. Scheinhorn et al., ''Post-ICU mechanical ventilation at 23 long-term care hospitals: a multicenter outcomes study,'' *Chest* 131, no. 1 (2007).

assessment at admission to document functional status, identify the need for therapy, set functional status goals and assist with discharge planning and care coordination.

Whether an LTCH patient is discharged home or to another care setting for continuing health care, functional status is an important aspect of a person's health status to document at the time of transition. The study [125] also reported that 28.8 percent of patients were discharged directly home or to assisted living, further supporting the importance of functional assessment and early rehabilitation to facilitate discharge planning and home discharge, when possible.

Reported benefits of early mobility and rehabilitation include: (1) Improved strength [126 127 128] and functional status; [129 130 131] (2) earlier achievement of mobilization milestones, such as out-of-bed mobilization; [132 133] (3) improvement in mobility and self-care function scores from admission to discharge; [134 135] (4) greater incidence of return to functional baseline in mobility and self-care, greater unassisted walking and walking distances, and improved self-reported physical function scores at hospital discharge compared with persons not participating in early mobility and rehabilitation; [136] (5) enhanced recovery of functional exercise capacity; [137] (6) improved self-perceived functional status; [138] and (7) reduced physiological and cognitive complications [139] and improved cognitive function.[140] Early mobility and rehabilitation have also been associated with reduced ICU and hospital length of stay; [141 142 143 144 145 146] reduced incidence of delirium and improved patient awareness; [147 148] increased ventilator-free days and improved weaning outcomes; [149 150 151] greater incidence of discharge home directly after hospitalization compared with patients not receiving early mobilization; [152 153] and reduced hospital readmission or death in the year following hospitalization.[154 155]

Short-term and long-term cognitive impairment are very frequent complications of critical illness, and negatively influence survivors' abilities to function independently.[156 157 158] Delirium during hospitalization is highly prevalent in critically ill patients and has been associated with longer lengths of stay, increased duration of mechanical ventilation, and higher risk of death.[159] A longer duration of delirium has been associated with worse short- and long-term cognition and executive function.[160 161] Given these adverse consequences, the importance of early assessment of cognitive function, including possible delirium, and early initiation of cognitive rehabilitation in critical care settings, is being increasingly recognized.[162 163] Also, given the positive effects of physical exercise on cognitive function in other populations, the potential positive influence of exercise on cognitive function in the critically ill population is being examined by researchers.

A technical expert panel convened by our measure development contractor provided input on the technical specifications of this quality measure, including the items included in the quality measure, inclusion and exclusion criteria and risk adjustors. We also solicited public comment on the draft specifications of this quality measure on the CMS Quality Measures Public Comment Page (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html*) between February 21 and March 14 2014, and received 22 responses from stakeholders with comments and suggestions. Additional information regarding these comments may be found on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/*.

Based on the evidence discussed above, we are proposing to adopt for the LTCHQR Program for the FY 2018 payment determination and subsequent years the quality measure entitled Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function. This quality measure was developed by CMS, and we plan to submit the quality measure to the NQF for review. The MAP met in December 2013 and January 2014, and provided input to CMS as required under section 1890A(a)(3) of the Act. In its January 2014 Pre-Rulemaking Report, the MAP

[125] Ibid.

[126] Schweickert and Kress, ''Implementing early mobilization interventions in mechanically ventilated patients in the ICU.''

[127] Dang, ''ABCDEs of ICU: Early mobility.''

[128] Li et al., ''Active mobilization for mechanically ventilated patients: a systematic review.''

[129] Adler and Malone, ''Early mobilization in the intensive care unit: a systematic review.''

[130] Schweickert et al., ''Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomised controlled trial.''

[131] Li et al., ''Active mobilization for mechanically ventilated patients: a systematic review.''

[132] Adler and Malone, ''Early mobilization in the intensive care unit: a systematic review.''

[133] P.E. Morris, ''Moving our critically ill patients: Mobility barriers and benefits,'' *Crit Care Clin* 23, no. 1 (2007).

[134] Li et al., ''Active mobilization for mechanically ventilated patients: a systematic review.''

[135] Scheinhorn et al., ''Post-ICU mechanical ventilation at 23 long-term care hospitals: a multicenter outcomes study.''

[136] Adler and Malone, ''Early mobilization in the intensive care unit: a systematic review.''

[137] Dang, ''ABCDEs of ICU: Early mobility.''

[138] Ibid.

[139] Ibid.

[140] Li et al., ''Active mobilization for mechanically ventilated patients: a systematic review.''

[141] Adler and Malone, ''Early mobilization in the intensive care unit: a systematic review.''

[142] Kress, ''Clinical trials of early mobilization of critically ill patients.''

[143] Schweickert et al., ''Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomised controlled trial.''

[144] Dang, ''ABCDEs of ICU: Early mobility.''

[145] Engel et al., ''ICU early mobilization: From recommendation to implementation at three medical centers.''

[146] Li et al., ''Active mobilization for mechanically ventilated patients: a systematic review.''

[147] Adler and Malone, ''Early mobilization in the intensive care unit: a systematic review.''

[148] Schweickert et al., ''Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomised controlled trial.''

[149] Adler and Malone, ''Early mobilization in the intensive care unit: a systematic review.''

[150] Dang, ''ABCDEs of ICU: Early mobility.''

[151] Li et al., ''Active mobilization for mechanically ventilated patients: a systematic review.''

[152] Schweickert et al., ''Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomised controlled trial.''

[153] Engel et al., ''ICU early mobilization: From recommendation to implementation at three medical centers.''

[154] Adler and Malone, ''Early mobilization in the intensive care unit: a systematic review.''

[155] Li et al., ''Active mobilization for mechanically ventilated patients: a systematic review.''

[156] Wilcox et al., ''Cognitive dysfunction in ICU patients: Risk factors, predictors, and rehabilitation interventions.''

[157] Brummel et al., ''A combined early cognitive and physical rehabilitation program for people who are critically ill: The activity and cognitive therapy in the intensive care unit (ACT–ICU) trial.''

[158] P.P. Pandharipande, T.D. Girard, and E.W. Ely, ''Long-term cognitive impairment after critical illness,'' *N Engl J Med* 370, no. 2 (2014).

[159] Wilcox et al., ''Cognitive dysfunction in ICU patients: Risk factors, predictors, and rehabilitation interventions.''

[160] Ibid.

[161] Pandharipande, Girard, and Ely, ''Long-term cognitive impairment after critical illness.''

[162] Brummel et al., ''A combined early cognitive and physical rehabilitation program for people who are critically ill: The activity and cognitive therapy in the intensive care unit (ACT–ICU) trial.''

[163] R.S. Miller et al., ''Outcomes of trauma patients who survive prolonged lengths of stay in the intensive care unit,'' *J Trauma* 48, no. 2 (2000).

conditionally supported this proposed measure and stated that the measure concept is promising, but requires modification or further development, and that functional status is a critical area of measurement. Since the time of the MAP meeting, we have continued further development of the measure with input from technical experts, including empirical data analysis. Subsequently, we released draft specifications for the function quality measures, and requested public comment between February 21 and March 14, 2014. We received 22 responses from stakeholders with comments and suggestions during the public comment period, and have updated the quality measures specifications based on these comments and suggestions. The updated specifications are available for review at the LTCHQR Program Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html?redirect=/LTCH-Quality-Reporting/*. We refer readers to section IX.C.2. of the preamble of this proposed rule for more information on the MAP.

In 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 the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed quality measures focused on assessment of function for patients in the LTCH setting. We are unaware of any other quality measures for functional assessment that have been endorsed or adopted by another consensus organization for the LTCH setting. Therefore, we are proposing to adopt this functional assessment measure for use in the LTCHQR Program for the FY 2018 payment determination and subsequent years under the Secretary's authority to select non-NQF-endorsed measures.

Additional information regarding the quality measure may be found on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/*.

We are proposing that data for the proposed quality measure be collected through the LTCH CARE Data Set, with the submission through the Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system. For more information on LTCHQR Program reporting using the QIES ASAP system, we refer readers to our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html*. We intend to revise the LTCH CARE Data Set to include new items that assess functional status, should this proposed measure be adopted. These items, which assess specific functional activities (that is, self-care, mobility, cognition, communication, and bladder continence), would be based on functional items included in the Post-Acute Care Payment Reform Demonstration version of the CARE Item Set. The items have been carefully developed and tested for reliability and validity.

We invite public comments on our proposal to adopt the quality measure entitled Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function for the LTCHQR Program, with data collection starting on April 1, 2016, for the FY 2018 payment determination and subsequent years. We refer readers to section IX.C.9.c. of the preamble of this proposed rule for more information on the proposed data collection and submission timeline for this proposed quality measure.

(2) Proposed Functional Status Quality Measure: Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support

Section 1206(c) of Division B of Public Law 113–67, the Pathway to SGR Reform Act of 2013, amended section 1886(m)(5)(D) of the Act to add a new clause (iv) requiring the Secretary to establish by no later than October 1, 2015, ''a functional status quality measure for change in mobility among inpatients requiring ventilator support.'' Accordingly, the second functional status quality measure that we are proposing is an outcome quality measure entitled the Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support. This measure estimates the risk-adjusted change in mobility score between the time of admission and the time of discharge among LTCH patients requiring ventilator support at the time of admission. As noted above, LTCH patients often have functional limitations and receive rehabilitation therapy services so that they can become more independent when performing functional activities. Functional improvement is particularly relevant for patients who require ventilator support because these patients have traditionally had limited mobility due to cardiovascular and pulmonary instability, delirium, sedation, lack of rehabilitation therapy staff, and lack of physician referral.[164]

Several studies have examined functional improvement among patients in the long-term care hospitals and setting. In a sample of 101 patients in LTCHs (three-quarters were ventilator-dependent), median functional status scores using the Functional Status Score (FSS)–ICU (rolling, supine-to-sit transfers, unsupported sitting, sit-to-stand transfers, and ambulation) improved significantly from admission to discharge, with significant change in all five functional items.[165] A separate study of 103 patients with respiratory failure examined functional improvement and found that by the end of the respiratory ICU stay, 69.4 percent of survivors ambulated more than 100 feet, 8.2 percent ambulated less than 100 feet, 15.3 percent could sit in a chair, 4.7 percent could sit on the edge of the bed, and 2.4 percent did not accomplish any of these activities.[166]

The importance of monitoring improvement in mobility skills among LTCH patients who require ventilator support at the time of admission is also supported by the high prevalence of therapy service provision as part of the treatment plan and the percent of patients discharged home after an LTCH stay. In a study of 1,419 ventilator-dependent patients from 23 LTCHs with weaning programs,[167] physical therapy, occupational therapy, and speech therapy were the three most commonly provided services among 34 procedures, services, and treatments provided during the LTCH admission. The very high frequency of physical (84.8 percent), occupational (81.5 percent), and speech (79.7 percent) therapy reflects use of the rehabilitative model of care adopted by many post-ICU

[164] Zanni et al., ''Rehabilitation therapy and outcomes in acute respiratory failure: An observational pilot project.''

[165] A. Thrush, M. Rozek, and J.L. Dekerlegand, ''The clinical utility of the functional status score for the intensive care unit (FSS–ICU) at a long-term acute care hospital: A prospective cohort study,'' *Phys Ther* 92, no. 12 (2012).

[166] P. Bailey et al., ''Early activity is feasible and safe in respiratory failure patients,'' *Crit Care Med* 35, no. 1 (2007).

[167] Scheinhorn et al., ''Post-ICU mechanical ventilation at 23 long-term care hospitals: A multicenter outcomes study.''

weaning programs, which is important in the restoration of function. Improvement in functional status, including mobility and self-care was noted from admission to discharge. Nearly 30 percent of all patients discharged alive returned directly home or to assisted living.[168]

A technical expert panel convened by our measure development contractor provided input on the technical specifications of this quality measure. We also solicited public comment on the draft specifications of this quality measure, on the CMS Quality Measures Public Comment Page (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html*) between February 21 and March 14, 2014 and received 22 responses from stakeholder with comments and suggestions.

Additional information regard the quality measure may be found on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/*.

We are proposing that data for the proposed quality measure be collected through the LTCH CARE Data Set, with the submission through the QIES ASAP system. For more information on LTCHQR Program reporting using the QIES ASAP system, we refer readers to our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html*. We intend to revise the LTCH CARE Data Set to include new items that assess the functional status and the risk adjustors, should this proposed application of the measure be adopted. These items, which assess specific functional activities (that is, self-care, mobility, cognition, communication, and bladder continence), would be based on functional status items included in the Post-Acute Care Payment Reform demonstration version of the CARE Item Set. The items have been carefully developed and tested for reliability and validity.

Based on the evidence discussed above, we are proposing to adopt for the LTCHQR Program for the FY 2018 payment determination and subsequent years the quality measure entitled Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support. This quality measure is developed by CMS, and we plan to submit the quality measure to the NQF for review. The MAP met in December 2013 and January 2014, and the NQF provided the MAP's input to CMS as required under section 1890A(a)(3) of the Act. In its January 2014 Pre-Rulemaking Report, the MAP conditionally supported this proposed measure and stated that the measure concept is promising, but requires modification or further development, and that functional status is a critical area of measurement. Since the time of the MAP meeting, we have continued further development of the measure with input from technical experts, including empirical data analysis. Subsequently, we have released draft specifications for the function quality measures, and requested public comment between February 21 and March 14, 2014. We received 22 responses from stakeholders with comments and suggestions during the public comment period, and have updated the quality measures specifications based on these comments and suggestions. The updated specifications are available for review at the LTCHQR Program Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html?redirect=/LTCH-Quality-Reporting/*. We refer readers to section IX.C.2. of the preamble of this proposed rule for more information on the MAP.

In 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 the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed quality measures focused on improvement of function among patients in the LTCH setting. We are unaware of any other quality measures for functional improvement that have been endorsed or adopted by another consensus organization for the LTCH setting. Moreover, as discussed above, the Secretary is now required to establish such a measure by October 1, 2015. Therefore, we are proposing to adopt this functional improvement measure for use in the LTCHQR Program for the FY 2018 payment determination and subsequent years under the Secretary's authority to select non-NQF-endorsed measures.

We invite public comments on our proposal to adopt the quality measure entitled Functional Outcome Measure: Change in Mobility among Patients Requiring Ventilator Support for the LTCHQR Program, with data collection starting on April 1, 2016, for the FY 2018 payment determination and subsequent years. We refer readers to section IX.C.9.c. of the preamble of this proposed rule for more information on the proposed data collection and submission timeline for this proposed quality measure.

b. Proposed Quality Measure: National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure

The third quality measure that we are proposing is the CDC-developed National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) outcome measure. The term ''Ventilator-Associated Events'' incorporates a range of ventilator-associated events, including ventilator-associated pneumonia (VAP), pulmonary edema, acute respiratory distress syndrome, sepsis, and atelectasis.[169] The NHSN VAE Outcome Measure provides increased measure sensitivity, more objective definitions for ventilator-associated conditions, and the potential for automated outcome detection.[170] The NHSN VAE Outcome Measure is designed for use across multiple inpatient care settings, including LTCHs. The measure specifications were created and tested in the acute care setting. During CY 2013, 105 LTCHs submitted VAE data to CDC's NHSN.[171]

According to the CDC, ''more than 300,000 patients receive mechanical ventilation in the United States each year.'' [172] These patients are at increased risk for infections, such as pneumonia and sepsis, as well as other serious complications including pulmonary edema, pulmonary embolism, and death.[173] [174] [175] These complications can

[168] Ibid.

[169] Klompas, M., Y. Khan, et al. (2011). ''Multicenter Evaluation of a Novel Surveillance Paradigm for Complications of Mechanical Ventilation.'' *PLoS ONE* 6(3): e18062.

[170] Magill, S. S., M. Klompas, et al. (2013). ''Developing a new, national approach to surveillance for ventilator-associated events*.'' *Crit Care Med* 41(11): 2467–2475.

[171] Data from CMS–CDC correspondence on February 10, 2014.

[172] Centers for Disease Control and Prevention (CDC). Ventilator-Associated Event (VAE). January 2014. *http://www.cdc.gov/nhsn/PDFs/pscManual/10-VAE_FINAL.pdf*.

[173] Esteban, A., A. Anzueto, et al. (2002). ''Characteristics and outcomes in adult patients

Continued

lead to longer stays in the ICU and hospital, increased health care costs and increased risk of disability (or death).[176] The estimated mortality rate in patients aged 85 years and older with acute lung injury on mechanical ventilation is 60 percent.[177]

Ventilator-Associated Events represent a high-priority complication in the LTCH setting, given the older, medically complex population in LTCHs and the high prevalence of mechanical ventilation in this setting. A MedPAC analysis of MedPAR data found that 16 percent of LTCH patients used at least one ventilator-related service in 2012.[178] In FY 2012, MS–LTC–DRG 207, a diagnosis-related group that refers to respiratory diagnosis with ventilator support for 96 or more hours, represented the most frequently occurring diagnosis among LTCH patients, at 11.3 percent of all LTCH discharges,[179] and MS–LTC–DRG–4, a diagnosis-related group that refers to tracheostomy with ventilator support for 96 or more hours or primary diagnosis except face, mouth, and neck without major OR procedure, represented an additional 1.3 percent of all LTCH discharges. Together, the two diagnosis-related groups account for a total of nearly 18,000 discharges. Furthermore, the number of ventilated patients in LTCHs is increasing—the number of discharged patients with respiratory diagnosis with ventilator support for 96 or more hours increased 7.4 percent between 2008 and 2011.[180]

Although there are no nationwide or LTCH-specific estimates of the prevalence of ventilator-associated conditions (VACs) and infection-related ventilator-associated complications (IVACs), a recent study of mechanically ventilated patients in ICUs found that approximately 10 percent developed a VAC and 5 percent developed an IVAC.[181] Adherence to clinical practice guidelines for the prevention of VAP has been associated with decreased VAC rates in ICUs.[182] Because VAP, one type of VAC, is considered preventable, surveillance and measurement of infection rates is important to improving quality of care and patient safety.

The importance of the NHSN VAE Outcome Measure in LTCHs was underscored by the MAP, which stated in its January 2014 Pre-Rulemaking Report that the measure addresses a National Quality Strategy aim or priority that is currently not adequately addressed. The MAP supported the addition of this measure addressing VAEs in the LTCH setting and stated that ''although this measure is not NQF-endorsed, it provides useful information for healthcare facilities to help them monitor ventilator use and identify improvements for preventing complications.'' [183]

The exception authority found in section 1886(m)(5)(D)(ii) of the Act provides that ''[i]n the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.'' We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed measures for VAEs in the LTCH setting (or a related setting). We are unaware of any other measures for VAEs that have been endorsed or adopted by another consensus organization for the LTCH setting (or a related inpatient setting). Therefore, we are proposing to adopt the NHSN VAE Outcome Measure for use in the LTCHQR Program for the FY 2018 payment determination and subsequent years under the Secretary's authority to select non-NQF-endorsed measures.

We are proposing to use the CDC's NHSN reporting and submission infrastructure for reporting of the proposed NHSN VAE Outcome Measure. Details related to the procedures for using CDC's NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the proposed NHSN VAE Outcome Measure can be found at: *http://www.cdc.gov/nhsn/PDFs/pscManual/10-VAE_FINAL.pdf*.

CDC's NHSN is the data collection and submission framework currently used for reporting the CAUTI (NQF #0138) and CLABSI (NQF #0139) measures for the LTCHQR Program. Further, CDC's NHSN is the data collection and submission framework adopted for data collection and reporting for the Influenza Vaccination Coverage among Healthcare Personnel measure (NQF #0431) starting on October 1, 2014, and for the NHSN Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) and NHSN Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) starting on January 1, 2015. By building on the CDC's 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. We refer readers to section IX.C.9.d. of the preamble of this proposed rule for more information on the proposed data collection and submission timeline for this proposed quality measure.

We invite public comments on our proposal to adopt the NHSN VAE Outcome Measure for the LTCHQR Program, with data collection beginning on January 1, 2016, for the FY 2018 payment determination and subsequent years. We also invite public comments on our proposal to use the CDC's NHSN for data collection and submission for this measure.

8. LTCHQR Program Quality Measures and Concepts Under Consideration for Future Years

We are considering whether to propose one or more of the quality measures and quality measure topics listed in the table below for future years in the LTCHQR Program. We invite public comments on these measures and measure topics. We specifically invite public comments regarding the clinical importance of these measures and measure topics in LTCH setting, feasibility of data collection and implementation, current use of these measures and measure topics in the LTCH setting, and the usability of data for these measures and measure topics

receiving mechanical ventilation: A 28-day international study.'' *JAMA* 287(3): 345–355.

[174] Klompas, M., Y. Khan, et al. (2011). ''Multicenter Evaluation of a Novel Surveillance Paradigm for Complications of Mechanical Ventilation.'' *PLoS ONE* 6(3): e18062.

[175] Rubenfeld, G.D., E. Caldwell, et al. (2005). ''Incidence and outcomes of acute lung injury.'' *N Engl J Med* 353(16): 1685–1693.

[176] Centers for Disease Control and Prevention (CDC). Ventilator-Associated Event (VAE). January 2014. *http://www.cdc.gov/nhsn/PDFs/pscManual/10-VAE_FINAL.pdf*.

[177] Rubenfeld G.D, Caldwell E, Peabody E, et al. Incidence and outcomes of acute lung injury. N Engl J Med 2005: 353:1685–93.

[178] MedPAC ''Report to Congress: Medicare Payment Policy'' Chapter 11 ''Long-term care hospital services.'' March 2014. *http://www.medpac.gov/chapters/Mar14_Ch11.pdf*.

[179] Ibid.

[180] Ibid.

[181] Muscedere, J., T. Sinuff, et al. (2013). ''The clinical impact and preventability of ventilator-associated conditions in critically ill patients who are mechanically ventilated.'' *Chest* 144(5): 1453–1460.

[182] Ibid.

[183] National Quality Forum. Measure Applications Partnership Pre-Rulemaking Report: Public Comment Draft: January 2014. Available: *http://www.qualityforum.org/map/*.

to inform future quality improvements in the LTCH setting.

FUTURE MEASURES AND MEASURE TOPICS UNDER CONSIDERATION FOR PROPOSAL FOR THE LTCH QUALITY REPORTING PROGRAM

National Quality Strategy Priority: Patient Safety:
- Measures addressing Ventilator Bundle.
- Measures addressing avoidable injuries secondary to polypharmacy.
- Application of Hospital-Based Inpatient Psychiatric Services (HBIPS)-2 Hours of Physical Restraint Use (NQF #0640).
- Application of Percent of Residents Who Were Physically Restrained (Long Stay) (NQF #0687).

National Quality Strategy Priority: Effective Clinical Processes:
- Severe Sepsis and Septic Shock: Management Bundle.
- Venous Thromboembolism Prophylaxis (NQF #0371).
- Ventilator Weaning Rate.
- Pain Management.

National Quality Strategy Priority: Patient- and Caregiver-Centered Care:
- Depression Assessment and Management.
- Application of Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (NQF #0166).
- Measures addressing patients' experience of care.
- Measures addressing pain control—patients' preference.

National Quality Strategy Priority: Communication and Coordination of Care:
- Application of Medication Reconciliation (NQF #0097).
- Application of Medication Reconciliation Post-Discharge (NQF #0554).
- Reconciled Medication List Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0646).
- Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0647).
- Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care) (NQF #0648).
- Measures addressing care transitions.

9. Form, Manner, and Timing of Quality Data Submission for the FY 2016 Payment Determination and Subsequent Years

a. Background

Section 1886(m)(5)(C) of the Act requires that, for the FY 2014 payment determination and subsequent years, each LTCH submit to the Secretary data on quality measures specified by the Secretary and that such data shall be submitted in a form and manner, and at a time, specified by the Secretary. As required by section 1886(m)(5)(A)(i) of the Act, for any LTCH that does not submit data in accordance with section 1886(m)(5)(C) of the Act with respect to a given rate year, any annual update to the standard Federal rate for discharges for the hospital during the rate year must be reduced by two percentage points.

b. Finalized Timeline for Data Submission Under the LTCHQR Program for the FY 2016 and FY 2017 Payment Determinations (Except NQF #0680 and NQF #0431)

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50857 through 50861 and 50878 through 50881), we finalized the data submission timelines and submission deadlines for measures for the FY 2016 and FY 2017 payment determinations. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for a more detailed discussion of these timelines and deadlines. Specifically, we refer readers to the table at 78 FR 50878 of the FY 2014 IPPS/LTCH PPS final rule for the data collection timelines and submission deadlines for the FY 2016 payment determination and the tables at 78 FR 50881 of that final rule for the data collection timelines and submission deadlines for the FY 2017 payment determination.

c. Proposed Revision to the Previously Adopted Data Collection Timelines and Submission Deadlines for Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680) for the FY 2016 Payment Determination and Subsequent Years

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50858 through 50861), we revised the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure for the FY 2016 payment determination and subsequent years. In that rule (78 FR 50861, 50880 through 50882), we also revised the data collection timelines and submission deadlines for the FY 2016 through FY 2018 payment determinations for this measure.

For the reasons discussed in section IX.C.6.a. of the preamble of this proposed rule, we are proposing to change to the data collection timeframes and submission deadlines for the FY 2016 payment determination and subsequent years. Specifically, as discussed in section IX.C.6.a. of the preamble of this proposed rule, for the FY 2016 payment determination, we are proposing submission deadlines of February 15, 2015, and May 15, 2015, respectively, for this measure for data collection periods October 1–December 31, 2014, and January 1–March 31, 2015, respectively, instead of the previously finalized submission deadline of May 15, 2015, for the data collection period of October 1, 2014–April 30, 2015. The proposed changes applicable to this measure (NQF #680) are illustrated below for the FY 2016 payment determination. Please refer to section IX.C.6 of the preamble of this proposed rule for further information regarding this proposed revision.

PROPOSED DATA COLLECTION TIMELINES AND SUBMISSION DEADLINES OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2016 PAYMENT DETERMINATION FOR PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE (SHORT-STAY) (NQF #0680)

Data collection timelines (CY)	Final submission deadlines for the LTCHQR Program FY 2016 payment determination
Q4 (October–December 2014)	February 15, 2015.
Q1 (January–March 2015)	May 15, 2015.

Further, as discussed in section IX.C.6.a. of the preamble of this proposed rule, we are proposing similar deadlines for the FY 2017 payment determination and subsequent years for the LTCHQR Program. The proposed changes applicable to this measure (NQF #680) are illustrated below.

PROPOSED DATA COLLECTION TIMELINES AND SUBMISSION DEADLINES OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS FOR PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE (SHORT-STAY) (NQF #0680)

Data collection timelines (CY)	Final submission deadlines for the LTCHQR Program payment determination (FY)
Q4 of the CY two years before the payment determination year (for example, October–December 2015 for the FY 2017 payment determination).	February 15, of the FY preceding the payment determination year (for example, February 15, 2016 for the FY 2017 payment determination).
Q1 of the CY one year before the payment determination year (for example, January–March 2016 for the FY 2017 payment determination).	May 15 of the FY preceding the payment determination year (for example, May 15, 2016 for the FY 2017 payment determination).

We invite public comment on the proposed submission deadlines for this measure (NQF #0680) for the FY 2016 payment determination and subsequent years.

d. Proposed Data Submission Mechanisms for the FY 2018 Payment Determination and Subsequent Years for Proposed New LTCHQR Program Quality Measures and for Proposed Revisions to Previously Adopted Quality Measures

For the two proposed functional status measures and the application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure, we are proposing that all LTCHs would be required to collect data using the LTCH CARE Data Set (Version 3.00).[184] We will release the technical data submission specifications and update LTCHQR Program Manual for the LTCH CARE Data Set (Version 3.00) to include items related to the functional status measures and the application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674) measure in CY 2015. The QIES ASAP system would remain the data submission mechanism for the LTCH CARE Data Set. Further information on data submission of the LTCH CARE Data Set for the LTCHQR Program Reporting using the QIES ASAP system is available at: *https://www.qtso.com/* and *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html*.

For the proposed VAE measure, we are proposing that LTCHs would be required to use the CDC's NHSN reporting and submission infrastructure. Details related to the procedures for using CDC's NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the proposed NHSN VAE Outcome Measure can be found at: *http://www.cdc.gov/nhsn/PDFs/pscManual/10-VAE_FINAL.pdf*.

We invite public comments on these proposals.

e. Proposed Data Collection Timelines and Submission Deadlines Under the LTCHQR Program for the FY 2018 Payment Determination

In sections IX.C.9.c. and f. of the preamble of this proposed rule, we are proposing, for the FY 2016 payment determination and subsequent years, to revise the data collection timelines and submission deadlines for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680) measure and, for the FY 2018 payment determination and subsequent years, to revise the data collection timelines and submission deadlines for the application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674) measure. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50882), we adopted the data collection timelines and submission deadlines for the remaining quality measures applicable to the FY 2018 payment determination as listed in the following tables.

TIMEFRAMES FOR DATA COLLECTION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2018 PAYMENT DETERMINATION

NQF measure ID	Data collection timelines
NQF #0138	January 1, 2016–December 31, 2016.

[184] The LTCH CARE Data Set (Version 2.01) was approved on June 10, 2013, by OMB in accordance with the PRA. The OMB Control Number is 0938–1163. Expiration Date June 30, 2016. Available on the Web site at: *http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionAct of1995/PRA-Listing-Items/CMS1252160.html*. CMS will revise the LTCH CARE Data Set (Version 3.00) and submit for OMB review for PRA approval to support data collection for the two functional status measures and the application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674). LTCH CARE Data Set (Version 3.00) is proposed for April 1, 2016, implementation date.

TIMEFRAMES FOR DATA COLLECTION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2018 PAYMENT DETERMINATION—Continued

NQF measure ID	Data collection timelines
NQF #0139	January 1, 2016–December 31, 2016.
NQF #0678	January 1, 2016–December 31, 2016.
NQF #0431	October 1, 2016 (or when vaccine becomes available)–March 31, 2017.
NQF #1716	January 1, 2016–December 31, 2016.
NQF #1717	January 1, 2016–December 31, 2016.

TIMELINE FOR SUBMISSION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2018 PAYMENT DETERMINATION FOR ALL MEASURES EXCEPT INFLUENZA VACCINATION COVERAGE AMONG HEALTHCARE PERSONNEL (NQF #0431) AND PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE (SHORT-STAY) (NQF #0680)

Data collection timeline: CY 2016	Final submission deadlines for the LTCHQR Program FY 2018 payment determination
Q1 (January–March 2016)	May 15, 2016.
Q2 (April–June 2016)	August 15, 2016.
Q3 (July–September 2016)	November 15, 2016.
Q4 (October–December 2016)	February 15, 2017.

TIMELINE FOR SUBMISSION OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2018 PAYMENT DETERMINATION: INFLUENZA VACCINATION COVERAGE AMONG HEALTHCARE PERSONNEL (NQF #0431)

Data collection timeline	Final submission deadlines for the LTCHQR Program FY 2018 payment determination
October 1 2016 (or when vaccine becomes available)–March 31, 2017	May 15, 2017.

For the new measures that we are proposing to adopt for the FY 2018 payment determination and subsequent years, we are proposing the following data collection timelines and submission deadlines.

PROPOSED DATA COLLECTION TIMELINES FOR NEW LTCHQR PROGRAM MEASURES FOR THE FY 2018 PAYMENT DETERMINATION

NQF Measure ID or Measure Name (when NQF Measure ID not available)	Data collection timeline
National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure.	January 1, 2016–December 31, 2016.
Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support.	April 1, 2016–December 31, 2016.
Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function.	April 1, 2016–December 31, 2016.

PROPOSED SUBMISSION DEADLINES OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2018 PAYMENT DETERMINATION: NATIONAL HEALTHCARE SAFETY NETWORK (NHSN) VENTILATOR-ASSOCIATED EVENT (VAE) OUTCOME MEASURE

Data collection timeline	Final submission deadlines for the LTCHQR Program FY 2018 payment determination
Q1 (January–March 2016)	May 15, 2016.
Q2 (April–June 2016)	August 15, 2016.
Q3 (July–September 2016)	November 15, 2016.
Q4 (October–December 2016).	February 15, 2017.

PROPOSED SUBMISSION DEADLINES OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2018 PAYMENT DETERMINATION: FUNCTIONAL OUTCOME MEASURE: CHANGE IN MOBILITY AMONG LONG-TERM CARE HOSPITAL PATIENTS REQUIRING VENTILATOR SUPPORT AND PERCENT OF LONG-TERM CARE HOSPITAL PATIENTS WITH AN ADMISSION AND DISCHARGE FUNCTIONAL ASSESSMENT AND A CARE PLAN THAT ADDRESSES FUNCTION

Data collection timeline	Final submission deadlines for the LTCHQR Program FY 2018 payment determination
Q2 (April–June 2016)	August 15, 2016.
Q3 (July–September 2016)	November 15, 2016.
Q4 (October–December 2016)	February 15, 2017.

We invite public comments on these data collection timelines and submission deadlines for the three proposed new quality measures for FY 2018 payment determination.

f. Proposed Data Collection Timelines and Submission Deadlines for the Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) for the FY 2018 Payment Determination and Subsequent Years

In the FY 2014 IPPS/LTCH PPS final rule, we revised the Application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure for the FY 2018 payment determination and subsequent years (78 FR 50874 through 50877). We are proposing, for the FY 2018 payment determination only, to move the start date for data collection of this measure to April 1, 2016, instead of the previously finalized start date of January 1, 2016. Data collection and submission of this measure would continue through December 31, 2016, as previously finalized for the FY 2018 payment determination. This proposed change in the data collection start date would only affect CY 2016 data collection and submission for the LTCHQR Program for the FY 2018 payment determination. For all subsequent years, data collection for this measure would begin on January 1 and continue through December 31. We note that these proposed changes would be applicable only to the Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure, and not applicable to any other LTCHQR Program measures, proposed or adopted, unless explicitly stated. We refer readers to section IX.C.6. of the preamble of this proposed rule for further information and rationale.

PROPOSED DATA COLLECTION TIMELINES AND SUBMISSION DEADLINES OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2018 PAYMENT DETERMINATION FOR THE APPLICATION OF PERCENT OF RESIDENTS EXPERIENCING ONE OR MORE FALLS WITH MAJOR INJURY (LONG STAY) (NQF #0674)

Data collection timeline: CY 2016	Final submission deadlines for the LTCHQR Program FY 2018 payment determination
Q2 (April–June 2016)	August 15, 2016.
Q3 (July–September 2016)	November 15, 2016.
Q4 (October–December 2016)	February 15, 2017.

We invite public comment on the proposed data collection timeline and quarterly submission deadlines for the Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) for the FY 2018 payment determination.

g. Proposed Data Collection Timelines and Submission Deadlines Under the LTCHQR Program for the FY 2019 Payment Determination and Subsequent Years

For the quality measures applicable to the FY 2019 payment determination and subsequent years, including those that we are proposing in section IX.C.7. of the preamble of this proposed rule, if finalized, we are proposing the following data collection timelines and submission deadlines.

PROPOSED DATA COLLECTION TIMELINES AND SUBMISSION DEADLINES OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2019 PAYMENT DETERMINATION

NQF Measure ID or Measure Name (when NQF Measure ID not available)	Data collection timeline
National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138).	January 1, 2017–December 31, 2017.
National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139).	January 1, 2017–December 31, 2017.
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678).	January 1, 2017–December 31, 2017.
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680).	October 1, 2017–March 31, 2018.
Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431).	October 1, 2017–March 31, 2018.

PROPOSED DATA COLLECTION TIMELINES AND SUBMISSION DEADLINES OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2019 PAYMENT DETERMINATION—Continued

NQF Measure ID or Measure Name (when NQF Measure ID not available)	Data collection timeline
National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-resistant *Staphylococcus areus* (MRSA) Bacteremia Outcome Measure (NQF #1716).	January 1, 2017–December 31, 2017.
National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717).	January 1, 2017–December 31, 2017.
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674).	January 1, 2017–December 31, 2017.
National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure.	January 1, 2017–December 31, 2017.
Functional Outcome Measure: Change in Mobility among Patients Requiring Ventilator Support.	January 1, 2017–December 31, 2017.
Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function.	January 1, 2017–December 31, 2017.

PROPOSED DATA COLLECTION TIMELINES AND SUBMISSION DEADLINES OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2019 PAYMENT DETERMINATION FOR ALL MEASURES EXCEPT INFLUENZA VACCINATION COVERAGE AMONG HEALTHCARE PERSONNEL (NQF #0431) AND PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE (SHORT-STAY) (NQF #0680)

Data collection timeline: CY 2017	Final submission deadlines for the LTCHQR Program FY 2019 payment determination
Q1 (January–March 2017)	May 15, 2017.
Q2 (April–June 2017)	August 15, 2017.
Q3 (July–September 2017)	November 15, 2017.
Q4 (October–December 2017)	February 15, 2018.

PROPOSED DATA COLLECTION TIMELINES AND SUBMISSION DEADLINES OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2019 PAYMENT DETERMINATION: PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE (SHORT-STAY) (NQF #0680)

Data collection timeline	Final submission deadlines for the LTCHQR Program FY 2019 payment determination
October 1, 2017–December 31, 2017	February 15, 2018.
January 1, 2018–March 31, 2018	May 15, 2018.

PROPOSED DATA COLLECTION TIMELINES AND SUBMISSION DEADLINES OF LTCHQR PROGRAM QUALITY DATA FOR THE FY 2019 PAYMENT DETERMINATION: INFLUENZA VACCINATION COVERAGE AMONG HEALTHCARE PERSONNEL (NQF #0431)

Data collection timeline	Final submission deadlines for the LTCHQR Program FY 2019 payment determination
October 1 2017–March 31, 2018	May 15, 2018.

We invite public comment on these proposals.

10. Proposed LTCHQR Program Data Completion Thresholds for the FY 2016 Payment Determination and Subsequent Years

a. Overview

Section 1886(m)(5)(C) of the Act requires that, for the FY 2014 payment determination and subsequent years, each LTCH submit to the Secretary data on quality measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. As required by section 1886(m)(5)(A)(i) of the Act, for any LTCH that does not submit data in accordance with section 1886(m)(5)(C) of the Act with respect to a given fiscal year, any annual update to the standard Federal rate for discharges for the hospital during the rate fiscal year must be reduced by two percentage points. To date, we have not established a standard for compliance other than that LTCHs submit all applicable required data for all finalized measures, by the previously finalized quarterly deadlines. In response to input from our stakeholders seeking additional specificity related to the LTCHQR Program compliance affecting FY payment update determinations and, due to the importance of ensuring the integrity of quality data submitted to CMS, we are proposing to set specific LTCHQR Program thresholds for completeness of LTCH quality data beginning with data affecting the FY 2016 payment determination and subsequent years.

The LTCHQR Program, through the FY 2012, FY 2013, and FY 2014 IPPS/LTCH PPS final rules, requires LTCHs to submit quality data using two separate

data collection/submission mechanisms: measures collected using the LTCH CARE Data Set (LCDS) are submitted through the CMS Quality Improvement Evaluation System (QIES); and measures stewarded by the CDC (such as Healthcare Acquired Infection (HAI) and vaccination measures), are submitted using the CDC's National Healthcare Safety Network (NHSN). We have also previously finalized a claims-based measure (All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Long Term Care Hospitals); however, claims-based measures do not require LTCHs to actually submit quality data to CMS, as they are calculated using claims data submitted to CMS for payment purposes. Thus, with claims-based measures, there is no submitted quality data to which we could apply data completion thresholds.

To ensure that LTCHs are meeting an acceptable standard for completeness of submitted data, we are proposing that for the FY 2016 payment determination and subsequent years, LTCHs meet or exceed two separate program thresholds: one threshold for completion of quality measures data collected using the LCDS and submitted through QIES; and a second threshold for quality measures data collected and submitted using the CDC's NHSN. We are proposing that LTCHs must meet or exceed both thresholds discussed below, in order to avoid receiving a 2 percentage point reduction to their annual payment update for a given FY, beginning with FY 2016.

We are proposing to hold LTCHs accountable for different data completion thresholds for each of the two data submission mechanisms; an 80 percent data completion threshold for data collected using the LCDS and submitted through the QIES mechanism; and a 100 percent data completion threshold for data submitted through the CDC's NHSN. We are proposing to hold LTCHs to the higher data completion threshold for the CDC's NHSN initially, because many LTCHs have been mandated by States to report infection data using the CDC's NHSN system for surveillance purposes, prior to the start of the LTCHQR Program on October 1, 2012, and, therefore, we believe LTCHs are more familiar with the NHSN collection and submission process.

In contrast, LTCHs had never submitted quality data using a standardized data collection instrument before October 1, 2012, such as the LCDS submitted through the QIES mechanism. In addition, we require the submission of LCDS admission and discharge data through QIES, in order for LTCHs to meet the proposed data accuracy compliance standard, which with regard to discharge data, may be more difficult to collect on patients that are discharged emergently or against medical advice, in effect making it more difficult to meet a higher level of compliance initially. Lastly, through the FY 2014 IPPS/LTCH PPS final rule, we finalized accelerated quarterly deadlines for submission of quality data, beginning January 2014, of 45 days beyond the end of each CY quarter, as opposed to the previous 135 day post-quarterly deadline LTCHs were previously required to meet. We feel that this is an additional challenge that LTCHs may face. We invite comment on other obstacles LTCHs may face in meeting a higher level of compliance with regard to submission of quality data using the LCDS.

b. Proposed LTCHQR Program Data Completion Threshold for the Required LTCH CARE Data Set (LCDS) Data Items

The LCDS is composed of data collection items designed to inform quality measure calculations, including risk-adjustment calculations, as well as internal consistency checks for logical inaccuracies. We are proposing that beginning with quality data affecting the FY 2016 payment determination and subsequent years, LTCHs must meet or exceed a proposed LCDS data completion threshold of 80 percent. We are proposing to assess the completeness of submitted data by verifying that for all LCDS assessments submitted by any given LTCH, at least 80 percent of those LCDS Assessments must have 100 percent of the required quality data items completed, where, for the purposes of this proposed rule, ''completed'' is defined as having provided actual patient data, as opposed to a non-informative response, such as a dash (-), that indicates the LTCH was unable to provide patient data. The proposed threshold of 80 percent is based on the need for substantially complete records, which allows appropriate analysis of quality measure data for the purposes of updating quality measure specifications as they undergo yearly and triennial measure maintenance reviews with the NQF. In addition, complete data is needed to understand the validity and reliability of quality data items, including risk-adjustment models. Finally, we want to ensure complete quality data from LTCHs, which will ultimately be reported to the public, allowing our beneficiaries to gain an understanding of LTCH performance related to these quality metrics, and helping them to make informed health care choices.

Our data suggest that the majority of current LTCHs are in compliance with, or exceeding, this proposed threshold already. Our decision to set this proposed data completion threshold at a lower level initially, with the intent to raise the proposed 80 percent threshold in subsequent program years, is based on our understanding that LTCHs are still new to quality reporting, and that their experience and understanding, with respect to reporting quality data using a standardized data collection instrument, and thus their compliance, will increase over time. However, we invite public comment on circumstances that might prevent LTCHs from meeting this level of compliance. All items that we are proposing to require under the LTCHQR Program are identified in Appendix D of the LTCHQR Program Manual version 2.01, which is available for download on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html*.

We are also proposing that any LTCH that does not meet the proposed requirement that 80 percent of all LCDS assessments submitted contain 100 percent of all required quality data items, will be subject to a reduction of 2 percentage points to the applicable FY annual payment update beginning with FY 2016. In order to establish this program threshold, we analyzed all LCDS submissions from January 2013 through September 2013, and we believe that the majority of LTCHs will be able to meet the proposed 80 percent data completion threshold. It is our intent to raise this threshold over the next 2 years, through the formal notice-and-comment rulemaking process. As stated above, we feel that as LTCHs continue to submit data using a standardized data collection instrument, such as the LCDS, and as they continue to take advantage of the resources we provide to guide LTCHs in their submission of this data (national trainings, CMS Special Open Door Forums, LTCHQR Program Manual, and technical trainings available on our Web site), we feel LTCH performance with respect to data completion will improve over time. We are proposing that this threshold will have to be met by LTCHs, in addition to the CDC NHSN threshold discussed below, in order to avoid receiving a 2 percentage point reduction to the applicable FY annual payment update.

c. LTCHQR Program Data Completion Threshold For Measures Submitted Using the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN)

The LTCHQR Program through the FY 2012, FY 2013, and FY 2014 IPPS/LTCH PPS final rules, requires that LTCHs submit CDC-stewarded quality measure data using the CDC's NHSN, including data for the previously finalized CAUTI, CLABSI, and Influenza Vaccination Coverage among Healthcare Personnel (HCP) quality measures. More specifically, we require LTCHs follow CDC quality measure protocols, which require them LTCHs to complete all data fields required for both numerator and denominator data within NHSN, including the ''no events'' field for any month during which no infection events were identified. LTCHs are required to submit this data on a monthly basis (except for the HCP measure, which is only required to be reported once per year). However, LTCHs have until the associated quarterly deadline (45 calendar days beyond the end of each CY quarter) by which to report infection data to the CDC for each of the three months within any given quarter. For more information on the LTCHQR Program quarterly deadlines, we refer readers to section IX.C.9.b. of the preamble of this proposed rule.

We are proposing that beginning with FY 2016 payment determination and subsequent years, this previously finalized requirement for monthly reporting must be met in addition to the proposed LCDS data completion threshold discussed above in order to avoid a 2 percentage point reduction to the applicable FY annual payment update. That is, we are proposing that LTCHs must meet a threshold of 100 percent for measures submitted via the NHSN, achieved by submitting relevant infection, vaccination, or other required quality measure data for each month of any given CY, in addition to meeting the above-proposed data item completion threshold for required quality data items on the LCDS. As the LTCHQR Program expands, and LTCHs begin reporting measures that were previously finalized, but not yet implemented, or newly proposed and finalized measures, we are proposing to apply this same threshold.

d. Application of the 2 Percentage Point Reduction for LTCHs That Fail To Meet the Proposed Data Completion Thresholds

Above we have proposed that LTCHs must meet two separate data completion thresholds in order to avoid a 2 percentage point reduction to their applicable FY annual payment update; a data completion threshold of 80 percent for those required data elements collected using the LCDS and submitted through QIES; and a second data completion threshold of 100 percent for quality measure data submitted through the CDC's NHSN. We are proposing that these data completion thresholds must be met in addition to the data validation threshold of 75 percent we are proposing below, in order to avoid a 2 percentage point reduction to their applicable FY annual payment update. While we are proposing that LTCHs must meet both the proposed data completion and data validation thresholds, LTCHs cannot have their applicable annual payment update reduced twice. That is, should an LTCH fail to meet either one or both of the proposed thresholds, it will only receive one reduction of 2 percentage points to its applicable fiscal year annual payment update.

We invite public comment on these proposals.

11. Proposed Data Validation Process for the FY 2016 Payment Determination and Subsequent Years

a. Proposed Data Validation Process

Historically, we have built consistency and internal validation checks into our data submission specifications to ensure that the basic elements of the LCDS assessments conform to requirements such as proper format and facility information. These internal consistency checks are automated and occur during the LTCH submission process, and help ensure the integrity of the data submitted by LTCHs by rejecting submissions or issuing warnings when LTCH data contain logical inconsistencies. These internal consistency checks are referred to as ''system edits'' and are further outlined in the LTCH Data Submission Specifications version 1.01, which are available for download on the LTCH Quality Reporting Technical Information Web page at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html*.

Validation is intended to provide added assurance of the accuracy of the data that will be reported to the public as required by section 1886(m)(5)(E) of the Act. We are proposing, for the FY 2016 payment determination and subsequent years, to validate the data elements submitted to CMS for quality purposes. Initially, for the FY 2016 payment determination, this data accuracy validation will apply only to the LCDS items that inform the measures Percent of Patients or Residents with Pressure Ulcers That are New or Worsened (Short-Stay) (NQF #0678). We intend to expand this validation process for quality measures affecting the FY 2017 payment determination and subsequent years through future notice-and-comment rulemaking.

We are proposing to validate the data elements submitted to CMS for Percent of Residents or Patients with Pressure Ulcers That are New or Have Worsened (Short-Stay) (NQF #0678) under the LTCHQR Program by requesting the minimum chart data necessary to confirm a statistically valid random sample of 260 LTCHs. From the random sample of 260 LTCHs, 5 LCDS assessments submitted through the National Assessment Collection Database would be randomly selected by the CMS validation contractor. In accordance with § 164.512 (d)(1)(iii) of the HIPAA Privacy Rule, we would request from these LTCHs the specified portions of the 5 Medicare patient charts that correspond to the randomly selected assessments, which would need to be copied and submitted via traceable mail to a CMS contractor for validation. We are proposing that the specific portions of the 5 beneficiary charts would be identified in the written request, but may include: admission and discharge assessments, relevant nursing notes following the admission, relevant nursing notes preceding the discharge, physician admission summary and discharge summary, and any Assessment of Pressure Ulcer Form the facility may utilize. We are proposing that the CMS contractor would utilize the portions of the patient charts to compare that information with the quality data submitted to CMS. Differences that would affect measure outcomes or measure rates would be identified and reported to CMS. These differences could include but are not limited to unreported worsened pressure ulcers.

We are proposing that all data that has been submitted to the National Assessment Collection Database under the LTCHQR Program would be subject to the data validation process. Specifically, we are proposing that the contractor would request copies of the randomly selected medical charts from each LTCH via certified mail (or other traceable methods that require an LTCH representative to sign for CMS correspondence), and the LTCH would have 45 days from the date of the request (as documented on the request letter) to submit the requested records to

the contractor. If the LTCH does not comply within 30 days, the contractor would send a second certified letter to them, reminding the LTCH that it must return copies of the requested medical records within 45 calendar days following the date of the initial contractor medical record request. If the LTCH still does not comply, then the contractor would assign a ''zero'' score to each measure in each missing record. If, however, the LTCH does comply, the contractor would review the data submitted by the LTCH on the LCDS assessments for the required data elements associated with the Pressure Ulcer measure, until such time that LTCHs begin to submit additional quality measures that are collected using the LCDS. Initially, this review would consist solely of those required data elements that inform the Pressure Ulcer measure calculation and checks for logical inconsistencies. As LTCHs begin to report additional finalized measures, we intend to expand this validation process to quality measures affecting the FY 2017 payment determination and subsequent years, through future notice-and-comment rulemaking. The contractor would then calculate the percentage of matching data elements which would constitute a validation score. Because we would not be validating all records, we would need to calculate a confidence interval that incorporates a potential sampling error.

To receive the full FY 2016 annual payment update, we are proposing that LTCHs in the random sample must attain at least a 75 percent validation score, based upon our validation process, which would use charts requested from patient assessments submitted for CY 2013. We would calculate a 95 percent confidence interval associated with the observed validation score. If the upper bound of this confidence interval is below the 75 percent cutoff point, we would not consider a hospital's data to be ''validated'' for payment purposes. We are proposing that LTCHs failing the validation requirements would be subject to the 2 percent annual payment update reduction, beginning with their fiscal year annual payment update. In addition, all LTCHs validated would receive educational feedback, including specific case details.

b. Application of the 2 Percentage Point Reduction for LTCHs That Fail To Meet the Proposed Data Accuracy Threshold

We are proposing that LTCHs must meet a data accuracy threshold of 75 percent in order to avoid receiving a 2 percentage point reduction to their applicable fiscal year annual payment update. We are proposing that this proposed data accuracy threshold of 75 percent must be met in addition to the proposed data completion thresholds (80 percent for data collected using the LTCH CARE Data Set and submitted using QIES, and 100 percent for data submitted using the CDC's NHSN), in order to avoid receiving a 2 percentage point reduction to their applicable FY annual payment update. While we are proposing that LTCHs must meet both the proposed data accuracy and data completion thresholds, LTCHs cannot have their applicable annual payment update reduced twice. That is, should an LTCH fail to meet either one or both of the proposed thresholds (data completion and/or data accuracy), it will only receive one reduction of 2 percentage points to its applicable FY annual payment update.

We invite public comment on these proposals and suggestions to improve the utility of the approach or to reduce the burden on LTCHs.

12. Public Display of Quality Measure Data for the LTCHQR Program

Under section 1886(m)(5)(E) of the Act, the Secretary is required to establish procedures for making data submitted under section 1886(m)(5)(C) of the Act available to the public. Section 1886(m)(5)(E) of the Act requires that such procedures shall ensure that an LTCH has the opportunity to review the data that is to be made public with respect to the LTCH prior to such data being made public. The statute also requires that the Secretary report quality measures that relate to services furnished in inpatient settings in LTCHs on our Web site. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53637), we received and responded to public comments regarding the public reporting of quality data under the LTCHQR Program.

Currently, we are developing plans regarding the implementation of these provisions. We appreciate the need for transparency into the processes and procedures that will be implemented to allow for public reporting of the LTCHQR Program data and to afford LTCHs the opportunity to review that data before it is made public. At this time, we have not established procedures or timelines for public reporting of data, but we intend to include related proposals in future rulemaking.

We welcome public comment on what we should consider when developing future proposals related to public reporting of quality measures for the LTCHQR Program.

13. Proposed LTCHQR Program Submission Exception and Extension Requirements for the FY 2017 Payment Determination and Subsequent Years

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50883 through 50885), we referred to these requirements as submission ''waiver'' requirements. We are proposing to instead use the phrase ''exception and extension'' requirements for purposes of clarity. For the FY 2017 payment determination and subsequent years, we are proposing to continue using the LTCHQR Program's requirements that we adopted in the FY 2014 IPPS/LTCH PPS final rule for the FY 2015 payment determination and subsequent years, although the term ''waiver'' is replaced by ''exception and extension.''

In the FY 2014 IPPS/LTCH PPS final rule, we finalized a process for LTCHs to request and for us to grant waivers with respect to the quality data reporting requirements of the LTCHQR Program for one or more quarters, beginning with the FY 2015 payment determination, when there are certain extraordinary circumstances beyond the control of the LTCH. We are proposing to continue to use this previously finalized process.

In the event that an LTCH seeks to request a submission exception or extension for quality reporting purposes, the LTCH must request an exception or extension within 30 days of the date that the extraordinary circumstances occurred by submitting a written request to CMS via email to the LTCH mailbox at *LTCHQRP Reconsiderations@cms.hhs.gov*. Exception or extension requests sent to CMS through any other channel will not be considered as a valid request for an exception or extension from the LTCHQR Program's reporting requirements for any payment determination. The written request must contain all of the finalized requirements in the FY 2014 IPPS/LTCH PPS final rule, and on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Reconsideration-and-Disaster-Waiver-Requests.html*.

When an exception or extension is granted, an LTCH will not incur payment reduction penalties for failure to comply with the requirements of the LTCHQR Program, for the timeframe specified by CMS. If an LTCH is granted an exception, we will not require that the LTCH submit any quality data for a given period of time. If we grant an extension to an LTCH, the LTCH will

still remain responsible for submitting quality data collected during the timeframe in question, although we will specify a revised deadline by which the LTCH must submit this quality data.

In addition, in the FY 2014 IPPS/LTCH PPS final rule, we finalized a policy that allowed CMS to grant exceptions or extensions to LTCHs that have not requested them if it is determined that extraordinary circumstances affects an entire region or locale. We stated that if this determination was made, we will communicate this decision through routine communication channels to LTCHs and vendors, including, but not limited to, issuing memos, emails, and notices at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html*. More information on the LTCHQR Program exception and extension requirements and processes, and all related announcements may be found at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html*.

For the FY 2017 payment determination and subsequent years, we are proposing that we may grant an exception or extension to LTCHs if we determine that a systemic problem with one of our data collection systems directly affected the ability of the LTCH to submit data. Because we do not anticipate that these types of systemic errors will happen often, we do not anticipate granting a waiver or extension on this proposed basis frequently. We are proposing that if we make the determination to grant an exception or extension, we would communicate this decision through routine communication channels to LTCHs and vendors, including, but not limited to, issuing memos, emails, and notices on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html*.

We invite public comment on these proposals.

14. Proposed LTCHQR Program Reconsideration and Appeals Procedures for the FY 2016 Payment Determination and Subsequent Years

a. Previously Finalized LTCHQR Program Reconsideration and Appeals Procedures for the FY 2014 and FY 2015 Payment Determinations

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50885 through 50887), we finalized a voluntary process that allowed LTCHs the opportunity to seek reconsideration of our initial noncompliance decision for the FY 2014 and FY 2015 payment determinations. We refer readers to that rule for a discussion of this process.

b. Proposed LTCHQR Program Reconsideration and Appeals Procedures for the FY 2016 Payment Determination and Subsequent Years

For the FY 2016 payment determination and subsequent years, we are proposing to adopt an updated process, as described below, that will enable an LTCH to request a reconsideration of our initial noncompliance decision in the event that an LTCH believes that it was incorrectly identified as being subject to the 2-percentage point reduction to its annual payment due to noncompliance with the LTCHQR Program reporting requirements for a given reporting period.

For the FY 2016 payment determination, and subsequent years, we are proposing that an LTCH would receive a notification of noncompliance if we determine that the LTCH did not submit data in accordance with section 1886(m)(5)(C) of the Act with respect to the applicable fiscal year and that the LTCH is therefore subject to a 2-percentage point reduction in the applicable payment determination as required by section 1886(m)(5)(A)(i) of the Act. We would only consider requests for reconsideration after an LTCH has been found to be noncompliant and not before.

An LTCH would have 30 days from the date of the initial notification of noncompliance to review its payment determination and submit to us a request for reconsideration. This proposed time frame would allow us to balance our desire to ensure that LTCHs have the opportunity to request reconsideration with our need to complete the process and provide LTCHs with our reconsideration decision in a timely manner. Notifications of noncompliance and any subsequent notifications from CMS would be sent via a traceable delivery method, such as certified U.S. mail or registered U.S. mail. We are proposing that an LTCH may withdraw its request at any time and may file an updated request within the proposed 30-day deadline. We also are proposing that, in very limited circumstances, we may grant a request by an LTCH to extend the proposed deadline for reconsideration requests. It would be the responsibility of an LTCH to request an extension and demonstrate that extenuating circumstances existed that prevented the filing of the reconsideration request by the proposed deadline.

We also are proposing that as part of the LTCH's request for reconsideration, the LTCH would be required to submit all supporting documentation and evidence demonstrating: (1) Full compliance with all LTCHQR Program reporting requirements during the reporting period; or (2) extenuating circumstances that affected noncompliance if the LTCH was not able to comply with the requirements during the reporting period. We would not review any reconsideration request that fails to provide the necessary documentation and evidence along with the request. The documentation and evidence may include copies of any communications that demonstrate its compliance with the program's requirements, as well as any other records that support the LTCH's rationale for seeking reconsideration. A sample list of acceptable supporting documentation and evidence, as well as instructions for LTCHs to retrieve copies of the data submitted to CMS for the appropriate program year can be found on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Reconsideration-and-Disaster-Waiver-Requests.html*.

We are proposing that an LTCH wishing to request a reconsideration of our initial noncompliance determination would be required to do so by submitting an email to the following email address: *LTCHQRP Reconsiderations@cms.hhs.gov*. Any request for reconsideration submitted to us by an LTCH would be required to follow the guidelines outlined on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Reconsideration-and-Disaster-Waiver-Requests.html*.

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 or CEO-designated representative that the request has been received; and
- Once we have reached a decision regarding the reconsideration request, an email to the LTCH CEO or CEO-designated representative, using the contact information provided in the reconsideration request, regarding our decision.

We are proposing to require an LTCH that believes it was incorrectly identified as being subject to the 2-percentage point reduction to its annual

payment update to submit a timely request for reconsideration and receive a decision on that request before the LTCH can file an appeal with the PRRB. If the LTCH is dissatisfied with the decision rendered at the reconsideration level, the LTCH could appeal the decision with the PRRB under 42 CFR 405.1835. We believe this proposed process is more efficient and less costly for CMS and for LTCHs because it decreases the number of PRRB appeals by resolving issues earlier in the process. Additional information about the reconsideration process including requirements for submitting a reconsideration request is posted on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Reconsideration-and-Disaster-Waiver-Requests.html*.

We invite public comment on the proposed procedures for reconsideration and appeals.

15. Electronic Health Records (EHR) and Health Information Exchange (HIE)

We are also interested in understanding the current state of electronic health record (EHR) adoption and use of Health Information Exchange (HIE) in the LTCH community. Therefore, we are soliciting feedback and input from LTCHs and the public on EHR adoption and HIE usage. We are especially interested in LTCH feedback and input on the following questions:

- Have you adopted an EHR in your LTCH setting?
- If your LTCH setting uses EHRs, what functional aspects of EHRs do you find most important (for example, the ability to send or receive transfer of care information; the ability to support medication orders/medication reconciliation)?
- Does the EHR system used in your LTCH setting support interoperable document exchange with other healthcare providers (for example, acute care hospitals, physician practices, skilled nursing facilities, etc.)?

In addition to seeking public feedback and input on the feasibility and desirability of EHR adoption and use of HIE in LTCHs, we are also interested in public comment on the need to develop electronic clinical quality measures, and the benefits and limitations of implementing these measures for LTCHs.

D. Electronic Health Record (EHR) Incentive Program and Meaningful Use (MU)

1. Background

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified electronic health record (EHR) technology (CEHRT). We refer to this program as the EHR Incentive Program. Eligible hospitals (EHs) and critical access hospitals (CAHs) may qualify for these incentive payments under Medicare (as authorized under sections 1886(n) and 1814(l) of the Act, respectively) if they successfully demonstrate meaningful use of CEHRT, which includes reporting on clinical quality measures (CQMs) using CEHRT. Sections 1886(b)(3)(B) and 1814(l) of the Act also establish downward payment adjustments under Medicare, beginning with fiscal year 2015, for eligible hospitals and CAHs that are not meaningful users of CEHRT for certain associated reporting periods. We refer to this part of the EHR Incentive Program as the Medicare EHR Incentive Program. Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for Medicaid incentive payments.

The set of CQMs from which eligible hospitals and CAHs will report under the EHR Incentive Program beginning in FY 2014 is listed in Table 10 of the EHR Incentive Program Stage 2 final rule (77 FR 54083 through 54087). We continue to believe there are important synergies with respect to the Medicare EHR Incentive Program and the Hospital IQR Program. We believe the financial incentives under the Medicare EHR Incentive Program for the adoption and meaningful use of CEHRT by EHs and CAHs will encourage the adoption and use of CEHRT for the electronic reporting of CQMs under the Hospital IQR Program. We expect that the electronic submission of quality data from EHRs under the EHR Incentive Program will provide a foundation for establishing the capacity of hospitals to send, and for CMS to receive, CQMs via CEHRT for certain Hospital IQR Program measures.

2. Alignment of the Medicare EHR Incentive Program Reporting and Submission Timelines for Clinical Quality Measures With Hospital IQR Program Reporting and Submission Timelines

We believe it is important to continue our goal of aligning the EHR Incentive Program with the Hospital IQR Program because alignment of these programs will serve to reduce hospital reporting burden and encourage the adoption and meaningful use of CEHRT by eligible hospitals and CAHs. Section 1886(n)(3)(B)(iii) of the Act requires that, in selecting measures and establishing the form and manner for reporting measures under the EHR Incentive Program, the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required, including reporting under section 1886(b)(3)(B)(viii) of the Act (the Hospital IQR Program). The reporting and submission timelines for the EHR Incentive Program for eligible hospitals and CAHs currently operate on a Federal fiscal year basis, while the reporting and submission timelines for the Hospital IQR Program currently operate on a calendar year basis. This difference may create confusion and additional burden for hospitals attempting to report data to both programs. To alleviate this possible confusion, reduce provider burden, and strengthen our commitment to aligning programs, we are proposing to align the reporting and submission periods for clinical quality measures for the Medicare EHR Incentive Program with that of the Hospital IQR Program on a calendar year basis in 2015 and 2016.

We realize that aligning the Medicare EHR Incentive Program to the calendar year would mean shifting the timeline for reporting and submission of CQMs such that the submission period would continue through February of the subsequent calendar year rather than ending in November as it is currently done, and therefore would delay the incentive eligibility assessment, and subsequently delay the EHR incentive payments under Medicare made to eligible hospitals and CAHs. In order to ease the transition of the reporting period to the calendar year, and to prevent the delay of Medicare EHR incentive payments, we are proposing to incrementally shift the Medicare EHR Incentive Program reporting periods for CQMs. Specifically, for 2015 and 2016, we are proposing for the Medicare EHR Incentive Program to require calendar year reporting for CQM data that are submitted electronically, but require that the data be reported only for the first three calendar quarters (that is, January through March, April through June and July through September) allowing the reporting period, incentive eligibility assessment, and incentive payments to remain on their current schedule.

We note that this proposal would only apply for eligible hospitals and CAHs submitting CQMs electronically for 2015

and 2016, and that hospitals demonstrating meaningful use for the first time in 2015 or 2016 would still be required to report CQMs by attestation for a continuous 90-day period in FY 2015 or 2016, or report CQMs electronically for a 3-month calendar year quarter, by July 1 of the given year to avoid the Medicare penalty in the subsequent year as finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50903 through 50905). Medicaid-only providers would continue to report according to State requirements. The proposal would not change the reporting periods or requirements for the meaningful use objectives and associated measures under 42 CFR 495.6 or for CQMs that are reported by attestation via the Registration and Attestation System. This proposal would allow us to align the CQM reporting periods for the Medicare EHR Incentive Program with that of the Hospital IQR Program without delaying payment of the Medicare EHR incentive payments for 2015 and 2016.

To further align CQM reporting for the two programs, we are proposing to require quarterly reporting of electronically reported CQMs for the Medicare EHR Incentive Program to align with the currently established quarterly electronic CQM reporting periods for the Hospital IQR Program. Additionally, the Hospital IQR Program is proposing to change its submission period for electronic CQMs from annual to quarterly submission in this rule. We refer readers to the Hospital IQR Program discussion in section IX.A.7.h. of the preamble of this proposed rule for more information about this proposal. Therefore, for the CY 2015 and 2016 reporting periods, we are also proposing to align the Medicare EHR Incentive Program submission period with that being proposed for the Hospital IQR Program. The table below illustrates the current reporting periods, and the following table further illustrates our proposals.

CURRENT (2014) TIMELINES FOR EHR INCENTIVE PROGRAM AND HOSPITAL IQR PROGRAM REPORTING AND SUBMISSION

	EHR incentive program CQM reporting requirements		Hospital IQR program reporting requirements for FY 2016 payment determination	
2014 Reporting Period	FY 2014 October 1, 2013–September 30, 2014.	Report one full year OR	Q4 CY 2013	October 1, 2013–December 31, 2013. N/A for 2014 Hospital IQR Program reporting.
		Report one three-month quarter OR. Report any continuous 90-day period.	Q1 CY 2014	January 1–March 31, 2014.
			Q2 CY 2014	April 1–June 30, 2014.
			Q3 CY 2014	July 1–September 30, 2014.
Submission Period	Jan 2, 2014–Nov 30, 2014		October 1, 2013–November 30, 2014.	

PROPOSED TIMELINES TO ALIGN THE EHR INCENTIVE PROGRAM WITH PROPOSED HOSPITAL IQR PROGRAM REPORTING AND SUBMISSION

	CY	EHR incentive program reporting requirements*	Hospital IQR program reporting requirements	Submission period**
2015 Reporting Period ..	Q1 ...	January 1–March 31, 2015	January 1–March 31, 2015	Data must be submitted by May 30, 2015.
	Q2 ...	April 1–June 30, 2015	April 1–June 30, 2015	Data must be submitted by August 30, 2015.
	Q3 ...	July 1–September 30, 2015	July 1–September 30, 2015	Data must be submitted by November 30, 2015.
	Q4 ...	N/A for EHR Incentive Program	October 1–December 31, 2015	For Hospital IQR Program, data must be submitted by February 28, 2016.
2016 Reporting Period ..	Q1 ...	January 1–March 31, 2016	January 1–March 31, 2016	Data must be submitted by May 30, 2016.
	Q2 ...	April 1–June 30, 2016	April 1–June 30, 2016	Data must be submitted by August 30, 2016.
	Q3 ...	July 1–September 30, 2016	July 1–September 30, 2016	Data must be submitted by November 30, 2016.
	Q4 ...	N/A for EHR Incentive Program	October 1–December 31, 2016	For Hospital IQR Program, data must be submitted by February 28, 2017.

* Calendar year alignment and quarterly reporting for 2015 and 2016 would apply for electronically reported CQM data only.

** Proposed EHR Incentive Program and Hospital IQR Program submission period would allow data submission on an ongoing basis starting January 2 of the reporting year, and ending approximately 60 days after the end of the quarter.

We invite public comment on these proposals.

3. Quality Reporting Data Architecture Category III (QRDA–III) Option in 2015

In the EHR Incentive Program Stage 2 final rule (77 FR 54088), we finalized two options for eligible hospitals and CAHs to electronically submit CQMs beginning in FY 2014 under the Medicare EHR Incentive Program. Option 1 was to electronically submit aggregate-level CQM data using QRDA–III. Option 2 was to electronically submit data using a method similar to the 2012 and 2013 EHR Incentive Program electronic reporting pilot for EHs and CAHs, which used QRDA–I (patient-level data). We also stated in

that final rule that, consistent with section 1886(n)(3)(B)(ii) of the Act, in the event the Secretary does not have the capacity to receive CQM data electronically, eligible hospitals and CAHs that are beyond their first year of meaningful use may continue to report aggregate CQM results through attestation.

We noted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50904 through 50905) that we had determined that the electronic submission of aggregate-level data using QRDA–III would not be feasible in 2014 for eligible hospitals and CAHs under the Medicare EHR Incentive Program. Therefore, for the 2014 reporting period under the Medicare EHR Incentive Program, eligible hospitals and CAHs would have the option to continue to report aggregate CQM results through attestation. We stated that we would reassess this policy for the 2015 and future reporting periods.

We have determined that the electronic submission of aggregate-level data using QRDA–III will not be feasible in 2015 for eligible hospitals and CAHs under the Medicare EHR Incentive Program. Therefore, for the 2015 reporting period under the Medicare EHR Incentive Program, eligible hospitals and CAHs would have the option to continue to report aggregate CQM results through attestation. We note that submissions of aggregate CQM data via attestation would not satisfy the reporting requirements for the Hospital IQR Program, and consistent with our proposal above regarding alignment of these programs, attested CQM data would need to be submitted for one full fiscal year in 2015 via the Registration and Attestation System, and would not require quarterly submissions. Hospitals in their first year of demonstrating meaningful use in 2015 would still be required to report CQMs by attestation for a continuous 90-day period in FY 2015, or report CQMs electronically for a 3-month calendar year quarter, by July 1, 2015 to avoid the Medicare penalty in FY 2016 as finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50903 through 50905). We also note that this policy does not apply to the Medicaid EHR Incentive Program. Therefore, States may still require the submission of QRDA–III files to fulfill the CQM reporting requirements for hospitals that participate in the Medicaid EHR Incentive Program.

In order to remain aligned with the Hospital IQR Program, and because over 66 percent of hospitals that participate in the Hospital IQR Program are already meaningful users, we strongly recommend that hospitals that are eligible to participate in both programs electronically submit up to 16 electronic clinical quality measures of the 28 inpatient measures identified by the Hospital IQR Program. We believe that keeping the two programs aligned will ultimately reduce reporting burden for hospitals. We note again that reporting via attestation would not count towards the reporting requirements for the Hospital IQR Program.

4. Electronically Specified Clinical Quality Measures (CQMs) Reporting for 2015

In the EHR Incentive Program Stage 2 final rule, we finalized the CQMs that eligible hospitals and CAHs would be required to report for purposes of meeting the CQM component of meaningful use under the EHR Incentive Program starting in 2014 (77 FR 54083 through 54077 Table 10). These CQMs are updated routinely to account for changes, including but not limited to changes in billing and diagnosis codes and changes in medical practices. The requirements specified in the EHR Incentive Program Stage 2 final rule allow for the reporting of different versions of the CQMs. For 2015, it is not technically feasible for CMS to accept data that is electronically reported according to the specifications of the older versions of the CQMs, including versions that may be allowed for reporting under the EHR Incentive Program. We stated in the EHR Incentive Program Stage 2 final rule that, consistent with section 1886(n)(3)(B)(ii) of the Act, in the event that the Secretary does not have the capacity to receive CQM data electronically, eligible hospitals and CAHs may continue to report aggregate CQM results through attestation (77 FR 54088). We are proposing that eligible hospitals and CAHs that seek to report CQMs electronically under the Medicare EHR Incentive Program must use the most recent version of the electronic specifications for the CQMs and have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs.

Eligible hospitals and CAHs that do not wish to report CQMs electronically using the most recent version of the electronic specifications (for example, if their CEHRT has not been certified for that particular version) would be allowed to report CQM data by attestation for the Medicare EHR Incentive Program.

We invite public comment on these proposals.

5. Clarification Regarding Reporting Zero Denominators

As we stated in the EHR Incentive Program Stage 2 final rule (77 FR 54079) we expect eligible hospitals and CAHs to adopt EHR technology that includes CQMs relevant to each eligible hospital's or CAH's patient mix. We understand, however, that there are situations in which an eligible hospital or CAH does not have data to report on a particular CQM, and its EHR is not certified to additional CQMs that can be used to replace that CQM with another for which it has data. For example, a health system with multiple eligible hospitals or CAHs may have an EHR certified for 16 CQMs, which is the minimum number of required CQMs for reporting, but not all of the eligible hospitals or CAHs in the health system may have cases to report on those particular 16 CQMs. We have received questions on how eligible hospitals and CAHs should meet their reporting requirements in this situation; therefore, we are clarifying our policy as set forth below regarding the reporting of a zero denominator for the purposes of the EHR Incentive Program and the Hospital IQR Program.

If the eligible hospital's or CAH's EHR is certified to a CQM, but the eligible hospital or CAH does not have patients that meet the denominator criteria of that CQM, the eligible hospital or CAH can submit a zero in the denominator for that CQM. Submission of a zero in the denominator for a CQM counts as a successful submission for that CQM for both the EHR Incentive Program and the Hospital IQR Program. For example, if the eligible hospital or CAH within the previously mentioned health system does not provide maternity services, but one of the 16 CQMs the health system's EHR is certified to is a maternity measure, that eligible hospital's or CAH's EHR may render a zero in the denominator for that CQM. The eligible hospital or CAH would therefore report a zero denominator for that maternity care CQM, and this would count toward the 16 required CQMs for the EHR Incentive Program and the Hospital IQR Program. Eligible hospitals or CAHs within that health system for which that maternity CQM does apply would provide data on that measure.

6. Case Threshold Exemption Policy; Clarification for 2014 and Proposed Change for 2015

In the EHR Incentive Program—Stage 2 final rule (77 FR 54080), we finalized the policy that eligible hospitals and CAHs that have 5 or fewer discharges per quarter in the same quarter as their

reporting period in FY 2014, or 20 or fewer discharges per full FY reporting period beginning in FY 2015, for which data are being electronically submitted (Medicare and non-Medicare combined) as defined by the clinical quality measure's denominator population are exempted from reporting the CQM. To be eligible for the exemption, eligible hospitals and CAHs must submit their aggregate population and sample size counts for Medicare and non-Medicare discharges for the CQM for the reporting period.

In the Health Information Technology: Revisions to the 2014 Edition Electronic Health Record Certification Criteria; and Medicare and Medicaid Programs; Revisions to the Electronic Health Record Incentive Program interim final rule, we revised the case threshold exemption policy to make it applicable for eligible hospitals and CAHs in all stages of meaningful use beginning with FY 2013, including those that are demonstrating meaningful use for the first time and submitting CQMs by attestation (77 FR 72988 through 72989). Eligible hospitals and CAHs with 5 or fewer discharges during the relevant EHR reporting period (if attesting to a 90-day EHR reporting period), or 20 or fewer discharges during the year (if attesting to a full year EHR reporting period) as defined by the CQM's denominator population would be exempted from reporting on that CQM.

We stated in the interim final rule (77 FR 72989) that beginning in FY 2014, the reporting requirement is to report 16 CQMs covering at least 3 domains from a list of 29 CQMs. We stated further that in order to be exempted from reporting fewer than 16 CQMs, the eligible hospital or CAH would need to qualify for the case threshold exemption for more than 13 of the 29 CQMs. If the eligible hospital or CAH does not meet the criteria for a case threshold exemption for 13 or more CQMs, the eligible hospital or CAH would be able to report at least 16 CQMs. Likewise, we stated that if the CQMs for which the eligible hospital or CAH can meet the case threshold of discharges do not cover at least 3 domains, the eligible hospital or CAH would be exempt from the requirement to cover the remaining domains. For example, if the eligible hospital or CAH does not meet the case threshold of discharges for 13 clinical quality measures, and thus could report 16 clinical quality measures, but the 16 clinical quality measures cover only 2 of the 3 domains, the eligible hospital or CAH would be exempt from covering the third domain.

For the reporting periods in 2014, our policy requires that an eligible hospital or CAH that claims a case threshold exemption for one CQM must choose another CQM on which to submit data, or continue to invoke the case threshold exemption until it exceeds 13 case threshold exemptions and may therefore report fewer than the 16 required CQMs. This policy assumes that the eligible hospital or CAH has an EHR that is certified to more than the minimum of 16 CQMs, and the eligible hospital or CAH has other CQMs in its EHR to choose from for reporting. We realize, however, that there could be many EHRs that are certified to only the minimum of 16 CQMs required by ONC's regulations at 45 CFR 170.102 (the definition of ''Base EHR''), and for eligible hospitals and CAHs using those EHRs, this policy may result in the eligible hospital or CAH needing to submit data on a CQM for which the EHR is not certified. It was not our intent to have eligible hospitals or CAHs report on measures for which their EHRs are not certified.

Beginning with the reporting periods in 2015, we are proposing to change the case threshold exemption policy so that if an eligible hospital or CAH qualifies for an exemption from reporting on a particular CQM, the exemption would count toward the 16 required CQMs. For example, if the eligible hospital's or CAH's EHR is certified to report 16 CQMs, and for one of those CQMs the eligible hospital or CAH has 5 or fewer discharges during the relevant EHR reporting period (if attesting to a 90-day EHR reporting period), or 20 or fewer discharges during the year (if attesting to a full year EHR reporting period) as defined by the CQM's denominator population, the eligible hospital or CAH would report data for the 15 CQMs for which the case threshold exemption does not apply, and invoke a case threshold exemption for the one CQM for which the exemption does apply for a total of 16 CQMs.

We expect eligible hospitals and CAHs to adopt EHR technology that includes CQMs relevant to the eligible hospital's or CAH's case mix, though we understand that in some cases, the eligible hospital or CAH may not meet the case threshold of discharges for a particular CQM. We believe this proposed policy better reflects our intent for eligible hospitals and CAHs to report on only those measures for which their EHRs are certified while meeting the reporting requirements for the EHR Incentive Program and Hospital IQR Program.

We invite public comment on this proposal.

X. Proposed Revision of Regulations Governing Use and Release of Medicare Advantage Risk Adjustment Data

A. Background

Section 1853 of the Act requires the Secretary to make payments to Medicare Advantage (MA) organizations offering local and regional MA plans with respect to coverage of individuals enrolled under Medicare Part C. Section 1853(a)(1)(C) of the Act requires the Secretary to adjust such payments for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines appropriate, including health status. To support these risk adjustments, section 1853(a)(3)(B) of the Act requires submission of data by MA organizations regarding the services provided to enrollees and other information the Secretary deems necessary but does not limit the Secretary's use of such data or information. In addition, section 1106 of the Act authorizes the Secretary to adopt regulations governing release of information gathered in the course of administering programs under the Act.

Implementing regulations at 42 CFR 422.310 set forth the requirements for the submission of risk adjustment data that CMS uses to risk-adjust payments. MA organizations must submit data, in accordance with CMS instructions, to characterize the context and purposes of items and services provided to their enrollees by a provider, supplier, physician, or other practitioner. Section 422.310(d)(1) provides that MA organizations submit risk adjustment data to CMS as specified by CMS. This includes comprehensive data equivalent to Medicare fee-for-service claims data (often referred to as encounter data) or data in abbreviated formats. Section 422.310(f) currently specifies CMS' uses of the risk adjustment data.

In this proposed rule, we are proposing to revise the existing regulation at § 422.310(f) to broaden the specified uses of risk adjustment data in order to strengthen program management and increase transparency in the MA program and to specify the conditions for release of risk adjustment data to entities outside of CMS.

B. Proposed Regulatory Changes

1. Proposed Expansion of Uses and Reasons for Disclosure of Risk Adjustment Data

We are first proposing to revise a reference in existing § 422.310(f) (now proposed paragraph (f)(1)) from ''data obtained under this section'' to ''data described in paragraphs (a) through (d) of this section'' in order to indicate that

the data used or released under proposed paragraph (f)(1) would not include the medical records and other data collected separately under paragraph (e) for the purpose of risk adjustment data validation (RADV) audits. We do not intend for the proposed § 422.310(f) to authorize any additional use or release of the data described in paragraph (e). The data described in paragraphs (a) through (d) would include those elements that constitute an encounter data record, including contract, plan, and provider identifiers, with the exception of disaggregated payment data as discussed below. In addition, we note that paragraph (d)(1) also authorizes the collection of abbreviated data.

The existing regulation at § 422.310(f) specifies five purposes for which CMS may use risk adjustment data obtained from MA organizations. We are clarifying in this proposed rule that CMS' uses of these data may include disclosure to CMS contractors or other agents that perform activities or analyses on CMS' behalf in connection with authorized use of the data. The existing specified purposes are: (1) To determine the risk adjustment factors used to adjust payments, as required under §§ 422.304(a) and (c); (2) to update risk adjustment models; (3) to calculate Medicare DSH percentages; (4) to conduct quality review and improvement activities; and (5) for Medicare coverage purposes. Under our proposal, paragraph (f) would be restructured to identify the purposes for which CMS may use and release risk adjustment data and to impose certain conditions on any release of that data.

We are proposing to revise paragraph (f) to add four purposes for which CMS may use risk adjustment data submitted by MA organizations: (1) To conduct evaluations and other analysis to support the Medicare program (including demonstrations) and to support public health initiatives and other health care-related research; (2) for activities to support the administration of the Medicare program; (3) for activities conducted to support program integrity; and (4) for purposes permitted by other laws. These new authorized purposes are proposed at § 422.310(f)(1)(vi) through (f)(1)(ix). In general, we anticipate that comprehensive risk adjustment data submitted by MA organizations, which MA organizations began submitting to CMS effective CY 2012, will enable CMS to generate improved data analyses that could support Medicare program evaluations, demonstration designs, and CMS' effective and efficient operational management of the Medicare program. Risk adjustment data also could be useful to support public health initiatives by governmental entities and to advance health care-related research by universities and other research organizations. We also believe that risk adjustment data can support CMS' program integrity activities in the Medicare program and other Federal health care and related programs; we intend this general term to encompass audits, investigations, efforts to combat waste, fraud, and abuse, and any other actions designed to ensure that the program operates within its authority. This includes audits, evaluations, and investigations by the Office of the Inspector General (OIG) as well as CMS' own efforts. In addition, risk adjustment data may be useful in supporting Medicare administrative activities, such as the review of the validity of bid and medical loss ratio data submitted by MA organizations. Finally, we are proposing to acknowledge that other laws may permit other uses of risk adjustment data and that this regulation is not intended to supersede such other laws.

Regarding the use of risk adjustment data outside of CMS, we are proposing at § 422.310(f)(2) that other HHS agencies, other Federal executive branch agencies, States, and external entities would only be able to obtain from CMS and use risk adjustment data for one or more of the purposes listed in proposed paragraph (f)(1). An external entity may be an individual, group, or organization. We anticipate that other HHS agencies and other Federal executive branch agencies may request this data for the same purposes CMS proposes to use the data and believe such use is appropriate. Under our proposal, other agencies that evaluate and analyze the Medicare program, perform health care-related research, support public health initiatives, perform activities in the administration of the Medicare program, or conduct activities to support program integrity in the Medicare program and other Federal health care and related programs would be able to access and use risk adjustment data for these purposes. States, such as while conducting program integrity activities for Medicaid programs or in the administration of Medicare-Medicaid demonstrations (for example, refer to the Web site at: *http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/FinancialModelstoSupportStatesEfforts inCareCoordination.html*), may access and use risk adjustment data under this proposal. We anticipate that nongovernmental external entities would generally only gain access to risk adjustment data under this proposal in connection with public health initiatives and health care-related research, as such external entities appear to have limited, if any, roles in the other purposes identified in our proposal.

CMS is seeking to balance protection of confidential beneficiary information and the proprietary interests of MA organizations with the need to effectively administer Federal health care programs and to encourage research into better ways to provide health care. CMS is seeking public comments on the proposed uses and release of data and how else to achieve the necessary balance. In particular, we are soliciting public comment on the extent to which a commercial purpose underlying a request for risk adjustment data should be a factor in evaluating whether the request is for one of the purposes that permit a disclosure under this regulation or if one of the purposes in paragraph (f)(1) of § 422.310, for which CMS would disclose data under this section, should address commercial uses of the data.

2. Proposed Conditions for CMS Release of Data

The existing regulations at § 422.310 do not specify conditions for release by CMS of risk adjustment data that are submitted by MA organizations to CMS. We are proposing to add a paragraph (2) to § 422.310(f) to address CMS' release of such data to non-CMS entities. First, as discussed above in connection with proposed paragraph (f)(1), our proposal is limited to the risk adjustment data described in § 422.310(a) through (d) and does not include the medical records and other data collected separately under paragraph (e) for the purpose of risk adjustment data validation (RADV) audits. We do not intend for the proposed revision to § 422.310(f) to authorize any additional use or release of the data described in paragraph (e).

Second, we are proposing that CMS would release only the minimum data that CMS determines is necessary to fulfill the analytical or operational goal for a particular project. In other words, CMS may determine that the appropriate data release for an approved research project is a subset of encounter data records requested to conduct the proposed inquiry (instead of all encounter data in CMS' systems for all years and provider types) or is a subset of the abbreviated data requested.

Third, we are proposing that CMS may release data under this authority to

Federal executive branch agencies, States, and external entities, only for purposes identified in paragraph (f)(1) (discussed above) and subject to a number of additional limitations: (i) Applicable Federal laws; (ii) CMS data sharing procedures; (iii) protection of beneficiary identifier elements and beneficiary confidentiality, including: (A) a prohibition against public disclosure of beneficiary identifying information; (B) release of beneficiary identifying information to other HHS agencies, other Federal executive branch agencies, Congressional support agencies, and States only when such information is needed to accomplish the purpose(s) of the disclosure; and (C) release of beneficiary identifying information to external entities only to the extent needed to link datasets; and (iv) the aggregation of payment data to protect commercially sensitive data.

These limitations are included at proposed paragraphs (f)(2)(i) through (f)(2)(iv), respectively, of § 422.310. We are soliciting public comment on other conditions or limitations on the release of this data that will help maintain a balance between protecting confidential and proprietary information with the need to effectively administer Federal health care programs and to encourage research into better ways to provide health care.

Under the provisions at proposed § 422.310(f)(2)(iv), we would not release payment data at the encounter level. We believe that release of payment data at the level of the encounter record might reveal proprietary negotiated payment rates between MA plans and providers. Given the commercially sensitive nature of this information, we are not proposing to release payment data at the level of the encounter record. In the interest of providing as much transparency as possible, while at the same time protecting proprietary information, we are proposing to authorize release of aggregate payment information. For example, we could aggregate the payment data by service category, by plan, by contract, or across contracts. We are seeking public comments on these or other approaches to aggregating payment data for release and whether the specified options are sufficiently aggregated to protect commercially sensitive information. In addition, we are seeking public comment on our conclusion that releasing payment rates at the level of the encounter data record would reveal proprietary negotiated payment rates. Specifically, we are requesting public comment on what strategies might be used under which payment data could be released while protecting commercially sensitive information.

To the extent that a requestor has separate statutory authority for requiring CMS disclosure of data, these proposed provisions do not limit or supersede such authority. For example, some Congressional support agencies may compel release of data under separate statutory authority, such as 31 U.S.C. 716; 2 U.S.C. 166(d)(1) and 601(d); and section 1805 of the Act (42 U.S.C. 1395b–6), for the purposes of conducting Congressional oversight, monitoring, making recommendations and analysis of the Medicare program. In addition, the OIG has separate statutory authority under section 1128J of the Act (42 U.S.C. 1320a–7k), coupled with section 6(a) of the Inspector General Act of 1978 (5 U.S.C. App. 3) authorizing the OIG to access data as necessary to perform its responsibilities. This regulation would not limit that authority.

3. Proposed Technical Change

We are proposing to amend § 422.300, which identifies the basis and scope of the regulations for payments to MA organizations, to add a reference to section 1106 of the Social Security Act, which governs the release of information gathered in the course of administering our programs under the Act.

XI. Proposed Changes to Enforcement Provisions for Organ Transplant Centers

A. Background

In February 2004, the Office of the Inspector General (OIG) published a report entitled ''Medicare-Approved Heart Transplant Centers'' (OEI–01–02–00520), in which the OIG outlined three recommendations for CMS' oversight of heart transplant centers: (1) That CMS expedite the development of continuing criteria for volume and survival-rate performance and for periodic recertification; (2) that CMS develop guidelines and procedures for taking actions against centers that do not meet Medicare criteria for volume and survival-rate performance requirements; and (3) that CMS take immediate steps to improve its ability to maintain accurate and timely data regarding the performance of transplant centers.

As part of CMS' efforts to strengthen oversight of organ transplant centers, we published the final rule ''Medicare Program: Hospital Conditions of Participation, Requirements for Approval and Reapproval of Transplant Centers To Perform Organ Transplants'' on March 30, 2007 in the **Federal Register** (72 FR 15198) that established conditions of participation (CoPs) for organ transplant centers and applied the survey and certification enforcement process (that is used for all other providers and suppliers of Medicare services) to Medicare-approved transplant centers. In the preamble of that final rule, we discussed our efforts to improve organ donation and transplantation services and our goals to: (1) Protect patients who are awaiting organs for transplantation; (2) establish key quality and procedural standards; and (3) improve outcomes for patients (such as patient survival) and reduce Medicare expenses by decreasing the likelihood that a transplant would fail.

In the March 30, 2007 final rule, we codified the CoPs for transplant centers at 42 CFR Part 482, Subpart E (§§ 482.68 through 482.104) and the special procedures for approval and re-approval of organ transplant centers at 42 CFR 488.61. The CoPs set forth explicit expectations for outcomes, patient safety, informed choice, and quality of transplantation services. In particular, §§ 482.80 and 482.82 specify that a transplant center's outcomes are not acceptable if, among other factors, the number of observed patient deaths or graft failures 1 year after receipt of a transplant exceeds the risk-adjusted expected number by 1.5 times, based on the most recent program-specific report from the Scientific Registry of Transplant Recipients (SRTR).

Failure to meet the transplant center requirements will lead CMS to deny approval or re-approval of a center's Medicare participation under § 488.61. However, §§ 488.61(a)(4) and (c)(4) authorize CMS to consider mitigating factors when determining approval and re-approval, respectively, for a transplant center that has not met the data submission, clinical experience, or outcome requirements, or other CoPs, if the center submits a formal, written request for such a review. The existing regulations do not limit the factors that CMS may consider, but enumerates, at a minimum, the following factors to be considered: (1) The extent to which outcome measures are met or exceeded; (2) the availability of Medicare-approved transplant centers in the area; and (3) extenuating circumstances that may have a temporary effect on a transplant center meeting the requirements under the CoPs, such as a natural disaster. CMS approval or re-approval based on mitigating factors permits a transplant center to operate as a Medicare-approved transplant center under certain circumstances despite a finding of noncompliance. Under existing regulations at

§§ 488.61(b)(4)(iv) and (c)(4)(iv), CMS will not approve a center with condition-level deficiencies but may re-approve a center with standard-level deficiencies.

B. Basis for Proposals in This Proposed Rule

In this proposed rule, we are proposing to strengthen, clarify, and provide additional transparency for the survey, certification, and enforcement procedures under § 488.61 for transplant centers that are requesting initial approval or re-approval for participation in the Medicare program when the centers have not met one or more of the CoPs but wish to have certain mitigating factors taken into consideration.

1. Proposed Expansion of Mitigating Factors Based on CMS' Experience

The existing organ transplant enforcement regulation at § 488.61 does not provide detailed information on the factors generally needed for approval or re-approval of a request based on mitigating factors that a transplant center may make in order to participate, or continue to participate, in Medicare. However, since the adoption of the organ transplant CoPs and corresponding enforcement regulations, we have expanded our knowledge regarding: (a) The factors and processes that promote improvement in transplant center outcomes; and (b) other mitigating factors that merit explicit recognition under CMS regulations.

The preponderance of requests for initial approval or re-approval based on mitigating factors that we have approved are for the transplant centers that have been able to effect substantial program improvements and, based on meaningful post-transplant survival data, demonstrated much-improved patient and graft survival subsequent to those program reforms. These performance improvements occurred after the program was cited for substandard performance by CMS and was at risk of losing Medicare participation, usually while the program was operating during the mitigating factors review process or under a binding Systems Improvement Agreement (SIA) with CMS. Under an SIA, CMS agrees to extend the effective date of a prospectively scheduled termination from Medicare participation (that is, denial of re-approval) and holds in temporary abeyance a final review of the transplant center's mitigating factors request if the transplant center agrees to engage in a structured regimen of quality improvement to improve performance during a specified period of time. At the end of the SIA period (typically 12 months), we review the transplant center's performance and make a final decision as to whether: (a) The transplant center's patient and graft survival is within the acceptable limits set forth in the regulations; or (b) the transplant center qualifies for approval or re-approval based on mitigating factors.

As of August 2013, CMS had rendered a final determination for 129 requests for approval to operate as a Medicare-approved transplant center based on mitigating factors. Of those determinations, 48 of the requests (37.8 percent) were approved based on information provided by the transplant center on its mitigating factors alone (that is, without entering into an SIA) because the transplant center had implemented substantial program improvements during the extended CMS review period, and CMS concluded that the most recent patient and graft survival data (taking into consideration the lag time in data inherent in the SRTR reports) demonstrated compliance with outcome requirements; 33 of the requests (25.6 percent) were eventually approved on the basis of the transplant center's successful SIA completion and much-improved outcomes data for the affected program; 24 of the requests (18.6 percent) involved transplant centers that were approved and the transplant centers were permitted to continue operation because CMS determined that the transplant centers met the outcome requirements during the time period it took for CMS to review the mitigating factors request; 2 of the requests (1.6 percent) were approved where the transplant center did not enter into a SIA but had made extensive use of innovative practices that were not included in the SRTR risk-adjustment methodology; 2 of the requests (1.6 percent) were approved because natural disasters temporarily impacted the transplant centers; and 20 of the requests (15.5 percent) were denied because the center failed to meet the outcome or clinical experience requirements and therefore voluntarily withdrew its participation from the Medicare program.

2. Coordination With Efforts of the Organ Procurement and Transplantation Network (OPTN) and Health Resources and Services Administration

When we adopted the outcome standards for transplant programs in 2007, we sought to harmonize CMS' outcome standards with standards of the Organ Procurement and Transplantation Network (OPTN) so that transplant centers would have a single, consistent set of outcome expectations on which to focus. We also sought to organize CMS activities in a manner that would reinforce and continue the OPTN as the first line of external review and quality improvement for transplant centers.

The OPTN is the unified transplant network established under the National Organ Transplant Act (NOTA) of 1984. The NOTA called for the network to be operated by a private, nonprofit organization under Federal contract. The OPTN is a public-private partnership that links all of the professionals involved in the donation and transplantation system. The primary goals of the OPTN are to: (a) Increase the effectiveness and efficiency of organ-sharing and equity in the national system of organ allocation; and (b) increase the supply of donated organs available for transplantation. For more details about the OPTN, we refer readers to the Web site at: *http://optn.transplant.hrsa.gov/optn/profile.asp.*

The OPTN and the Health Resources and Services Administration (HRSA) are considering adoption of an alternative methodology for calculating expected transplant outcomes, known as the ''Bayesian'' methodology, and for setting a threshold that would ''flag'' a transplant center for OPTN review of performance. However, CMS has insufficient experience with the new ''Bayesian'' methodology, and insufficient data to determine an appropriate threshold for a Medicare outcomes deficiency under a ''Bayesian'' methodology. Therefore, we are not proposing any changes in our regulations regarding this new methodology. However, we wish to continue to coordinate with, and reinforce, the OPTN's efforts if the OPTN chooses to adopt a new methodology. Therefore, we are proposing that if a program has been cited for an outcomes deficiency by CMS, but has not been flagged for review by the OPTN, CMS would take these facts into consideration if the transplant program has requested approval based on mitigating factors. For a perspective on the ''Bayesian'' methodology, we refer readers to the Web site at: *http://www.srtr.org/faqs/16.aspx.*

C. Provisions of the Proposed Regulations

We are proposing to revise the regulations at § 488.61 to include specific additional provisions describing and expanding the mitigating factors that CMS may consider when determining requests and explain the conditions under which each factor would apply.

1. Proposed Expansion of Mitigating Factors List

Existing §§ 488.61(a)(4) and (c)(4) provide three specific mitigating factors for review by CMS when determining whether a transplant center can be approved or re-approved, respectively, based on mitigating factors. These mitigating factors are: (1) The extent to which outcome measures are met or exceeded; (2) the availability of Medicare-approved transplant centers in the area; and (3) extenuating circumstances that may have a temporary effect on meeting the CoPs. We are proposing to move the listing of mitigating factors from paragraphs (a)(4)(i) through (a)(4)(iii) and (c)(4)(i) through (c)(4)(iii) to new proposed paragraphs (f), (g), and (h) under § 488.61, and to include additional factors under these three new proposed paragraphs that may be reviewed in addition to the existing three factors. We are proposing to move existing paragraphs (a)(4)(iv) and (c)(4)(iv) to the proposed new paragraph (g)(2). We also are proposing to provide clarification of the existing three mitigating factors and the conditions under which they would apply. Finally, we are proposing to revise existing paragraphs (a)(4) and (c)(4) of § 488.61 to include cross-references to the new proposed paragraphs (f), (g), and (h).

Under proposed new paragraph (f) of § 488.61, we are proposing to relist the existing three mitigating factors under paragraphs (a)(4)(i) through (a)(4)(iii) and paragraphs (c)(4)(i) through (c)(4)(iii) and expand the mitigating factors that CMS may consider by adding more description to those factors, as well as by adding new factors for review. We also are proposing to specify the procedures and timeframes for transplant centers to request consideration for approval based on mitigating factors.

Specifically, in proposed new paragraph (f)(1), we are proposing to specify the mitigating factors, except for situations of immediate jeopardy, as follows:

- The extent to which outcome measures are not met or exceeded (existing paragraphs (a)(4)(i) and (c)(4)(i); now proposed paragraph (f)(1)(i)).
- Availability of Medicare-approved transplant centers in the area (existing paragraphs (a)(4)(ii) and (c)(4)(ii); now proposed paragraph (f)(1)(ii)).
- Extenuating circumstances (for example, natural disaster) that may have a temporary effect on meeting the CoPs (existing paragraphs (a)(4)(iii) and (c)(4)(iii); now proposed paragraph (f)(1)(iii)).
- Program improvements that substantially address root causes of graft failures or patient deaths and that have been implemented and institutionalized on a sustainable basis (proposed new paragraph (f)(1)(iv)).
- Recent patient and graft survival data to determine if there is sufficient clinical experience and survival for CMS to conclude that the program is in compliance with CMS requirements, except for the data lag inherent in the reports from the SRTR (proposed new paragraph (f)(1)(v)).
- Extensive use of innovative transplantation practices relative to other transplant programs, such as a high rate of transplantation of individuals who are highly sensitized or children who have undergone the Fontan procedure, where CMS finds that the innovative practices are supported by evidence-based, published research or nationally recognized standards or Institutional Review Board (IRB) approvals, and the SRTR risk-adjustment methodology does not take the relevant key factors into consideration (proposed new paragraph (f)(1)(vi)).
- The program's performance, based on the OPTN method of calculating patient and graft survival, is within the OPTN's thresholds for acceptable performance and does not flag OPTN performance review under the applicable OPTN policy (proposed new paragraph (f)(1)(vii)).

Under proposed new paragraph (f)(2), we are proposing to include details on the content of the request for consideration of mitigating factors, based on examples that have proven to be most useful in considering successful mitigating requests. Specifically, we are proposing that a request for consideration of mitigating factors include sufficient information to permit an adequate review and understanding of the transplant program, the factors that have contributed to outcomes, program improvements or innovations that have been implemented or planned, and, in the case of natural disasters, the recovery actions planned. Examples of information to be submitted with each request could include, but are not limited to, the following:

(i) The name and contact information for the transplant hospital and the names and roles of key personnel of the transplant program;

(ii) The type of organ transplant program(s) for which approval is requested;

(iii) The CoPs that the program failed to meet, and with respect to which the transplant center is requesting CMS' review of mitigating factors;

(iv) The rationale and relevant supporting evidence for CMS' review must include, but not be limited to—

- Root Cause Analysis of patient deaths and graft failures, including factors the program has identified as likely causal or contributing factors for patient deaths and graft failures;
- Program improvements or innovations (where applicable) that have been implemented and improvements that are planned;
- Patient and donor/organ selection criteria and evaluation protocols, including methods for pre-transplant patient evaluation by cardiologists, hematologists, nephrologists, and psychiatrists or psychologists, to the extent applicable;
- Organizational chart with full-time equivalent levels, roles, and structure for reporting to hospital leadership;
- Waitlist management protocols and practices relevant to outcomes;
- Pre-operative management protocols and practices;
- Immunosuppression/infection prophylaxis protocols;
- Post-transplant monitoring and management protocols and practices;
- Quality Assessment and Performance Improvement (QAPI) Program meeting minutes from the most recent four meetings and attendance rosters from the most recent 12 months;
- Quality dashboard and other performance indicators;
- Recent outcomes data for both patient survival and graft survival; and
- Documentation of whether the program has engaged with the OPTN to review program outcomes, the status of any such review, and any steps taken to address program outcomes in accordance with the OPTN review.

Under proposed new paragraph (f)(3), we are proposing to specify a timeline for the transplant program to submit a request for mitigating factors and to make clear that, for requests related to clinical experience or outcomes, the program has additional time within which to submit supporting information. Specifically, we are proposing that within 10 days after CMS has issued formal written notice of a condition-level deficiency to the program, CMS must receive notice of the program's request to seek consideration of mitigating factors. CMS would require that all information necessary for consideration be received within 30 days of CMS' initial notification for any deficiency, except a deficiency based on insufficient clinical experience or outcomes; and within 120 days of CMS' written notification for a

deficiency based on insufficient clinical experience or outcomes. Failure of a transplant program to meet these timeframes may be the basis for denial of requests for consideration based on mitigating factors.

2. Content and Timeframe for Mitigating Factors Requests

Under proposed new § 488.61(g), we propose to clarify and expand on the description of the mitigating factors application and review process. Under existing regulations, a transplant center seeking initial approval or re-approval of Medicare participation based on the presence of mitigating factors is required to submit a formal written request to the CMS Central Office, as described earlier. If there are no deficiencies that constitute immediate jeopardy to a patient's health and safety, in limited circumstances, CMS may approve continued Medicare participation based on mitigating factors. However, where a transplant program demonstrates that it is making significant progress toward correction and program improvement, but does not yet qualify for approval based on mitigating factors, we believe there may be merit in many cases to temporarily extend the effective date of the program's Medicare participation termination in exchange for a hospital's agreement to engage in a significant and directed regimen of further quality improvement under a Systems Improvement Agreement (SIA). As we noted above, programs that have entered into SIAs have demonstrated significant improvements. Therefore, we are proposing to provide an explicit procedure in the regulations at proposed new § 488.61(g)(1)(iii) for CMS to offer an SIA and hold in abeyance a final decision on the mitigating factors request until the SIA period has ended. Proposed new paragraphs (g)(1)(i), (g)(1)(ii), and (g)(1)(iii) outline the three outcomes of CMS mitigating factors decisions: (i) Initial approval or re-approval of a program's Medicare participation based upon consideration of mitigating factors; (ii) denial of the program's request; or (iii) offer of a time-limited SIA when a transplant program has waived its appeal rights, has committed to substantial program improvements that address root causes and are institutionally supported by the hospital's governing body on a sustainable basis, and has requested more time to design or implement additional improvements or demonstrate compliance with CMS outcome requirements. The proposed new paragraph (g)(1)(iii) would clarify that, during the SIA, CMS holds the mitigating factors request in abeyance and makes a final decision to approve or deny Medicare participation when the SIA is ended, based on the results of the program's performance of the SIA.

Existing regulations at §§ 488.61(a)(4)(iv) and (c)(4)(iv)) state that CMS will not approve any program with a condition-level deficiency. However, CMS could approve a program with a standard-level deficiency upon receipt of an acceptable plan of correction. A condition-level deficiency represents a serious classification and, unless the deficiency is remedied, precludes a provider from participating in Medicare. A standard-level deficiency represents a less serious deficiency, such as one in which just a small part of a CoP is found to be out of compliance. We are proposing to move this to the proposed new paragraph § 488.61(g)(2).

3. System Improvement Agreements (SIAs)

We are proposing to add proposed new paragraph (h) to § 488.61 to set forth the purpose, intent, and contents of an SIA and the timeframes for an approved SIA with CMS.

a. Purpose and Intent of an SIA

Based on information and documentation provided by the transplant program at the time of its request, CMS may determine that, despite a deficiency or deficiencies, the transplant center has made substantial progress, has full support of the hospital governing body, and is on a quality improvement path that promises to improve prospects for patient survival. In such cases, we exercise our limited discretion to offer the transplant program the opportunity to enter into an SIA. In the absence of a written request for consideration on the basis of mitigating factors, CMS would otherwise proceed with the proposed date of termination based on noncompliance with one or more of the CoPs. In this proposed regulation, we are clarifying and specifying the terms for such SIAs.

CMS may offer an SIA to a transplant program if the transplant center can show that it has identified, or is actively improving its identification of, the root causes of its noncompliance and if the transplant center has initiated actions to correct those root causes. However, if we conclude that a transplant center does not qualify for initial approval or re-approval based on mitigating factors, the proposed rule would explicitly provide CMS with the option of offering a time-limited SIA to those transplant centers that have demonstrated progress in making substantive program improvements to address root causes of deficient outcomes, agree to undertake a structured regimen of further quality improvement, and agree to waive their appeal rights. In some instances, a voluntary period of inactivity of the transplant center is warranted, or a period of inactivity may be required by CMS as a condition of an SIA approval, as a requirement of initiating an SIA for a specified period, or until certain milestones are achieved.

During the SIA period, CMS' oversight and enforcement authority continue and CMS may conduct routine unannounced surveys, complaint investigations, and/or terminate the transplant center's participation in the Medicare program if there is not substantial compliance with Federal requirements under 42 CFR Part 482 or if the program fails to follow the terms of the SIA. In consideration for the opportunity to continue to participate in the Medicare program under an SIA during the time that structured improvements and corrections are made, despite having been found to be in noncompliance with the requirements, a transplant center would be required to waive any appeal rights that they may have, either administratively or judicially, if CMS ultimately terminates Medicare participation or denies initial approval of the transplant center. We are proposing that such a waiver applies, regardless of whether revocation or termination of approval/re-approval occurs due to a finding that the hospital failed to fulfill the terms of the SIA or due to the deficiency findings that the SIA was designed to address, pursuant to CMS' enforcement authority under the regulations.

A transplant center's approval to operate as a Medicare-approved transplant center does not guarantee any subsequent re-approvals and may be time-limited. The transplant center must submit a separate request for consideration of mitigating factors, including updated supporting documentation each time a CMS review (generally a 3–5 year cycle) or complaint investigation determines that the transplant center does not meet one or more of the data submission, clinical experience, and outcomes requirements, or other CoPs. At such time, we would review any prior mitigating factors approval to determine if the circumstances that originally warranted approval would still apply. However, in the case of past mitigating factors approval based on innovative practice, CMS may seek information in advance of a recertification survey to determine

if the reasons for past approval still prevail and, in such a case, CMS may consider mitigating factors concomitantly with the recertification survey.

b. Description and Contents of an SIA

The SIA is a binding agreement between CMS and the hospital within which a transplant center operates. A transplant center, in turn, may have one or more organ-specific programs, such as a heart, kidney, pancreas, liver, or lung transplant program. Each SIA is focused on a particular organ transplant program. The SIA is a plan for a series of actions, activities, and goals that provide opportunities for the hospital and transplant center to conduct internal improvement analysis and action, and engage external experts to ensure that the transplant center is in compliance with evidence-based standards and advances in the field that would optimize the care provided to patients.

Through an SIA, CMS is able to offer transplant centers additional time to achieve compliance with the CoPs through a structured and monitored process. In particular, the use of the formal SIA process reflects CMS' recognition that it may sometimes require more than the usual time to correct the 1-year post-transplant patient or graft survival and have the results of such improvement become manifest in the tracking data, or to develop and implement a plan to correct low-volume performance rates. We generally do not expect to use an SIA in cases of noncompliance with other CoPs, although we do not preclude such a possibility if highly unusual circumstances are present.

The SIA process (discussed in more detail below) has demonstrated effectiveness in improving patient and graft survival. An important measure of outcome is the extent to which observed patient deaths 1 year after transplant compare with the risk-adjusted expected number of deaths or graft failure for a particular transplant program. The SRTR risk adjustment methodology (used to calculate the expected numbers) takes into consideration the organs transplanted and the characteristics of the donors and recipients (for example, factors that have a bearing on the risk to patient or graft survival, such as diabetes, hypertension, advanced age, cold ischemic time of the organ to be transplanted, among others). For example, the national number of expected deaths 1 year after transplant for all transplant centers in the United States is 1.0. A transplant center that had twice the expected number of deaths would have a standardized mortality ratio (SMR) of 2.0. As of August 2013, adult kidney transplant programs cited by CMS for substandard outcomes and placed on a Medicare enforcement track, for which there was a 2-year post-CMS survey tracking period (N=15), improved their average SMR for 1-year post-transplant patient survival performance rate from 2.05 to 1.17 (close to the 1.0 national average). The transplant centers under an approved SIA improved their outcomes from an average SMR ranging from 2.41 before the SIA to 0.76 after the SIA (much better than the national average). Transplant centers not cited for substandard kidney transplant outcomes improved outcomes slightly from 0.89 to 0.84.[185]

The proposed new § 488.61(h) explicitly incorporates and specifies elements that have been important to the successful use of the SIA structure. We propose to define an SIA as a binding agreement, entered into voluntarily by the hospital and CMS, through which CMS extends the effective date of a prospectively scheduled termination of the center's Medicare participation (thereby permitting the program additional time to achieve compliance with the CoPs), contingent on the hospital's agreement to participate in a structured regimen of quality improvement activities and subsequent demonstration of improved outcomes. In some cases, transplant programs have entered a period of inactivity—voluntarily, or imposed as a condition of the SIA.

Under proposed new § 488.61(h)(1)(i) through (h)(1)(x), we are proposing that in the SIA, in exchange for additional time to initiate or continue activities to achieve compliance with the CoPs, the transplant center must agree to a regimen of specified activities, including (but not limited to) all of the following:

- Patient notification about the degree and type of noncompliance by the program, an explanation of what the program improvement efforts mean for patients, and financial assistance to defray the out-of-pocket costs of copayments and testing expenses for any wait-listed individual who wishes to be listed with another program (proposed paragraph (h)(1)(i)).
- An external independent peer review team that conducts an onsite assessment of program policies, staffing, operations, relationship to hospital services, and factors that contribute to program outcomes; that suggests quality improvements the hospital should consider; that provides both verbal and written feedback to the hospital; and that provides a verbal debriefing to CMS. Neither the hospital nor the peer review team may be required to provide a written report to CMS. The peer review team would include a transplant surgeon with expertise in the relevant organ type(s), a transplant administrator, an individual with expertise in transplant QAPI systems, a social worker or psychologist or psychiatrist, and a specialty physician with expertise in conditions particularly relevant to the applicable organ types(s) such as a cardiologist, nephrologist, or hepatologist. Except for the transplant surgeon, CMS may permit substitution of an individual with one type of expertise for another individual who has expertise particularly needed for the type of challenges experienced by the program, such as substitution of an infection control specialist in lieu of, or in addition to, a social worker (proposed paragraph (h)(1)(ii)).
- An action plan that addresses systemic quality improvements and is updated after the onsite peer review (proposed paragraph (h)(1)(iii)).
- An onsite consultant whose qualifications are approved by CMS, and who provides services for 8 days per month on average for the duration of the agreement, except that CMS may permit a portion of the time to be spent offsite and may agree to fewer consultant days each month after the first 3 months of the SIA (proposed paragraph (h)(1)(iv)).
- A comparative effectiveness analysis that compares policies, procedures, and protocols of the transplant program with those of other programs in areas of endeavor that are relevant to the transplant center's current quality improvement needs (proposed paragraph (h)(1)(v)).
- Development of increased proficiency, or demonstration of current proficiency, with patient-level data from the SRTR and the use of registry data to analyze outcomes and inform quality improvement efforts (proposed paragraph (h)(1)(vi)).
- A staffing analysis that examines the level, type, training, and skill of staff in order to inform transplant center efforts to ensure the engagement and appropriate training and credentialing of staff (proposed paragraph (h)(1)(vii)).
- Activities to strengthen performance of the Quality Assessment and Performance Improvement (QAPI) Program to ensure full compliance with

[185] Hamilton, Thomas E., *Regulatory Oversight in Transplantation: Are Patients Really Better Off,* Curr Opin Organ Transplant 2013, 18:203–209. Available at: at *http://www.co-transplantation.com.*

the requirements at § 482.96 (proposed paragraph (h)(1)(viii)).

- Monthly (unless otherwise specified) reporting and conference calls with CMS regarding the status of programmatic improvements, the results of the actions, data, reports, or other deliverables specified in the SIA, and regarding the number of transplants, the death and graft failures that occur within 1 year post-transplant (proposed paragraph (h)(1)(ix)).
- Additional or alternative requirements specified by CMS, tailored to the transplant program type and circumstances (proposed paragraph (h)(1)(x)).

c. Effective Period for an SIA

Under proposed new § 488.61(h)(2), we are proposing to specify that an SIA will be established for a 12-month period, subject to CMS' discretion to determine if a shorter time period would suffice. At the hospital's request and at CMS's discretion, CMS may extend an SIA for up to one additional 6-month period.

XII. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2014 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the proposed policies set forth in this proposed rule. MedPAC recommendations for the IPPS for FY 2015 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.*

XIII. 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/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* 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 to 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 2011 Medicare cost reports used to create the proposed FY 2015 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.J. of the preamble of this proposed rule.

Processing year	Wage data year	PPS fiscal year
2014	2011	2015
2013	2010	2014
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 2015 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.J. of the preamble of this proposed rule.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage.*

Period Available: FY 2015 IPPS Update.

3. Provider Occupational Mix Adjustment Factors for Each Occupational Category Public Use File

This file contains each hospital's occupational mix adjustment factors by occupational category. Two versions of these files are created each year to support the rulemaking.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage.*

Period Available: FY 2015 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 2015 IPPS Update.

5. FY 2015 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 2015 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 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 to support the rulemaking.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Periods Available: FY 1985 through FY 2015.

9. MS–DRG Relative Weights (Also Table 5—MS–DRGs)

This file contains a listing of MS–DRGs, MS–DRG narrative descriptions, relative weights, and geometric and arithmetic mean lengths of stay for the annual rulemaking. There are two versions of this file to support the rulemaking. (We note that Table 5 is issued concurrently with the proposed rule and the final rule and is available only via the Internet on the CMS Web site.)

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Periods Available: FY 2005 through FY 2015 IPPS Update.

10. IPPS Payment Impact File

This file contains data used to estimate payments under Medicare's hospital inpatient prospective payment systems for operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, HCRIS Cost Report Data, 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 to support the rulemaking.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/HIF/list.asp#TopOfPage*.

Periods Available: FY 1994 through FY 2015 IPPS Update.

11. AOR/BOR Tables

This file contains data used to develop the MS–DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by MS–DRG for length of stay and standardized charges. The BOR tables are ''Before Outliers Removed'' and the AOR is ''After Outliers Removed.'' (Outliers refer to statistical outliers, not payment outliers.)

Two versions of this file are created each year to support the rulemaking.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Periods Available: FY 2005 through FY 2015 IPPS Update.

12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the hospital inpatient operating and capital prospective payment systems. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, indirect medical education (IME) adjustment, disproportionate share, and the Core-based Statistical Area (CBSA). The file supports the rulemaking.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Period Available: FY 2015 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 rulemaking.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage.*

Period Available: FY 2015 IPPS Update.

14. Medicare Disproportionate Share Hospital (DSH) Supplemental File

This file contains information on the calculation of the uncompensated care payments for FY 2015. Variables include a hospital's SSI days and Medicaid days used to determine a hospital's share of uncompensated care payments, total uncompensated care payments and estimated per claim uncompensated care payment amounts. The file supports the rulemaking.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage*.

Period Available: FY 2015 IPPS Update.

15. Hospital-Acquired Condition (HAC) Reduction Program File

This file contains information on the calculation of the payment adjustment under the HAC Reduction Program. Variables include the current estimate of a hospital's total HAC Score for use in the FY 2015 HAC reduction program, the associated percentile, and a flag if the hospital would be subject to the FY 2015 reduction under section 1886(p)(1) of the Act based on this percentile. The file supports the rulemaking.

Media: Internet at: *http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage.*

Period Available: FY 2015 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.

In this proposed rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

2. ICRs for 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 2016 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 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, 2013, FY 2014, and FY 2015, we received 1, 4, 5, 3, 3, 5, 5, and 7 applications, respectively.

3. ICRs for the Proposed Occupational Mix Adjustment to the Proposed FY 2015 Index (Hospital Wage Index Occupational Mix Survey)

Section III.F. of the preamble of this proposed rule discusses the occupational mix adjustment to the proposed FY 2015 wage index, respectively. While the preamble of this proposed rule does not contain any new ICRs, we 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; it is currently approved under OCN 0938–0907.

4. Hospital Applications for Geographic Reclassifications by the MGCRB

Section III.H.2. of the preamble of this proposed rule discusses proposed changes to the wage index based on hospital reclassifications. 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 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. The burden associated with this requirement is subject to the PRA. It is currently approved under OCN 0938–0573.

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.J.3. of this preamble, are not subject to the Paperwork Reduction Act, as stated in section 5506 of the Affordable Care Act.

6. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

The Hospital 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. All of the information collection requirements previously approved under OMB control number 0938–0918 have been combined with the information collection request previously approved under OMB control number 0938–1022. We no longer use OMB control number 0938–0918.

We added additional quality measures to the Hospital IQR Program and submitted the information collection request to OMB for approval. This expansion of the Hospital IQR measures was part of our implementation of section 5001(a) of the DRA. Section 1886(b)(3)(B)(viii)(III) of the Act, added by section 5001(a) of the DRA, requires that the Secretary expand the ''starter set'' of 10 quality measures that were established by the Secretary as of November 1, 2003, to include measures ''that the Secretary determines to be appropriate for the measurement of the quality of care furnished by hospitals in inpatient settings.'' The burden associated with these reporting requirements was previously approved under OMB control number 0938–1022.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53666), we stated that, for the FY 2016 payment determinations and subsequent years updates, we sought OMB approval for a revised information collection request using the same OMB control number (0938–1022). The FY 2014 IPPS/LTCH PPS final rule (78 FR 50955) does not change the method for information collection requests. In a revised request for the FY 2017 payment determination, we will add the 4 claims-based measures that we are proposing in this proposed rule: (1) Hospital 30-day, all-cause, unplanned, risk-standardized readmission rate (RSRR) following coronary artery bypass graft (CABG) surgery; (2) Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following coronary artery bypass graft (CABG) surgery; (3) Hospital-level, risk-standardized 30-day episode-of-care payment measure for pneumonia; and (4) Hospital-level, risk-standardized 30-day episode-of-care payment measure for heart failure. We will also add the chart-abstracted measure we are proposing in this proposed rule: Severe sepsis and septic shock: management bundle (NQF#0500).

In addition, we believe there will be a reduction in the burden associated with the removal of 20 total measures proposed for removal in this rule:[186] (1) AMI–1 Aspirin at Arrival; (2) AMI–3 ACEI/ARB for left ventricular systolic dysfunction; (3) AMI–5 Beta-blocker prescribed at discharge; (4) AMI–8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI); (5) HF–2 Evaluation of left ventricular systolic function; (6) SCIP–INF–1 Prophylactic antibiotic received within 1 hour prior to surgical incision; (7) SCIP–INF–2 Prophylactic antibiotic selection for surgical patients; (8) SCIP INF–3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery); (9) SCIP INF–4: Cardiac surgery patients with controlled 6AM postoperative serum glucose; (10) SCIP INF–6 Appropriate hair removal; (11) SCIP–INF–9 Postoperative urinary catheter removal on post-operative day 1 or 2 with day of surgery being day zero; (12) SCIP–VTE–2: Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post-surgery; (13) SCIP Cardiovascular-2: Surgery Patients on a Beta Blocker prior to arrival who received a Beta Blocker during the perioperative period; (14) PN–6 Appropriate initial antibiotic

[186] We note that some of these measures are being proposed to be removed as chart-abstracted measures, but are being proposed to be retained as electronic clinical quality measures. We refer readers to section IX.A.2.b. of the preamble of this proposed rule for further discussion.

selection; (15) STK–2 Antithrombotic therapy for ischemic stroke; (16) STK–3 Anticoagulation therapy for Afib/flutter; (17) STK–5 Antithrombotic therapy by the end of hospital day 2; (18) STK–10 Assessed for rehab; and (19) VTE–4 Patients receiving un-fractionated Heparin with doses/labs monitored by protocol, and (20) one structural measure: Participation in a systematic database for cardiac surgery.

Because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe no additional information collection will be required from the hospitals for the four proposed claims-based measures. However, we believe that the proposed chart-abstracted measure will cause some additional burden. For the FY 2017 payment determination, we estimate the burden to be 1,775 hours annually per hospital. We estimate the total burden for chart abstraction and structural measures for the approximately 3,300 Hospital IQR Program-participating hospitals to be 5.86 million hours. The table below describes the hospital burden associated with the all Hospital IQR Program requirements.

BURDEN IMPACT OF HOSPITAL IQR PROGRAM REQUIREMENTS

Hospital IQR program requirement	Number of hospitals impacted	Burden per hospital for previously finalized requirements	Burden per hospital for all requirements as proposed (continuing, removed, added)	Net change in burden per hospital
Chart-abstracted and structural measures, forms	3,300	1,291 hours	963 hours	−328 hours.
Review reports for claims-based measures	3,300	4 hours	4 hours	0.
Reporting of voluntary electronic clinical quality measures (E–CQM) in place of chart-abstracted measures.	Unknown	−570 hours	−554 hours	16 hours.
Validation templates	Up to 600	144 hours	144 hours	0.
E–CQM validation test	Up to 100	0	16 hours	16 hours.
Validation charts photocopying	Up to 600	$8,640	$8,496	−$144.

In addition, we believe that there will be a reduction in burden for 15 of the 20 chart-abstracted measures that we are proposing for removal: (1) AMI–8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI); (2) HF–2 Evaluation of left ventricular systolic function; (3) SCIP–INF–1 Prophylactic antibiotic received within 1 hour prior to surgical incision; (4) SCIP–INF–2 Prophylactic antibiotic selection for surgical patients; (5) SCIP INF–3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery); (6) SCIP INF–4: Cardiac surgery patients with controlled 6AM postoperative serum glucose; (7) SCIP–INF–9 Postoperative urinary catheter removal on postoperative day 1 or 2 with day of surgery being day zero; (8) SCIP–VTE–2: Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/postsurgery; (9) SCIP Cardiovascular-2: Surgery Patients on a Beta Blocker prior to arrival who received a Beta Blocker during the perioperative period; (10) PN–6 Appropriate initial antibiotic selection; (11) STK–2 Antithrombotic therapy for ischemic stroke; (12) STK–3 Anticoagulation therapy for Afib/flutter; (13) STK–5 Antithrombotic therapy by the end of hospital day 2; (14) STK–10 Assessed for rehab; and (15) VTE–4 Patients receiving un-fractionated Heparin with doses/labs monitored by protocol.

The four chart-abstracted measures that we are proposing to remove have been suspended from the program; therefore, their removal will not impact the reporting burden. The structural measure we have proposed to remove, participation in a systematic database for cardiac surgery (NQF #0113), has an estimated a burden of nearly zero hours; therefore, its removal will not result a reduction in a significant burden reduction. Therefore, for the FY 2017 payment determination, we estimate a reduction in burden from our proposed removal of 20 measures (both chart-abstracted and structural) to be 1,775 hours annually per hospital. We estimate the total reduction in burden for chart abstraction and structural measures for the approximately 3,300 Hospital IQR Program-participating hospitals to be 5.86 million hours.

Utilizing the estimates above, we estimate an overall reduction in burden from the from the FY 2016 estimate of 5.9 million hours annually to 3.7 million hours annually for the FY 2017 payment determination year. This burden estimate includes both the new proposed measures and the measures which we are reproposing. It excludes the burden associated with the NHSN and HCAHPS measures, both of which are submitted under separate information collection requests and are approved under separate OMB control numbers.

We intend to enroll up to 100 hospitals in a voluntary large scale test of validation for electronic clinical quality measures for the Hospital IQR Program. We estimate a total of 16 hours each. We intend to reimburse hospitals $26 per hour for up to 16 hours for their participation in this test. Details regarding this reimbursement rate are as follows:

- The labor performed can be accomplished by medical records and health information technology staff, with a mean hourly wage in general medical and surgical hospitals of $19.24.[187]
- Applying OMB Circular A–76, we assumed full fringe benefits of 36.25 percent, for a fully burdened labor rate of $26.25 per hour, rounding to $26 per hour, that accounts for the full cost of labor. The circular is available at *http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a076/a76_incl_tech_correction.pdf.*

For the FY 2017 payment determination, we also are encouraging hospitals to voluntarily submit up to 16 measures electronically for the Hospital IQR Program in a manner that would permit eligible hospitals to partially align Hospital IQR Program requirements with some requirements under the Medicare EHR Incentive Program. We estimate that the total burden associated with the electronic

[187] In May 2012, the hourly wage was $18.68. Occupational employment and wages, May 2012, 29–2071 Medical records and health information technicians. Bureau of Labor Statistics, *http://www.bls.gov/oes/2012/may/oes292071.htm*, last accessed 3/31/2014. We increased this wage by 3.0 percent to account for inflation in the past 24 months. U.S. Inflation Calculator. *http://www.usinflationcalculator.com/inflation/current-inflation-rates/,* last accessed 3/31/2014.

clinical quality measure reporting option will be similar to the burden outlined for hospitals in the EHR Incentive Program Stage 2 final rule (77 FR 53968 through 54162). As described above for participation in the test of validation for electronic clinical quality metrics in the Hospital IQR Program, we believe an individual with commensurate skills will submit electronic clinical quality measures on behalf of the hospital at a rate of approximately $26.00 per hour. Therefore, we believe it will cost a hospital approximately $277.33 ($26.00 x 10 hours and 40 minutes) to report 16 electronic clinical quality measures. Additional information about the chart abstraction burden is detailed in section II.K. of Appendix A to this proposed rule.

Previously, we required hospitals to provide 96 patient charts for validation per hospital per year, including 36 charts for HAI validation (with an average page length of 1,500) and 60 charts for clinical process of care measure validation (with an average page length of 300) for a total of 72,000 pages per hospital per year. For the FY 2017 payment determination and subsequent years, we are proposing to reduce this requirement to 72 charts per hospital per year, including 40 charts for HAI validation and 36 charts for clinical process of care validation, for a total of 70,800 pages per hospital per year—a decrease of 1,200 pages per hospital per year. We reimburse hospitals at 12 cents per photocopied page (68 FR 67956 and 70 FR 23667). Therefore, the reduced burden is $144 per hospital for up to 600 hospitals.

To support validation of four HAI measures for the FY 2017 payment determination and subsequent years, we estimate an annual burden of 43,200 hours. This estimate is based on up to 600 hospitals completing HAI Templates averaging 18 hours per quarter over 4 quarters. This burden is 10,800 hours more than that for the FY 2016 payment determination as finalized in the FY 2014 IPPPS/LTCH PPS final rule (78 FR 50822 through 50825) of 32,400 hours because the HAI measures are to be validated for 4 quarters instead of 3 quarters.

7. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

As discussed in section IX.B. of the preamble of this proposed rule, section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year.

In this proposed rule, we are proposing to adopt one new clinical effectiveness measure (External Beam Radiotherapy for Bone Metastases) for the FY 2017 program and subsequent years, which, if finalized, would increase the total number of measures for the FY 2017 PCHQR measure set to 19 measures.

We also are proposing to update the specifications for the 5 previously finalized clinical process/oncology care measures to require PCHs to report all-patient data for each of these measures, and to adopt a new sampling methodology that PCHs can use to report these measures. Furthermore, we are proposing to require PCHs to submit population and sample size counts for these measures.

We believe that requiring PCHs to submit the proposed new clinical effectiveness measure data as well as the proposed sample and population size data will not prove burdensome. At least seven PCHs are currently reporting quality measure data (including population and sampling data for HCAHPS measures) on a voluntary basis to CMS. PCHs may also have experience submitting quality and population/sample size data to other entities, such as State survey agencies and The Joint Commission. As a result, we believe that the new reporting requirements we are proposing to adopt will not significantly impact PCHs.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50957 through 50959), we included burden estimates for the FY 2015 and FY 2016 programs. We noted in that final rule that those estimates represented a worst case scenario of estimated burden. In this proposed rule, we are providing a revised burden estimate for FY 2016 and a burden estimate for FY 2017. The revised estimate for FY 2016 takes into account our proposal to adopt a new sampling methodology that PCHs can use to report the five clinical process/oncology care measures. The revised FY 2016 and new FY 2017 burden estimates also incorporate the sampling methodology allowed for the SCIP measures and HCAHPS Survey because last year's burden reflected the ''worst-case scenario'' of our burden estimates (78 FR 50958). The anticipated revised burden on PCHs for the FY 2016 program and the anticipated new burden on PCHs for the FY 2017 program consist of the following: new measure training and measure maintenance, as well as the time required for collection, aggregation, and submission of data for all measures.

We estimate that 11 PCHs will submit quality measure data on approximately 37,496 cancer cases annually beginning with FY 2016 and 43,266 cancer cases annually beginning with FY 2017.[188] In addition, we estimate that PCHs will spend 0.5 hours on chart abstraction and data submission per case/event, 0.5 hours on training per each new measure, 0.25 hours on measure maintenance per each existing measure, and a maximum of 5 hours summarizing and reporting population and sample size counts for the six SCIP measures and five oncology care measures.

We are reducing the burden estimates for the HCAHPS Survey, the six SCIP measures, and the five clinical process/oncology care measures in this proposed rule to take into consideration the sampling that PCHs may use for these measures. As a result, we estimate that the reporting burden on each PCH for the FY 2016 program will be 18,758 hours. We estimate that the reporting burden on each PCH for FY 2017 would increase by 2,885 hours because PCHs would be required to report an additional quality measure (External Beam Radiotherapy for Bone Metastases). Therefore, we estimate the overall burden for all of the FY 2017 PCHQR Program requirements to be 21,643 hours per PCH. This FY 2017 estimate, which includes an additional proposed measure, represents a decrease of 30,287 hours [189] per PCH from the FY 2016 burden estimate that we published in the FY 2014 IPPS/LTCH final rule (78 FR 50957 through 50959), or an overall decrease of 58 percent in the number of hours for each PCH. Coupled with our estimated salary costs,[190] this revised estimate results in a net reduction in estimated cost of $285,252 per PCH. We believe that this burden estimate more accurately captures the hour and cost impact on PCHs participating in the PCHQR Program and reflects efforts to minimize the burden impact through the proposed adoption of a new sampling methodology that PCHs can use to report the clinical process/oncology care measures.

However, we note that these estimates are based on PCH reporting of Medicare data only. We intend to update the burden estimate to more accurately reflect the burden to PCHs for reporting

[188] FY 2011 CMS MedPAR file based on Medicare data alone.

[189] Represents the difference between previous burden estimate (51,930 hours) in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50958) and current burden estimate (21,643 hours).

[190] We are now estimating an hourly salary of $33 (*http://swz.salary.com/salarywizard/Staff-Nurse-RN-Hourly-Salary-Details.aspxper*). After accounting for employee benefits and overhead, this results in a total cost of $66 per labor hour.

all-patient data in future years, should we adopt our proposal to use all-patient data.

We will be submitting a revision of the information collection request currently approved under ONC 0938–1175 to account for the aforementioned proposed changes to the program when they are finalized.

8. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section IV.I. of the preamble of this proposed rule, we discuss requirements for the Hospital VBP Program. Specifically, in this proposed rule, we are proposing to adopt three new measures for the FY 2017 Hospital VBP Program: (1) Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia; (2) *Clostridium difficile* are measures of healthcare-associated infections reported via the CDC's National Healthcare Safety Network; and (3) PC–01: Elective Delivery Prior to 39 Completed Weeks Gestation is a chart-abstracted measure. We also are proposing to adopt Hospital-level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) for the FY 2019 Hospital VBP Program.

As provided for in section 1886(o)(2)(A) of the Act, all of these additional 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

As discussed in sections IX.C.3. through IX.C.5. of the preamble of this proposed rule, for the LTCHQR Program, for the FY 2015 payment determination and subsequent years, we are retaining the following three quality measures: (1) National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infections (CAUTI) Outcome Measure (NQF #0138); (2) National Healthcare Safety Network (NHSN) Central Line Catheter-Associated Blood Stream Infection Event (CLABSI) Outcome Measure (NQF #0139); and (3) and Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678). For the FY 2016 payment determination and subsequent years, we are retaining the following two measures in addition to the measures finalized for previous years: (1) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680); and (2) Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431). For the FY 2017 payment determination and subsequent years, we are retaining the following three measures in addition to the measures finalized for previous years: (1) National Health Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); (2) National Health Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium Difficile* Infection (CDI) Outcome Measure (NQF #1717); and (3) All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals. For the FY 2018 payment determination and subsequent years, we are retaining the following measure in addition to the measures finalized for previous years: Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).

As discussed in section IX.C.7.of the preamble of this proposed rule, we are proposing three new quality measures for inclusion in the LTCHQR Program for the FY 2018 payment determination and subsequent years: (1) Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function; (2) Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support; and (3) National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure.

Six of the previously adopted and newly proposed measures either will or would be collected via the NHSN. The NHSN is a secure, Internet-based healthcare-associated infection (HAI) tracking system maintained and managed by the CDC. The NHSN enables health care facilities to collect and use data about HAIs, adherence to clinical practices known to prevent HAIs, and other adverse events within their organizations. NHSN data collection occurs via a Web-based tool hosted by the CDC and provided free of charge to facilities. We believe that any burden increase related to complying with the submission of the proposed NHSN VAE Outcome Measure would be minimal because LTCHs have already completed the initial setup of the NHSN submission process and have become familiar with reporting data in the NHSN system due to the requirement to report CAUTI and CLABSI measures. While this requirement is subject to the PRA, we believe that the associated burden is approved under OMB control number 0920–0666, for those measures previously finalized, with an expiration date of November, 31, 2016.

The All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals is a Medicare claims-based measure. Because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe that this measure will not add any additional reporting burden for LTCHs.

The remaining five previously adopted and newly proposed measures either will or would be collected utilizing the LTCH CARE Data Set. The LTCH CARE Data Set, in its current form, has been approved under OMB control number 0938–1163. Additions will need to be made to the LTCH CARE Data Set in order to allow for collection of the two functional status measures we are proposing in section IX.C.7.a. of the preamble of this proposed rule: (1) Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function; and (2) Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support. The revised data collection will be resubmitted to OMB for approval. While this requirement is subject to the PRA, we believe the associated burden is either approved under OMB control number 0938–1163, for those measures previously finalized, with an expiration date of June 30, 2016, or will be contained in the updated information collection request.

Assuring data accuracy is vital to public reporting programs. In section IX.C.11. of the preamble of this proposed rule, we are proposing, for the FY 2016 payment determination and subsequent years, to validate data submitted to CMS on the LTCH CARE Data Set by requesting that a statistically valid random sample of 260 LTCHs copy and send portions of five patient charts each from a given CY (for a total of portions of 1,300 LTCH patient charts) to a CMS validation contractor. We are proposing that the specific portions of the patient charts would be identified in the written request, but may include the following sections, which are listed with our estimated number of pages for each: first 3 days of nurses' notes would be approximately 15 pages; the last 3 days of nurses' notes would be approximately 10 pages; the physician, physician's assistant, or nurse practitioner's admission history

and physical would be approximately 30 pages; the physician, physician's assistant, or nurse practitioner's discharge summary would be approximately 15 pages; the nurses' admission database would be approximately 40 pages; pressure ulcer assessments will would approximately 30 pages; physician's progress notes would be approximately 30 pages; physician's orders would be approximately 30 pages; and laboratory reports would be approximately 70 pages. We estimate the total submission to be no more than 270 pages in length. We estimate that 1,300 charts will allow us to validate data submitted to CMS with an estimated reliability of 70 percent, with a 5-percent margin of error, at a 95-percent confidence level. Although charts will be randomly selected, we are proposing to limit the request to specific portions of five charts per LTCH.

10. Electronic Health Record (EHR) Incentive Program and Meaningful Use (MU)

In section IX.D. of the preamble of this proposed rule, we are proposing to align the Medicare EHR Incentive Program reporting and submission timelines for clinical quality measures for eligible hospitals and CAHs with the Hospital IQR Program's reporting and submission timelines. In addition, we provide guidance and clarification of certain policies for reporting zero denominators on clinical quality measures and our policy on case threshold exemptions. Because these proposals for data collection would align with the reporting requirements in place for the Hospital IQR Program, we do not believe there is any additional burden for this collection of information.

11. ICR Regarding Proposed Revision of Regulations Governing Use and Release of Medicare Advantage (MA) Risk Adjustment Data (§ 422.310(f))

Medicare Advantage (MA) organizations are required to submit risk adjustment data to CMS organizations under current authority at § 422.310(b) through (d). The proposed changes we are proposing to make to the use and release of MA risk adjustment data under section X. of the preamble of this proposed rule provision do not change the requirements on MA organizations for submission of information to CMS, which have been in place for several years. Therefore, this proposal does not impose new information collection requirements on MA organizations. Consequently, because there are no new information collection requirements in our proposal, the proposal does not require a review by OMB under the authority of the Paperwork Reduction Act of 1995.

If you comment on these information collection and recordkeeping requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

C. Response to Public 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 public 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 public comments in the preamble of that document.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping, rural areas, X-rays.

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 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance, organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, 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 set forth below:

Title 42—Public Health

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart R—Provider Reimbursement Determinations and Appeals

■ 1. The authority citation for Subpart R is revised to read as follows:

Authority: Secs. 205, 1102, 1814(b), 1815(a), 1816, 1833, 1861(v), 1871, 1872, 1874A, 1878, and 1886 of the Social Security Act (42 U.S.C. 405, 1302, 1395f(b), 1395g(a), 1395l, 1395x(v), 1395hh, 1395ii, 1395oo, and 1395ww).

■ 2. Section 405.1801 is amended by—

■ a. Removing the definition of ''Intermediary determination'' under paragraph (a).

■ b. Adding in alphabetical order a new definition of ''Medicare Administrative Contractor determination (contractor determination)'' under paragraph (a).

■ c. Revising paragraph (b)(1).

The additions and revisions read as follows:

§ 405.1801 Introduction.

(a) * * *

Medicare Administrative Contractor determination (contractor determination) means the following:

(1) With respect to a provider of services that has filed a cost report under §§ 413.20 and 413.24 of this chapter, the term means a final determination of the amount of total reimbursement due the provider, pursuant to § 405.1803 following the close of the provider's cost reporting period, for items and services furnished to beneficiaries for which reimbursement may be made on a reasonable cost basis under Medicare for the period covered by the cost report.

(2) With respect to a hospital that receives payments for inpatient hospital services under the prospective payment system (part 412 of this chapter), the term means a final determination of the total amount of payment due the hospital, pursuant to § 405.1803 following the close of the hospital's cost reporting period, under that system for the period covered by the final determination.

(3) For purposes of appeal to the Provider Reimbursement Review Board, the term is synonymous with the phrases ''intermediary's final determination,'' ''final determination of the organization serving as its fiscal

intermediary,'' ''Secretary's final determination'' and ''final determination of the Secretary'', as those phrases are used in section 1878(a) of the Act, and with the phrases ''final Medicare administrative contractor determination, '' ''final contractor determination'', and ''final Secretary determination'' as those phrases are used in this subpart.

(4) For purposes of § 405.376 concerning claims collection activities, the term does not include an action by CMS with respect to a compromise of a Medicare overpayment claim, or termination or suspension of collection action on an overpayment claim, against a provider or physician or other supplier.

* * * * *

(b) * * *(1) *Providers.* In order to be paid for covered services furnished to Medicare beneficiaries, a provider must file a cost report with its contractor as specified in § 413.24 of this chapter. For purposes of this subpart, the term ''provider'' includes a hospital (as described in part 482 of this chapter), hospice program (as described in § 418.3 of this chapter), critical access hospital (CAH), comprehensive outpatient rehabilitation facility (CORF), renal dialysis facility, Federally qualified health center (FQHC), home health agency (HHA), rural health clinic (RHC), skilled nursing facility (SNF), and any other entity included under the Act. (FQHCs and RHCs are providers, for purposes of this subpart, effective with cost reporting periods beginning on or after October 1, 1991).

* * * * *

■ 3. Section 405.1803 is amended by revising the section heading and paragraph (a) introductory text to read as follows:

§ 405.1803 Contractor determination and notice of amount of program reimbursement.

(a) *General requirement.* Upon receipt of a provider's cost report, or amended cost report where permitted or required, the contractor must within a reasonable period of time (as described in § 405.1835(a)(2)(ii)), furnish the provider and other parties as appropriate (see § 405.1805) a written notice reflecting the contractor's final determination of the total amount of reimbursement due the provider. The contractor must include the following information in the notice, as appropriate:

* * * * *

■ 4. Section 405.1811 is amended by—

■ a. Revising the section heading.

■ b. Revising paragraph (a).

■ c. Revising paragraph (b) introductory text and paragraphs (b)(1) and (b)(2).

■ d. Revising paragraphs (c)(1), (c)(2), and (c)(3).

The revisions read as follows:

§ 405.1811 Right to contractor hearing; contents of, and adding issues to, hearing request.

(a) *Right to a contractor hearing on final contractor determination.* A provider (but no other individual, entity, or party) has a right to a contractor hearing, as a single provider appeal, for specific items claimed for a cost reporting period that is subject to a final contractor or Secretary determination if—

(1) The amount in controversy (as determined in accordance with § 405.1839) is at least $1,000 but less than $10,000; and

(2) Unless the provider qualifies for a good cause extension under § 405.1813, the date of receipt by the contractor of the provider's hearing request is—

(i) No later than 180 days after the date of receipt by the provider of the final contractor or Secretary determination; or

(ii) If the final contractor determination is not issued (through no fault of the provider) within 12 months of the date of receipt by the contractor of the provider's perfected cost report or amended cost report (as specified in § 413.24(f) of this chapter), no later than 180 days after the expiration of the 12-month period for issuance of the final contractor determination. The date of receipt by the contractor of the provider's perfected cost report or amended cost report is presumed to be the date the contractor stamped ''Received'' unless it is shown by a preponderance of the evidence that the contractor received the cost report on an earlier date.

(b) *Contents of request for a contractor hearing.* The provider's request for a contractor hearing must be submitted in writing to the contractor, and the request must include the elements described in paragraphs (b)(1) through (b)(3) of this section. If the provider submits a hearing request that does not meet the requirements of paragraph (b)(1), (b)(2), or (b)(3) of this section, the contractor hearing officer may dismiss with prejudice the appeal, or take any other remedial action he or she considers appropriate.

(1) A demonstration that the provider satisfies the requirements for a contractor hearing as specified in paragraph (a) of this section, including a specific identification of the final contractor or Secretary determination under appeal.

(2) For each specific item under appeal, a separate explanation of why, and a description of how, the provider disagrees with the specific aspects of the final contractor or Secretary determination under appeal, including an account of all of the following:

(i) Why the provider believes Medicare payment is incorrect for each disputed item (or, where applicable, why the provider is unable to determine whether Medicare payment is correct because it allegedly does not have access to underlying information concerning the calculation of its payment);

(ii) How and why the provider believes Medicare payment should be determined differently for each disputed item; and

(iii) If the provider self-disallows a specific item (as specified in § 413.24(j) of this chapter), an explanation of the nature and amount of each self-disallowed item, the reimbursement sought for the item, and why the provider self-disallowed the item instead of claiming reimbursement for the item.

* * * * *

(c) * * *

(1) The request to add issues complies with the requirements of paragraphs (a) and (b) of this section as to each new specific item at issue.

(2) The specific items raised in the initial hearing request and the specific matters identified in subsequent requests to add issues, when combined, satisfy the requirements of paragraph (a)(1) of this section.

(3) The contractor hearing officer receives the requests to add issues no later than 60 days after the expiration of the applicable 180-day period prescribed in paragraph (a)(2) of this section.

§ 405.1813 [Amended]

■ 5. In § 405.1813, paragraphs (a) and (b) are amended by removing the cross-reference ''§ 405.1811(a)(3)'' and adding in its place the cross-reference ''§ 405.1811(a)(2)''.

§ 405.1814 [Amended]

■ 6. Section 405.1814 is amended by removing paragraph (b)(3).

■ 7. A new § 405.1832 is added to read as follows:

§ 405.1832 Contractor hearing officer review of compliance with the substantive reimbursement requirement of an appropriate cost report claim.

(a) *General.* In order to receive or potentially qualify for reimbursement for a specific item, the provider must include in its cost report an appropriate

claim for the specific item (as prescribed in § 413.24(j) of this chapter). If the provider files an appeal to the contractor seeking reimbursement for a specific item and any party to such appeal questions whether the provider's cost report included an appropriate claim for the specific item, the contractor hearing officer(s) must address such questions in accordance with the procedures set forth in this section.

(b) *Summary of procedures.* (1) *Preliminary steps.* The contractor hearing officer(s) must give each party to the appeal an adequate opportunity to submit factual evidence and legal argument regarding the question of whether the provider's cost report included an appropriate claim for the specific item under appeal. Upon receipt of timely submitted factual evidence and legal argument (if any), the contractor hearing officer(s) must review such evidence and argument, and prepare written specific findings of fact and conclusions of law on the question of whether the provider's cost report complied with, for the specific item under appeal, the cost report claim requirements prescribed in § 413.24(j) of this chapter. In reaching such specific factual findings and legal conclusions, the contractor hearing officer(s) must follow the procedures set forth in § 413.24(j)(3) of this chapter for determining whether the provider's cost report included an appropriate claim for the specific item under appeal. The contractor hearing officer(s) must promptly give a copy of such written specific factual findings and legal conclusions to each party to the appeal, and such factual findings and legal conclusions must be included in the record of administrative proceedings for the appeal (as prescribed in § 405.1827).

(2) *Limits on contractor hearing officer(s) actions.* The contractor hearing officer(s)'s specific findings of fact and conclusions of law (pursuant to paragraph (b)(1) of this section) must not be invoked or relied on by the contractor hearing officer(s) as a basis to deny, or decline to exercise, jurisdiction over a specific item or take any other of the actions specified in paragraph (c) of this section. Upon giving the parties to the appeal the contractor hearing officer(s)'s written specific factual findings and legal conclusions (pursuant to paragraph (b)(1) of this section) on the question of whether the provider's cost report included an appropriate cost report claim for the specific item under appeal, the contractor hearing officer(s) must proceed to issue one of the two types of overall decisions specified in paragraphs (d) and (e) of this section with respect to the specific item. If the contractor hearing officer(s) issues an overall contractor hearing decision (as specified in paragraph (d) of this section) regarding the specific item under appeal, the contractor hearing officer(s)'s written specific factual findings and legal conclusions (pursuant to paragraph (b)(1) of this section) must be included in such overall contractor hearing decision regarding the specific item, along with the other matters that are required by the regulations for an overall contractor hearing decision. However, if the contractor hearing officer(s) issues an overall jurisdictional dismissal decision (as specified in paragraph (e) of this section) regarding the specific item under appeal, the contractor hearing officer(s)'s written specific factual findings and legal conclusions (pursuant to paragraph (b)(1) of this section) must not be included in the overall jurisdictional dismissal decision regarding the specific item. The contractor hearing officer(s) may permit reimbursement for the specific item under appeal, as part of an overall contractor hearing decision, but such reimbursement may be permitted only to the extent authorized by paragraph (f) of this section.

(c) *Prohibition of certain types of decisions, orders, and other actions.* (1) If the contractor hearing officer(s) determines, in its findings of fact and conclusions of law (as prescribed by paragraph (b)(1) of this section), that the provider's cost report did not include an appropriate claim for the specific item under appeal, the contractor hearing officer(s) may not—

(i) Deny jurisdiction over the specific item under appeal, based on (in whole or in part) the contractor hearing officer(s)'s factual findings and legal conclusions (reached under paragraph (b)(1) of this section);

(ii) Decline to exercise jurisdiction over the specific item under appeal, based on (in whole or in part) the contractor hearing officer(s)'s factual findings and legal conclusions (reached under paragraph (b)(1) of this section); or

(iii) Impose any sanction or take any other action against the interests of any party to the appeal except as provided in paragraph (f) of this section, based on (in whole or in part) the contractor hearing officer(s)'s factual findings and legal conclusions (reached under paragraph (b)(1) of this section).

(2) Regardless of whether the contractor hearing officer(s) determines, in its findings of fact and conclusions of law (as prescribed by paragraph (b)(1) of this section), that the provider's cost report did or did not include an appropriate claim for the specific item under appeal, the contractor hearing officer(s) may not—

(i) Deny jurisdiction over the specific item under appeal, based on (in whole or in part) the absence, in the final contractor or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item. *Exception:* If the provider's appeal of the specific item is based on a reopening of such item (pursuant to § 405.1885) where the specific item is not revised, adjusted, corrected, or otherwise changed in a revised final contractor or Secretary determination, the contractor must deny jurisdiction over the specific item under appeal (as prescribed in §§ 405.1887(d) and 405.1889(b));

(ii) Decline to exercise jurisdiction over the specific item under appeal, based on (in whole or in part) the absence, in the final contractor or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item; or

(iii) Impose any sanction or take any other action against the interests of any party to the appeal except as provided in paragraph (f) of this section, based on (in whole or in part) the absence, in the final contractor or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item.

(d) *Contractor hearing decision must include any factual findings and legal conclusions under paragraph (b)(1) of this section.* If the contractor hearing officer(s) issues a hearing decision regarding the specific item under appeal (pursuant to § 405.1831), any specific findings of fact and conclusions of law by the contractor hearing officer(s) (reached under paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the specific item, must be included in such hearing decision along with the other matters prescribed by § 405.1831. The contractor hearing officer(s)'s factual findings and legal conclusions (reached under paragraph (b)(1) of this section) about whether there was an appropriate cost report claim for the specific item under appeal are subject to the provisions of

§ 405.1833 just as those provisions apply to the other parts of the contractor hearing decision. If the contractor hearing officer(s) determines that the provider's cost report—

(1) Included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j) of this chapter), the contractor hearing decision must also address whether the other substantive reimbursement requirements for the specific item are also satisfied; or

(2) Did not include an appropriate claim for the specific item under appeal, the contractor hearing officer(s) has discretion whether or not to address in the contractor hearing decision whether the other substantive reimbursement requirements for the specific item are also satisfied.

(e) *Contractor jurisdictional dismissal decision must not include factual findings and legal conclusions under paragraph (b)(1) of this section.* If the contractor hearing officer(s) issues a jurisdictional dismissal decision regarding the specific item under appeal (pursuant to § 405.1814(c)), the contractor hearing officer(s)'s specific findings of fact and conclusions of law (reached under paragraph (b)(1) of this section) on the question of whether the provider's cost report included an appropriate claim for the specific item must not be included in such jurisdictional dismissal decision.

(f) *Effects of the contractor hearing officer(s)'s factual findings and legal conclusions under paragraph (b)(1) of this section when part of a final contractor hearing decision.* If the contractor hearing officer(s) determines, as part of a final and binding contractor hearing decision (pursuant to § 405.1833 and paragraphs (b)(1) and (d) of this section), that the provider's cost report—

(1) Included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j) of this chapter), the specific item is reimbursable in accordance with Medicare policy, but only if the contractor hearing officer(s) further determines in such final contractor hearing decision that all the other substantive reimbursement requirements for the specific item are also satisfied; or

(2) Did not include an appropriate cost report claim for the specific item under appeal, then the specific item is not reimbursable, regardless of whether the contractor hearing officer(s) further determines in such final contractor hearing decision that the other substantive reimbursement requirements for the specific item are or are not satisfied.

■ 8. Section 405.1834 is amended by adding a new paragraph (b)(2)(iii) to read as follows:

§ 405.1834 CMS reviewing official procedure.

* * * * *

(b) * * *

(2) * * *

(iii) If the CMS reviewing official reviews an contractor hearing decision regarding a specific item, the CMS reviewing official's review of such a contractor hearing decision will include, and any decision issued by the CMS reviewing official (under paragraph (e) of this section) will address, the contractor hearing officer(s)'s specific findings of fact and conclusions of law in such contractor hearing decision (as prescribed in § 405.1832(b)(1) and (d)) on the question of whether the provider's cost report included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j) of this chapter).

* * * * *

■ 9. Section 405.1835 is amended by—

■ a. Revising paragraph (a).

■ b. Revising paragraphs (b)(1), (b)(2) introductory text, and (b)(2)(iii).

■ c. Revising paragraphs (c)(1), (c)(2), and (c)(3).

The revisions read as follows:

§ 405.1835 Right to Board hearing; contents of, and adding issues to, hearing request.

(a) *Right to hearing on final contractor determination.* A provider (but no other individual, entity, or party) has a right to a Board hearing, as a single provider appeal, for specific items claimed in its cost report for a cost reporting period that is subject to a final contractor or Secretary determination, if—

(1) The amount in controversy (as determined in accordance with § 405.1839) is $10,000 or more; and

(2) Unless the provider qualifies for a good cause extension under § 405.1836, the date of receipt by the Board of the provider's hearing request is—

(i) No later than 180 days after the date of receipt by the provider of the final contractor or Secretary determination; or

(ii) If the final contractor determination is not issued (through no fault of the provider) within 12 months of the date of receipt by the contractor of the provider's perfected cost report or amended cost report (as specified in § 413.24(f) of this chapter), no later than 180 days after the expiration of the 12-month period for issuance of the final contractor determination. The date of receipt by the contractor of the provider's perfected cost report or amended cost report is presumed to be the date the contractor stamped ''Received'' unless it is shown by a preponderance of the evidence that the contractor received the cost report on an earlier date.

(b) * * *

(1) A demonstration that the provider satisfies the requirements for a Board hearing as specified in paragraph (a) of this section, including a specific identification of the final contractor or Secretary determination under appeal.

(2) For each specific item under appeal, a separate explanation of why, and a description of how, the provider disagrees with the specific aspects of the final contractor or Secretary determination under appeal, including an account of all of the following:

* * * * *

(iii) If the provider self-disallows a specific item (as specified in § 413.24(j) of this chapter), an explanation of the nature and amount of each self-disallowed item, the reimbursement sought for the item, and why the provider self-disallowed the item instead of claiming reimbursement for the item.

* * * * *

(c) * * *

(1) The request to add issues complies with the requirements of paragraphs (a) and (b) of this section as to each new specific item at issue.

(2) The specific items raised in the initial hearing request and the specific items identified in subsequent requests to add issues, when combined, satisfy the requirements of paragraph (a)(2) of this section.

(3) The Board receives the request to add issues no later than 60 days after the expiration of the applicable 180-day period prescribed in paragraph (a)(2) of this section.

§ 405.1836 [Amended]

■ 10. In § 405.1836, paragraphs (a) and (b) are amended by removing the cross-reference ''§ 405.1835(a)(3)'' and adding in its place the cross-reference ''§ 405.1835(a)(2)''.

■ 11. Section 405.1837 is amended by revising paragraphs (a)(1), (c)(2) introductory text, (c)(2)(iii) and (e)(4) to read as follows:

§ 405.1837 Group appeals.

(a) * * *

(1) The provider satisfies individually the requirements for a Board hearing under § 405.1835(a)(1);

* * * * *

(c) * * *

(2) An explanation (for each specific item at issue) of each provider's

disagreement with its final contractor or Secretary determination under appeal, including an account of—

* * * * *

(iii) If the provider self-disallows a specific item (as specified in § 413.24(j) of this chapter), an explanation of the nature and amount of each self-disallowed item, the reimbursement sought for the item, and why the provider self-disallowed the item instead of claiming reimbursement for the item.

* * * * *

(e) * * *

(4) A provider may submit a request to the Board to join a group appeal any time before the Board issues one of the decisions specified in § 405.1875(a)(1). By submitting a request, the provider agrees that, if the request is granted, the provider is bound by the Board's actions and decision in the appeal. If the Board denies a request, the Board's action is without prejudice to any separate appeal the provider may bring in accordance with § 405.1811, § 405.1835, or this section. For purposes of determining timeliness for the filing of any separate appeal and for the adding of issues to such appeal, the date of receipt of the provider's request to form or join the group appeal is considered the date of receipt for purposes of meeting the applicable 180-day period prescribed in § 405.1835(a)(2).

* * * * *

§ 405.1839 [Amended]

■ 12. In 405.1839, paragraph (a)(1) is amended by removing the cross-reference ''§ 405.1811(a)(2) of this subpart'' and adding in its place the cross-reference ''§ 405.1811(a)(1)''; and by removing the cross-reference ''§ 405.1835(a)(2) of this subpart'' and adding in its place the cross-reference ''§ 405.1835(a)(1)''.

§ 405.1840 [Amended]

■ 13. Section 405.1840 is amended by removing paragraph (b)(3).

■ 14. A new § 405.1873 is added to read as follows:

§ 405.1873 Board review of compliance with the reimbursement requirement of an appropriate cost report claim.

(a) *General.* In order to receive or potentially receive reimbursement for a specific item, the provider must include in its cost report an appropriate claim for the specific item (as prescribed in § 413.24(j) of this chapter). If the provider files an appeal to the Board seeking reimbursement for the specific item and any party to such appeal questions whether the provider's cost report included an appropriate claim for the specific item, the Board must address such question in accordance with the procedures set forth in this section.

(b) *Summary of procedures.* (1) *Preliminary steps.* The Board must give the parties an adequate opportunity to submit factual evidence and legal argument regarding the question of whether the provider's cost report included an appropriate claim for the specific item under appeal. Upon receipt of timely submitted factual evidence or legal argument (if any), the Board must review such evidence and argument and prepare written specific findings of fact and conclusions of law on the question of whether the provider's cost report complied with, for the specific item under appeal, the cost report claim requirements prescribed in § 413.24(j) of this chapter. In reaching such specific factual findings and legal conclusions, the Board must follow the procedures set forth in § 413.24(j)(3) of this chapter for determining whether the provider's cost report included an appropriate claim for the specific item under appeal. The Board must promptly give a copy of such written specific factual findings and legal conclusions to each party to the appeal, and such factual findings and legal conclusions must be included in the record of administrative proceedings for the appeal (as prescribed in § 405.1865).

(2) *Limits on Board actions.* The Board's specific findings of fact and conclusions of law (pursuant to paragraph (b)(1) of this section) must not be invoked or relied on by the Board as a basis to deny, or decline to exercise, jurisdiction over a specific item or take any other of the actions specified in paragraph (c) of this section. Upon giving the parties to the appeal the Board's written specific factual findings and legal conclusions (pursuant to paragraph (b)(1) of this section) on the question of whether the provider's cost report included an appropriate cost report claim for the specific item under appeal, the Board must proceed to issue one of the four types of overall decisions specified in paragraphs (d) and (e) of this section with respect to the specific item. If the Board issues either of two types of overall Board decisions (as specified in paragraph (d) of this section) regarding the specific item under appeal, the Board's written specific factual findings and legal conclusions (pursuant to paragraph (b)(1) of this section) must be included in such overall Board decision regarding the specific item, along with the other matters that are required by the regulations for the pertinent type of overall Board decision. However, if the Board issues either of two other types of overall Board decisions (as specified in paragraph (e) of this section) regarding the specific item under appeal, the Board's written specific factual findings and legal conclusions (pursuant to paragraph (b)(1) of this section) must not be included in the overall Board decision regarding the specific item. The Board may permit reimbursement for the specific item under appeal, as part of one of the two types of overall Board decisions that are specified in paragraph (d) of this section, but such reimbursement may be permitted only to the extent authorized by paragraph (f) of this section.

(c) *Prohibition of certain types of decisions, orders, and other actions.* (1) If the Board determines, in its findings of fact and conclusions of law (as prescribed by paragraph (b)(1) of this section), that the provider's cost report did not include an appropriate claim for the specific item under appeal, the Board may not—

(i) Deny jurisdiction over the specific item under appeal, based on (in whole or in part) the Board's factual findings and legal conclusions (reached under paragraph (b)(1) of this section);

(ii) Decline to exercise jurisdiction over the specific item under appeal, based on (in whole or in part) the Board's factual findings and legal conclusions (reached under paragraph (b)(1) of this section); or

(iii) Take any of the actions set forth in § 405.1868(b), (c), or (d), impose any sanction, or take any other action against the interests of any party to the appeal, except as provided in paragraph (f) of this section, based on (in whole or in part) the Board's factual findings and legal conclusions (reached under paragraph (b)(1) of this section).

(2) Regardless of whether the Board determines, in its findings of fact and conclusions of law (as prescribed by paragraph (b)(1) of this section), that the provider's cost report did or did not include an appropriate claim for the specific item under appeal, the Board may not—

(i) Deny jurisdiction over the specific item under appeal, based on (in whole or in part) the absence, in the final contractor determination or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item. *Exception:* If the provider's appeal of the specific item is based on a reopening of such item (pursuant to § 405.1885) where the specific item is not revised, adjusted, corrected, otherwise changed

in a revised final contractor or Secretary determination, the Board must deny jurisdiction over the specific item under appeal (as prescribed in §§ 405.1887(d) and 405.1889(b));

(ii) Decline to exercise jurisdiction over the specific item under appeal, based on (in whole or in part) the absence, in the final contractor determination or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item; or

(iii) Take any of the actions set forth in § 405.1868(b), (c), or (d), impose any sanction, or take any other action against the interests of any party to the appeal, except as provided in paragraph (f) of this section, based on (in whole or in part) the absence, in the final contractor determination or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item.

(d) *Two types of Board decisions that must include any factual findings and legal conclusions under paragraph (b)(1) of this section.* (1) *Board hearing decision.* If the Board issues a hearing decision regarding the specific item under appeal (pursuant to § 405.1871), any specific findings of fact and conclusions of law by the Board (reached under paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the specific item, must be included in such hearing decision along with the other matters prescribed by § 405.1871(a). The Board's factual findings and legal conclusions (reached under paragraph (b)(1) of this section), about whether there was an appropriate cost report claim for the specific item under appeal, are subject to the provisions of § 405.1871(b) just as those provisions apply to the other parts of the Board's hearing decision. If the Board determines that the provider's cost report—

(i) Included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j) of this chapter), the Board's hearing decision must also address whether the other substantive reimbursement requirements for the specific item are also satisfied; or

(ii) Did not include an appropriate claim for the specific item under appeal, the Board has discretion whether or not to address in the Board's hearing decision whether the other substantive reimbursement requirements for the specific item are also satisfied.

(2) *Board expedited judicial review (EJR) decision, where EJR is granted.* If the Board issues an EJR decision where EJR is granted regarding a legal question that is relevant to the specific item under appeal (pursuant to § 405.1842(f)(1)), the Board's specific findings of fact and conclusions of law (reached under paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the specific item, must be included in such EJR decision along with the other matters prescribed by § 405.1842(f)(1). The Board's factual findings and legal conclusions (reached under paragraph (b)(1) of this section) about whether there was an appropriate cost report claim for the specific item under appeal are subject to the provisions of § 405.1842(g)(1), (g)(2), (h)(1), and (h)(3) just as those provisions apply to the other parts of the Board's EJR decision.

(e) *Two other types of Board decisions that must not include the Board's factual findings and legal conclusions under paragraph (b)(1) of this section.* (1) *Board jurisdictional dismissal decision.* If the Board issues a jurisdictional dismissal decision regarding the specific item under appeal (pursuant to § 405.1840(c)), the Board's specific findings of fact and conclusions of law (reached under paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the specific item, must not be included in such jurisdictional dismissal decision.

(2) *Board expedited judicial review (EJR) decision, where EJR is denied.* If the Board issues an EJR decision where EJR is denied regarding a legal question that is relevant to the specific item under appeal (pursuant to § 405.1842(f)(2)), the Board's specific findings of fact and conclusions of law (reached under paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the same item, must not be included in such EJR decision. If the Board conducts further proceedings and issues another decision (as specified in § 405.1842(h)(2)(i)), the Board's specific findings of fact and conclusions of law (reached under paragraph (b)(1) of this section)—

(i) Must be included in any further hearing decision or EJR decision where EJR is granted regarding the specific item under appeal (as prescribed in paragraph (d) of this section); but

(ii) Must not be included in any further jurisdictional dismissal decision or EJR decision where EJR is denied regarding the specific item under appeal (as prescribed in paragraph (e) of this section).

(f) *Effects of the Board's factual findings and legal conclusions under paragraph (b)(1) of this section in two types of final decisions.* (1) *When part of a final hearing decision.* If the Board determines, as part of a final and binding hearing decision (pursuant to § 405.1871(b) and paragraphs (b)(1) and (d)(1) of this section), that the provider's cost report—

(i) Included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j) of this chapter), the specific item is reimbursable in accordance with Medicare policy, but only if the Board further determines in such final hearing decision that all the other substantive reimbursement requirements for the specific item are also satisfied; or

(ii) Did not include an appropriate cost report claim for the specific item under appeal, then the specific item is not reimbursable, regardless of whether the Board further determines in such final hearing decision that the other substantive reimbursement requirements for the specific item are or are not satisfied.

(2) *When part of a final EJR decision that grants EJR.* If the Board determines or the Administrator of CMS determines (pursuant to § 405.1875), as applicable, in a final and binding EJR decision that grants EJR regarding a legal question that is relevant to the specific item under appeal (pursuant to § 405.1842(g)(1) and paragraphs (b)(1) and (d)(2) of this section), that the provider's cost report—

(i) Included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j) of this chapter), the specific item is reimbursable in accordance with Medicare policy, but only to the extent permitted by the final decision of a Federal court pursuant to the EJR provisions of section 1878(f)(1) of the Act (see also §§ 405.1842 and 405.1877)); or

(ii) Did not include an appropriate claim for the specific item under appeal, then the specific item is not reimbursable, unless—

(A) The specific factual findings and legal conclusions (reached under paragraph (b)(1) of this section) of the Board or the Administrator, as applicable, on the question of whether the provider's cost report included an appropriate claim for the specific item under appeal, are reversed or modified by the final decision of a Federal court (pursuant to section 1878(f)(1) of the Act and § 405.1877); and

(B) Only to the extent otherwise permitted by the final decision of a Federal court pursuant to the EJR provisions of section 1878(f)(1) of the Act (see also §§ 405.1842 and 405.1877) and by Medicare policy.

■ 15. Section 405.1875 is amended by—

■ a. Revising the last sentence of paragraph (a) introductory text.

■ b. Adding a new paragraph (a)(2)(v).

■ c. Revising paragraph (f)(5).

The revisions and additions read as follows:

§ 405.1875 Administrator review.

(a) * * * The Board is required to send to the Office of the Attorney Advisor a copy of each decision specified in paragraphs (a)(2)(i), (a)(2)(ii), and (a)(2)(iii) of this section upon issuance of the decision.

* * * * *

(2) * * *

(v) If the Administrator reviews a Board hearing decision regarding a specific item, or for a Board EJR decision, on the question of whether there is Board jurisdiction over a specific item, the Administrator's review of such a hearing decision or EJR decision, as applicable, will include, and any decision issued by the Administrator (under paragraph (e) of this section) will address, the Board's specific findings of fact and conclusions of law in such hearing decision or EJR decision (as prescribed in § 405.1873(b)(1) and (d)) on the question of whether the provider's cost report included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j) of this chapter).

* * * * *

(f) * * *

(5) In addition to ordering a remand to the Board, the Administrator may order a remand to any component of HHS or CMS or to a contractor under appropriate circumstances, including, but not limited to, for the purpose of effectuating a court order (as described in § 405.1877(g)(2)). When the contractor's denial of the relief, that the provider sought before the Board and that is under review by the Administrator, was based on procedural grounds (such as the alleged failure of the provider to satisfy a time limit) or was based on the alleged failure to supply adequate documentation to support the provider's claim, and the Administrator rules that the basis of the contractor's denial is invalid, the Administrator remands to the contractor for the contractor to make a determination on the merits of the provider's claim.

Nomenclature Changes

Subpart R—[Amended]

■ 16. Amend Subpart R of part 405 by removing the term or phrase in the first column and replacing it with the term or phrase in the second column:

Remove	Add
an intermediary	''a contractor''
intermediary	''contractor''
intermediaries	''contractors''
intermediaries	''contractors'''
''intermediary's''	''contractor's''

Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

■ 17. The authority citation for Subpart X, continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 18. Section 405.2468 is amended by revising paragraph (f)(1) to read as follows:

§ 405.2468 Allowable costs.

* * * * *

(f) * * *

(1) Effective for portions of cost reporting periods occurring on or after January 1, 1999, if an RHC or an FQHC incurs ''all or substantially all'' of the costs for the training program in the nonhospital setting as defined in § 413.75(b) of this chapter, the RHC or FQHC may receive direct graduate medical education payment for those residents. However, in connection with cost reporting periods for which ''all or substantially all of the costs for the training program in the nonhospital setting'' is not defined in § 413.75(b) of this chapter, if an RHC or an FQHC incurs the salaries and fringe benefits (including travel and lodging where applicable) of residents training at the RHC or FQHC, the RHC or FQHC may receive direct graduate medical education payments for those residents.

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 19. The authority citation for Part 412 is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 124 of Public Law 106–113 (113 Stat. 1501A–332), sec. 1206 of Public Law 113–67, and sec. 112 of Public Law 113–93.

■ 20. Section 412.23 is amended by—

■ a. Revising paragraphs (e)(6)(i), (e)(6)(ii) introductory text, and (e)(6)(ii)(B)(*2*).

■ b. Revising paragraphs (e)(7)(i) and (e)(7)(ii) introductory text.

■ c. Adding new paragraph (e)(7)(iii).

The revisions and additions read as follows:

§ 412.23 Excluded hospitals: Classifications.

* * * * *

(e) * * *

(6) * * * (i) *General rule.* Except as specified in paragraphs (e)(6)(ii) and (e)(6)(iii) of this section for the period beginning December 29, 2007 and ending December 28, 2012, and the period beginning April 1, 2014 and ending September 30, 2017, a moratorium applies to the establishment and classification of a long-term care hospital as described in paragraphs (e) and (e)(1) through (e)(5) of this section or a long-term care hospital satellite facility as described in § 412.22(h).

(ii) *Exception.* The moratorium specified in paragraph (e)(6)(i) of this section is not applicable to the establishment and classification of a long-term care hospital that meets the requirements of paragraphs (e) and (e)(1) through (e)(5) of this section, or a long-term care hospital satellite facility that meets the requirements of § 412.22(h), if the long-term care hospital or long-term care satellite facility meets the following criteria on or before December 29, 2007, or on or before April 1, 2014, as applicable:

* * * * *

(B) * * *

(*2*)(*i*) Has expended before December 29, 2007, at least 10 percent (or, if less, $2.5 million) of the estimated cost of the project specified in paragraph (e)(6)(ii)(B)(*1*) of his section;

(*ii*) Has expended, before April 1, 2014, at least 10 percent (or, if less, $2.5 million) of the estimated cost of the project specified in paragraph (e)(6)(ii)(B)(*1*) of this section.

* * * * *

(7) * * * (i) For purposes of this paragraph, an existing long-term care hospital or long-term care hospital satellite facility means a long-term care hospital that meets the requirements of paragraph (e) of this section or long-term care hospital satellite facility that meets the requirements of § 412.22(h) and received payment under the provisions of subpart O of this part prior to the dates noted in the following moratorium clauses.

(ii) December 29, 2007, through December 28, 2007—

* * * * *

(iii) April 1, 2014 through September 30, 2017—The number of Medicare-certified beds in an existing long-term

care hospital or an existing long-term care hospital satellite facility must not be increased beyond the number of Medicare-certified beds on April 1, 2014.

* * * * *

■ 21. Section 412.64 is amended by—
■ a. Removing paragraph (b)(1)(ii)(D).
■ b. Revising paragraph (b)(3)(i).
■ c. Revising paragraphs (d)(1), (d)(2)(i) introductory text, (d)(2)(ii), and (d)(3) introductory text.
■ d. In paragraphs (h)(4) and (h)(4)(vi), removing the date ''October 1, 2014'' and adding in its place the date ''October 1, 2015''.

The revisions read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(b) * * *

(3)(i) For discharges occurring on or after October 1, 2004, a hospital that is located in a rural county adjacent to one or more urban areas is deemed to be located in an urban area and receives the Federal payment amount for the urban area to which the greater number of workers in the county commute if the rural county would otherwise be considered part of an urban area, under the standards for designating MSAs if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or central counties of all adjacent MSAs. Qualifying counties are determined based upon OMB standards, using the most recent OMB standards for delineating statistical areas adopted by CMS.

* * * * *

(d) * * *

(1) The applicable percentage change for updating the standardized amount for all hospitals in all areas is—

(i) For fiscal year 2005 through fiscal year 2009, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraph (d)(2) of this section.

(ii) For fiscal year 2010, for discharges—

(A) On or after October 1, 2009 and before April 1, 2010, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraph (d)(2) of this section; and

(B) On or after April 1, 2010 and before October 1, 2010, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraph (d)(2) of this section, less 0.25 percentage point.

(iii) For fiscal year 2011, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this subchapter) for prospective payment hospitals, subject to the provisions of paragraph (d)(2) of this section, less 0.25 percentage point.

(iv) For fiscal years 2012 and 2013, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraph (d)(2) of this section, less a multifactor productivity adjustment (as determined by CMS) and less 0.1 percentage point.

(v) For fiscal year 2014, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraph (d)(2) of this section, less a multifactor productivity adjustment (as determined by CMS) and less 0.3 percentage point.

(vi) For fiscal year 2015, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraphs (d)(2) and (d)(3) of this section, less a multifactor productivity adjustment (as determined by CMS) and less 0.2 percentage point.

(2)(i) In the case of a ''subsection (d) hospital,'' as defined under section 1886(d)(1)(B) of the Act, that does not submit quality data on a quarterly basis to CMS, in the form and manner specified by CMS, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals is reduced—

* * * * *

(ii) Any reduction pursuant to this paragraph (d)(2) will apply only to the fiscal year involved and will not be taken into account in computing the applicable percentage change for a subsequent fiscal year.

(3) Beginning fiscal year 2015, in the case of a ''subsection (d) hospital,'' as defined under section 1886(d)(1)(B) of the Act, that is not a meaningful electronic health record (EHR) user as defined in Part 495 of this chapter for the applicable EHR reporting period and does not receive an exception, three-fourths of the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals is reduced—

* * * * *

■ 22. Section 412.101 is amended by revising paragraphs (b)(2)(i), (b)(2)(ii), (c)(1), (c)(2) introductory text, and (d) to read as follows:

§ 412.101 Special treatment: Inpatient hospital payment adjustment for low-volume hospitals.

* * * * *

(b) * * *

(2) * * *

(i) For FY 2005 through FY 2010 and the portion of FY 2015 beginning on April 1, 2015, and subsequent fiscal years, a hospital must have fewer than 200 total discharges, which includes Medicare and non-Medicare discharges, during the fiscal year, based on the hospital's most recently submitted cost report, and be located more than 25 road miles (as defined in paragraph (a) of this section) from the nearest ''subsection (d)'' (section 1886(d) of the Act) hospital.

(ii) For FY 2011 through FY 2014, and the portion of FY 2015 before April 1, 2015, a hospital must have fewer than 1,600 Medicare discharges, as defined in paragraph (a) of this section, during the fiscal year, based on the hospital's Medicare discharges from the most recently available MedPAR data as determined by CMS, and be located more than 15 road miles, as defined in paragraph (a) of this section, from the nearest ''subsection (d)'' (section 1886(d) of the Act) hospital.

* * * * *

(c) * * *

(1) For FY 2005 through FY 2010 and the portion of FY 2015 beginning on April 1, 2015 and subsequent fiscal years, the adjustment is an additional 25 percent for each Medicare discharge.

(2) For FY 2011 through FY 2014 and the portion of FY 2015 before April 1, 2015, the adjustment is as follows:

* * * * *

(d) *Eligibility of new hospitals for the adjustment.* For FYs 2005 through 2010 and the portion of FY 2015 beginning on April 1, 2015, and subsequent fiscal years, a new hospital will be eligible for a low-volume adjustment under this section once it has submitted a cost report for a cost reporting period that indicates that it meets discharge requirements during the applicable fiscal year and has provided its fiscal intermediary or Medicare administrative contractor with sufficient evidence that it meets the distance requirement, as specified under paragraph (b)(2) of this section.

■ 23. Section 412.102 is revised to read as follows:

§ 412.102 Special treatment: Hospitals located in areas that are changing from urban to rural as a result of a geographic redesignation.

An urban hospital that was part of an MSA, but was redesignated as rural as a result of the most recent OMB standards for delineating statistical areas adopted by CMS, may receive an adjustment to its rural Federal payment amount for operating costs for 2 successive fiscal years as provided in paragraphs (a) and (b) of this section.

(a) *First year adjustment.* (1) Effective on or after October 1, 1983 and before October 1, 2014, the hospital's rural average standardized amount and disproportionate share payments as described in § 412.106 are adjusted on the basis of an additional amount that equals two-thirds of the difference between the urban standardized amount and disproportionate share payments applicable to the hospital before its geographic redesignation and the rural standardized amount and disproportionate share payments otherwise applicable to the Federal fiscal year for which the adjustment is made.

(2) Effective on or after October 1, 2014, the hospital's rural disproportionate share payments as described in § 412.106 are adjusted on the basis of an additional amount that equals two-thirds of the difference between the disproportionate share payments as an urban hospital applicable to the hospital before its geographic redesignation to a rural area as a result of implementation of the most recent OMB standards for delineating statistical areas adopted by CMS and the rural disproportionate share payment otherwise applicable to the Federal fiscal year for which the adjustment is made.

(b) *Second year adjustment.* (1) Effective on or after October 1, 1983 and before October 1, 2014, if a hospital's status continues to be rural as a result of geographic redesignation, its rural average standardized amount and disproportionate share payments are adjusted on the basis of an additional amount that equals one-third of the difference between the urban standardized amount and disproportionate share payments applicable to the hospital before its redesignation and the rural standardized amounts and disproportionate share payments otherwise applicable to the Federal fiscal year for which the adjustment is made.

(2) Effective on or after October 1, 2014, if a hospital's status continues to be rural as a result of geographic redesignation, its disproportionate share payments are adjusted on the basis of an additional amount that equals one-third of the difference between the disproportionate share payments applicable to the hospital before its geographic redesignation to a rural area as a result of implementation of the most recent OMB standards for delineating statistical areas adopted by CMS and the rural disproportionate share payments otherwise applicable to the Federal fiscal year for which the adjustment is made.

■ 24. Section 412.103 is amended by adding a new paragraph (a)(6) to read as follows:

§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.

(a) * * *

(6) For any period on or after October 1, 2014, a CAH in a county that was not in an urban area as defined by the Office of Management and Budget (OMB), but was included in an urban area as a result of the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, may be reclassified as being located in a rural area for purposes of meeting the rural location requirement at § 485.610(b) of this chapter for a period of 2 years, beginning with the date of the implementation of the new labor market area delineations, if it meets any of the requirements under paragraph (a)(1), (a)(2), or (a)(3) of this section.

* * * * *

■ 25. Section 412.105 is amended by revising paragraphs (a)(1)(ii), (f)(1)(iv)(D), and (f)(1)(v), to read as follows:

§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

* * * * *

(a) * * *

(1) * * *

(ii) (A) For new programs started prior to October 1, 2012, the exception for new programs described in paragraph (f)(1)(vii) of this section applies to each new program individually for which the full-time equivalent cap may be adjusted based on the period of years equal to the minimum accredited length of each new program.

(B) For new programs started on or after October 1, 2012, the exception for new programs described in paragraph (f)(1)(vii) of this section applies to each new program individually during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that precedes the start of the sixth program year of the first new program started, for hospitals for which the full-time equivalent cap may be adjusted in accordance with § 413.79(e)(1) of this chapter, and prior to the beginning of the applicable hospital's cost reporting period that precedes the start of the sixth program year of the each individual new program started, for hospitals for which the full-time equivalent cap may be adjusted in accordance with § 413.79(e)(3) of this chapter.

* * * * *

(f) * * *

(1) * * *

(iv) * * *

(D) A rural hospital redesignated as urban after September 30, 2004, as a result of the most recent census data and implementation of the new labor market area definitions announced by OMB on June 6, 2003, may retain the increases to its full-time equivalent resident cap that it received under paragraphs (f)(1)(iv)(A) and (f)(1)(vii) of this section while it was located in a rural area. Effective for cost reporting periods beginning on or after October 1, 2014, if a rural hospital is redesignated as urban due to the most recent OMB standards for delineating statistical areas adopted by CMS and was training residents in a new program prior to the redesignation becoming effective, the redesignated urban hospital may retain any existing increases to its full-time equivalent resident cap and receive an increase to its full-time equivalent resident cap for the new program in which it was training residents when the redesignation became effective, in accordance with paragraph (f)(1)(vii) of this section.

(v)(A) For a hospital's cost reporting periods beginning on or after October 1, 1997, and before October 1, 1998, the total number of full-time equivalent residents for payment purposes is equal to the average of the actual full-time equivalent resident counts (subject to the requirements listed in paragraphs (f)(1)(ii)(C) and (f)(1)(iv) of this section) for that cost reporting period and the preceding cost reporting period.

(B) For a hospital's cost reporting periods beginning on or after October 1, 1998, the total number of full-time equivalent residents for payment purposes is equal to the average of the actual full-time equivalent resident count (subject to the requirements set forth in paragraphs (f)(1)(ii)(C) and (f)(1)(iv) of this section) for that cost reporting period and the preceding two cost reporting periods.

(C) For new programs started prior to October 1, 2012, if a hospital qualified for an adjustment to the limit

established under paragraph (f)(1)(iv) of this section for new medical residency programs created under paragraph (f)(1)(vii) of this section, the count of residents participating in new medical residency training programs above the number included in the hospital's full-time equivalent count for the cost reporting period ending during calendar year 1996 is added after applying the averaging rules in paragraphs (f)(l)(v)(A), (f)(1)(v)(B), and this paragraph (f)(1)(v)(C) for a period of years. Residents participating in new medical residency training programs are included in the hospital's full-time equivalent count before applying the averaging rules after the period of years has expired. For purposes of this paragraph, for each new program started, the period of years equals the minimum accredited length for each new program. The period of years for each new program begins when the first resident begins training in each new program.

(D) For new programs started on or after October 1, 2012, for hospitals for which the full-time equivalent cap may be adjusted in accordance with § 413.79(e) of this chapter, full-time equivalent residents participating in new medical residency training programs are excluded from the hospital's full-time equivalent count before applying the averaging rules during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that precedes the start of the sixth program year of the first new program started, for hospitals for which the full-time equivalent cap may be adjusted in accordance with § 413.79(e)(1) of this chapter, and prior to the beginning of the applicable hospital's cost reporting period that precedes the start of the sixth program year of the each individual new program started, for hospitals for which the full-time equivalent cap may be adjusted in accordance with § 413.79(e)(3) of this chapter. After the applicable hospital's cost reporting period that precedes the start of the sixth program year of the first new program started for hospitals for which the full-time equivalent cap may be adjusted in accordance with § 413.79(e)(1) of this chapter, and after the applicable hospital's cost reporting period that precedes the start of the sixth program year of each individual new program started for hospitals for which the full-time equivalent cap may be adjusted in accordance with § 413.79(e)(3) of this chapter, full-time equivalent residents participating in new medical residency training programs are included in the hospital's full-time equivalent count before applying the averaging cap.

(E) Subject to the provisions of paragraph (f)(1)(ix) of this section, full-time equivalent residents that are displaced by the closure of either another hospital or another hospital's program are added to the full-time equivalent count after applying the averaging rules in this paragraph (f)(1)(v)(B) for the receiving hospital for the duration of time that the displaced residents are training at the receiving hospital.

(F) Subject to the provisions of paragraph (f)(1)(x) of this section, effective for cost reporting periods beginning on or after April 1, 2000, full-time equivalent residents at an urban hospital in a rural track program are included in the urban hospital's rolling average calculation described in this paragraph (f)(1)(v)(B).

* * * * *

■ 26. Section 412.106 is amended by revising paragraph (g)(1)(iii)(C) to read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(g) * * *

(1)

(iii) * * *

(C) For fiscal year 2014 and for fiscal year 2015, CMS will base its estimates of the amount of hospital uncompensated care on the most recent available data on utilization for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section.

* * * * *

§ 412.108 [Amended]

■ 27. In § 412.108, paragraph (a)(1) introductory text and paragraph (c)(2)(iii) introductory text, remove the date ''April 1, 2014'' and add in its place the date ''April 1, 2015''.

■ 28. Section 412.140 is amended by revising paragraph (c)(2) to read as follows:

§ 412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Reporting (IQR) Program.

* * * * *

(c) * * *

(2) *Exception.* Upon request by a hospital, CMS may grant an extension or exemption of one or more data submission deadlines in the event of extraordinary circumstances beyond the control of the hospital. Specific requirements for submission of a request for an extension or exemption are available on QualityNet.org.

* * * * *

■ 29. Section 412.152 is amended by revising the definition of ''Applicable hospital'' to read as follows:

§ 412.152 Definitions for the Hospital Readmissions Reduction Program.

* * * * *

Applicable hospital is a hospital described in section 1886(d)(1)(B) of the Act or a hospital paid under section 1814(b)(3) of the Act.

* * * * *

§ 412.154 [Amended]

■ 30. Section 412.154 is amended by removing and reserving paragraph (d).

■ 31. Section 412.160 is amended by revising the definitions of ''Base operating DRG payment amount'' and ''Performance standards'' to read as follows:

§ 412.160 Definitions for the Hospital Value-Based Purchasing (VBP) Program.

* * * * *

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. With respect to a Medicare-dependent, small rural hospital that receives payments under § 412.108(c) (for discharges occurring in FY 2013) or a sole community hospital that receives

payments under § 412.92(d), 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.

* * * * *

Performance standards are the levels of performance that hospitals must meet or exceed in order to earn points under the Hospital VBP Program, and are calculated with respect to a measure for a fiscal year no later than 60 days prior to the start of the performance period for that measure for that fiscal year. The performance standards for a measure may be updated as follows:

(1) To make a single correction to correct a calculation error, data issue, or other problem that would significantly change the performance standards; or

(2) To incorporate nonsubstantive technical updates made to the measure between the time that CMS first displays the performance standards for that measure for a fiscal year and the time that CMS calculates hospital performance on that measure at the conclusion of the performance period for that measure for a fiscal year.

* * * * *

■ 32. Section 412.161 is revised to read as follows:

§ 412.161 Applicability of the Hospital Value-Based Purchasing (VBP) Program

The Hospital VBP Program applies to hospitals, as that term is defined in § 412.160.

§ 412.172 [Amended]

■ 33. Section 412.172 is amended by removing and reserving paragraph (c).

■ 34. Section 412.232 is amended by revising paragraph (b)(2) to read as follows:

§ 412.232 Criteria for all hospitals in a rural county seeking urban redesignation.

* * * * *

(b) * * *

(2) For fiscal years beginning with FY 2005, the group of hospitals must demonstrate that the county in which the hospitals are located meets the standards for redesignation to an MSA as an outlying county using the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data.

* * * * *

■ 35. Section 412.234 is amended by revising paragraph (a)(3)(iv) to read as follows:

§ 412.234 Criteria for all hospitals in an urban county seeking redesignation to another urban area.

(a) * * *

(3) * * *

(iv) For Federal fiscal year 2008 and thereafter, hospitals located in counties that are in the same Combined Statistical Area (CSA) or Core-Based Statistical Area (CBSA) (under the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data) as the urban area to which they seek redesignation qualify as meeting the proximity requirement for reclassification to the urban area to which they seek redesignation.

* * * * *

■ 36. Section 412.500 is amended by adding paragraphs (a)(4), (a)(5), and (a)(6) to read as follows:

§ 412.500 Basis and scope of subpart.

(a) * * *

(4) Section 4302(a) of Public Law 111–5, which amended sections 114(c) and (d) of Public Law 110–173 relating to several moratoria on the establishment of new long-term care hospitals and satellite facilities and on the increase in the number of beds in existing long-term care hospitals and satellite facilities under the long-term care hospital prospective payment system.

(5) Sections 3106(a) and 10312(a) of Public Law 111–148, which extended certain payment rules and moratoria under the long-term care hospital prospective payment system by further amending sections 114(c) and (d) of Public Law 110–173.

(6) Section 1206 of Public Law 113–67, which further extended certain payment rules and moratoria under the long-term care hospital prospective payment system by amending sections 114(c) and (d) of Public Law 110–173, and which:

(i) Added a new section 1886(m)(6) to the Act to establish a site neutral payment amount for long-term care hospital discharges that fail to meet the applicable criteria in cost reporting periods beginning on or after October 1, 2015; and

(ii) Requires the Secretary's review of the payment rates and regulations governing long-term care hospitals established under section 1886(d)(1)(B)(iv)(II) of the Act and application of payment adjustments based on that review.

* * * * *

■ 37. Section 412.521 is amended by revising paragraph (a)(2) to read as follows:

§ 412.521 Basis for payment.

(a) * * *

(2) Except as provided for in § 412.526, the amount of payment under the prospective payment system is based on the Federal payment rate established in accordance with § 412.523, including adjustments described in § 412.525, and, if applicable during a transition period, on a blend of the Federal payment rate and the cost-based reimbursement rate described in § 412.533.

* * * * *

■ 38. Section 412.523 is amended by adding a new paragraph (c)(3)(xi) to read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) * * *

(xi) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2014, and ending September 30, 2015.* The standard Federal rate for the long-term care hospital prospective payment system beginning October 1, 2014, and ending September 30, 2015, 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.

* * * * *

§ 412.525 [Amended]

■ 39. Section 412.525 is amended by removing and reserving paragraph (d)(3).

■ 40. A new § 412.526 is added to read as follows:

§ 412.526 Payment provisions for a ''subclause (II)'' long-term care hospital.

(a) *Definition.* A ''subclause (II)'' long-term care hospital is a hospital that qualifies as an LTCH under section 1886(d)(1)(B)(iv)(II) of the Act.

(b) *Method of payment.*—(1) For cost reporting periods beginning on or after October 1, 2003 and before September 30, 2014, payment to a ''subclause (II)'' long-term care hospital is made under the prospective payment system specified in § 412.1(a)(4) and Subpart O of this part.

(2) For cost reporting periods beginning on or after October 1, 2014, payment to a ''subclause (II)'' long-term care hospital is made under the prospective payment system specified in § 412.1(a)(4) and under Subpart O of this part, as adjusted. The adjusted payment amount is determined based on reasonable cost, as described at § 412.526(c).

(c) *Determining the adjusted payment for Medicare inpatient operating and capital-related costs under the*

reasonable cost-based reimbursement rules. Medicare inpatient operating costs are paid based on reasonable cost, subject to a ceiling. The ceiling is the aggregate upper limit on the amount of a hospital's net Medicare inpatient operating costs that the program will recognize for payment purposes, as determined under paragraph (c)(1) of this section.

(1) *Ceiling.* For each cost reporting period, the ceiling is determined by multiplying the updated target amount, as defined in paragraph (c)(2) of this section, for that period by the number of Medicare discharges paid under this subpart during that period.

(2) *Target amounts.*—(i) For cost reporting periods beginning during Federal fiscal year 2015, the target amount equals the hospital's target amount determined under § 413.40(c)(4) for its cost reporting period beginning during Federal fiscal year 2000, updated by the applicable annual rate-of-increase percentages specified in § 413.40(c)(3) to the subject period.

(ii) For subsequent cost reporting periods, the target amount equals the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period.

(3) *Payment for inpatient operating costs.* For cost reporting periods subject to this section, the hospital's Medicare allowable net inpatient operating costs for that period (as defined at § 413.40(a)(3)) are paid on a reasonable cost basis, subject to that hospital's ceiling (as determined under paragraph (c)(1) of this section) for that period.

(4) *Payment for inpatient capital-related costs.* Medicare allowable net inpatient capital costs are paid on a reasonable cost basis, in accordance with the regulations under Part 413 of this chapter.

■ 41. Section 412.531 is amended by—

■ a. Revising paragraph (a)(2) introductory text.

■ b. Adding a new paragraph (a)(3).

■ c. Revising paragraph (b)(4) introductory text.

■ d. Adding a new paragraph (b)(5).

The revisions and additions read as follows:

§ 412.531 Special payment provisions when an interruption of a stay occurs in a long-term care hospital.

(a) * * *

(2) *A greater than 3-day interruption of stay defined.* For long-term care hospital discharges occurring on or before September 30, 2014, ''a greater than 3-day or less interruption of stay'' means a stay in a long-term care hospital during which a Medicare inpatient is discharged from the long-term care hospital to an acute care hospital, an IRF, or a SNF for a period of greater than 3 days but within the applicable fixed-day period specified in paragraphs (a)(2)(i) through (a)(2)(iii) of this section before being readmitted to the same long-term care hospital.

* * * * *

(3) For long-term care hospital discharges occurring on or after October 1, 2014, ''a greater than 3-day or less interruption of stay'' means a stay in a long-term care hospital during which a Medicare inpatient is discharged from the long-term care hospital to an acute care hospital, an IRF, or a SNF for a fixed day period of between 4 days and 30 consecutive days before being readmitted to the same long-term care hospital.

(b) * * *

(4) Except as provided in paragraph (b)(5) of this section, if a patient who has been discharged from a long-term care hospital to another facility and is readmitted to the long-term care hospital for additional treatment or services in the long-term care hospital directly following the stay at the other facility, the subsequent admission to the long-term care hospital is considered a new stay, even if the case is determined to fall into the same MS–LTC–DRG, and the long-term care hospital will receive two separate Federal prospective payments if one of the following conditions are met:

* * * * *

(5) For long-term care hospital discharges occurring on or after October 1, 2014, if a patient who has been discharged from a long-term care hospital to another facility is readmitted to the long-term care hospital for additional treatment or services directly following the stay at the other facility, the subsequent admission to the long-term care hospital is considered a new stay, even if the case is determined to fall into the same MS–LTC–DRG, and the long-term care hospital will receive two separate Federal prospective payments only if the patient has a length of stay at the other facility that exceeded 30 days from the initial date of discharge from the long-term care hospital.

* * * * *

§ 412.532 [Removed]

■ 42. Section 412.532 is removed.

■ 43. Section 412.534 is amended by—

■ a. Revising and paragraph (c)(1).

■ b. Removing the year ''2013'' and adding in its place the year ''2016'' in paragraph (c)(1)(i) and (ii) and (c)(2) paragraph heading.

■ c. Revising paragraph (c)(3).

■ d. Removing the year ''2013'' and adding in its place the year ''2016'' in paragraphs (d)(1) heading, (d)(1)(i), and (d)(2) heading.

■ e. Revising paragraph (d)(3).

■ f. Removing the year ''2013'' and adding in its place the year ''2016'' in paragraphs (e)(1) heading, (e)(1)(i), and (e)(2) heading.

■ g. Revising paragraph (e)(3).

■ h. Revising paragraphs (h) introductory text, (h)(4), and (h)(5).

■ i. Removing paragraph (h)(6).

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) * * *

(1) *For cost reporting periods beginning on or after October 1, 2004 and before October 1, 2007 and for cost reporting periods beginning on or after October 1, 2016.* (i) Except as provided in paragraphs (c)(3), (g), and (h) of this section, for any cost reporting period beginning on or after October 1, 2004 and before October 1, 2007, and for cost reporting periods beginning on or after October 1, 2016 in which the long-term care hospital or its satellite facility has a discharged Medicare inpatient population of whom no more than 25 percent were admitted to the hospital or its satellite facility from the co-located hospital, payments are made under the rules at §§ 412.500 through 412.541 in this subpart with no adjustment under this section.

* * * * *

(3) For a long-term care hospital satellite facility described in § 412.22(h)(3)(i), for cost reporting periods beginning on or after July 1, 2007 and before July 1, 2016, payments will be determined using the methodology specified in paragraph (c)(1) of this section, except that the applicable percentage threshold for Medicare discharges is 50 percent.

(d) * * *

(3) For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2016, payment for a long-term care hospital satellite facility described in § 412.22(h)(3)(i) will be determined using the methodology specified in paragraph (c)(1) of this section, except that the applicable percentage threshold for Medicare discharges is 75 percent.

(e) * * *

(3) For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2016, payments for a long-term care hospital satellite facility described in § 412.22(h)(3)(i) will be

determined using the methodology specified in paragraph (c)(1) of this section, except that the applicable percentage threshold for Medicare discharges is 75 percent.

* * * * *

(h) *Effective date of policies in this section for certain co-located long-term care hospitals and satellite facilities of long-term care hospitals.* Except as specified in paragraph (h)(4) of this section, the policies set forth in this paragraph (h) apply to Medicare patient discharges that were admitted from a hospital located in the same building or on the same campus as a long-term care hospital described in § 412.23(e)(2)(i) that meets the criteria in § 412.22(f) and a satellite facility of a long-term care hospital as described under § 412.22(h)(3)(i) for discharges occurring in cost reporting periods beginning on or after July 1, 2007.

* * * * *

(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.

(5) For a long-term care hospital or a 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 do not apply for discharges occurring in cost reporting periods beginning on or after July 1, 2007 and before July 1, 2016.

■ 44. Section 412.536 is amended by—

■ a. Removing and reserving paragraph (a)(1)(iii).

■ b. Revising paragraph (a)(2) introductory text.

■ c. Removing and reserving paragraph (a)(2)(ii).

■ d. Removing paragraph (a)(3).

The revisions 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) * * *

(1) * * *

(iii) [Reserved].

* * * * *

(2) For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2016, the policies set forth in this section are not applicable to discharges from:

* * * * *

(ii) [Reserved].

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END–STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 45. The authority for Part 413 continues to read as follows:

Authority: Secs. 1102, 1861(v)(1)(A), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x(v)(1)(A), and 1395hh).

Nomenclature Changes

PART 413 [Amended]

■ 46. Throughout Part 413, according to the list below, remove the term or phrase in the first column and replace it with the term or phrase in the second column:

Remove	Add
an intermediary's	"a contractor's"
fiscal intermediary ..	"contractor"
fiscal intermediary's	"contractor's"
intermediary	"contractor"
intermediaries	"contractors"
intermediary's	"contractor's"

■ 47. Section 413.24 is amended by reserving paragraph (i) and adding a new paragraph (j) to read as follows:

§ 413.24 Adequate cost data and cost finding.

* * * * *

(i) [Reserved]

(j) *Substantive reimbursement requirement of an appropriate cost report claim.* (1) *General requirement.* In order for a provider to receive or potentially qualify for reimbursement for a specific item for its cost reporting period, the provider's cost report, whether determined on an as submitted, as amended, or as adjusted basis (as prescribed in paragraph (j)(3) of this section), must include an appropriate claim for the specific item, by either—

(i) Claiming full reimbursement in the provider's cost report for the specific item in accordance with Medicare policy, if the provider seeks payment for the item that it believes comports with program policy; or

(ii) Self-disallowing the specific item in the provider's cost report, if the provider seeks payment that it believes may not be allowable or may not comport with Medicare policy (for example, if the provider believes the contractor lacks the authority or discretion to award the reimbursement the provider seeks for the item), by following the procedures (set forth in paragraph (j)(2) of this section) for properly self-disallowing the specific item in the provider's cost report as a protested amount.

(2) *Self-disallowance procedures.* In order to properly self-disallow a specific item, the provider must—

(i) Include an estimated reimbursement amount for each specific self-disallowed item in the protested amount line (or lines) of the provider's cost report; and

(ii) Attach a separate work sheet to the provider's cost report for each specific self-disallowed item, explaining why the provider self-disallowed each specific item (instead of claiming full reimbursement in its cost report for the specific item) and describing how the provider calculated the estimated reimbursement amount for each specific self-disallowed item.

(3) *Procedures for determining whether there is an appropriate cost report claim.* Whether the provider's cost report for its cost reporting period includes an appropriate claim for a specific item (as prescribed in paragraph (j)(1) of this section) must be determined by reference to the cost report that the provider submits originally to, and was accepted by, the contractor for such period, provided that none of the following exceptions applies:

(i) If the provider submits an amended cost report for its cost reporting period and such amended cost report is accepted by the contractor, whether there is an appropriate cost report claim for the specific item must be determined by reference to such amended cost report, provided that neither of the exceptions set forth in paragraphs (j)(3)(ii) and (j)(3)(iii) of this section applies;

(ii) If the contractor adjusts the provider's cost report, as submitted originally by the provider and accepted by the contractor or as amended by the provider and accepted by the contractor, whichever is applicable, with respect to the specific item, whether there is an appropriate cost report claim for the specific item must be determined by reference to the provider's cost report, as such cost report claim is adjusted for the specific item in the initial contractor determination (as defined in § 405.1801(a) of this chapter) for the provider's cost reporting period, provided that the exception set forth in paragraph (j)(3)(iii) of this section does not apply;

(iii) If the contractor reopens either the initial contractor determination for

the provider's cost reporting period (pursuant to § 405.1885 of this chapter) or a revised contractor determination for such period (issued pursuant to § 405.1889 of this chapter) and the contractor adjusts the provider's cost report with respect to the specific item, whether there is an appropriate cost report claim for the specific item must be determined by reference to the provider's cost report, as such cost report claim is adjusted for the specific item in the most recent revised contractor determination for such period.

(4) *Reimbursement effects of contractor's determination of whether there is an appropriate cost report claim.* If the contractor determines that the provider's cost report included an appropriate claim for a specific item (as specified in paragraphs (j)(1), (j)(2), and (j)(3) of this section) and that all the other substantive reimbursement requirements for the specific item are also satisfied, the final contractor determination (as defined in § 405.1801(a) of this chapter) must include reimbursement for the specific item to the extent permitted by Medicare policy. If the contractor determines that the provider made an appropriate cost report claim for a specific item but the contractor disagrees with material aspects of the provider's claim for the specific item, the contractor must make appropriate adjustments to the provider's cost report and include reimbursement for the specific item in the final contractor determination in accordance with such cost report adjustments and to the extent permitted by program policy. If the contractor determines that the provider did not make an appropriate cost report claim for a specific item, the final contractor determination must not include any reimbursement for the specific item, regardless of whether the other substantive reimbursement requirements for the specific item are or are not satisfied.

(5) *Administrative review of whether there is an appropriate cost report claim.* If the provider files an administrative appeal (pursuant to Part 405, Subpart R of this chapter) seeking reimbursement for a specific item and any party to such appeal questions whether the provider's cost report included an appropriate claim for the specific item under appeal (as specified in paragraphs (j)(1), (j)(2), (j)(3), and (j)(4) of this section), the reviewing entity (as defined in § 405.1801(a) of this chapter) must follow the procedures prescribed in § 405.1873 of this chapter (if the appeal was filed originally with the Board), or the procedures set forth in § 405.1832 of this chapter (if the appeal was filed initially with the contractor), for review of whether the substantive reimbursement requirement of an appropriate cost report claim for the specific item under appeal is satisfied. The reviewing entity must follow the procedures set forth in paragraph (j)(3) of this section in determining whether the provider's cost report included an appropriate claim for the specific item under appeal. The reviewing entity may permit reimbursement for the specific item under appeal solely to the extent authorized by § 405.1873(f) of this chapter (if the appeal was filed originally with the Board) or by § 405.1832(f) of this chapter (if the appeal was filed initially with the contractor).

■ 48. Section 413.75 is amended by revising the definition of ''Rural track FTE limitation'' under paragraph (b) to read as follows:

§ 413.75 Direct GME payments: General requirements.

* * * * *

(b) * * *

Rural track FTE limitation means the maximum number of residents (as specified in § 413.79(k)) training in a rural track residency program that an urban hospital may include in its FTE count and that is in addition to the number of FTE residents already included in the hospital's FTE cap.

* * * * *

■ 49. Section 413.78 is amended by revising paragraph (g)(6) to read as follows:

§ 413.78 Direct GME payment: Determination of the total number of FTE residents.

* * * * *

(g) * * *

(6) The provisions of paragraphs (g)(1)(ii), (g)(2), (g)(3), and (g)(5) of this section shall not be applied in a manner that requires reopening of any settled cost reports as to which there is not a jurisdictionally proper appeal pending as of March 23, 2010, on direct GME or IME payments. Cost reporting periods beginning before July 1, 2010 are not governed by paragraph (g) of this section.

* * * * *

■ 50. Section 413.79 is amended by revising paragraphs (c)(6), (d)(5), and (k)(7), to read as follows:

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

* * * * *

(c) * * *

(6) *FTE resident caps for rural hospitals that are redesignated as urban.* A rural hospital redesignated as urban after September 30, 2004, as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003, may retain the increases to its FTE resident cap that it received under paragraphs (c)(2)(i), (e)(1)(iii), and (e)(3) of this section while it was located in a rural area. Effective for cost reporting periods beginning on or after October 1, 2014, if a rural hospital is redesignated as urban due to the most recent OMB standards for delineating statistical areas adopted by CMS, and was training residents in a new program prior to the redesignation becoming effective, the redesignated urban hospital may retain any existing increases to its FTE resident cap, and receive an increase to its FTE resident cap for the new program in which it was training residents when the redesignation became effective, in accordance with paragraph (e) of this section.

(d) * * *

(5)(i) For new programs started prior to October 1, 2012, if a hospital qualifies for an adjustment to the limit established under paragraph (c)(2) of this section for new medical residency programs created under paragraph (e) of this section, the count of the residents participating in new medical residency training programs above the number included in the hospital's FTE count for the cost reporting period ending during calendar year 1996 is added after applying the averaging rules in this paragraph (d), for a period of years. Residents participating in new medical residency training programs are included in the hospital's FTE count before applying the averaging rules after the period of years has expired. For purposes of this paragraph (d), for each new program started, the period of years equals the minimum accredited length for each new program. The period of years begins when the first resident begins training in each new program.

(ii) For new programs started on or after October 1, 2012, for hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e) of this chapter, FTE residents participating in new medical residency training programs are excluded from the hospital's FTE count before applying the averaging rules during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that precedes the start of the sixth program year of the first new program started, for hospitals for which the FTE may be adjusted in accordance with § 413.79(e)(1) of this chapter, and

prior to the beginning of the applicable hospital's cost reporting period that precedes the start of the sixth program year of the each individual new program started, for hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(3) of this chapter. After the applicable hospital's cost reporting period that precedes the start of the sixth program year of the first new program started for hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(1) of this chapter, and after the applicable hospital's cost reporting period that precedes the start of the sixth program year of the each individual new program started for hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(3) of this chapter, FTE residents participating in new medical residency training programs are included in the hospital's FTE count before applying the averaging rules.

* * * * *

(k) * * *

(7) (i) Effective for cost reporting periods beginning prior to October 1, 2014, if an urban hospital had established a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and that rural area subsequently becomes an urban area due to the most recent census data and implementation of the new labor market area definitions announced by OMB on June 6, 2003, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) for the rural track programs established prior to the adoption of such new labor market area definitions. In order to receive an adjustment to its FTE resident cap for a new rural track residency program, the urban hospital must establish a rural track program with hospitals that are designated rural based on the most recent geographical location delineations adopted by CMS.

(ii) Effective for cost reporting periods beginning on or after October 1, 2014, if an urban hospital had started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and, during the 3-year period that is used to calculate the urban hospital's rural track FTE limit, that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) and subject to paragraph (k)(7)(iii) for the rural track programs established prior to the adoption of such new OMB standards for delineating statistical areas.

(iii) Effective for cost reporting periods beginning on or after October 1, 2014, if an urban hospital had established a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, regardless of whether the redesignation of the rural hospital occurs during the 3-year period that is used to calculate the urban hospital's rural track FTE limit, or after the 3-year period used to calculate the urban hospital's rural track FTE limit, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) based on the rural track programs established prior to the change in the hospital's geographic designation. In order for the urban hospital to receive or use the adjustment to its FTE resident cap for training FTE residents in the rural track residency program that was established prior to the most recent OMB standards for delineating statistical areas adopted by CMS, one of the following two conditions must be met by the end of a 2-year period that begins when the most recent OMB standards for delineating statistical areas are adopted by CMS: the hospital that has been redesignated from rural to urban must reclassify as rural under § 412.103 of this chapter, for purposes of IME only; or the urban hospital must find a new site that is geographically rural consistent with the most recent geographical location delineations adopted by CMS. In order to receive an adjustment to its FTE resident cap for an additional new rural track residency program, the urban hospital must establish a rural track program with sites that are geographically rural based on the most recent geographical location delineations adopted by CMS.

* * * * *

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 51. The authority citation for Part 415 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).

■ 52. Section 415.70 is amended by revising paragraph (b) to read as follows:

§ 415.70 Limits on compensation for physician services in providers.

* * * * *

(b) *Methodology for establishing limits.* (1) *For cost reporting periods beginning before January 1, 2015.* CMS establishes a methodology for determining annual reasonable compensation equivalency limits and, to the extent possible, considers average physician incomes by specialty and type of location using the best available data.

(2) *For cost reporting periods beginning on or after January 1, 2015.* CMS establishes a methodology for determining annual reasonable compensation equivalency limits and, to the extent possible, considers average physician incomes by specialty using the best available data.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 53. The authority citation for Part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 54. Section 422.300 is revised to read as follows:

§ 422.300 Basis and scope.

This subpart is based on sections 1106, 1853, 1854, and 1858 of the Act. It sets forth the rules for making payments to Medicare Advantage (MA) organizations offering local and regional MA plans, including calculation of MA capitation rates and benchmarks, conditions under which payment is based on plan bids, adjustments to capitation rates (including risk adjustment), collection of risk adjustment data, conditions for use and disclosure of risk adjustment data, and other payment rules. See § 422.458 in subpart J for rules on risk sharing payments to MA regional organizations.

■ 55. Section 422.310 is amended by revising paragraph (f) to read as follows:

§ 422.310 Risk adjustment data.

* * * * *

(f) *Use and release of data.*

(1) *CMS use of data.* CMS may use the data described in paragraphs (a) through (d) of this section for the following purposes:

(i) To determine the risk adjustment factors used to adjust payments, as required under §§ 422.304(a) and (c);

(ii) To update risk adjustment models;

(iii) To calculate Medicare DSH percentages;

(iv) To conduct quality review and improvement activities;

(v) For Medicare coverage purposes;

(vi) To conduct evaluations and other analysis to support the Medicare program (including demonstrations) and to support public health initiatives and other health care-related research;

(vii) For activities to support the administration of the Medicare program;

(viii) For activities conducted to support program integrity; and

(ix) For purposes permitted by other laws.

(2) *CMS release of data.* Regarding data described in paragraphs (a) through (d) of this section, CMS may release the minimum data it determines is necessary for one or more of the purposes listed in paragraph (f)(1) of this section to other HHS agencies, other Federal executive branch agencies, States, and external entities in accordance with the following:

(i) Applicable Federal laws;

(ii) CMS data sharing procedures;

(iii) Subject to the protection of beneficiary identifier elements and beneficiary confidentiality, including—

(A) A prohibition against public disclosure of beneficiary identifying information;

(B) Release of beneficiary identifying information to other HHS agencies, other Federal executive branch agencies, Congressional support agencies, and States only when such information is needed; and

(C) Release of beneficiary identifying information to external entities only to the extent needed to link datasets.

(iv) Subject to the aggregation of payment data to protect commercially sensitive data.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 56. 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)).

■ 57. Section 424.11 is amended by revising paragraph (d)(5) to read as follows:

§ 424.11 General procedures.

* * * * *

(d) * * *

(5) For all inpatient hospital services, including inpatient psychiatric facility services, a delayed certification may not extend past discharge.

* * * * *

■ 58. Section 424.15 is amended by revising paragraph (b) to read as follows:

§ 424.15 Requirements for inpatient CAH services.

* * * * *

(b) *Certification begins with the order for inpatient admission.* The certification must be completed, signed, and documented in the medical record no later than 1 day before the date on which the claim for payment for the inpatient CAH service is submitted.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 59. The authority citation for Part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

■ 60. Section 485.610 is amended by revising paragraph (b) introductory text and adding a new paragraph (b)(5) to read as follows:

§ 485.610 Conditions of participation: Status and location.

* * * * *

(b) *Standard: Location in a rural area or treatment as rural.* The CAH meets the requirements of either paragraph (b)(1) or (b)(2) of this section or the requirements of paragraph (b)(3), (b)(4), or (b)(5) of this section.

* * * * *

(5) Effective on or after October 1, 2014, for a period of 2 years beginning with the effective date of the most recent Office of Management and Budget (OMB) standards for delineating statistical areas adopted by CMS, the CAH no longer meets the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, prior to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, was located in a rural area as defined by OMB, but under the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, is located in an urban area.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 61. The authority citation for Part 488 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

■ 62. Section 488.61 is amended by—

■ a. Revising paragraphs (a)(4) and (c)(4).

■ b. Adding new paragraphs (f), (g), and (h).

The revisions and additions read as follows:

§ 488.61 Special procedures for approval and re-approval of organ transplant centers.

* * * * *

(a) * * *

(4) CMS will consider mitigating factors in accordance with paragraphs (f), (g), and (h) of this section.

* * * * *

(c) * * *

(4) CMS will consider mitigating factors in accordance with paragraphs (f), (g), and (h) of this section.

* * * * *

(f) *Consideration of mitigating factors in initial approval and re-approval survey, certification, and enforcement actions for transplant centers.*

(1) *Factors.* Except for situations of immediate jeopardy, CMS will consider mitigating factors, including (but not limited to) the following, in making a decision of initial and re-approval of a transplant center that does not meet the data submission, clinical experience, or outcome requirements, or other conditions of participation:

(i) The extent to which outcome measures are not met or exceeded;

(ii) Availability of Medicare-approved transplant centers in the area;

(iii) Extenuating circumstances (for example, natural disaster) that have a temporary effect on meeting the conditions of participation;

(iv) Program improvements that substantially address root causes of graft failures or patient deaths and that have been implemented and institutionalized on a sustainable basis;

(v) Recent patient and graft survival data to determine if there is sufficient clinical experience and survival for CMS to conclude that the program is in compliance with CMS requirements, except for the data lag inherent in the reports from the Scientific Registry of Transplant Recipients (SRTR);

(vi) Whether the program has made extensive use of innovative transplantation practices relative to other transplant programs, such as a high rate of transplantation of individuals who are highly sensitized or children who have undergone a Fontan procedure compared to most other transplant programs, where CMS finds that the innovative practices are supported by evidence-based published research literature or nationally recognized standards or Institution Review Board (IRB) approvals, and the SRTR risk-adjustment methodology does not take the relevant key factors into consideration; and

(vii) Whether the program's performance, based on the OPTN method of calculating patient and graft survival, is within the OPTN's

thresholds for acceptable performance and does not flag OPTN performance review under the applicable OPTN policy.

(2) *Content.* A request for consideration of mitigating factors must include sufficient information to permit an adequate review and understanding of the transplant program, the factors that have contributed to outcomes, program improvements or innovations that have been implemented or planned, and in the case of natural disasters, the recovery actions planned. Examples of information to be submitted with each request include (but are not limited to) the following:

(i) The name and contact information for the transplant hospital and the names and roles of key personnel of the transplant program;

(ii) The type of organ transplant program(s) for which approval is requested;

(iii) The conditions of participation that the program does not meet for which the transplant center is requesting CMS' review for mitigating factors;

(iv) The rationale and supporting evidence for CMS' review may include (but is not limited to)—

(A) Root Cause Analysis for patient deaths and graft failures, including factors the program has identified as likely causal or contributing factors for patient deaths and graft failures;

(B) Program improvements or innovations (where applicable) that have been implemented and improvements that are planned;

(C) Patient and donor/organ selection criteria and evaluation protocols, including methods for pre-transplant patient evaluation by cardiologists, hematologists, nephrologists, and psychiatrists or psychologists to the extent applicable;

(D) Organizational chart with full-time equivalent levels, roles, and structure for reporting to hospital leadership;

(E) Waitlist management protocols and practices relevant to outcomes;

(F) Pre-operative management protocols and practices;

(G) Immunosuppression/infection prophylaxis protocols;

(H) Post-transplant monitoring and management protocols and practices;

(I) Quality Assessment and Performance Improvement (QAPI) Program meeting minutes from the most recent four meetings and attendance rosters from the most recent 12 months;

(J) Quality dashboard and other performance indicators;

(K) Recent outcomes data for both patient survival and graft survival; and

(L) Whether the program has engaged with the OPTN to review program outcomes, the status of any such review, and any steps taken to address program outcomes pursuant to the OPTN review.

(3) *Timing.* Within 10 days after CMS has issued formal written notice of a condition-level deficiency to the program, CMS must receive notification of the program's intent to seek mitigating factors approval or re-approval, and receive all information for consideration of mitigating factors within 30 days of the CMS written notification for any deficiency that is not for insufficient clinical experience or outcomes, and 120 days of the CMS written notification for a deficiency due to clinical experience or outcomes. Failure to meet these timeframes may be the basis for denial of mitigating factors.

(g) *Results of mitigating factors review.*

(1) *Actions.* Upon review of the request to consider mitigating factors, CMS may take the following actions:

(i) Approve initial approval or re-approval of a program's Medicare participation based upon approval of mitigating factors;

(ii) Deny the program's request for Medicare approval or re-approval based on mitigating factors.

(iii) Offer a time-limited Systems Improvement Agreement, in accordance with paragraph (h) of this section, when a transplant program has waived its appeal rights, has implemented substantial program improvements that address root causes and are institutionally supported by the hospital's governing body on a sustainable basis, and has requested more time to design or implement additional improvements or demonstrate compliance with CMS outcome requirements. Upon completion of the Systems Improvement Agreement or a CMS finding that the hospital has failed to meet the terms of the Agreement, CMS makes a final determination of whether to approve or deny a program's request for Medicare approval or re-approval based on mitigating factors. A Systems Improvement Agreement follows the process specified in paragraph (h) of this section.

(2) *Limitation.* CMS will not approve any program with a condition-level deficiency. However, CMS may approve a program with a standard-level deficiency upon receipt of an acceptable plan of correction.

(h) *Transplant Systems Improvement Agreement.* A Systems Improvement Agreement is a binding agreement, entered into voluntarily by the hospital and CMS, through which CMS extends a prospective Medicare termination date and offers the program additional time to achieve compliance with the conditions of participation, contingent on the hospital's agreement to participate in a structured regimen of quality improvement activities, demonstrate improved outcomes, and waive the right to appeal termination based on the identified deficiency or deficiencies that led to the Agreement in consideration for more time to demonstrate compliance. In some cases, transplant programs may enter a period of inactivity—voluntarily, or imposed as a condition of the Systems Improvement Agreement.

(1) *Content.* In exchange for the additional time to initiate or continue activities to achieve compliance with the conditions of participation, the hospital must agree to a regimen of specified activities, including (but not limited to) all of the following:

(i) Patient notification about the degree and type of noncompliance by the program, an explanation of what the program improvement efforts mean for patients, and financial assistance to defray the out-of-pocket costs of copayments and testing expenses for any wait-listed individual who wishes to be listed with another program;

(ii) An external independent peer review team that conducts: An onsite assessment of program policies, staffing, operations, relationship to hospital services, and factors that contribute to program outcomes; that suggests quality improvements the hospital should consider; that provides both verbal and written feedback to the hospital; and that provides a verbal debriefing to CMS. Neither the hospital nor the peer review team is required to provide a written report to CMS. The peer review team must include a transplant surgeon with expertise in the relevant organ type(s), a transplant administrator, an individual with expertise in transplant QAPI systems, a social worker or psychologist or psychiatrist, and a specialty physician with expertise in conditions particularly relevant to the applicable organ types(s) such as a cardiologist, nephrologist, or hepatologist. Except for the transplant surgeon, CMS may permit substitution of one type of expertise for another individual who has expertise particularly needed for the type of challenges experienced by the program, such as substitution of an infection control specialist in lieu of, or in addition to, a social worker;

(iii) An action plan that addresses systemic quality improvements and is updated after the onsite peer review;

(iv) An onsite consultant whose qualifications are approved by CMS, and who provides services for 8 days per month on average for the duration of the agreement, except that CMS may permit a portion of the time to be spent offsite and may agree to fewer consultant days each month after the first 3 months of the Systems Improvement Agreement;

(v) A comparative effectiveness analysis that compares policies, procedures, and protocols of the transplant program with those of other programs in areas of endeavor that are relevant to the center's current quality improvement needs;

(vi) Development of increased proficiency, or demonstration of current proficiency, with patient-level data from the Scientific Registry of Transplant Recipients and the use of registry data to analyze outcomes and inform quality improvement efforts;

(vii) A staffing analysis that examines the level, type, training, and skill of staff in order to inform transplant center efforts to ensure the engagement and appropriate training and credentialing of staff.

(viii) Activities to strengthen performance of the Quality Assessment and Performance Improvement Program to ensure full compliance with the requirements of § 482.96 of this chapter;

(ix) Monthly (unless otherwise specified) reporting and conference calls with CMS regarding the status of programmatic improvements, results of the deliverables in the Systems Improvement Agreement, and the number of transplants, deaths, and graft failures that occur within 1 year post-transplant; and

(x) Additional or alternative requirements specified by CMS, tailored to the transplant program type and circumstances.

(2) *Timeframe.* A Systems Improvement Agreement will be established for up to a 12-month period, subject to CMS' discretion to determine if a shorter timeframe may suffice. At the hospital's request, CMS may extend the agreement for up to an additional 6-month period.

(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 18, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Dated: April 22, 2014.

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, 2014 and Payment Rates for LTCHs Effective for Discharges Occurring On or After October 1, 2014.

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 2015 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 2015. 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, 2014.

In addition, we are setting forth a description of the methods and data we used to determine the proposed standard Federal rate that will be applicable to Medicare LTCHs for FY 2015.

In general, except for SCHs, MDHs and hospitals located in Puerto Rico, for FY 2015, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate (including, as discussed in section IV.F. of the preamble to this proposed rule, uncompensated care payments under section 1886(r)(2) of the Act); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge.

We note that, as discussed in section IV.G. of the preamble of this proposed rule, section 1106 of the Pathway to SGR Reform Act of 2013 (Pub. L. 113–67), enacted on December 26, 2013, extended the MDH program from the end of FY 2013 (that is, for discharges occurring after September 30, 2013) through the first half of FY 2014 (that is, for discharges occurring before April 1, 2014). Subsequently, section 106 of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93), enacted on April 1, 2014, further extended the MDH program through the first half of FY 2015 (that is, for discharges occurring before April 1, 2015). Prior to the enactment of Public Law 113–67, the MDH program was only to be in effect through the end of FY 2013. Under current law, the MDH program will expire for discharges on or after April 1, 2015.

Under section 1886(d)(5)(G) of the Act, MDHs historically have been paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever was higher. Section 5003(c) of Public Law 109–171 further required that MDHs be paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital-specific rate. Further, based on the provisions of section 5003(d) of Public Law 109–171, MDHs are no longer subject to the 12-percent cap on their DSH payment adjustment factor.

For hospitals located in Puerto Rico, the payment per discharge is based on the sum of 25 percent of an updated Puerto Rico-specific rate based on average costs per case of Puerto Rico hospitals for the base year and 75 percent of the Federal national rate. (We refer readers to section II.D.2. 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 2015. 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 2015. 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 2015. In section V. of this Addendum, we discuss proposed policy changes for determining the standard Federal rate for LTCHs paid under the LTCH PPS for FY 2015. 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 2015

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. Below we discuss the factors we are using for determining the proposed prospective payment rates for FY 2015.

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.

For FY 2015, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount. We refer the reader to section IV.B. of the preamble of this proposed rule for a complete discussion on the FY 2015 proposed inpatient hospital update. Below is a table with these four options:

FY 2015	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.675	−0.675
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−0.675	0.0	−0.675
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.4	−0.4	−0.4	−0.4
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.2	−0.2	−0.2	−0.2
Proposed Applicable Percentage Increase Applied to Standardized Amount	2.1	1.425	1.425	0.75

- A proposed update of 2.1 percent to the Puerto Rico-specific standardized amount (that is, the FY 2015 estimate of the market basket rate-of-increase of 2.7 percent less a proposed adjustment of 0.4 percentage point for MFP and less 0.2 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 under 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 under section 1886(d)(8)(D) of the Act, by removing the FY 2014 budget neutrality factor and applying a revised factor.
- As discussed below and in section III. of the preamble of this proposed rule, an adjustment to offset the cost of the transitional wage index provisions provided by CMS as a result of the proposed adoption of the new OMB labor market area delineations.
- An adjustment to ensure the effects of the rural community hospital demonstration program required under section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, which extended the demonstration program for an additional 5 years, are budget neutral as required under section 410A(c)(2) of Public Law 108–173.
- An adjustment to remove the FY 2014 outlier offset and apply an offset for FY 2015, as provided for under section 1886(d)(3)(B) of the Act.
- As discussed below and in section II.D. of the preamble of this proposed rule, a proposed recoupment to meet the requirements of section 631 of ATRA to adjust the standardized amount to offset the estimated amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013.

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 2014, for FY 2015, consistent with current law, we are proposing to continue to apply the rural floor budget neutrality adjustment to hospital wage indexes rather than the standardized amount. Also, consistent with section 3141 of the Affordable Care Act, instead of applying a State level rural floor budget neutrality adjustment

to the wage index, we are proposing to apply a uniform, national budget neutrality adjustment to the proposed FY 2015 wage index for the rural floor. We note that, in section III.G.2.b. of the preamble to this proposed rule, we are proposing to extend the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2015.

Therefore, for this proposed rule, we are proposing to continue to include the imputed floor (calculated under the original and alternative methodologies) in calculating the uniform, national rural floor budget neutrality adjustment, which will be reflected in the proposed FY 2015 wage index.

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 2015, we are proposing to use the national and Puerto Rico-specific labor-related and nonlabor-related shares established for FY 2014, using the FY 2010-based hospital market basket. Specifically, under section 1886(d)(3)(E) of the Act, the Secretary estimates from time to time the proportion of payments that are labor-related: ''[T]he 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 proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.'' For FY 2015, as discussed in section III. of the preamble of this proposed rule, we are proposing to establish a labor-related share of 69.6 percent for the national standardized amounts, and 63.2 percent for the Puerto Rico-specific standardized amount, if the hospital has a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals 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 69.6 percent of the national standardized amount. For FY 2015, all Puerto Rico hospitals have a proposed wage index value that is less than 1.0000 because the proposed average hourly rate of every hospital in Puerto Rico divided by the proposed national average hourly rate (the sum of all salaries and hours for all hospitals in the 50 United States and Puerto Rico) results in a proposed wage index that is below 1.0000. However, when we divide the proposed average hourly rate of every hospital located in Puerto Rico by the proposed Puerto Rico-specific national average hourly rate (the sum of all salaries and hours for all hospitals located only in Puerto Rico), we determine a proposed Puerto Rico-specific wage index value for some hospitals that is either above, or below 1.0000, depending on the hospital's location within Puerto Rico.

Therefore, for hospitals located in Puerto Rico, we are proposing to apply a labor-related share of 63.2 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 proposing to apply a labor share of 62 percent.

The proposed standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this proposed rule and are available via the Internet.

2. Computing the National Average Standardized Amount and Puerto Rico-Specific 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 2015 national average standardized amount and Puerto Rico-specific standardized amount irrespective of whether a hospital is located in an urban or rural location.

3. Updating the National Average Standardized Amount and Puerto Rico-Specific Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, in this proposed rule, we are using the revised and rebased FY 2010-based IPPS operating and capital market baskets for FY 2015 (which replaced the FY 2006-based IPPS operating and capital market baskets in FY 2014). As discussed in section IV.B. of the preamble of this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing to reduce the proposed FY 2015 applicable percentage increase (which is based on IHS Global Insight, Inc.'s (IGI's) first quarter 2014 forecast of the FY 2010-based IPPS market basket) by the proposed MFP adjustment (the

10-year moving average of MFP for the period ending FY 2015) of 0.4 percentage point, which is calculated based on IGI's first quarter 2014 forecast.

In addition, in accordance with section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are proposing to further update the standardized amount for FY 2015 by the estimated market basket percentage increase less 0.2 percentage point for hospitals in all areas. Sections 1886(b)(3)(B)(xi) and (xii) of Act, as added and amended by sections 3401(a) and 10319(a) of the Affordable Care Act, further state that these adjustments may result in the applicable percentage increase being less than zero. The percentage increase in the market basket reflects the average change in the price of goods and services comprising routine, ancillary, and special care unit hospital inpatient services.

Based on IGI's 2014 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 2015 is 2.7 percent. As discussed above, for FY 2015, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that could be applied to the standardized amount. We refer readers to section IV. of the preamble of this proposed rule for a complete discussion on the FY 2015 proposed inpatient hospital update to the standardized amount. We also refer readers to the table above for the four possible proposed applicable percentage increases that would be applied to update the national standardized amount. The proposed standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the Internet reflect these differential amounts.

Section 401(c) of Public Law 108–173 amended section 1886(d)(9)(C)(i) of the Act and states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for FY 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount is subject to the applicable percentage increase set forth under 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 to establish an applicable percentage increase to the Puerto Rico-specific standardized amount of 2.1 percent for FY 2015.

Although the update factors for FY 2015 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 2015 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 2015 standardized amount to remove the effects of the FY 2014 geographic reclassifications and outlier payments before applying the proposed FY 2015 updates. We then apply budget neutrality offsets for outliers and geographic reclassifications to the proposed standardized amount based on proposed FY 2015 payment policies.

We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS–DRG classifications, recalibration of the MS–DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

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 anti-hemophilic 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 readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.

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 through 50423), we examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field 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.

The Bundled Payments for Care Improvement (BPCI) initiative, developed under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of four broadly defined models of care, which link payments for multiple services beneficiaries receive during an episode of care. Under the BPCI initiative, organizations enter into payment arrangements that include

financial and performance accountability for episodes of care. On January 31, 2013, CMS announced the health care organizations selected to participate in the BPCI initiative. For additional information on the BPCI initiative, we refer readers to the CMS Center for Medicare and Medicaid Innovation's Web site at: *http://innovation.cms.gov/initiatives/Bundled-Payments/index.html*.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343), for FY 2013 and subsequent fiscal years, we finalized a methodology to treat hospitals that participate in the BPCI initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process (which includes recalibration of the MS–DRG relative weights, ratesetting, calculation of the budget neutrality factors, and the impact analysis) without regard to a hospital's participation within these bundled payment models (that is, as if they are not participating in those models under the BPCI initiative). Therefore, for FY 2015, as discussed in section II.H.4.of the preamble to this proposed rule, we are proposing to continue 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. We refer the reader to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals in the BPCI initiative in our rate setting process.

The Affordable Care Act established the Hospital Readmissions Reduction Program and the Hospital VBP 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, in this proposed rule, consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for these programs within our budget neutrality calculations. We discuss the treatment of these two programs in the context of budget neutrality adjustments below.

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 are reduced to account for certain excess readmissions. Under the Hospital Readmissions Reduction Program, for discharges beginning on October 1, 2012 discharges from an ''applicable hospital'' are paid at 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 plus any applicable add-on payments. We refer readers to section IV.H. of the preamble of this proposed rule for full details of our implementation of and proposed FY 2015 policy changes to the Hospital Readmissions Reduction Program. We also note that the Hospital Readmissions Reduction Program provided for under section 1886(q) of the Act is not budget neutral.

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which, for discharges beginning on October 1, 2012, value-based incentive payments are made in a fiscal year to eligible subsection (d) hospitals that meet performance standards established for a performance period for that fiscal year. As specified under section 1886(o)(7)(B)(i) of the Act, 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. As required by section 1886(o)(7)(A) of the Act, the total amount of allocated funds available for value-based incentive payments with respect to a fiscal year is equal to the total amount of base-operating DRG payment reductions, as estimated by the Secretary. In a given fiscal year, hospitals may earn a value-based incentive payment amount for a fiscal year that is greater than, equal to, or less than the reduction amount, based on their performance on quality measures under the Hospital VBP Program. Thus, the Hospital VBP Program is estimated to have no net effect on overall payments. We refer readers to section IV.I. of the preamble of this proposed rule for full details regarding the Hospital VBP Program.

Both the hospital readmissions payment adjustment (reduction) and the hospital VBP payment adjustment (redistribution) are applied on a claim-by-claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations. For example, when we calculate the budget neutrality factor for MS–DRG reclassification and recalibration of the relative weights, we compare aggregate payments estimated using the prior year's GROUPER and relative weights to estimated payments using the new GROUPER and relative weights. (We refer readers to section II.A.4.a. of this Addendum for full details.) 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 changes of MS–DRG reclassification and recalibration.

In order to properly determine aggregate payments on each side of the comparison, as we did for FY 2014, for FY 2015 and subsequent years, we are proposing to continue to apply the hospital readmissions payment adjustment and the hospital VBP payment adjustment on each side of the comparison, consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). That is, we are proposing to apply the readmissions payment adjustment factor and the hospital VBP payment adjustment factor on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

For the purpose of calculating the proposed FY 2015 readmissions payment adjustment factors, we are proposing to use excess readmission ratios and aggregate payments for excess readmissions based on admissions from the prior fiscal year's applicable period because hospitals have had the opportunity to review and correct these data before the data were made public under the policy we adopted regarding the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act. For this proposed rule, we are proposing to calculate the readmissions payment adjustment factors using excess readmission ratios and aggregate payments for excess readmissions based on admissions from the finalized applicable period for FY 2015 as hospitals have had the opportunity to review and correct these data under our policy regarding the reporting of hospital-specific readmission rates consistent with section 1886(q)(6) of the Act. We discuss our policy regarding the reporting of hospital-specific readmission rates for FY 2015 in section IV.H.3.f. of the preamble of this proposed rule. (For additional information on our general policy for the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53400).)

In addition, for this proposed rule, for the purpose of modeling aggregate

payments when determining all budget neutrality factors, we are proposing to use proxy hospital VBP payment adjustment factors for FY 2015 that are based on data from a historical period because hospitals have not yet had an opportunity to review and submit corrections for their data from the FY 2015 performance period. (For additional information on our policy regarding the review and correction of hospital-specific measure rates under the Hospital VBP Program, consistent with section 1886(o)(10)(A)(ii) of the Act, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53578 through 53581), the CY 2012 OPPS/ASC final rule with comment period (76 FR 74544 through 74547), and the Hospital Inpatient VBP final rule (76 FR 26534 through 26536).)

The Affordable Care Act also established section 1886(r) of the Act, which modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments will receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the current statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under age 65 who are uninsured, will be available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. In order to properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY2014, we included estimated Medicare DSH payments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

To do this for FY 2015 and subsequent years (as we did for FY 2014), we are proposing to include estimated empirically justified Medicare DSH payments that will be paid in accordance with section 1886(r)(1) of the Act and also to include estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we are proposing to consider estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

We note that, when calculating total payments for budget neutrality, to determine total payments for SCHs we model total hospital-specific rate payments and total federal rate payments and then include whichever one of the total payments are greater. As discussed in section IV.F. of the preamble to this proposed rule and below, we are continuing the FY 2014 finalized methodology under which we will take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we are including estimated uncompensated care payments in this comparison.

Similarly, for MDHs, as discussed in section IV. of the preamble to this proposed rule, when computing the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital-specific rate, we are continuing to take into consideration uncompensated care payments in the computation of payments under the Federal rate and the hospital-specific rate for MDHs.

Also, for FY 2015, CMS has yet to finalize a list of hospitals that are not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act. Therefore, we are proposing not to include this adjustment to the standardized amount (for those hospitals that are not meaningful EHR users) in our modeling of aggregate payments for budget neutrality for FY 2015. CMS intends to release a final list of hospitals that are not meaningful EHR user in September 2014. Hospitals identified on this list will be paid based on the applicable proposed standardized amount in Table 1A for discharges occurring in FY 2015.

We finally note that the wage index value is calculated and assigned to a hospital based on the hospital's labor market area. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core-Based Statistical Areas (CBSAs) established by the Office of Management and Budget (OMB). The current statistical areas used in FY 2014 are based on OMB standards published on December 27, 2000 (65 FR 82228) and Census 2000 data and Census Bureau population estimates for 2007 and 2008 (OMB Bulletin No. 10–02). For purposes of determining all of the FY 2014 budget neutrality factors, we determined aggregate payments on each side of the comparison for our budget neutrality calculations using wage indexes based on the current CBSAs.

As stated in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27552) and final rule (78 FR 50586), on February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. In order to implement these changes for the IPPS, it is necessary to identify the new OMB labor market area delineation for each county and hospital in the country. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50586), we stated that we intended to propose changes to the wage index policy based on the new OMB delineations in this FY 2015 proposed rule. As discussed in section III. of the preamble of this proposed rule, we are proposing to adopt the new OMB labor market area delineations as described in the February 28, 2013 OMB Bulletin No. 13–01, effective for the FY 2015 IPPS wage index.

Consistent with our proposal to adopt the new OMB delineations, in order to properly determine aggregate payments on each side of the comparison for our budget neutrality calculations, we are proposing to use wage indexes based on the new OMB delineations in the determination of all of the proposed budget neutrality factors discussed below (with the exception of the proposed transitional budget neutrality factor and proposed outlier threshold as explained below). We also note that, consistent with past practice as finalized in the FY 2005 IPPS final rule (69 FR 49034), we are not adopting the new OMB delineations themselves in a budget neutral manner. We continue to believe that the revision to the labor market areas in and of itself do not constitute an ''adjustment or update'' to the adjustment for area wage differences, as provided under section 1886(d)(3)(E) of the Act.

a. Proposed Recalibration of MS–DRG Relative 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 MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are proposing to make a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0000, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage 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 1.0000 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2015, we are proposing to adjust 100 percent of the wage index factor for occupational mix. We describe the proposed occupational mix adjustment in section III.F. of the preamble of this proposed rule.

For FY 2015, to comply with the requirement that MS–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 2013 discharge data to simulate payments and compared the following:

- Aggregate payments using the new OMB labor market area delineations proposed for FY 2015, the FY 2014 relative weights, and the FY 2014 pre-reclassified wage data, and applied the proposed FY 2015 hospital readmissions payment adjustments and estimated FY 2015 hospital VBP payment adjustments; and
- Aggregate payments using the new OMB labor market area delineations proposed for FY 2015, the proposed FY 2015 relative weights, and the FY 2014 pre-reclassified wage data, and applied the same hospital readmissions payment adjustments and estimated hospital VBP payment adjustments applied above.

Based on this comparison, we computed a proposed budget neutrality adjustment factor equal to 0.992938. As discussed in section IV. of this Addendum, we also are proposing to apply the proposed MS–DRG reclassification and recalibration budget neutrality factor of 0.992938 to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2014.

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 MS–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. Under the first step, we determined a proposed MS–DRG reclassification and recalibration budget neutrality factor of 0.992938 (by using the same methodology described above to determine the MS–DRG reclassification and recalibration budget neutrality factor for the Puerto Rico standardized amount and hospital-specific rates). Under the second step, to compute a proposed budget neutrality factor for wage index and labor-related share changes we used FY 2013 discharge data to simulate payments and compared the following:

- Aggregate payments using the new OMB labor market area delineations proposed for FY 2015, proposed FY 2015 relative weights and the FY 2014 pre-reclassified wage indices, applied the FY 2014 labor-related share of 69.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0), and applied the proposed FY 2015 hospital readmissions payment adjustment and the proposed FY 2015 estimated hospital VBP payment adjustment; and
- Aggregate payments using the new OMB labor market area delineations proposed for FY 2015, proposed FY 2015 relative weights and the proposed FY 2015 pre-reclassified wage indices, applied the proposed labor-related share for FY 2015 of 69.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0), and applied the same proposed FY 2015 hospital readmissions payment adjustments and estimated proposed FY 2015 hospital VBP payment adjustments applied above.

In addition, we applied the proposed MS–DRG reclassification and recalibration budget neutrality factor (derived in the first step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2014 to FY 2015. By applying this methodology, we determined a proposed budget neutrality adjustment factor of 1.000578 for changes to the wage index. Finally, we multiplied the proposed MS–DRG reclassification and recalibration budget neutrality adjustment factor of 0.992938 (derived in the first step) by the proposed budget neutrality adjustment factor of 1.000578 for changes to the wage index (derived in the second step) to determine the proposed MS–DRG reclassification and recalibration and updated wage index budget neutrality adjustment factor of 0.993512.

b. Reclassified Hospitals—Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) shall not be taken into account in ''applying any budget neutrality adjustment with respect to such index'' under section

1886(d)(8)(D) of the Act. To calculate the proposed budget neutrality factor for FY 2015, we used FY 2013 discharge data to simulate payments and compared the following:

- Aggregate payments using the new OMB labor market area delineations proposed for FY 2015, proposed FY 2015 relative weights, and proposed FY 2015 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the proposed FY 2015 hospital readmissions payment adjustments and the proposed estimated FY 2015 hospital VBP payment adjustments; and
- Aggregate payments using the new OMB labor market area delineations proposed for FY 2015, proposed FY 2015 relative weights, and proposed FY 2015 wage data after such reclassifications, and applied the same proposed hospital readmissions payment adjustments and the estimated hospital VBP payment adjustments applied above.

We note that the reclassifications applied under the second simulation and comparison are those listed in Tables 9A2 and 9C2, which are posted on the CMS Web site. These tables reflect reclassification crosswalks based on the new OMB labor market area delineations proposed for FY 2015, and apply the policies explained in section III. of the preamble to this proposed rule. Based on these simulations, we calculated a proposed budget neutrality adjustment factor of 0.991412 to ensure that the effects of these provisions are budget neutral, consistent with the statute.

The proposed FY 2015 budget neutrality adjustment factor was applied to the proposed standardized amount after removing the effects of the FY 2014 budget neutrality adjustment factor. We note that the proposed FY 2015 budget neutrality adjustment reflects proposed FY 2015 wage index reclassifications approved by the MGCRB or the Administrator.

c. Proposed Rural Floor Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) and the imputed floor under § 412.64(h)(4) are equal to the aggregate prospective payments that would have been made in the absence of such provisions. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.G. of the preamble of this proposed rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural and imputed floor is a national adjustment to the wage index.

As noted above and as discussed in section III.G.2.b. of the preamble of this proposed rule, in the FY 2012 IPPS/LTCH PPS final rule, we extended the imputed floor calculated under the original methodology through FY 2013 (76 FR 51594). In the FY 2013 IPPS/LTCH PPS final rule, we established an alternative methodology for calculating the imputed floor and established a policy that the minimum wage index value for an all-urban state would be the higher of the value determined under the original methodology or the value computed using the alternative methodology (77 FR 53368 through 53369). Consistent with the methodology for treating the imputed floor, similar to the methodology we used in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53368 through 53369), we included this alternative methodology for computing the imputed floor index in the calculation of the uniform, national rural floor budget neutrality adjustment for FY 2014. For FY 2015, as discussed in section III.G.2.b. of the preamble of this proposed rule, we are proposing to extend the imputed floor using the higher of the value determined under the original methodology or the alternative methodology for FY 2015. Therefore, in order to ensure that aggregate payments to hospitals are not affected, similar to prior years, we would follow our policy of including the imputed floor in the rural floor budget neutrality adjustment to the wage index.

As discussed above, for FY 2015, we are proposing to implement the new OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13–01, effective for the FY 2015 IPPS wage index. Therefore, the budget neutrality adjustment for the rural floor and imputed floor would be calculated using the new OMB delineations.

Under the OMB delineations used for FY 2014, the imputed floor (both the original methodology and alternative methodology) was applied to New Jersey and Rhode Island because these were the only two all-urban States. Under OMB's 2010 revised delineations based on Census 2010 data, in addition to New Jersey and Rhode Island, Delaware would become an all-urban state. Therefore, for FY 2015, the proposed imputed floor would be applied to New Jersey, Rhode Island, and Delaware.

Similar to our calculation in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593 and 51788), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53689), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50975 through 50976), for FY 2015, we are calculating a proposed national rural Puerto Rico wage index (used to adjust the labor-related share of the national standardized amount for hospitals located in Puerto Rico which receive 75 percent of the national standardized amount) and a proposed rural Puerto Rico-specific wage index (which is used to adjust the labor-related share of the Puerto Rico-specific standardized amount for hospitals located in Puerto Rico that receive 25 percent of the Puerto Rico-specific standardized amount). Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the FY 2015 rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). That is, we will use the unweighted average of the wage indexes from all CBSAs (urban areas) that are contiguous (share a border with) to the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Under the new OMB labor market area delineations, except for Arecibo, Puerto Rico (CBSA 11640), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the FY 2015 rural Puerto Rico wage index is calculated based on the average of the FY 2015 wage indices for the following urban areas: Aguadilla-Isabela, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660), San German, PR (CBSA 41900) and San Juan-Carolina-Caguas, PR, PR (CBSA 41980).

To calculate the proposed national rural floor and imputed floor budget neutrality adjustment factor and the proposed Puerto Rico-specific rural floor budget neutrality adjustment factor, we used FY 2013 discharge data to simulate payments, the proposed FY 2015 new OMB labor market area delineations, and post-reclassified national and Puerto Rico-specific wage indices and compared the following:

- The national and Puerto Rico-specific simulated payments without the national rural floor and imputed floor and Puerto Rico-specific rural floor applied; and
- The national and Puerto Rico-specific simulated payments with the national rural floor and imputed floor and Puerto Rico-specific rural floor applied.

Based on this comparison, we determined a proposed national rural budget neutrality adjustment factor of 0.989455 and the proposed Puerto Rico-

specific budget neutrality adjustment factor of 0.991359. The proposed national adjustment was applied to the proposed national wage indexes to produce a proposed national rural floor budget neutral wage index and the proposed Puerto Rico-specific adjustment was applied to the proposed Puerto Rico-specific wage indexes to produce a proposed Puerto Rico-specific rural floor budget neutral wage index.

d. Proposed Wage Index Transition Budget Neutrality

As discussed in section III. of the preamble to this proposed rule, in the past, we have provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts.

Similar to FY 2005, for FY 2015, we have determined that the proposed transition to using the new OMB delineations would have the largest impact on hospitals that are currently located in an urban county that would become rural under the new OMB delineations. To alleviate the decreased payments associated with having a rural wage index, in calculating the area wage index, similar to the transition provided in the FY 2005 IPPS final rule, we generally are proposing a policy to assign them the urban wage index value of the CBSA to which they are physically located for FY 2014 for FYs 2015, 2016, and 2017.

In addition to the 3-year transition adjustment for hospitals being transitioned from urban to rural status as discussed above, we are proposing a 1-year blended wage index for all hospitals that would experience any decrease in their actual payment wage index (that is, a hospital's actual wage index used for payment, which accounts for all applicable effects of reclassification and redesignation) exclusively due to the proposed implementation of the new OMB delineations. Similar to the policy adopted in the FY 2005 IPPS final rule (69 FR 49033), we are proposing that a post-reclassified wage index with the rural and imputed floor applied would be computed based on the hospital's FY 2014 CBSA (that is, using all of its FY 2014 constituent county/ies), and another post-reclassified wage index with the rural and imputed floor applied would be computed based on the hospital's new FY 2015 CBSA (that is, the FY 2015 constituent county/ies). We are proposing to compare these two wage indexes. If the proposed FY 2015 wage index with FY 2015 CBSAs would be lower than the proposed FY 2015 wage index with FY 2014 CBSAs, we are proposing that a blended wage index would be computed, consisting of 50 percent of each of the two wage indexes added together. We are proposing that this blended wage index would be the hospital's wage index for FY 2015. Hospitals that benefit from the proposed adoption of the new OMB delineations would receive their new wage index based on the new OMB delineations. We refer readers to section III. of the preamble to this proposed rule for a completer discussion on the transitional wage index policy.

In the past, CMS has budget neutralized transitional wage indexes. Because we are proposing a policy that allows for the application of a transitional wage index only when it would benefit the hospital, we believe that it would be appropriate to ensure that such a transitional policy does not increase aggregate Medicare payments beyond the payments that would be made had we simply adopted the new OMB delineations without any transitional provisions. Therefore, for FY 2015, we are proposing to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to make an adjustment to the national and Puerto Rico-specific standardized amounts to ensure that total payments, including the effect of the transitional wage index provisions, would equal what payments would have been if we had proposed to fully adopt the new OMB delineations without any transitional provisions.

As stated above, the proposed 50/50 blended wage indexes would use post-reclassified wage index data with the rural and imputed floor applied computed based on FY 2014 CBSAs. Because the proposed 50/50 blend methodology would use data based on FY 2014 CBSAs, in order to properly calculate the proposed transitional budget neutrality factor, it was first necessary to calculate the following proposed budget neutrality factors based on the FY 2014 CBSAs: An MS–DRG and a wage index budget neutrality, a reclassification budget neutrality, and a rural floor budget neutrality. It was necessary to compute the first three budget neutrality factors of MS–DRG, wage index, and reclassification budget neutrality (which are applied to the standardized amount) to ensure that the calculation of the rural and imputed floor budget neutrality factor applied to the wage index based on FY 2014 CBSAs is accurate. We calculated these four budget neutrality factors using the same methodology stated above, but used the FY 2014 CBSAs instead of the proposed FY 2015 CBSAs on both the sides of the comparison.

After calculating all of the proposed budget neutrality factors using FY 2014 and FY 2015 CBSAs, to calculate the proposed transitional wage index budget neutrality factor for FY 2015, we used FY 2013 discharge data to simulate payments and compared the following:

- Aggregate payments using new OMB delineations proposed for FY 2015, the proposed FY 2015 relative weights, proposed FY 2015 wage data after such reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act (using the new OMB delineations), applied the proposed rural floor budget neutrality factor to the wage index (using the new OMB delineations), and applied the proposed FY 2015 hospital readmissions payment adjustments and the proposed estimated FY 2015 hospital VBP payment adjustments; and
- Aggregate payments using proposed FY 2015 relative weights, proposed FY 2015 wage data after applying the transitional wage indexes, and applied the same proposed hospital readmissions payment adjustments and the estimated hospital VBP payment adjustments applied above. We note that hospitals that did not receive the proposed transitional 50/50 blended wage index were assigned the post-reclassified wage index values with the proposed rural floor budget neutrality based on the proposed FY 2015 new OMB delineations.

Based on these simulations, we calculated a proposed budget neutrality adjustment factor of 0.998856. Therefore, for FY 2015, we are proposing to apply a transitional wage index budget neutrality adjustment factor of 0.998856 to the national average and Puerto Rico-specific standardized amounts to ensure that the effects of these proposed transitional wage indices are budget neutral.

We note that the proposed budget neutrality adjustment factor calculated above is based on the increase in payments in FY 2015 that would result from the transitional wage indexes. Therefore, we are proposing to apply this budget neutrality adjustment factor as a one-time adjustment to the FY 2015 national and Puerto Rico-specific standardized amounts in order to offset the increase in payments in FY 2015 as a result of these transitional wage indexes. For subsequent fiscal years, we are proposing to not take into consideration the adjustment factor applied to the national and Puerto Rico-specific standardized amounts in the previous fiscal year's update when calculating the current fiscal year transitional wage index budget neutrality adjustment factor (that is, we

are proposing that this adjustment would not be applied cumulatively). Because we are proposing a 3-year transitional wage index policy for urban hospitals that became rural as a result of the proposed adoption of the new OMB delineations, we intend to propose transitional wage index budget neutrality adjustment factors to apply to the FY 2016 and FY 2017 national and Puerto Rico-specific standardized amounts during those respective rulemaking cycles. Similar to the proposal for FY 2015, we plan on proposing that the FYs 2016 and 2017 adjustments would be applied as ''one-time'' adjustments and not cumulative adjustments applied each fiscal year.

d. Proposed Case-Mix Budget Neutrality Adjustment

Below we summarize the proposed recoupment adjustment to the proposed FY 2015 payment rates, as required by section 631 of ATRA, to account for the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. We refer readers to section II.D. of the preamble of this proposed rule for a complete discussion regarding our proposed policies for FY 2015 in this proposed rule and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case-mix.

(1) Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA) to the National Standardized Amount

Section 631 of the ATRA amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment totaling $11 billion by FY 2017. Our actuaries estimated that if CMS were to fully account for the $11 billion recoupment required by section 631 of ATRA in FY 2014, a one-time −9.3 percent adjustment to the standardized amount would be necessary. It is often our practice to delay or phase-in payment rate adjustments over more than 1 year, in order to moderate the effect on payment rates in any 1 year. Therefore, consistent with the policies that we have adopted in many similar cases, for FY 2014, we applied a −0.8 percent adjustment to the standardized amount. In this proposed rule, we are proposing to apply an additional −0.8 percent adjustment to the standardized amount for FY 2015. We note that, as section 631 of the ATRA instructs the Secretary to make a recoupment adjustment only to the standardized amount, this adjustment would not apply to the Puerto Rico-specific standardized amount and hospital-specific payment rates.

e. Rural Community Hospital Demonstration Program Adjustment

As discussed in section IV.L. of the preamble of this proposed rule, section 410A of Public Law 108–173 originally required the Secretary to establish a demonstration program that modifies reimbursement for inpatient services for up to 15 small rural hospitals. Section 410A(c)(2) of Public Law 108–173 requires that ''[i]n conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented.''

Sections 3123 and 10313 of the Affordable Care Act extended the demonstration program 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 2013 IPPS/LTCH PPS final rule (77 FR 53449 through 53453), in order to achieve budget neutrality, we adjusted the national IPPS payment rates by an amount sufficient to account for the added costs of this demonstration program 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 program, consistent with past practice. We stated that we believe 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.

As we did for FY 2014, for FY 2015, we are proposing to adjust the national IPPS payment rates according to the same methodology that we used for FY 2013, as set forth in section IV.L. of the preamble of this proposed rule, to account for the estimated additional costs of the demonstration program for FY 2015. For this proposed rule, the estimated amount of this proposed budget neutrality adjustment factor applied to the national IPPS payment rates for FY 2015 is $53,673,008. In addition, similar to previous years, we are proposing to include in the budget neutrality offset amount the amount by which the actual demonstration costs corresponding to an earlier given year (which would be determined once we have finalized cost reports for that year) exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule. For this FY 2015 IPPS/LTCH PPS proposed rule, we have calculated the amount by which the actual costs of the demonstration in FY 2008, (that is, the costs of the demonstration for the 10 hospitals that participated in FY 2008, as shown in these hospitals' finalized cost reports for the cost report period beginning in that calendar year), exceeded the amount that was finalized in the FY 2008 IPPS final rule. We are proposing a budget neutrality offset amount of $10,389,771 for this proposed rule, but we note that this amount may change based on data used for the FY 2015 IPPS/LTCH PPS final rule subject to methodological refinements. We also are currently working with the MACs that service the hospitals participating in the demonstration to obtain finalized cost reports for FYs 2009, 2010, and 2011). Depending on our progress in obtaining these cost reports, we may also include in the FY IPPS final rule the difference between the demonstration costs for one or more of these years and the amounts that were finalized in the respective fiscal years' final rules.

Therefore, the final total budget neutrality offset amount that we are proposing to be applied to the FY 2015 IPPS rates is $ 64,062,779. This amount is the sum of two separate components: (1) The difference between the total estimated FY 2014 reasonable cost amount to be paid under the demonstration to the 22 participating hospitals participating in the demonstration program for covered inpatient services, and the total estimated amount that would be otherwise be paid to the participating hospitals in FY 2014 without the demonstration ($53,673,008); and (2) the amount by which the actual costs of demonstration for FY 2008, which are calculated in accordance with the finalized cost reports for the hospitals that participated in the demonstration during FY 2008, exceed the budget neutrality offset amount that was

finalized in the FY 2008 IPPS final rule ($10,389,771).

Accordingly, using the most recent data available to account for the estimated costs of the demonstration program, for FY 2015, we computed a proposed factor of 0.999283 for the rural community hospital demonstration program budget neutrality adjustment that will be applied to the IPPS standard Federal payment rate.

g. Proposed Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the DRG, any IME and DSH payments, any new technology add-on payments, and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the DRG, any IME and DSH payments, any new technology add-on payments, and the outlier threshold as the outlier ''fixed-loss cost threshold.'' To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2015 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 (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.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.html.*

(1) Proposed FY 2015 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977–50983), in response to public comments on the FY 2013 IPPS/LTCH proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for detailed discussion of the changes. In this proposed rule, for FY 2015, we are proposing to continue to use the outlier threshold methodology used in FY 2014.

As we have done in the past, to calculate the proposed FY 2015 outlier threshold, we simulated payments by applying proposed FY 2015 payment rates and policies using cases from the FY 2013 MedPAR file. Therefore, in order to determine the proposed FY 2015 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2013 to FY 2015. As discussed in the FY 2014 IPPS/LTCH PPS final rule, we believe a methodology that is based on 1-year of charge data will provide a more stable measure to project the average charge per case because our prior methodology used a 6-month measure, which inherently uses fewer claims than a 1-year measure and makes it more susceptible to fluctuations in the average charge per case as a result of any significant charge increases or decreases by hospitals. Under this new methodology, to compute the 1-year average annualized rate-of-change in charges per case for FY 2015, we are proposing to compare the second quarter of FY 2012 through the first quarter of FY 2013 (January 1, 2012, through December 31, 2012) to the second quarter of FY 2013 through the first quarter of FY 2014 (January 1, 2013, through December 31, 2013). This rate-of-change is 5.6 percent (1.055736) or 11.5 percent (1.114579) over 2 years.

As we have done in the past, we are proposing to establish the proposed FY 2015 outlier threshold using hospital CCRs from the December 2013 update to the Provider-Specific File (PSF)—the most recent available data at the time of this proposed rule. For FY 2015, we also are proposing to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below). In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital CCR from the most recent update of the PSF to the national average case-weighted operating and capital CCR from the same period of the prior year.

Therefore, as we did for FY 2014, for FY 2015, we are proposing to adjust the CCRs from the December 2013 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the December 2012 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2013 update of the PSF. We note that we used total transfer adjusted cases from FY 2013 to determine the national average case-weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison as this will produce the true percentage change in the average case-weighted operating and capital CCR from one year to the next without any effect from a change in case count on different sides of the comparison.

Using the proposed methodology above, we calculated a December 2012 operating national average case-weighted CCR of 0.295101 and a December 2013 operating national average case-weighted CCR of 0.289587. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the December 2012 operating national average case-weighted CCR from the December 2013 operating national average case-weighted CCR and then dividing the result by the December 2012 national operating average case-weighted CCR. This resulted in a proposed national operating CCR adjustment factor of 0.981315.

We also used the same methodology proposed above to adjust the capital CCRs. Specifically, we calculated a December 2012 proposed capital national average case-weighted CCR of 0.025079 and a December 2013 proposed capital national average case-weighted CCR of 0.024868. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the

December 2012 capital national average case-weighted CCR from the December 2013 capital national average case-weighted CCR and then dividing the result by the December 2012 capital national average case-weighted CCR. This resulted in a proposed national capital CCR adjustment factor of 0.991587.

Consistent with our methodology in the past and as stated in the FY 2009 IPPS final rule (73 FR 48763), we continue to believe that 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 2015 is approximately 1 year. Therefore, as stated above, we believe a 1-year adjustment factor to the CCRs is appropriate.

As stated above, for FY 2015, we applied the proposed FY 2015 payment rates and policies using cases from the FY 2013 MedPAR files in calculating the proposed outlier threshold.

As discussed above, for FY 2015, we are proposing to apply transitional wage indexes because of the proposed adoption of the new OMB labor market area delineations. Also, 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 note 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 2015, it was necessary to apply the proposed transitional wage indexes and adjust 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 2015. If we did not take the above into account, our estimate of total FY 2015 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.

As we did in establishing the FY 2009 outlier threshold (73 FR 57891), in our projection of FY 2015 outlier payments, we are proposing not 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.H. and IV.I., respectively, of the preamble of this proposed rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe that it is appropriate to include the hospital VBP payment adjustments and the hospital readmissions payment adjustments in the outlier threshold calculation or the outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we are proposing to exclude the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the outlier fixed-loss cost threshold.

We note, to the extent section 1886(r) of the Act modifies the existing DSH payment methodology under section 1886(d)(5)(F), the new uncompensated care payment under section 1886(r)(2), like the empirically justified Medicare DSH payment under section 1886(r)(1), may be considered an amount payable under section 1886(d)(5)(F) of the Act such that it would be reasonable to include the payment in the outlier determination under section 1886(d)(5)(A). As we did for FY 2014, for FY 2015 we also are proposing to allocate an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally. Furthermore, we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used in FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2015, we are proposing to include estimated FY 2015 uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we are proposing to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the outlier fixed-loss cost threshold methodology.

Using this methodology, we calculated a proposed outlier fixed-loss cost threshold for FY 2015 equal to the proposed prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus $25,799.

We note that, the proposed FY 2015 fixed-loss cost threshold is higher than the FY 2014 final outlier fixed-loss cost

threshold of $21,748. We believe that the increase in the charge inflation factor (compared to the FY 2014 charge inflation factor) contributed to a higher proposed outlier fixed-loss threshold for FY 2015. As charges increase, so do outlier payments. As a result, it would be necessary for us to raise the outlier fixed-loss cost threshold to decrease the amount of outlier payments expended in order to reach the 5.1 percent target.

(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 2015 will result in outlier payments that will equal 5.1 percent of operating DRG payments and 6.26 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 proposed FY 2015 standardized amount by the same percentage to account for the projected proportion of payments paid as outliers.

The proposed outlier adjustment factors that would be applied to the standardized amount based on the FY 2015 outlier threshold are as follows:

	Operating standardized amounts	Capital Federal rate
National	0.949000	0.937425
Puerto Rico	0.928942	0908313

We are proposing to apply the outlier adjustment factors to the proposed FY 2015 payment rates after removing the effects of the FY 2014 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 1.22 or capital CCRs greater than 0.173, or hospitals for which the fiscal intermediary or MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available only via the Internet) 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, 2014, these statewide average ratios would replace the ratios posted on our Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY-2014-IPPS-Final-Rule-Home-Page-Items/FY-2014-IPPS-Final-Rule-CMS-1599-F-Tables.html*. 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 2015 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, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR ratio at any time as long as the guidelines of Change Request 3966 are followed. In addition, as mentioned above, we published an additional manual update (Change Request 7192) to our outlier policy on December 3, 2010, which also updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update outlines the outlier reconciliation process for hospitals and Medicare contractors. To download and view the manual instructions on outlier reconciliation, we refer readers to the CMS Web site: *http://www.cms.hhs.gov/manuals/downloads/clm104c03.pdf*.

(3) FY 2013 and FY 2014 Outlier Payments

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50983 through 50984), we stated that, based on available data, we estimated that actual FY 2013 outlier payments would be approximately 4.77 percent of actual total MS–DRG payments. This estimate was computed based on simulations using the FY 2012 MedPAR file (discharge data for FY 2012 claims). That is, the estimate of actual outlier payments did not reflect actual FY 2013 claims, but instead reflected the application of FY 2013 payment rates and policies to available FY 2012 claims.

Our current estimate, using available FY 2013 claims data, is that actual outlier payments for FY 2013 were approximately 4.81 percent of actual total MS–DRG payments. Therefore, the data indicate that, for FY 2013, the percentage of actual outlier payments relative to actual total payments is lower than we projected for FY 2013. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier

payments to ensure that total outlier payments for FY 2013 are equal to 5.1 percent of total MS–DRG payments.

We currently estimate that, using the latest CCRs from the December 2013 update of the PSF, actual outlier payments for FY 2014 will be approximately 5.79 percent of actual total MS–DRG payments, approximately 0.69 percentage point higher than the 5.1 percent we projected when setting the outlier policies for FY 2014. This estimate of 5.79 percent is based on simulations using the FY 2013 MedPAR file (discharge data for FY 2013 claims).

5. Proposed FY 2015 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 2015. The proposed Puerto Rico-specific amounts are shown in Table 1C listed and published in section VI. of this Addendum (and available via the Internet). The proposed amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 69.6 percent, and the labor-related share applied to the standardized amounts in Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are proposing to apply a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we will apply a labor-related share of 62 percent for all hospitals whose wage indices are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the proposed standardized amounts reflecting the proposed applicable percentage increases for FY 2015.

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 2015 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-specific standardized amounts. The labor-related share applied to the Puerto Rico-specific standardized amount is the proposed labor-related share of 63.2 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 2014 national standardized amount. The second through fifth columns display the proposed changes from the FY 2014 standardized amounts for each applicable FY 2015 proposed standardized amount. The first row of the table shows the updated (through FY 2014) average standardized amount after restoring the FY 2014 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 MS–DRG reclassification and recalibration wage index budget neutrality adjustment factors are cumulative. Therefore, those FY 2014 adjustment factors are not removed from this table.

COMPARISON OF FY 2014 STANDARDIZED AMOUNTS TO THE FY 2015 PROPOSED STANDARDIZED AMOUNTS

	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
FY 2014 Base Rate after removing: 1. FY 2014 Geographic Reclassification Budget Neutrality (0.990718) 2. FY 2014 Rural Community Hospital Demonstration Program Budget Neutrality (0.999415) 3. Cumulative Factor: FY 2008, FY 2009, FY 2012, FY 2013, and FY 2014 Documentation and Coding Adjustment as Required under Sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90 and Documentation and Coding Recoupment Adjustment as required under Section 631 of the American Taxpayer Relief Act of 2012 (0.9403) 4. FY 2014 Operating Outlier Offset (0.948995)	If Proposed Wage Index is Greater Than 1.0000: Labor (69.6%): $4,230.38 Nonlabor (30.4%): $1,847.75. If Proposed Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,768.45 Nonlabor (38%): $2,309.70.	If Proposed Wage Index is Greater Than 1.0000: Labor (69.6%): $4,230.38 Nonlabor (30.4%): $1,847.75. If Proposed Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,768.45 Nonlabor (38%): $2,309.70.	If Proposed Wage Index is Greater Than 1.0000: Labor (69.6%): $4,230.38 Nonlabor (30.4%): $1,847.75. If Proposed Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,768.45 Nonlabor (38%): $2,309.70	If Proposed Wage Index is Greater Than 1.0000: Labor (69.6%): $4,230.38 Nonlabor (30.4%): $1,847.75. If Proposed Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,768.45 Nonlabor (38%): $2,309.70.
Proposed FY 2015 Update Factor	1.021	1.01425	1.01425	1.0075.
Proposed FY 2015 MS-DRG Recalibration and Wage Index Budget Neutrality Factor.	0.993512	0.993512	0.993512	0.993512.
Proposed FY 2015 Reclassification Budget Neutrality Factor.	0.991412	0.991412	0.991412	0.991412.
Proposed FY 2015 Rural Community Demonstration Program Budget Neutrality Factor.	0.999283	0.999283	0.999283	0.999283.
Proposed FY 2015 Operating Outlier Factor	0.949000	0.949000	0.949000	0.949000.

COMPARISON OF FY 2014 STANDARDIZED AMOUNTS TO THE FY 2015 PROPOSED STANDARDIZED AMOUNTS—Continued

	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Cumulative Factor: FY 2008, FY 2009, FY 2012, FY 2013, FY 2014 and FY 2015 Documentation and Coding Adjustment as Required under Sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90 and Documentation and Coding Recoupment Adjustment as required under Section 631 of the American Taxpayer Relief Act of 2012.	0.9329	0.9329	0.9329	0.9329.
Proposed FY 2015 New Labor Market Delineation Wage Index Transition Budget Neutrality Factor.	0.998856	0.998856	0.998856	0.998856.
Proposed National Standardized Amount for FY 2015 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (69.6/30.4).	Labor: $3,759.46 Nonlabor: $1,642.06	Labor: $3,734.61 Nonlabor: $1,631.20	Labor: $3,734.61 Nonlabor: $1,631.20	Labor: $3,709.75. Nonlabor: $1,620.35.
Proposed National Standardized Amount for FY 2015 if Wage Index is less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38).	Labor: $3,384.94 Nonlabor: $2,052.58	Labor: $3,326.80 Nonlabor: $2,039.01	Labor: $3,326.80 Nonlabor: $2,039.01	Labor: $3,304.66. Nonlabor: $2,025.44.

The following table illustrates the proposed changes from the FY 2014 Puerto Rico-specific payment rate for hospitals located in Puerto Rico. The second column shows the proposed changes from the FY 2014 Puerto Rico specific payment rate for hospitals with a Puerto Rico-specific wage index greater than 1.0000. The third column shows the proposed changes from the FY 2014 Puerto Rico specific payment rate for hospitals with a Puerto Rico-specific wage index less than or equal to 1.0000. The first row of the table shows the updated (through FY 2014) Puerto Rico-specific payment rate after restoring the FY 2014 offsets for Puerto Rico-specific outlier payments, rural community hospital demonstration program budget neutrality, and the geographic reclassification budget neutrality. The MS–DRG recalibration budget neutrality adjustment factor is cumulative and is not removed from this table.

COMPARISON OF FY 2014 PUERTO RICO-SPECIFIC PAYMENT RATE TO THE FY 2015 PROPOSED PUERTO RICO-SPECIFIC PAYMENT RATE

	Update (2.1 percent); proposed wage index is greater than 1.0000; labor/non-labor share percentage (63.2/36.8)	Update (2.1 percent); proposed wage index is less than or equal to 1.0000; labor/non-labor share percentage (62/38)
FY 2014 Puerto Rico Base Rate, after removing: 1. FY 2014 Geographic Reclassification Budget Neutrality (0.990718) 2. FY 2014 Rural Community Hospital Demonstration Program Budget Neutrality (0.999415) 3. FY 2014 Puerto Rico Operating Outlier Offset (0.943455)	Labor: $1,722.31 Nonlabor: $1,002.86	Labor: $1,689.61 Nonlabor: $1,035.56.
Proposed FY 2015 Update Factor	1.021	1.021.
Proposed FY 2015 MS–DRG Recalibration Budget Neutrality Factor	0.992938	0.992938.
Proposed FY 2015 Reclassification Budget Neutrality Factor	0.991412	0.991412.
Proposed FY 2015 Rural Community Hospital Demonstration Program Budget Neutrality Factor.	0.999283	0.999283.
Proposed FY 2015 New Labor Market Delineation Wage Index Transition Budget Neutrality Factor.	0.998856	0.998856.
Proposed FY 2015 Puerto Rico Operating Outlier Factor	0.928942	0.928942.
Proposed Puerto Rico-Specific Payment Rate for FY 2015	Labor: $1,605.07 Nonlabor: $934.59.	Labor: $1,574.59. Nonlabor: $965.07.

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 2015. 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 2015 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 located in Alaska and Hawaii by an adjustment factor.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by the U.S. Office of Personnel Management (OPM) every 4 years (at the same time as the update to the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively).

For FY 2014, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50985 through 50987), we updated the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule.

Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, we are proposing to use the same COLAs factors established in FY 2014 for FY 2015 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. Below is a table listing the proposed COLA factors for FY 2015.

PROPOSED FY 2015 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	1.19
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, the next update to the COLA factors for Alaska and Hawaii would occur in FY 2018.

C. Calculation of the Proposed Prospective Payment Rates

General Formula for Calculation of the Prospective Payment Rates for FY 2015

In general, the operating prospective payment rate for all hospitals paid under the IPPS located outside of Puerto Rico, except SCHs and MDHs, for FY 2015 equals the Federal rate (which includes uncompensated care payments).

We note that, as discussed in section IV.G. of the preamble of this proposed rule, section 1106 of the Pathway to SGR Reform Act of 2013 (Pub. L. 113–67), enacted on December 26, 2013, extended the MDH program from the end of FY 2013 through the first half of FY 2014 (that is, for discharges occurring before April 1, 2014). Subsequently, section 106 of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93), enacted on April 1, 2014, further extended the MDH program through the first half of FY 2015 (that is, for discharges occurring before April 1, 2015). Prior to the enactment of Public Law 113–67, the MDH program was only to be in effect through the end of FY 2013. Under current law, the MDH program will expire for discharges beginning on April 1, 2015.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (which, as discussed in section IV.F. of the preamble of this proposed rule, includes uncompensated care payments); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2015 equals the higher of the applicable Federal rate, or the hospital-specific rate as described below.

The prospective payment rate for MDHs for FY 2015 discharges occurring before April 1, 2015 equals the higher of the Federal rate or the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate as described below. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987 or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

The prospective payment rate for hospitals located in Puerto Rico for FY 2015 equals 25 percent of the Puerto Rico-specific payment 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 and is a meaningful EHR user, as described above.

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 located 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 payment 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. The base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively. Finally, we add the uncompensated care payment to the total claim payment amount. We note that, as discussed above, we take uncompensated care payments into consideration when calculating outlier payments.

2. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate (which, as discussed in section IV.F. of the preamble of this proposed rule, includes uncompensated care payments); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

As discussed previously, currently MDHs are paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the greater of the updated hospital-specific rates based on either FY 1982, FY 1987, or FY 2002 costs per discharge.

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082). We also refer readers to section IV.F. of the preamble of this proposed rule for a complete discussion on empirically justified Medicare DSH and uncompensated care payments.

b. Updating the FY 1982, FY 1987, FY 1996 and FY 2006 Hospital-Specific Rate for FY 2015

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the proposed applicable percentage increases to the hospital-specific rates applicable to SCHs and MDHs are the following:

FY 2015	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.675	−0.675
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−0.675	0.0	−0.675
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.4	−0.4	−0.4	−0.4
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.2	−0.2	−0.2	−0.2
Proposed Applicable Percentage Increase Applied to Hospital-Specific Rate	2.1	1.425	1.425	0.75

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs and MDHs, we refer readers to section IV.B. of the preamble of this proposed rule.

In addition, because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS–DRG classifications and the recalibration of the MS–DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, a SCH's and MDH's hospital-specific rate is adjusted by the proposed MS–DRG reclassification and recalibration budget neutrality factor of 0.992938, as discussed in section III. of this Addendum. The resulting rate is used in determining the payment rate that an SCH would receive for its discharges beginning on or after October 1, 2014, and the payment rate that an MDH would receive for its discharges beginning on or after October 1, 2014, and before April 1, 2015. We note that, in this proposed rule, for FY 2015, we are not proposing to make a documentation and coding adjustment to the hospital-specific rate. We refer readers to section II.D. of the preamble of this proposed rule for a complete discussion regarding our proposed policies and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case-mix.

3. General Formula for Calculation of Prospective Payment Rates for Hospitals Located in Puerto Rico Beginning On or After October 1, 2014, and Before October 1, 2015

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-Specific Rate

The Puerto Rico-specific prospective payment rate is determined as follows:

Step 1—Select the applicable average standardized amount considering the applicable wage index (obtained from 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 (obtained from 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 Prospective Payment Rate

The national prospective payment rate is determined as follows:

Step 1—Select the applicable national average standardized amount.

Step 2—Multiply the labor-related portion of the national average 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 (obtained from 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-specific rate and the national prospective payment rate computed above equals the prospective payment rate for a given discharge for a hospital located in Puerto Rico. This payment rate is then further adjusted if the hospital qualifies for either the IME or DSH adjustment.

Finally, we add the uncompensated care payment to the total claim payment amount. We note that, as discussed above, we take uncompensated care payments into consideration when calculating outlier payments.

III. Proposed Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2015

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, over a 10-year transition period (which extended through FY 2001) the payment methodology for Medicare acute care hospital inpatient capital-related costs changed 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 2015, which would be effective for discharges occurring on or after October 1, 2014.

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 the FY 2013 IPPS/LTCH PPS final rule (77 FR 53705), there is generally no longer a need for an exceptions payment adjustment factor.) However, in limited circumstances, an additional payment exception for extraordinary circumstances is provided for under § 412.348(f) for qualifying hospitals. Therefore, in accordance with § 412.308(c)(3), an exceptions payment adjustment factor may need to be applied if such payments are made. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for 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 Public Law 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 made 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 the 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 2015. In particular, we explain why the proposed FY 2015 capital Federal rate increases approximately 0.9 percent, compared to the FY 2014 capital Federal rate. As discussed in the impact analysis in Appendix A to this proposed rule, we estimate that capital payments per discharge would increase 1.2 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 2015 under that framework is 1.5 percent based on the best data available at this time. The proposed update factor under that framework is based on a projected 1.5 percent increase in the FY 2010-based CIPI, a 0.0 percentage point adjustment for intensity, a 0.0 percentage point adjustment for case-mix, a 0.0 percentage point adjustment for the FY 2013 DRG reclassification and recalibration, and a forecast error correction of 0.0 percentage point. 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 2015 CIPI projection in that same section of this Addendum. Below we describe the policy adjustments that we are proposing to apply in the update framework for FY 2015.

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-weighted DRG assignments (''coding effects''); and
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients as opposed to changes in documentation and coding behavior that result in assignment of cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts as discussed in section II. of Appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2015, 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 2015. 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 2015 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 2013 DRG reclassification and recalibration as part of our update for FY 2015. We estimate that FY 2013 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 percentage point adjustment for reclassification and recalibration in the update framework for FY 2015.

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 2015 update. Historically, when forecast error of the CIPI is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended under this framework. Current historical data indicate that the forecasted FY 2013 rate-of-increase of the FY 2006-based CIPI (1.2 percent) used in calculating the FY 2013 update factor slightly understated the actual realized FY 2013 price increases of the FY 2006-based CIPI (1.3 percent) by 0.1 percentage point because the prices associated with both the depreciation and other capital-related cost categories grew more quickly than anticipated. Because this forecast error does not exceed the 0.25 percentage point threshold, we are proposing to make a 0.0 percentage point adjustment for forecast error in the update for FY 2015.

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 noncost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the 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 a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2015 (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 2015, 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 2007 and extending through FY 2012. Based on these data, we estimated that case-mix constant intensity declined during FYs 2007 through 2012. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this approach, because we estimate that intensity declined during that 5-year period, we believe it is appropriate to propose to continue to apply a zero intensity adjustment for FY 2015. Therefore, we are proposing to make a 0.0 percentage point adjustment for intensity in the update for FY 2015.

Above, we described the basis of the components used to develop the proposed 1.5 percent capital update factor under the capital update framework for FY 2015 as shown in the table below.

PROPOSED CMS FY 2015 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	1.5
Intensity:	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	−0.5
Projected Case-Mix Change	0.5
Subtotal	1.5
Effect of FY 2013 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Update	1.5

* The capital input price index is based on the FY 2010-based CIPI.

b. Comparison of CMS and MedPAC Update Recommendation

In its March 2014 Report to Congress, MedPAC did not make a specific update recommendation for capital IPPS payments for FY 2015. (We refer readers to MedPAC's Report to the Congress: Medicare Payment Policy, March 2014, 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 2014, we estimated that outlier payments for capital will equal 6.07 percent of inpatient capital-related payments based on the capital Federal rate in FY 2014. Based on the proposed thresholds as set forth in section II.A. of this Addendum, we estimate that outlier payments for capital-related costs would equal 6.26 percent for inpatient capital-related payments based on the proposed capital Federal rate in FY 2015. Therefore, we are proposing to apply an outlier adjustment factor of 0.9374 in determining the proposed capital Federal rate for FY 2015. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2015 will be slightly higher than the percentage for FY 2014.

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 2015 outlier adjustment of 0.9374 is a −0.82 percent change from the FY 2014 outlier adjustment of 0.9393. Therefore, the proposed net change in the outlier adjustment to the capital Federal rate for FY 2015 is 0.9980 (0.9374/0.9393). Thus, the outlier adjustment would decrease the proposed FY 2015 capital Federal rate by 0.82 percent compared to the FY 2014 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 2015, we compared (separately for the national capital rate and the Puerto Rico capital rate) estimated aggregate capital Federal rate payments based on the FY 2014 MS–DRG classifications and relative weights and the FY 2014 GAF to estimated aggregate capital Federal rate payments based on the FY 2014 MS–DRG classifications and relative weights and the proposed FY 2015 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 factor of 1.0000 for FY 2015 to the previous cumulative FY 2014 adjustment factor of 0.9891, yielding a proposed adjustment factor of 0.9891 through FY 2015. For the Puerto Rico GAFs, we are proposing to apply an incremental budget neutrality adjustment factor of 1.0011 for FY 2015 to the previous cumulative FY 2014 adjustment factor of 1.0076, yielding a proposed cumulative adjustment factor of 1.0087 through FY 2015.

We then compared estimated aggregate capital Federal rate payments based on the FY 2014 MS–DRG relative weights and the proposed FY 2015 GAFs to estimated aggregate capital Federal rate payments based on the cumulative effects of the proposed FY 2015 MS–DRG classifications and

relative weights and the proposed FY 2015 GAFs. The proposed incremental adjustment factor for DRG classifications and changes in relative weights is 0.9957 both nationally and for Puerto Rico. The proposed cumulative adjustment factors for MS–DRG classifications and changes in relative weights and for changes in the GAFs through FY 2015 are 0.9848 nationally and 1.0043 for Puerto Rico. (We note that all the values are calculated with unrounded numbers.) The GAF/DRG budget neutrality adjustment factors are built permanently into the capital rates; that is, they are applied cumulatively in determining the capital Federal rate. This follows the requirement under § 412.308(c)(4)(ii) that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of geographic reclassifications are determined separately from the effects of other changes in the hospital wage index and the MS–DRG relative weights. Under the capital IPPS, there is a single GAF/DRG budget neutrality adjustment factor (the national capital rate and the Puerto Rico capital rate are determined separately) for changes in the GAF (including geographic reclassification) and the MS–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.

The proposed cumulative adjustment 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 2015 geographic reclassification decisions made by the MGCRB compared to FY 2014 decisions. However, it does not account for proposed changes in payments due to changes in the DSH and IME adjustment factors.

4. Proposed Capital Federal Rate for FY 2015

For FY 2014, we established a capital Federal rate of $429.31 (78 FR 50990). We are proposing to establish an update of 1.5 percent in determining the FY 2015 capital Federal rate for all hospitals. As a result of this proposed update and the proposed budget neutrality factors discussed above, we are proposing to establish a national capital Federal rate of $433.01 for FY 2015. The proposed national capital Federal rate for FY 2015 was calculated as follows:

- The proposed FY 2015 update factor is 1.015, that is, the proposed update is 1.5 percent.
- The proposed FY 2015 budget neutrality adjustment factor that is applied to the proposed capital Federal rate for proposed changes in the MS–DRG classifications and relative weights and changes in the GAFs is 0.9957.
- The proposed FY 2015 outlier adjustment factor is 0.9374.

(We note that, as discussed in section VI.C. of the preamble of this proposed rule, we are not proposing to make an additional MS–DRG documentation and coding adjustment to the capital IPPS Federal rates for FY 2015.)

Because the proposed FY 2015 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 Federal rate for these factors, other than the proposed budget neutrality factor for proposed changes in the MS–DRG classifications and relative weights and for proposed changes in the GAFs.

We are providing the following chart that shows how each of the proposed factors and adjustments for FY 2015 affects the computation of the proposed FY 2015 national capital Federal rate in comparison to the FY 2014 national capital Federal rate. The proposed FY 2015 update factor has the effect of increasing the capital Federal rate by 1.5 percent compared to the FY 2014 capital Federal rate. The proposed GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.43 percent. The proposed FY 2015 outlier adjustment factor has the effect of decreasing the capital Federal rate by 0.20 percent compared to the FY 2014 capital Federal rate. The combined effect of all the proposed changes would increase the proposed national capital Federal rate by 0.86 percent compared to the FY 2014 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2014 CAPITAL FEDERAL RATE AND PROPOSED FY 2015 CAPITAL FEDERAL RATE

	FY 2014	Proposed FY 2015	Change	Percent change
Update Factor [1]	1.0090	1.0150	1.0150	1.50
GAF/DRG Adjustment Factor [1]	0.9987	0.9957	0.9957	−0.43
Outlier Adjustment Factor [2]	0.9393	0.9374	0.9980	−0.20
Capital Federal Rate	429.31	433.01	1.0086	0.86

[1] The proposed update factor and the proposed GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rates. Thus, for example, the proposed incremental change from FY 2014 to FY 2015 resulting from the application of the proposed 0.9957 GAF/DRG budget neutrality adjustment factor for FY 2015 is a proposed net change of 0.9957 (or −0.43 percent).

[2] The proposed outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the proposed capital Federal rate. Thus, for example, the proposed net change resulting from the application of the proposed FY 2015 outlier adjustment factor is 0.9374/0.9393, or 0.9918 (or −0.82 percent).

5. Proposed Special Capital Rate for Puerto Rico Hospitals

Section 412.374 provides for the use of a blended payment system for payments made 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 made 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 adjustment factors for the national GAF and for the Puerto Rico GAF. However, we apply the same budget neutrality adjustment factor for MS–DRG reclassifications and recalibration nationally and for Puerto Rico. The proposed budget neutrality adjustment factors for the national GAF and for the Puerto Rico GAF and the proposed budget neutrality factor for MS–DRG reclassifications and recalibration (which is the same nationally and for Puerto Rico) are discussed 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 2014, the special capital rate for hospitals located in Puerto Rico was $209.82 (78 FR 50991). With the changes we are proposing to make to the other factors used to determine the proposed capital Federal rate, the proposed FY 2015 special capital rate for hospitals in Puerto Rico is $206.82.

B. Calculation of the Proposed Inpatient Capital-Related Prospective Payments for FY 2015

For purposes of calculating payments for each discharge during FY 2015, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year. Section 412.312(c) provides for a single set of thresholds to identify outlier cases for both inpatient operating and inpatient capital-related payments. The proposed outlier thresholds for FY 2015 are in section II.A. of this Addendum. For FY 2015, a case would qualify as a cost outlier if the cost for the case plus the (operating) IME and DSH payments (including both the empirically justified Medicare DSH payment and the estimated uncompensated care payment, as discussed in section II.A.4.g.(1) of this Addendum) is greater than the prospective payment rate for the MS–DRG plus the proposed fixed-loss amount of $25,799.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50603 through 50607), we rebased and revised the CIPI to a FY 2010 base year to reflect the more current structure of capital costs in hospitals. For a complete discussion of this rebasing, we refer readers to the FY 2014 IPPS/LTCH PPS final rule.

2. Forecast of the CIPI for FY 2015

Based on the latest forecast by IHS Global Insight, Inc. (first quarter of 2014), we are forecasting the FY 2010-based CIPI to increase 1.5 percent in FY 2015. This reflects a projected 1.9 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 2.6 percent increase in other capital expense prices in FY 2015, partially offset by a projected 1.0 percent decline in vintage-weighted interest expenses in FY 2015. The weighted average of these three factors produces the forecasted 1.5 percent increase for the FY 2010-based CIPI as a whole in FY 2015.

IV. Proposed Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2015

Payments for services furnished in children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are made on the basis of reasonable costs based on the hospital's own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. (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 FY 2015 IPPS/LTCH PPS proposed rule, we are proposing that the FY 2015 rate-of-increase percentage for updating the target amounts for the 11 cancer hospitals, children's hospitals, and the short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, as well as RNHCIs would be the estimated percentage increase in the FY 2015 IPPS operating market basket, in accordance with applicable regulations at § 413.40. As we did in FY 2014, we would use the percentage increase in the FY 2010-based IPPS operating market basket to update these target amounts. Based on IHS Global Insight, Inc.'s 2014 first quarter forecast, we estimate that the FY

2010-based IPPS operating market basket update for FY 2015 is 2.7 percent (that is, the estimate of the market basket rate-of-increase). However, we are proposing that if more recent data become available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2015.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule for the proposed update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2015. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Proposed Updates to the Payment Rates for the LTCH PPS for FY 2015

A. Proposed LTCH PPS Standard Federal Rate for FY 2015

1. Background

In section VII. of the preamble of this proposed rule, we discuss our proposed updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2015.

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. Therefore, 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 FYs 2012, 2013, and 2014, 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 as set forth in the regulations at §§ 412.523(c)(3)(viii) through (c)(3)(ix).

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.C.2. 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.C.2.a. of the preamble of this proposed rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

For FY 2014, 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 2.5 percent and the 0.8 percentage point reductions required by sections 1886(m)(3)(A)(i) and 1886(m)(3)(A)(ii) with 1886(m)(4)(C) of the Act. Accordingly, at § 412.523(c)(3)(x) of the regulations, we established an annual update of 1.7 percent to the standard Federal rate for FY 2014 (78 FR 50761 through 50763).

For FY 2015, as discussed in greater detail in section VII.C.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 LTCH PPS market basket, less the proposed MFP adjustment consistent with section 1886(m)(3)(A)(i) of the Act, and less the 0.2 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(E) of the Act. In addition, as discussed in greater detail in section VII.C.2. of the preamble of this proposed rule, beginning in FY 2014, the annual update would be further reduced by 2.0 percentage points for LTCHs that fail to submit quality reporting data in accordance with the requirements of the LTCHQR Program under section 1886(m)(5) of the Act.

Specifically, in this proposed rule, based on the best available data, we are proposing to establish an annual update to the standard Federal rate of 2.1 percent, which is based on the full estimated increase in the LTCH PPS market basket of 2.7 percent, less the proposed MFP adjustment of 0.4 percentage point consistent with section 1886(m)(3)(A)(i) of the Act, and less the 0.2 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(E) of the Act. As discussed in greater detail in section VII.C.2.c. of the preamble of this proposed rule, for LTCHs that fail to submit the required quality reporting data for FY 2015 in accordance with the LTCHQR Program, the proposed annual update would be further reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act. Accordingly, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 0.1 percent for LTCHs that fail to submit the required quality reporting data for FY 2015. This proposed 0.1 percent update is calculated based on the full estimated increase in the LTCH PPS market basket of 2.7 percent, less a proposed MFP adjustment of 0.4 percentage point, less an additional adjustment of 0.2 percentage point required by the statute, and less 2.0 percentage points for failure to submit quality reporting data as required by section 1886(m)(5) of the Act.

2. Development of the Proposed FY 2015 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, for FY 2015, we are proposing to apply the proposed annual update to the LTCH PPS standard Federal rate from the previous year. Furthermore, in determining the proposed standard Federal rate for FY 2015, we also are proposing to make certain regulatory adjustments. Specifically, we are proposing to apply an adjustment factor for the final year of the 3-year phase-in of the one-time prospective adjustment to the standard Federal rate under § 412.523(d)(3), as discussed in greater detail in section VII.C.3. of the preamble of this proposed rule. In addition, in determining the proposed FY 2015 standard Federal rate, we are proposing to apply a budget neutrality adjustment factor for the proposed changes related to the area wage adjustment (that is, proposed changes to the wage data, including the proposal to adopt the new OMB delineations, and labor-related share) in accordance with § 412.523(d)(4).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50993 and 50993), we established an annual update to the LTCH PPS standard Federal rate of 1.7 percent for FY 2014 based on the full estimated LTCH PPS market basket increase of 2.5 percent, less the MFP adjustment of 0.5 percentage point consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.3 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(C) of the Act. Accordingly, at § 412.523(c)(3)(x), we established an annual update to the standard Federal rate for FY 2014 of 1.7 percent. That is, we applied an update factor of 1.017 to the FY 2013 Federal rate of $40,607.31 to determine the FY 2014 standard Federal rate. We also adjusted the standard Federal rate for FY 2014 by the one-time prospective adjustment factor for FY 2014 of 0.98734 under § 412.523(d)(3)(ii). Furthermore, for FY 2014, we applied an area wage level budget neutrality factor of 1.0010531 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 2014 of $40,607.31 (calculated as $40,397.96 × 1.017 × 0.98734 × 1.0010531).

In this proposed rule, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 2.1 percent (that is, an update factor of 1.021) for FY 2015, based on the full estimated increase in the LTCH PPS market basket of 2.7 percent, less the proposed MFP adjustment of 0.4 percentage point, consistent with section 1886(m)(3)(A)(i) of the Act, and less the 0.2 percentage point required by sections 1886(m)(3)(A)(ii) and(m)(4)(E) of the Act. Therefore, under proposed § 412.523(c)(3)(xi), we are proposing to apply a factor of 1.021 to the FY 2014 standard Federal rate of $40,607.31 to determine the proposed FY 2015 standard Federal rate. These proposed factors are based on IGI's first quarter 2014 forecast, which are the best available data at this time. Consistent with our historical practice of using the best available data, we also 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 LTCHs that fail to submit quality reporting data for FY 2015 under the LTCHQR Program, under proposed § 412.523(c)(3)(xi) in conjunction with § 412.523(c)(4), we are proposing to reduce the proposed annual update to the LTCH PPS standard Federal rate by an additional 2 percentage points consistent with section 1886(m)(5) of the Act. Therefore, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 0.1 percent (that is, 2.1 percent minus 2.0 percentage points = 0.1 percent or an update factor of 1.001) for FY 2015 for LTCHs that fail to submit the required quality reporting data for FY 2015 under the LTCHQR Program. We also are proposing that the standard Federal rate for FY 2015 would be further adjusted by a proposed adjustment factor of 0.98734 for FY 2015 under the final year of the 3-year phase-in of the one-time prospective adjustment at § 412.523(d)(3)(ii). In addition, for FY 2015, we are proposing to apply an area wage level budget neutrality factor of 1.0002034 to the standard Federal rate to ensure that any proposed changes to the area wage level adjustment (that is, the proposed annual update of the wage index values and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, we are proposing to establish a standard Federal rate of $40,943.51 (calculated as $40,607.31 × 1.021 × 0.98734 × 1.002034) for FY 2015. The proposed standard Federal rate of $40,943.51 would apply in determining the payments for FY 2015 discharges from LTCHs that submit quality reporting data for FY 2015 in accordance with the requirements of the LTCHQR Program under section 1886(m)(5) of the Act. For LTCHs that fail to submit quality reporting data for FY 2015 in accordance with the requirements of the LTCHQR Program under section 1886(m)(5) of the Act, we are proposing to establish a standard Federal of $40,141.47 (calculated as $40,607.31 × 1.001 × 0.98734 × 1.002034) for FY 2015.

B. Proposed Adjustment for Area Wage Levels Under the LTCH PPS for FY 2015

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 under § 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.

When we implemented the LTCH PPS, we established a 5-year transition to the full area wage level adjustment. The area wage level adjustment was completely phased-in for cost reporting periods beginning in FY 2007. Therefore, for cost reporting periods beginning on or after October 1, 2006, the applicable LTCH area wage index values are the full LTCH PPS area wage index values calculated based on acute care hospital inpatient wage index data without taking into account geographic reclassification under section 1886(d)(8) and section 1886(d)(10) of the Act. For additional information on the phase-in of the area wage level adjustment under the LTCH PPS, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56015 through 56019) and the RY 2008 LTCH PPS final rule (72 FR 26891).

2. Proposed Geographic Classifications (Labor Market Areas) Based on the New OMB Delineations

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's

Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an ''urban area,'' or a ''rural area,'' as defined in § 412.503. Under § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (MSAs) (which includes a Metropolitan division, where applicable), as defined by the Executive OMB and a ''rural area'' is defined as any area outside of an urban area.

The CBSA-based geographic classification (labor market area) definitions currently used under the LTCH PPS, effective for discharges occurring on or after July 1, 2005, are based on the OMB's CBSA definitions that were developed based on 2000 U.S. Census data. As discussed in greater detail in section VII.D. of the preamble of this proposed rule, OMB announced revisions to the statistical boundaries of its labor market areas for MSAs, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the uses of the delineations of these areas in OMB Bulletin No. 13–01, issued on February 28, 2013 (referred hereinafter as the ''new OMB delineations''). As previously stated, at that time, the FY 2014 IPPS/LTCH PPS proposed rule was in the advanced stages of development, and the proposed FY 2014 LTCH PPS area wage indexes had already been developed based on the previous OMB CBSA-based labor market area definitions that are currently used to define CBSA-based labor market areas (referred hereinafter as ''CBSA designations'') under the LTCH PPS. Therefore, we did not implement changes to the CBSA designations under the LTCH PPS for FY 2014 based on the new OMB labor market areas delineations that were developed based on 2010 Decennial Census data. Rather, to allow for sufficient time to assess the new changes and their ramifications, we stated that we intended to propose to adopt the new OMB delineations, and the corresponding changes to the area wage index values based on those delineations, under the LTCH PPS for FY 2015 through notice and comment rulemaking. This approach was consistent with the approach used under the IPPS. (We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50994 through 50995).)

As discussed in sections III.B. and VII.D. of the preamble of 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 adopt the new OMB delineations beginning in FY 2015. We believe that these new OMB delineations are based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas. We also believe that the new OMB delineations would ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We note that this proposal is consistent with the IPPS proposal discussed in section III.B. of the preamble of this proposed rule. For additional details on our proposal to adopt the new OMB delineations, we refer readers to section VII.D. of the preamble of this proposed rule.

3. Proposed LTCH PPS Labor-Related Share

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's PPS Federal prospective payment is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs (Wages and Salaries; Employee Benefits; Professional Fees 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. 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) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

For FY 2013, we revised and rebased the market basket used under the LTCH PPS by adopting the newly created FY 2009-based LTCH-specific market basket. In addition, we determined the labor-related share for FY 2013 as the sum of the FY 2013 relative importance of each labor-related cost category of the FY 2009-based LTCH-specific market basket. For more details, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479).

Consistent with our historical practice, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50995 through 50996), we determined the LTCH PPS labor-related share for FY 2014 based on the FY 2014 relative importance of each labor-related cost category, which reflected the different rates of price change for these cost categories between the base year (FY 2009) and FY 2014. Specifically, based on IGI's second quarter 2013 forecast of the FY 2009-based LTCH-specific market basket, we established a labor-related share under the LTCH PPS for FY 2014 of 62.537 percent.

For FY 2015, we are proposing to establish a labor-related share under the LTCH PPS based on IGI's first quarter 2014 forecast of the FY 2009-based LTCH-specific market basket. Consistent with our historical practice, if more recent data becomes available, we are proposing to use that data to determine the final FY 2015 labor-related share under the LTCH PPS.

The table below shows the proposed FY 2015 labor-related share relative importance using IGI's first quarter 2014 forecast of the FY 2009-based LTCH-specific market basket. The sum of the proposed relative importance for FY 2015 for operating costs (Wages and Salaries; Employee Benefits; Professional Fees Labor-Related, Administrative and Business Support Services; and All Other: Labor-Related Services) is 58.366 percent. We are proposing that the portion of capital-related costs that is influenced by the local labor market continue to be estimated to be 46 percent. Because the relative importance for capital-related costs would be 9.142 percent of the FY 2009-based LTCH-specific market basket in FY 2015, we are proposing to take 46 percent of 9.142 percent to determine the proposed labor-related share of capital-related costs for FY 2015, which would result in 4.205 percent (0.46 x 9.142). We are proposing to then add that 4.205 percent for the capital-related cost amount to the 58.366 percent for the operating cost amount to determine the total proposed labor-related share for FY 2015.

Therefore, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of BIPA, to determine appropriate payment adjustments under the LTCH PPS, we are proposing to establish a labor-related share under the LTCH PPS in FY 2015 of 62.571 percent. This proposed labor-related share is determined using the same methodology as used in calculating all previous fiscal years LTCH labor-related shares.

PROPOSED FY 2015 LABOR-RELATED SHARE RELATIVE IMPORTANCE BASED ON THE FY 2009-BASED LTCH-SPECIFIC MARKET BASKET

	Proposed FY 2015 labor-related share relative importance
Wages and Salaries	45.034
Employee Benefits	8.128
Professional Fees: Labor-Related	2.208
Administrative and Business Support Services	0.502
All Other: Labor-Related Services	2.494
Subtotal	58.366
Proposed Labor-Related Portion of Capital Costs (46%)	4.205
Proposed Total Labor-Related Share	62.571

4. Proposed LTCH PPS Wage Index for FY 2015

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the ''urban'' or ''rural'' designation of any related or affiliated provider.

In the FY 2014 LTCH PPS final rule (78 FR 50996 through 50997), we calculated the FY 2014 LTCH PPS area wage index values using the same data used for the FY 2014 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2010), 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 2014 LTCH PPS area wage index values consistent with the urban and rural geographic classifications (labor market areas) that were in place at that time, and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments under the LTCH PPS). As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also continued to use our existing policy for determining area wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable area wage index values under the LTCH PPS for FY 2015, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, to determine appropriate payment adjustments under the LTCH PPS, we are proposing to use wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2011, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act. We are proposing to use FY 2011 wage data because these data are the most recent complete data available. These are the same data used to compute the proposed FY 2015 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 area 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).)

For this proposed rule, the proposed FY 2015 LTCH PPS area wage index values were computed consistent with the proposed ''urban'' and ''rural'' geographic classifications (that is, using the new OMB labor market area delineations), as discussed in section VII.D. of the preamble of 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, we are proposing to continue to apportion wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, as discussed in section III.G. of the preamble of this proposed rule. Furthermore, in determining the proposed FY 2015 LTCH PPS area wage index values, we are proposing to continue to use our existing policy for determining area wage index values for areas where there are no IPPS wage data. We established this methodology for determining LTCH PPS wage index values for areas that have no IPPS wage data in the RY 2009 LTCH PPS final rule. For more information about this methodology, we refer readers to the RY 2009 LTCH PPS final rule (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 market areas without IPPS hospital wage data (or IPPS hospitals). However, should an LTCH open in one of these labor market areas, LTCH PPS wage index values for such an area would be calculated using our established methodology. 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 2011 IPPS wage data that we are proposing to use to determine the proposed FY 2015 LTCH PPS area wage index values in this proposed rule, there are no IPPS wage data for the urban area Hinesville, GA (CBSA 25980). Consistent with the methodology discussed above, we calculated the proposed FY 2015 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table

12A, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site). We note that, as IPPS wage data are dynamic, it is possible that urban areas without IPPS wage data will vary in the future.

Based on FY 2011 IPPS wage data that we are proposing to use to determine the proposed FY 2015 LTCH PPS area wage index values in this proposed rule, there are no proposed rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate an LTCH PPS wage index value for proposed rural areas with no IPPS wage data for FY 2015. We note that, as IPPS wage data are dynamic, it is possible that rural areas without IPPS wage data will vary in the future.

For FY 2015, we are proposing to use the new OMB delineations under the LTCH PPS, as discussed in greater detail in section VII.D. of the preamble of this proposed rule. Under this proposal, there would be some changes to the current CBSA compositions as a result of the new OMB delineations, which would result in the creation of new CBSAs, ''urban'' counties that are now ''rural,'' ''rural'' counties that are now ''urban,'' and existing CBSAs that are divided into separate boundaries. Under existing § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area as defined by the Executive OMB, and a ''rural area'' is defined as any area outside of an urban area. We are not proposing any changes to the current definitions of ''urban area'' and ''rural area'' because our proposal to use the new OMB delineations under the LTCH PPS is consistent with the definitions in existing § 412.503.

As discussed in sections III.B. and VII.D.2.e. of the preamble of this proposed rule, overall we believe that using the new OMB delineations would result in LTCH PPS area wage index values being more representative of the actual costs of labor in a given area. However, we also recognize that, as a result of our proposal to adopt the new OMB delineations, some LTCHs would experience decreases in area wage index values, while other LTCHs would experience increases in area wage index values. Therefore, to mitigate any short-term instability in LTCH PPS payments that could result from our proposal to use the new OMB delineations, we are proposing a transitional wage index policy. Under our proposed transitional wage index policy, any LTCH that would experience a decrease in its area wage index solely as a result of the proposal to adopt the new OMB delineations under the LTCH PPS would receive a blended area wage index for FY 2015. That is, for purposes of determining an LTCH's area wage index for FY 2015, we are proposing to compute LTCH PPS area wage index values using the proposed area wage data discussed above and in section V.B.4. of the Addendum to this proposed rule under both the current (FY 2014) CBSA designations and the proposed new OMB delineations. If the area wage index value under the proposed new OMB delineations would be lower than the proposed are wage index value under the FY 2014 CBSA designations, the LTCH would be paid based on a blended area wage index for FY 2015, which would be computed as the sum of 50 percent of each wage index value (referred to as the proposed 50/50 blended wage index), as described below.

Therefore, to determine the applicable area wage index value for each LTCH under this proposed transitional wage index policy that would be effective for discharges occurring on or after October 1, 2014, through September 30, 2015, for this proposed rule, we computed the following two area wage index values: (1) The wage index values calculated using the proposed new OMB delineations; and (2) the wage index values calculated using the current (FY 2014) CBSA designations. The proposed FY 2015 LTCH area wage index values calculated using the new OMB delineations are presented in section VI. of the Addendum to this proposed rule in Table 12A (for urban areas) and Table 12B (for rural areas), which are available via the Internet on the CMS Web site. The proposed FY 2015 LTCH area wage index values calculated using the current (FY 2014) CBSA designations are presented in section VI. of the Addendum to this proposed rule in Table 12C (for urban areas) and Table 12D (for rural areas), which are available via the Internet on the CMS Web site. Where applicable, the wage index values in Tables 12C and 12D would be used to calculate a LTCH's proposed 50/50 blended wage index value under the proposed transitional wage index policy. As explained previously, under our proposed transitional wage index policy, an LTCH would only receive the proposed 50/50 blended area wage index value for FY 2015 if the LTCH's proposed area wage index value under the new OMB delineations (shown in Table 12A or 12B) would be lower than the proposed area wage index value under the FY 2014 CBSA designations (shown in Tables 12C or 12D). If an LTCH's proposed area wage index under the new OMB delineations (shown in Tables 12A or 12B) would be higher than the proposed wage index under the FY 2014 CBSA designations (shown in Tables 12C or 12D), we are proposing to pay the LTCH based on 100 percent of the proposed area wage index under the new OMB delineations shown in Tables 12A or 12B (as such the LTCH would not receive the proposed 50/50 blended area wage index). Furthermore, as discussed below and in section VII.D.2.e. of the preamble of this proposed rule, we are proposing to apply this transitional wage index policy in a budget neutral manner. Each LTCH's proposed labor market area under the new OMB delineations and the current (FY 2014) CBSA-based labor market area designation can be found in the LTCH PPS impact file for this proposed rule, which is available via the Internet on the CMS Web site.

5. Proposed Budget Neutrality Adjustment for Proposed 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. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage-level adjustment budget neutrality factor that will be applied to the standard Federal rate to ensure that any changes to the area wage-level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we apply an area wage-level adjustment budget neutrality factor in determining the standard Federal rate, and we also established a methodology for calculating an area wage-level adjustment budget neutrality factor. (For additional information on the establishment of our budget neutrality policy for changes to the area wage-level adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809).)

For FY 2015, 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 the proposed adjustments or updates to the area wage-

level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments using a methodology that is consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). For this proposed rule, in addition to the proposed updates for FY 2015 to the area wage index data and labor-related share discussed above, we are proposing a transitional wage index policy to mitigate the impacts of implementing changes to the LTCH PPS labor market areas (CBSAs) based on new OMB delineations, as discussed above and in section VII.D.2.e. of the preamble of this proposed rule. Because our proposed transitional wage index policy for LTCHs that would experience a decrease in the their area wage index solely as a result of the proposed adoption of the new OMB delineations under the LTCH PPS would result in an increase in estimated aggregate LTCH PPS payments without such changes, we are proposing to include the proposed 50/50 blended area wage index when determining the proposed area wage-level adjustment budget neutrality factor that we would be applied to the standard Federal rate under § 412.523(d)(4) to ensure that any changes to the area wage-level adjustments are budget neutral.

For this proposed rule, using the proposed steps in the proposed methodology described in section VII.D.2.e. of this preamble, we determined a proposed FY 2015 area wage-level adjustment budget neutrality factor of 1.0002034. Accordingly, in section V.A.2. of the Addendum to this proposed rule, to determine the FY 2015 LTCH PPS standard Federal rate, we are proposing to apply a proposed area wage level adjustment budget neutrality factor of 1.0002034, in accordance with § 412.523(d)(4). The proposed FY 2015 LTCH PPS standard Federal rate shown in Table 1E of the Addendum to this proposed rule reflects this adjustment factor.

C. Proposed LTCH PPS Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels described above.

Prior to FY 2014, we used the most recent updated COLA factors obtained from the U.S. Office of Personnel Management (OPM) Web site at *http://www.opm.gov/oca/cola/rates.asp* to adjust the LTCH PPS payments for LTCHs located in Alaska and Hawaii. Statutory changes have transitioned the Alaska and Hawaii COLAs to locality pay (phased in over a 3-year period beginning in January 2010, with COLA rates being frozen as of October 28, 2009, and then proportionately reduced to reflect the phase-in of locality pay). For FY 2013, we believed that it was appropriate to use ''frozen'' COLA factors to adjust payments, while we explored alternatives for updating the COLA factors in the future, and we continued to use the same ''frozen'' COLA factors used in FY 2012 to adjust the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska and Hawaii in FY 2013 under § 412.525(b). We also established a methodology to update the COLA factors for Alaska and Hawaii, every 4 years (at the same time as the update to the labor-related share of the IPPS market basket), beginning in FY 2014 (77 FR 53712 through 53713). The methodology we established to update the COLA factors is 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). It also incorporates a 25-percent cap on the CPI-updated COLA factors, which is consistent with a statutorily mandated 25-percent cap that was applied to OPM's published COLA factors. We believe that determining updated COLA factors using this methodology would appropriately adjust the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska and Hawaii. (For additional details on the methodology we established in the FY 2013 IPPS/LTCH PPS final rule to update the COLA factors for Alaska and Hawaii beginning in FY 2014, we refer readers to section VII.D.3. of the preamble of that final rule (77 FR 53481 through 53482).)

For FY 2014, we updated the COLA factors published for Alaska and Hawaii by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule. Under our finalized methodology, we used COLA factors for FY 2014 for the three specified urban areas of Alaska (Anchorage, Fairbanks and Juneau) of 1.23; for the City and County of Honolulu, the County of Kauai, the County of Maui, the County of Kalawao, and ''All other'' areas of Alaska of 1.25; and for the County of Hawaii of 1.19. For additional details on our policy, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50997through 50998).

Under our finalized policy, we update the COLA factors using the methodology described above every 4 years; the first year began in FY 2014 (77 FR 53482). Accordingly, in this proposed rule, for FY 2015, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of the BIPA, to determine appropriate payment adjustments under the LTCH PPS, we are proposing to continue to use the COLA factors established in the FY 2014 IPPS/LTCH PPS final rule, which were 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. (We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50998) for a discussion of the FY 2014 COLA factors.) Consistent with our historical practice, we are proposing that the proposed COLA factors shown in the table below would adjust the nonlabor-related portion of the proposed standard Federal rate for LTCHs located in Alaska and Hawaii under § 412.525(b).

PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII HOSPITALS UNDER THE LTCH PPS FOR FY 2015

Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
All other areas of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.19
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 the 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 an 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 an 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, an LTCH's CCR is calculated by dividing an 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, an LTCH is assigned the applicable statewide average CCR if, among other things, an 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 CCRs based on erroneous data should not be used to identify and make payments for outlier cases. Therefore, under our established policy, generally, if an 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 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 2013 update of the PSF, we are proposing to establish a total CCR ceiling of 1.341under the LTCH PPS for FY 2015 in accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCOs and § 412.529(f)(4)(iii)(B) for SSOs. Consistent with our historical policy of using the best available data, we also are proposing that if more recent data become available, we would use such data to establish a total CCR ceiling for FY 2015 in the final rule.

c. 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 MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (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 MAC may consider in determining an LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data, in this proposed rule, using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the December 2013 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, 2014 through September 20, 2015, 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 statewide average total CCRs for urban and rural LTCHs for FY 2015 in the final rule.

Under the proposed changes to the LTCH PPS labor market areas based on the new OMB delineations, all areas in Delaware, the District of Columbia, New Jersey, and Rhode Island would be classified as urban. Therefore, there are no proposed rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although Connecticut and Massachusetts have areas that are designated as rural, there are no short-term, acute care IPPS hospitals or LTCHs located in those areas as of December 2013. Therefore, consistent with our existing methodology, we are proposing to use the national average total CCR for rural IPPS hospitals for rural Connecticut and Massachusetts in Table 8C listed in section VI. of the Addendum to this proposed rule (and available via the Internet).

In addition, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, we are proposing to continue to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We are proposing to use this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

d. Reconciliation of 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 2015

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 the FY 2014 IPPS/LTCH PPS final rule (78 FR 53715), we presented our policies regarding the methodology and data we used to establish the fixed-loss amount of $13,314 for FY 2014, which was calculated using our existing methodology to calculate the fixed-loss amount for FY 2014 (based on the data and the rates and policies presented in that final rule) in order to maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments. Consistent with our historical practice of using the best data available, in determining the fixed-loss amount for FY 2014, we used the most recent available LTCH claims data and CCR data, that is, LTCH claims data from the March 2013 update of the FY 2012 MedPAR file and CCRs from the March 2013 update of the PSF, as these data were the most recent complete LTCH data available at that time.

In this proposed rule, for FY 2015, in general, we are proposing to continue to use our existing methodology to calculate a fixed-loss amount for FY 2015 using the best available data that would maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments (based on the rates and policies presented in this proposed rule). Specifically, for this proposed rule, we are proposing to use LTCH claims data from the December 2013 update of the FY 2013 MedPAR file and CCRs from the December 2013 update of the PSF to determine a fixed-loss amount that would result in estimated outlier payments projected to be equal to 8 percent of total estimated payments in FY 2015 because these data are the most recent complete LTCH data available at this time. We also are proposing that if more recent data become available, we would use such data to determine a fixed-loss amount for FY 2015 in the final rule. (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 FY 2003 LTCH PPS final rule (67 FR 56022 through 56024).)

Under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of BIPA, we are proposing to establish a fixed-loss amount of $15,730 for FY 2015. Therefore, 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 outlier threshold (the sum of the adjusted Federal LTCH payment for the MS–LTC–DRG and the proposed fixed-loss amount of $15,730). We also note that the proposed fixed-loss amount of $15,730 for FY 2015 is slightly higher than the FY 2014 fixed-loss amount of $13,314. Based on our payment simulations using the most recent available data at this time, the proposed increase in the fixed-loss amount for FY

2015 is necessary to maintain the existing requirement that estimated outlier payments equal 8 percent of estimated total LTCH PPS payments. (As noted above, for further information on the existing 8 percent HCO ''target'' requirement, 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 more than the current regulatory 8-percent requirement because a lower fixed-loss amount would result in more cases qualifying as outlier cases, as well as higher outlier payments for qualifying HCO cases because the maximum loss that an LTCH must incur before receiving an HCO payment (that is, the fixed-loss amount) would be smaller. For these reasons, we believe that proposing to raise 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 the Outlier Policy to SSO Cases

As we discussed in the August 30, 2002 final rule (67 FR 56026), under some rare circumstances, an 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. Therefore, for an SSO case in FY 2015, 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 $15,730 and the amount paid under the SSO policy as specified in § 412.529).

E. Proposed Update to the IPPS Comparable/Equivalent Amounts To Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule, we established a policy for reflecting the changes to the Medicare IPPS DSH payment adjustment methodology provided for by section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' under the SSO policy at § 412.529 and the ''IPPS equivalent amount'' under the 25-percent threshold payment adjustment policy at § 412.534 and § 412.536. Historically, the determination of both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' include an amount for inpatient operating costs ''for the costs of serving a disproportionate share of low-income patients.'' Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under the age of 65 who are uninsured, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all IPPS hospitals that receive Medicare DSH payments.

To reflect the statutory changes to the Medicare DSH payment adjustment methodology in the calculation of the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS, we stated that we will include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating DSH payment amount that has historically been reflected in the LTCH PPS payments that is based on IPPS rates). We also stated that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. As explained in the FY 2014 IPPS/LTCH PPS final rule (79 FR 50766 through 50767), we believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS.

For FY 2014, aggregate Medicare IPPS operating DSH payments are projected to be reduced to 95.7 percent of the amount that would otherwise have been paid under the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act. Accordingly, for FY 2014, the calculation of the ''IPPS comparable amount'' under § 412.529 and the ''IPPS equivalent amount'' under § 412.534 and § 412.536 includes an applicable operating Medicare DSH payment amount that is equal to 95.7 percent of the operating Medicare DSH payment amount based the current statutory Medicare DSH payment formula (that is, the operating Medicare DSH payment amount historically included in those calculations) (76 FR 50766). As discussed in greater detail in section IV.F.3.d.(2) of the preamble of this proposed rule, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) would be adjusted to 80.35 percent of that amount to reflect the change in the percentage of individuals that are uninsured. The resulting amount is then used to determine the amount of proposed uncompensated care payments that would be made to eligible IPPS hospitals in FY 2015. In other words, Medicare DSH payments prior to the amendments made by the Affordable Care Act are adjusted to 60.26 percent (the product of 75 percent and 80.35 percent) and the resulting amount is used to calculate the proposed uncompensated care payments to eligible hospitals. As a result, for FY 2015, we project that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the proposed payments for uncompensated care under section 1886(r)(2) of the Act, would result in overall Medicare DSH payments of 85.26 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of amendments made by the Affordable Care Act (that is, 25 percent + 60.26 percent = 85.26 percent). Therefore, in this proposed rule, for FY 2015, we are proposing that the calculation of the

''IPPS comparable amount'' under § 412.529 and the ''IPPS equivalent amount'' under § 412.534 and § 412.536 would include an applicable operating Medicare DSH payment amount that would be equal to 85.26 percent of the operating Medicare DSH payment amount based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act. Consistent with our historical practice of using the best available data, if more recent data become available, for the final rule, we would use such data to determine the percentage of the operating Medicare DSH payment amount based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act used in the calculation of the ''IPPS comparable amount'' under § 412.529 and the ''IPPS equivalent amount'' under § 412.534 and § 412.536 for FY 2015.

F. Computing the Proposed Adjusted LTCH PPS Federal Prospective Payments for FY 2015

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 2015 values are shown in Tables 12A through 12D listed in section VI. of the Addendum of this proposed rule and are available via the Internet). The proposed standard Federal rate is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the proposed FY 2015 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this proposed rule, we are proposing to establish a standard Federal rate for FY 2015 of $40,943.51 (applicable to discharges from LTCHs that submit the required quality reporting data for FY 2015 in accordance with the LTCHQR Program under section 1886(m)(5) of the Act), as discussed above in section V.A.2. of the Addendum to this proposed rule. We illustrate the methodology to adjust the proposed LTCH PPS Federal standard rate for FY 2015 in the following example:

Example: During FY 2015, a Medicare patient is in an LTCH located in Chicago, Illinois (CBSA 16974). The proposed FY 2015 LTCH PPS wage index value for CBSA 16974 is 1.0369 (obtained from Table 12A listed in section VI. of the Addendum of this proposed rule and available via the Internet on the CMS Web site). The Medicare patient is classified into MS–LTC–DRG 198 (Pulmonary Edema & Respiratory Failure), which has a proposed relative weight for FY 2015 of 0.9122 (obtained from Table 11 listed in section VI. of the Addendum of this proposed rule and available via the Internet on the CMS Web site). The LTCH submitted quality reporting data for FY 2015 in accordance with the LTCHQR Program under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted proposed Federal prospective payment for this Medicare patient in FY 2015, we compute the wage-adjusted proposed Federal prospective payment amount by multiplying the unadjusted proposed FY 2015 standard Federal rate ($40,943.51, for LTCHs that submit quality reporting data for FY 2015 in accordance with the LTCHQR Program under section 1886(m)(5) of the Act) by the proposed labor-related share (62.571 percent) and the proposed wage index value (1.0369). This wage-adjusted amount is then added to the proposed nonlabor-related portion of the unadjusted proposed standard Federal rate (37.429 percent; adjusted for cost of living, if applicable) to determine the adjusted proposed Federal rate, which is then multiplied by the proposed MS–LTC–DRG relative weight (0.9122) to calculate the total adjusted proposed Federal LTCH PPS prospective payment for FY 2015 ($38,211.00). The table below illustrates the components of the calculations in this example.

Unadjusted Proposed Standard Federal Prospective Payment Rate (applicable to discharges from LTCHs that submit the required quality data in accordance with the LTCHQR Program under section 1886(m)(5) of the Act)	$40,943.51
Proposed Labor-Related Share	× 0.62571
Proposed Labor-Related Portion of the Federal Rate	= $25,618.76
Proposed Wage Index (CBSA 16974)	× 1.0369
Proposed Wage-Adjusted Labor Share of Federal Rate	= $26,564.09
Proposed Nonlabor-Related Portion of the Federal Rate ($40,943.51 × 0.37429)	+ $15,324.75
Adjusted Proposed Federal Rate Amount	= $41,888.84
Proposed MS–LTC–DRG 198 Relative Weight	× 0.9122
Total Adjusted Proposed Federal Prospective Payment	= $38,211.00

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 FYs 2012 through 2014, for the FY 2015 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, all IPPS Tables listed below with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E will be available only through the Internet. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register** as part of the annual proposed and final rules.

As discussed in section II.G.11. and 13. of the preamble of this proposed rule, Tables 6A through 6F will not be issued with this FY 2015 proposed rule because there are no proposed new, revised, or deleted diagnosis or procedure codes for FY 2015. As discussed in section IV.D. of this proposed rule, section 106 of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93), enacted on April 1, 2014, extended, through the first half of FY 2015 (that is, for discharges occurring before April 1, 2015), the temporary changes in the low-volume hospital definition and methodology for determining the payment adjustment originally made by the Affordable Care Act (and extended by subsequent legislation through March 31, 2014). We refer the reader to section IV.D. for complete details on the low-volume hospital payment adjustment. Therefore, Table 14 associated with this proposed rule lists the proposed low-volume payment adjustments. In addition, under section 3008 of the Affordable Care Act, a hospital's total payment may be reduced by 1 percent if it is in the lowest HAC performance quartile. We

refer the reader to section IV.J. for complete details on this adjustment. Therefore, Table 17 contains the FY 2015 proposed proxy list of providers subject to the HAC Reduction Program. Finally, a hospital's proposed Factor 3 is the proposed proportion of the uncompensated care amount that a DSH will receive under section 3133 of the Affordable Care Act. Factor 3 is the hospital's estimated number of Medicaid days and Medicare SSI days relative to the estimate of all DSHs' Medicaid days and Medicare SSI days. Therefore, Table 18 contains the proposed FY 2015 Medicare DSH uncompensated care payment Factor 3 for all hospitals and identifies whether or not a hospital is projected to receive DSH and, therefore, eligible to receive the additional payment for uncompensated care for FY 2015.

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

The following IPPS tables for this FY 2015 proposed rule are available only through the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Click on the link on the left side of the screen titled, ''FY 2015 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download''.

Table 2–1.—Hospital Average Hourly Wages for Federal Fiscal Years 2013 (2009 Wage Data), 2014 (2010 Wage Data), and 2015 (2011 Wage Data); and Proposed 3-Year Average of Hospital Average Hourly Wages; Based on CBSA Delineations Used in FY 2014

Table 2–2.—Acute Care Hospitals Case-Mix Indexes for Discharges Occurring in Federal Fiscal Year 2012; Proposed Hospital Wage Indexes for Federal Fiscal Year 2015; Hospital Average Hourly Wages for Federal Fiscal Years 2013 (2009 Wage Data), 2014 (2010 Wage Data), and 2015 (2011 Wage Data; Based on Proposed FY 2015 CBSA Delineations); and 3-Year Average of Hospital Average Hourly Wages

Table 3A–1.—Proposed FY 2015 and 3-Year * Average Hourly Wage for Acute Care Hospitals in Urban Areas by CBSA; Based on CBSA Delineations Used in FY 2014

Table 3A–2.—Proposed FY 2015 and 3-Year * Average Hourly Wage for Acute Care Hospitals in Urban Areas by CBSA; Based on CBSA Delineations Used in FY 2015

Table 3B–1.—Proposed FY 2015 and 3-Year * Average Hourly Wage for Acute Care Hospitals in Rural Areas by CBSA; Based on CBSA Delineations Used in FY 2014

Table 3B–2.—Proposed FY 2015 and 3-Year * Average Hourly Wage for Acute Care Hospitals in Rural Areas by CBSA; Based on CBSA Delineations Used in FY 2015

Table 4A–1.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Urban Areas by CBSA and by State—FY 2015; Based on CBSA Delineations Used in FY 2014

Table 4A–2.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Urban Areas by CBSA and by State—FY 2015; Based on CBSA Delineations Used in FY 2015

Table 4B–1.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Rural Areas by CBSA and by State—FY 2015; Based on CBSA Delineations Used in FY 2014

Table 4B–2.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Rural Areas by CBSA and by State—FY 2015; Based on CBSA Delineations Used in FY 2015

Table 4C–1.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals That Are Reclassified by CBSA and by State—FY 2015; Based on CBSA Delineations Used in FY 2014

Table 4C–2.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals That Are Reclassified by CBSA and by State—FY 2015; Based on CBSA Delineations Used in FY 2015

Table 4D–1.—States Designated as Frontier, with Acute Care Hospitals Receiving at a Minimum the Frontier State Floor Wage Index; Urban Areas with Acute Care Hospitals Receiving the Proposed Statewide Rural Floor or Imputed Floor Wage Index—FY 2015; Based on CBSA Delineations Used in FY 2014

Table 4D–2.—States Designated as Frontier, with Acute Care Hospitals Receiving at a Minimum the Frontier State Floor Wage Index; Urban Areas with Acute Care Hospitals Receiving the Proposed Statewide Rural Floor or Imputed Floor Wage Index—FY 2015; Based on CBSA Delineations Used in FY 2015

Table 4E–1.—Urban CBSAs and Constituent Counties for Acute Care Hospitals—FY 2015; Based on CBSA Delineations Used in FY 2014

Table 4E–2.—Urban CBSAs and Constituent Counties for Acute Care Hospitals—FY 2015; Based on CBSA Delineations Used in FY 2015

Table 4F–1.—Proposed Puerto Rico Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals by CBSA—FY 2015; Based on CBSA Delineations Used in FY 2014

Table 4F–2.—Proposed Puerto Rico Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals by CBSA—FY 2015; Based on CBSA Delineations Used in FY 2015

Table 4J.—Proposed Out-Migration Adjustment for Acute Care Hospitals—FY 2015

Table 5.—List of Proposed Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2015

Table 6I.—Proposed Major CC List—FY 2015

Table 6J.—Proposed Complete CC List—FY 2015

Table 6K.—Proposed Complete List of CC Exclusions—FY 2015

Table 7A.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2013 MedPAR Update—December 2013 GROUPER V31.0 MS–DRGs

Table 7B.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2013 MedPAR Update—December 2013 GROUPER V32.0 MS–DRGs

Table 8A.—Proposed FY 2015 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)

Table 8B.—Proposed FY 2015 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals

Table 9A–1.—Hospital Reclassifications and Redesignations—FY 2015; Based on CBSA Delineations Used in FY 2014

Table 9A–2.—Hospital Reclassifications and Redesignations—FY 2015; Based on CBSA Delineations Used in FY 2015

Table 9C–1.—Hospitals Redesignated as Rural Under Section 1886(d)(8)(E) of the Act—FY 2015; Based on CBSA Delineations Used in FY 2014

Table 9C–2.—Hospitals Redesignated as Rural under Section 1886(d)(8)(E) of the Act—FY 2015; Based on CBSA Delineations Used in FY 2015

Table 10.—Proposed New Technology Add-On Payment Thresholds [1] [2] for Applications for FY 2016

Table 12C.—Proposed LTCH PPS Wage Index for Urban Areas under the Current CBSA Designations for Discharges Occurring From October 1, 2014 through September 30, 2105

Table 12D.—Proposed LTCH PPS Wage Index for Rural Areas Under the Current CBSA Designations for Discharges Occurring From October 1, 2014 Through September 30, 2015

Table 14.—List of Hospitals With Fewer Than 1,600 Medicare Discharges Based on the December 2013 Update of the FY 2013 MedPAR file and Potentially Eligible Hospitals' FY 2015 Low-Volume Payment Adjustment for Discharges Occurring Before April 1, 2015 (Eligibility for the low-volume payment adjustment is also dependent upon meeting the mileage criteria specified at § 412.101(b)(2)(ii) of the regulations.)

Table 15.—Proposed FY 2015 Readmissions Adjustment Factors

Table 16.—Proposed Updated Proxy Hospital Inpatient Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2015

Table 17.—FY 2015 Preliminary Analysis of the Hospital-Acquired Conditions Reduction Program

Table 18.—Proposed FY 2015 Medicare DSH Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2015 proposed rule are available only through the Internet on the CMS

Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1607–P.

Table 8C.—Proposed FY 2015 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, Short-Stay Outlier (SSO) Threshold, and ''IPPS Comparable Threshold'' for Discharges Occurring From October 1, 2014 Through September 30, 2015 Under the LTCH PPS

Table 12A.—Proposed LTCH PPS Wage Index for Urban Areas Under the New OMB CBSA Delineations for Discharges Occurring From October 1, 2014 Through September 30, 2015

Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas Under the New OMB CBSA Delineations for Discharges Occurring From October 1, 2014 Through September 30, 2015

Table 13A.—Proposed Composition of Low-Volume Quintiles for MS–LTC–DRGs—FY 2015

Table 13B.—Proposed No-Volume MS–LTC–DRG Crosswalk for FY 2015

TABLE 1A—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (69.6 PERCENT LABOR SHARE/30.4 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)—FY 2015

Hospital submitted quality data and is a meaningful EHR user (Update = 2.1 percent)		Hospital did not submit quality data and is a meaningful EHR user (Update = 1.425 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (Update = 1.425 percent)		Hospital did not submit quality data and is NOT a meaningful EHR user (Update = 0.75 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,759.46	$1,642.06	$3,734.61	$1,631.20	$3,734.61	$1,631.20	$3,709.75	$1,620.35

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 2015

Hospital submitted quality data and is a meaningful EHR user (Update = 2.1 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (Update = 1.425 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (Update = 1.425 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (Update = 0.75 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,348.94	$2,052.58	$3,326.80	$2,039.01	$3,326.80	$2,039.01	$3,304.66	$2,025.44

TABLE 1C—PROPOSED ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1; PUERTO RICO: 63.2 PERCENT LABOR SHARE/36.8 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1 OR 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1—FY 2015

Standardized amount	Rates if wage index is greater than 1		Rates if wage index is less than or equal to 1	
	Labor	Nonlabor	Labor	Nonlabor
National [1]	[2]	[2]	$3,348.94	$2,052.58
Puerto Rico	$1,605.07	$934.59	1,574.59	965.07

[1] For FY 2015, there are no CBSAs in Puerto Rico with a national wage index greater than 1.
[2] Not applicable.

TABLE 1D—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2015

	Rate
National	$433.01
Puerto Rico	206.82

TABLE 1E—PROPOSED LTCH STANDARD FEDERAL PROSPECTIVE PAYMENT RATE—FY 2015

	Full update (2.1 percent)	Reduced update * (0.1 percent)
Standard Federal Rate	$40,943.51	$40,141.47

* For LTCHs that fail to submit quality reporting data for FY 2015 in accordance with the LTCH Quality Reporting (LTCHQR) Program, the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. 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 2015 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 proposed payment changes in this proposed rule, would result in an estimated $864 million decrease in FY 2015 operating payments (or −0.8 percent change) and an estimated $126 million increase in FY 2015 capital payments (or 1.2 percent change). These changes are relative to payments made in FY 2014. The impact analysis of the capital payments can be found in section I.J. of this Appendix. In addition, as described in section I.K. of this Appendix, LTCHs are expected to experience an increase in payments by $44 million in FY 2015 relative to FY 2014.

Our operating impact estimate includes the proposed −0.8 percent documentation and coding adjustment applied to the IPPS standardized amount, which represents part of the recoupment required under section 631 of the ATRA. In addition, our operating payment impact estimate includes the proposed 2.1 percent hospital update to the standardized amount (which includes the estimated 2.7 percent market basket update less 0.4 percentage point for the proposed multifactor productivity adjustment and less 0.2 percentage point required under the Affordable Care Act). The estimates of proposed IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This proposed rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget has reviewed this proposed rule.

B. Statement of Need

This proposed rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This proposed rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS 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 that the proposed changes in this proposed rule would further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these proposed changes 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 2014, on various hospital groups. We estimate the effects of individual proposed policy changes by estimating payments per case while holding all other payment policies constant. We use the best data available, but, generally, 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, hospitals in Maryland are paid in accordance with the Maryland All-Payer Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 5 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling.

As of December 2013, there were 3,468 IPPS acute care hospitals included in our analysis. This represents approximately 57 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,332 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs rather than under the IPPS. IPPS-excluded hospitals and units include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, 11 cancer hospitals, and 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, which are paid under separate payment systems. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts for these IPPS-excluded hospitals and units are not included in this proposed rule. The impact of the proposed update and proposed policy changes to the LTCH PPS for FY 2015 is discussed in section I.L. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of March 2014, there were 97 children's hospitals, 11 cancer hospitals, 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa, and 18 RNHCIs being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCIs are paid under § 413.40.) Among the remaining providers, 244 rehabilitation hospitals and 896 rehabilitation units, and 432 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 487 psychiatric hospitals and 1,139 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.K. of this Appendix.

For children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNHCIs, the proposed update of the rate-of-increase limit (or target amount) is the estimated FY 2015 percentage increase in the IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. As discussed in section IV. of the preamble of the FY 2014 IPPS/LTCH PPS final rule, we rebased the IPPS operating market basket to a FY 2010 base year. Therefore, we are proposing to use the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for FY 2015 and subsequent fiscal years for children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNHCIs that are paid based on reasonable costs subject to the rate-of-increase limits. Consistent with current law, based on IHS Global Insight, Inc.'s 2014 first quarter forecast of the FY 2010-based market basket increase, we are estimating that the proposed FY 2015 update based on the IPPS operating market basket is 2.7 percent (that is, the current estimate of the market basket rate-of-increase). However, the Affordable Care Act requires an adjustment for multifactor productivity (currently estimated to be 0.4 percentage point for FY 2015) and a 0.2 percentage point reduction to the market

basket update resulting in a proposed 2.1 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section IV.B. of the preamble of this proposed rule. Children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNCHIs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. Therefore, for those hospitals paid under § 413.40 of the regulations, the proposed update would be the percentage increase in the FY 2015 IPPS operating market basket, estimated at 2.7 percent, without the reductions required under the Affordable Care Act.

The impact of the proposed update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with 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 paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of: (1) 50 percent of its reasonable costs in excess of 110 percent of the limit, or (2) 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

G. Quantitative Effects of the Proposed Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this proposed rule, we are announcing proposed policy changes and payment rate updates for the IPPS for FY 2015 for operating costs of acute care hospitals. The proposed FY 2015 updates to the capital payments to acute care hospitals are discussed in section I.J. of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2015 operating payments will decrease by 0.8 percent compared to FY 2014. In addition to the applicable percentage increase, this amount reflects the proposed FY 2015 recoupment adjustment for documentation and coding described in section II.D. of the preamble of this proposed rule of −0.8 percent to the IPPS national standardized amounts. 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 changes in this proposed rule. However, there are other proposed changes for which we do not have data available that will allow us to estimate the payment impacts using this model. For those proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of changes in payments per case presented below are taken from the FY 2013 MedPAR file and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the operating PPS do not incorporate cost data, data from the most recently available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2013 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 2015 are discussed in section I.J. of this Appendix.

We discuss the following proposed changes below:

- The effects of the proposed application of the documentation and coding adjustment and the proposed 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 changes to the relative weights and MS–DRG grouper.
- The effects of the proposed changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2011, compared to the FY 2010 wage data, and the proposed adoption of new OMB labor market area delineations to calculate the FY 2015 wage index.
- The combined effects of the proposed recalibration of the MS–DRG relative weights as required by section 1886(d)(4)(C) of the Act and the proposed wage index (including the updated wage data and the proposed adoption of new OMB labor market area delineations), including the proposed wage and recalibration budget neutrality factors.
- The effects of the geographic reclassifications by the MGCRB (as of publication of this proposed rule) and the effects of the proposed adoption of new OMB labor market area delineations on these reclassifications, that would be effective for FY 2015.
- The effects of the proposed rural floor and imputed floor with the application of the national budget neutrality factor applied to the wage index where the rural floor and imputed floor wage index are calculated based on the proposed adoption of the new OMB labor market area delineations.
- The effects of the proposed adoption of the new labor market area delineations announced by OMB in February 2013 on hospital redesignations.
- The effects of the proposed 3-year transition for urban hospitals redesignated as rural and the transitional blended wage index for hospitals whose FY 2015 wage indexes will decrease solely as a result of adopting the new OMB delineations.
- The effects of the proposed frontier State wage index adjustment under the statutory provision that requires that hospitals located in States that qualify as frontier States to not have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the proposed implementation of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes.
- The effects of the proposed policies for implementation of the Hospital Readmissions Reduction Program under section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act, that adjusts a hospital's base operating DRG amount by an adjustment factor to account for a hospital's excess readmissions.
- The effects of the proposed policies for continued implementation of section 3133 of the Affordable Care Act that reduces Medicare DSH payments to 25 percent of what hospitals had been previously paid under section 1886(d)(5)(F) of the Act and establishes an additional payment to be made to hospitals that receive DSH payments for their relative share of the total amount of uncompensated care.
- The effects of the proposed FY 2015 implementation of section 1886(o) of the Act, as added by section 3008 of the Affordable Care Act, which establishes payment reductions under the HAC Reduction Program. Hospitals ranked in the lowest 25 percent of performance on HACs are subject to a 1-percent reduction in total IPPS payments.
- The total estimated change in payments based on the proposed FY 2015 policies relative to payments based on FY 2014 policies that include the applicable

percentage increase of 2.1 percent (or 2.7 percent market basket update with a proposed reduction of 0.4 percentage point for the multifactor productivity adjustment, and a 0.2 percentage point reduction, as required under the Affordable Care Act). The total estimated change in payments for FY 2015 reflects the extension of MDH payment status for the first 6 months of FY 2015, in accordance with the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) enacted on April l, 2014.

To illustrate the impact of the proposed FY 2015 changes, our analysis begins with a FY 2014 baseline simulation model using: The proposed FY 2015 applicable percentage increase of 2.1 percent and the proposed documentation and coding recoupment adjustment of 0.8 percent to the Federal standardized amount; the FY 2014 MS–DRG GROUPER (Version 31.0); the current FY 2014 CBSA designations for hospitals based on the OMB delineations; the FY 2014 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Public Law 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111–5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111–148), provides that, for FY 2007 and each subsequent year through FY 2014, the update factor will include a reduction of 2.0 percentage points for any subsection (d) hospital that does not submit data on measures in a form and manner and at a time specified by the Secretary. Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act, or one-quarter of the market basket update. Therefore, for FY 2015, we are proposing that hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act will receive an applicable percentage increase of 1.425 percent. At the time that this impact was prepared, 64 hospitals did not receive the full market basket rate-of-increase for FY 2014 because they failed the quality data submission process or did not choose to participate. For purposes of the simulations shown below, we modeled the payment changes for FY 2015 using a reduced update for these 64 hospitals. However, we do not have enough information at this time to determine which hospitals will not receive the full update factor for FY 2015.

Beginning in FY 2015, in accordance with section 1886(b)(3)(B)(ix) of the Act, a hospital that has been identifies as not an EHR meaningful user will be subject to a reduction of one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act, or one-quarter of the market basket update. Therefore, for FY 2015, we are proposing that hospitals that are identified as not EHR meaningful users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act will receive an applicable percentage increase of 1.425 percent. Hospitals that are identified as not EHR meaningful users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act will receive an applicable percentage increase of 0.75 percent, which reflects a one-quarter reduction of the market basket update for failure to submit quality data and a one-quarter reduction of the market basket update for being identified as not an EHR meaningful user. For FY 2015, we have yet to finalize a list of hospitals that are not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act. Therefore, we are proposing not to include this adjustment to the standardized amount (for those hospitals that are not meaningful EHR users) in our modeling of aggregate payments for FY 2015. We intend to release a final list of hospitals that are not meaningful EHR user in September 2014. Hospitals identified on this list will be paid based on the applicable proposed standardized amount in Table 1A for discharges occurring in FY 2015.

Each proposed policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2015 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 2014 to FY 2015. 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 updating the standardized amounts for FY 2015 using a proposed applicable percentage increase of 2.1 percent. This includes our forecasted IPPS operating hospital market basket increase of 2.7 percent with a proposed reduction of 0.4 percentage point for the multifactor productivity adjustment and a 0.2 percentage point reduction as required under the Affordable Care Act. (Hospitals that fail to comply with the quality data submission requirements and are meaningful EHR users would receive a proposed update of 1.425 percent. This update includes a reduction of one-quarter of the market basket update for failure to submit these data). We note that hospitals that do comply with the quality data submission requirements but are not meaningful EHR users would receive a proposed update of 1.425 percent, which includes a reduction of one-quarter of the market basket update. Furthermore, hospitals that do not comply with the quality data submission requirements and also are not meaningful EHR users would receive a proposed update of 0.75 percent. However, as discussed earlier, we do not have a list of hospitals that are not meaningful EHR users and have not included this adjustment to the standardized amount (for those hospitals that are not meaningful EHR users) in our modeling of aggregate payments for FY 2015. Under section 1886(b)(3)(B)(iv) of the Act, the updates to the hospital-specific amounts for SCHs also are 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, if the hospital submits quality data and is a meaningful EHR user.

A second significant factor that affects the changes in hospitals' payments per case from FY 2014 to FY 2015 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 2014 that are no longer reclassified in FY 2015. Conversely, payments may increase for hospitals not reclassified in FY 2014 that are reclassified in FY 2015.

A third significant factor is that we currently estimate that actual outlier payments during FY 2014 will be 5.79 percent of total MS–DRG payments. When the FY 2014 IPS/LTCH PPS final rule was published, we projected FY 2014 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 2014 (as discussed in the Addendum to this proposed rule) are reflected in the analyses below comparing our current estimates of FY 2014 payments per case to estimated FY 2015 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 2015. 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 3,388 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 2,542 hospitals located in urban areas included in our analysis. Among these, there are 1,395 hospitals located in large urban areas (populations over 1 million), and 1,147 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 846 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 2015 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 2,558; 1,408; 1,150; and 830, respectively.

The next three groupings examine the impacts of the proposed changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive

Medicare DSH payments, or some combination of these two adjustments. There are 2,352 nonteaching hospitals in our analysis, 792 teaching hospitals with fewer than 100 residents, and 244 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 208 RRCs, 324 SCHs, and 154 MDHs (MDH status is extended through March 31, 2015 only under Pub. L. 113–93), 124 hospitals that are both SCHs and RRCs, and 11 hospitals that are MDHs and RRCs (MDH status is through March 31, 2015 only under Pub. L. 113–93).

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 2012 or FY 2011 Medicare cost reports.

The next two groupings concern the geographic reclassification status of hospitals. The first grouping displays all urban hospitals that were reclassified by the MGCRB for FY 2015. The second grouping shows the MGCRB rural reclassifications. The final category shows the impact of the proposed policy changes on the 15 cardiac hospitals.

TABLE I.—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2014

	No. of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment[2] (2)	Proposed FY 2015 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	Proposed FY 2015 Wage Data with Application of Wage Budget Neutrality[4] (4)	Proposed FY 2015 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	Proposed FY 2015 MGCRB Reclassifications[6] (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Proposed Impact of the New OMB CBSA Designations[8] (8)	Proposed Application of the CBSA Transition Wage Index with Budget Neutrality[9] (9)	Proposed Application of the Frontier Wage Index and Out-Migration Adjustment[10] (10)	Proposed Hospital Readmissions Reduction Program[11] (11)	Proposed Changes to Medicare DSH[12] (12)	Proposed Implementation of the HAC Reduction Program[13] (13)	All Proposed FY 2015 Changes[14] (14)
All Hospitals	3,388	1.3	0	0	0	0	0	0	0	0.1	-0.4	-1	-0.3	-0.8
By Geographic Location:														
Urban hospitals	2,542	1.3	0.1	0	0.1	-0.1	0	0	0	0.1	-0.4	-1	-0.3	-0.9
Large urban areas	1395	1.3	0.1	0.1	0.2	-0.3	0	0	0	0	-0.4	-1.1	-0.4	-0.9
Other urban areas	1147	1.3	0	-0.2	-0.1	0.2	0	0.1	0	0.2	-0.3	-1	-0.3	-0.8
Rural hospitals	846	1.7	-0.6	0.1	-0.5	1.8	-0.3	0.1	0	0.2	-0.4	-0.7	-0.2	-0.2
Bed Size (Urban):														
0-99 beds	655	1.4	-0.2	0.1	-0.1	-0.3	0.1	0.2	0	0.3	-0.3	-0.6	-0.2	-0.5
100-199 beds	788	1.3	-0.1	-0.1	-0.2	0.1	0.2	0	0	0.1	-0.5	-1	-0.2	-0.8
200-299 beds	469	1.3	0	0	0	0.1	0	0.1	0	0.1	-0.4	-0.9	-0.3	-0.5
300-499 beds	417	1.3	0.1	-0.1	0.1	-0.3	0.1	0	0	0.1	-0.3	-1.1	-0.3	-0.9
500 or more beds	213	1.3	0.2	0	0.3	-0.2	-0.2	0	0	0	-0.3	-1.1	-0.4	-1.2
Bed Size (Rural):														
0-49 beds	325	1.8	-1	0	-1	0.7	-0.4	0	0.1	0.3	-0.5	-0.5	-0.2	-0.8
50-99 beds	298	1.7	-0.8	0.2	-0.7	1	-0.3	0	0.1	0.2	-0.4	-0.7	-0.2	-1
100-149 beds	136	1.6	-0.6	0	-0.6	2	-0.3	0	0	0.2	-0.6	-0.6	-0.2	0.3
150-199 beds	50	1.5	-0.3	0.3	-0.2	2.2	-0.3	0	-0.1	0.3	-0.4	-0.9	-0.1	-0.1
200 or more beds	37	1.7	-0.2	0.1	-0.1	3.1	-0.3	0.1	-0.1	0	-0.3	-0.6	-0.3	0.6
Urban by Region:														
New England	120	1.3	0.1	0.9	0.9	1.3	2.7	0.1	-0.1	0	-0.5	-0.7	-0.4	-0.8
Middle Atlantic	324	1.3	0	0.3	0.3	-0.1	-0.5	-0.4	0.4	0.1	-0.5	-0.9	-0.3	-0.6
South Atlantic	406	1.3	0	-0.3	-0.3	-0.3	-0.4	0.1	-0.1	0	-0.4	-1	-0.3	-1.1
East North Central	397	1.3	0.1	-0.2	0	-0.2	-0.6	0.1	-0.1	0	-0.5	-0.9	-0.3	-1
East South Central	153	1.3	0.1	-0.6	-0.5	-0.3	-0.4	0	0	0	-0.5	-1.1	-0.4	-1.5

	No. of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment[2] (2)	Proposed FY 2015 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	Proposed FY 2015 Wage Data with Application of Wage Budget Neutrality[4] (4)	Proposed FY 2015 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	Proposed FY 2015 MGCRB Reclassifications[6] (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Proposed Impact of the New OMB CBSA Designations[8] (8)	Proposed Application of the CBSA Transition Wage Index with Budget Neutrality[9] (9)	Proposed Application of the Frontier Wage Index and Out-Migration Adjustment[10] (10)	Proposed Hospital Readmissions Reduction Program[11] (11)	Proposed Changes to Medicare DSH[12] (12)	Proposed Implementation of the HAC Reduction Program[13] (13)	All Proposed FY 2015 Changes[14] (14)
West North Central	162	1.3	0.1	0	0.1	-0.7	-0.5	0.1	-0.1	0.8	-0.2	-0.9	-0.2	-0.5
West South Central	385	1.3	0.2	-0.3	-0.1	-0.4	-0.5	0.1	-0.1	0	-0.3	-1.5	-0.2	-1.4
Mountain	159	1.4	0.1	-0.1	0	0	0	0.1	-0.1	0.3	-0.2	-1.3	-0.4	-0.8
Pacific	384	1.3	0.1	0.4	0.5	-0.2	1.5	0.1	-0.1	0	-0.2	-1.1	-0.3	-0.2
Puerto Rico	52	1.5	-0.4	0.2	-0.2	-0.7	0	0	0	0	0	-6.8	0	-7.2
Rural by Region:														
New England	22	1.5	-0.3	0.7	0.3	2.4	-0.5	0.4	-0.1	0	-0.1	-0.3	-0.1	-0.2
Middle Atlantic	57	1.7	-0.8	0.8	-0.2	1.3	0	-0.3	0.1	0.2	-0.4	-0.5	-0.2	-0.6
South Atlantic	132	1.8	-0.7	0.1	-0.9	2.5	-0.4	0	0	0.1	-0.4	-0.8	-0.2	-0.6
East North Central	115	1.7	-0.5	0	-0.5	1.6	-0.3	0.2	0	0	-0.5	-0.4	-0.2	0.6
East South Central	165	1.4	-0.3	-0.2	-0.5	2.8	-0.5	0	-0.1	0.1	-0.7	-1	-0.2	-1.1
West North Central	102	1.8	-0.8	0.1	-0.7	0.6	-0.1	0.2	0	0.7	-0.2	-0.3	-0.2	1.2
West South Central	168	1.5	-0.5	0.2	-0.3	1.7	-0.4	-0.1	0.1	0.1	-0.8	-1.2	-0.1	-1.9
Mountain	61	1.8	-0.7	-0.3	-1	0.4	-0.2	0	0	0.9	-0.1	-0.4	-0.2	1.5
Pacific	24	2	-1.1	0.9	-0.2	1.2	-0.3	0.1	0	0	-0.1	0	-0.1	2.4
By Payment Classification:														
Large urban areas	1408	1.3	0.1	0.1	0.2	-0.3	0	0	0	0	-0.4	-1.1	-0.4	-0.9
Other urban areas	1150	1.3	0	-0.2	-0.1	0.2	0	0.1	0	0.1	-0.3	-1	-0.3	-0.8
Other urban areas	1,764	1.3	0	0	0	0	0.1	0	0	0.1	-0.4	-1	-0.3	-0.8
Rural areas	830	1.7	-0.6	0.1	-0.6	1.4	-0.3	0	0	0.4	-0.4	-0.6	-0.2	0
Teaching Status:														
Nonteaching	2,352	1.4	-0.2	-0.1	-0.2	0.2	0.1	0.1	0	0.1	-0.5	-0.8	-0.2	-0.5
Fewer than 100 residents	792	1.4	0	0	0	-0.1	0	0	0	0.2	-0.3	-1	-0.3	-0.7
100 or more residents	244	1.3	0.3	0.2	0.5	-0.2	-0.2	-0.1	0	0	-0.3	-1.2	-0.5	-1.3
Urban DSH:														
Non-DSH	682	1.3	-0.1	0	0	0	0	0.1	0.1	0.2	-0.4	-0.2	-0.2	0.3

	No. of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment[2] (2)	Proposed FY 2015 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	Proposed FY 2015 Wage Data with Application of Wage Budget Neutrality[4] (4)	Proposed FY 2015 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	Proposed FY 2015 MGCRB Reclassifications[6] (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Proposed Impact of the New OMB CBSA Designations[8] (8)	Proposed Application of the CBSA Transition Wage Index with Budget Neutrality[9] (9)	Proposed Application of the Frontier Wage Index and Out-Migration Adjustment[10] (10)	Proposed Hospital Readmissions Reduction Program[11] (11)	Proposed Changes to Medicare DSH[12] (12)	Proposed Implementation of the HAC Reduction Program[13] (13)	All Proposed FY 2015 Changes[14] (14)
100 or more beds	1,591	1.3	0.1	0	0.1	-0.1	0	0	0	0.1	-0.4	-1.2	-0.3	-1.1
Less than 100 beds	366	1.4	-0.3	0.1	-0.2	0.2	0.1	0.3	0	0.3	-0.4	-1	-0.2	-1.3
Rural DSH:														
SCH	388	1.9	-1	0.1	-1	0.1	-0.1	0	0	0.1	-0.4	-0.4	-0.2	0.1
RRC	212	1.6	-0.4	0.1	-0.3	2.2	-0.3	0	0	0.5	-0.4	-0.7	-0.2	0.2
100 or more beds	24	1.3	-0.3	-0.2	-0.5	2.5	-0.6	0.1	0	0.2	-0.6	-1.4	-0.1	-1.3
Less than 100 beds	125	1.3	-0.5	-0.1	-0.6	1.2	-0.6	-0.2	0.1	0.7	-0.5	-1.2	-0.2	-1.2
Urban teaching and DSH:														
Both teaching and DSH	842	1.3	0.2	0	0.2	-0.2	-0.1	0	0	0.1	-0.3	-1.2	-0.4	-1.2
Teaching and no DSH	133	1.3	0	0.2	0.2	0.1	0.2	-0.1	0.1	0.1	-0.4	-0.2	-0.2	0.5
No teaching and DSH	1,115	1.3	-0.1	-0.1	-0.1	0.1	0.3	0.1	0	0.1	-0.5	-1	-0.2	-0.8
No teaching and no DSH	468	1.3	-0.1	-0.1	-0.2	-0.1	-0.2	0.2	0	0.1	-0.4	-0.2	-0.2	0.2
Special Hospital Types:														
RRC	208	1.3	-0.1	0.1	0	2.6	-0.5	0.1	-0.1	0.6	-0.4	-1	-0.2	-1
SCH	324	1.9	-0.8	0	-0.9	-0.1	-0.1	0	0	0.1	-0.2	-0.2	-0.2	2
MDH	154	1.7	-0.9	0.1	-1	0.4	-0.1	0	0	0.2	-0.8	-0.6	-0.1	-4.6
SCH and RRC	124	1.9	-0.6	0.1	-0.6	0.8	-0.1	0.1	0	0.1	-0.2	-0.2	-0.2	2.2
MDH and RRC	11	1.8	-0.8	-0.1	-0.9	1	-0.3	0	0	0	-0.9	-0.2	-0.2	-5.9
Type of Ownership:														
Voluntary	1,925	1.3	0	0	0.1	0	0	0	0	0.1	-0.4	-0.9	-0.3	-0.7
Proprietary	883	1.3	0	-0.1	0	0.2	0.1	0.1	-0.1	0.1	-0.5	-1.1	-0.2	-0.8
Government	540	1.4	0	-0.2	-0.2	0	0	0	0	0	-0.3	-1.5	-0.5	-1.6
Medicare Utilization as a Percent of Inpatient Days:														
0-25	445	1.3	0.2	0.1	0.3	-0.3	0	0	0	0	-0.2	-2.3	-0.5	-2.5
25-50	2,004	1.3	0	0	0.1	-0.1	0	0	0	0.1	-0.4	-0.9	-0.3	-0.7

	No. of Hospitals[1] (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment [2] (2)	Proposed FY 2015 Weights and DRG Changes with Application of Recalibration Budget Neutrality[3] (3)	Proposed FY 2015 Wage Data with Application of Wage Budget Neutrality[4] (4)	Proposed FY 2015 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality[5] (5)	Proposed FY 2015 MGCRB Reclassifications[6] (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality[7] (7)	Proposed Impact of the New OMB CBSA Designations [8] (8)	Proposed Application of the CBSA Transition Wage Index with Budget Neutrality [9] (9)	Proposed Application of the Frontier Wage Index and Out-Migration Adjustment[10] (10)	Proposed Hospital Readmissions Reduction Program[11] (11)	Proposed Changes to Medicare DSH[12] (12)	Proposed Implementation of the HAC Reduction Program [13] (13)	All Proposed FY 2015 Changes[14] (14)
50-65	718	1.4	-0.2	0	-0.2	0.7	0	0.2	0	0.1	-0.6	-0.5	-0.2	-0.1
Over 65	131	1.5	-0.6	0.1	-0.8	0.4	0	0	0	0.1	-0.7	-0.5	-0.2	-1.4
Proposed FY 2015 Reclassifications by the Medicare Geographic Classification Review Board:														
All Reclassified Hospitals	804	1.4	-0.1	0.1	0.1	1.8	0	0	0	0	-0.5	-0.8	-0.3	-0.6
Non-Reclassified Hospitals	2,584	1.3	0	0	0	-0.6	0	0.1	0	0.1	-0.4	-1.1	-0.3	-0.9
Urban Hospitals Reclassified	533	1.3	0	0.1	0.2	1.6	0.1	-0.1	0	0	-0.5	-0.9	-0.3	-0.7
Urban Nonreclassified Hospitals, FY 2015	1,965	1.3	0.1	-0.1	0.1	-0.7	0	0.1	0	0.1	-0.4	-1.1	-0.3	-0.9
All Rural Hospitals Reclassified FY 2015	271	1.7	-0.5	0.1	-0.4	2.9	-0.3	0	0	0	-0.5	-0.6	-0.2	0.2
Rural Nonreclassified Hospitals FY 2015	511	1.7	-0.8	0.1	-0.7	-0.1	-0.3	0	0	0.4	-0.4	-0.7	-0.2	-0.4
All Section 401 Reclassified Hospitals	48	1.7	-0.6	-0.1	-0.6	-0.9	-0.1	0	0	2.2	-0.3	-0.7	-0.1	0.2
Other Reclassified Hospitals (Section 1886(d)(8)(B))	66	1.4	-0.5	0.3	-0.1	3.5	-0.5	0.6	0.1	0.1	-0.5	-1.2	-0.1	-2.3
Specialty Hospitals														
Cardiac specialty Hospitals	15	1.3	0.9	0.3	1.2	-0.8	-0.1	0.1	-0.1	0.7	-0.1	-0.1	-0.1	1.7

[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 2013, and hospital cost report data are from reporting periods beginning in FY 2011 and FY 2010.
[2] This column displays the payment impact of the proposed hospital rate update and the proposed documentation and coding adjustment including the 2.1 percent adjustment to the national standardized amount (the estimated 2.7 percent market basket update reduced by the proposed 0.4 percentage point for the multifactor productivity adjustment and the 0.2 percentage point reduction under the Affordable Care Act) and the proposed 0.8 percent documentation and coding adjustment to the national standardized amount.
[3] This column displays the payment impact of the proposed changes to the Version 32.0 GROUPER, the changes to the relative weights and the proposed recalibration of the MS-DRG weights based on FY 2013 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 0.992938 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 2011 cost report data and the proposed new OMB labor market area delineations. This column displays the payment impact of the proposed application of 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 1.000578.
[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 0.993512 is the product of the proposed wage budget neutrality factor and the proposed recalibration budget neutrality factor.
[6] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB) along with the effects of the proposed adoption of the new OMB labor market area delineations on these reclassifications. The effects demonstrate the proposed FY 2015 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2015. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the proposed geographic budget neutrality factor of 0.991412.
[7] This column displays the effects of the proposed rural floor and imputed floor based on the proposed adoption of new OMB labor market area delineations. The Affordable Care Act requires the rural floor budget neutrality adjustment to be 100 percent national level adjustment. The proposed rural floor budget neutrality factor (which includes the imputed floor) applied to the wage index is 0.989455.
[8] This column displays the effects of the proposed adoption of the new OMB labor market area delineations. It does not reflect the proposed 3-year transition for hospitals that are currently located in urban counties that would become rural under the proposed new OMB delineations and the one-year transition to the new OMB delineations where the proposed wage indexes are blended such that hospitals receive 50 percent of their wage index based on the new OMB delineations, and 50 percent of their wage index based on their current labor market area. Rather, it shows the proposed impact if the new OMB delineations were to be fully implemented in FY 2015.
[9]. This column shows the effects of the proposal to apply both the 3-year transition for hospitals that are currently located in urban counties that would become rural under the proposed new OMB delineations, and the 50/50 blended wage index adjustments in a budget neutral manner. For FY 2015, we are proposing to apply both the 3-year transition and 50/50 blended wage index adjustments in a budget neutral manner, with a proposed budget neutrality factor of 0.998856 applied to the standardized amount.
[10] This column shows the combined impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0 and of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108-173, which provides for an increase in a hospital's

wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are nonbudget neutral policies.

[11] This column displays the impact of the implementation of the Hospital Readmissions Reduction Program, section 3025 of the Affordable Care Act, a nonbudget neutral provision that adjusts a hospital's payment for excess readmissions.

[12] This column displays the impact of the implementation of section 3133 of the Affordable Care Act that reduces Medicare DSH payments by 75 percent and establishes an additional uncompensated care payment.

[13] This column displays the impact of the implementation of the HAC Reduction Program, section 3008 of the Affordable Care Act, a nonbudget neutral provision that reduces total IPPS payments by 1 percent to hospitals ranked in the lowest quartile of performance on HAC rates.

[14] This column shows the proposed changes in payments from FY 2014 to FY 2015. It reflects the impact of the proposed FY 2015 hospital update and the proposed adjustment for documentation and coding. It also reflects proposed changes in hospitals' reclassification status in FY 2015 compared to FY 2014, and the extension of MDH payment status for the first half of FY 2015, under Public Law 113-93 enacted on April1, 2014. It incorporates all of the proposed changes displayed in Columns 2, 5, 6, 7, 8, 9, 10, 11, 12 and 13 (the proposed 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.

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 proposed 2.7 percent market basket update, the proposed reduction of 0.4 percentage point for the multifactor productivity adjustment, and the 0.2 percentage point reduction in accordance with the Affordable Care Act. In addition, this column includes the proposed FY 2015 documentation and coding recoupment adjustment of -0.8 percent on the national standardized amount as part of the recoupment required by section 631 of the ATRA. As a result, we are proposing to make a 1.3 percent update to the national standardized amount. This column also includes the proposed 2.1 percent update to the hospital-specific rates which also includes the proposed 2.7 percent market basket update, the proposed reduction of 0.4 percentage point for the multifactor productivity adjustment, and the 0.2 percentage point reduction in accordance with the Affordable Care Act.

Overall, hospitals would experience a 1.3 percent increase in payments primarily due to the effects of the hospital update and documentation and coding adjustment on the national standardized amount. Hospitals that are paid under the hospital-specific rate, namely SCHs, would experience a 2.1 percent increase in payments; therefore, hospital categories with SCHs paid under the hospital-specific rate would experience increases in payments of more than 1.3 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 proposed recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we are proposing to calculate a recalibration budget neutrality factor to account for the proposed changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this proposed rule, the FY 2015 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2015, the MS–DRGs are calculated using the FY 2013 MedPAR data grouped to the Version 32.0 (FY 2015) MS–DRGs. The proposed methodology to calculate the relative weights and the proposed 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 MS–DRGs and relative weights would result in a 0.0 percent change in payments with the application of the proposed recalibration budget neutrality factor of 0.992938 on to the standardized amount. Hospital categories that generally treat more surgical cases than medical cases would experience increases in their payments due to the changes to the relative weight methodology. Rural hospitals would experience a 0.6 percent decrease in payments because rural hospitals tend to treat fewer surgical cases than medical cases, while teaching hospitals with more than 100 residents would experience an increase in payments by 0.3 percent as those hospitals treat more surgical cases than medical cases.

c. Effects of the Proposed Wage Index Changes (Column 4)

Column 4 shows the impact of updated wage data using FY 2011 cost report data and the proposed new OMB labor market area delineations, with the application of the proposed wage budget neutrality factor. The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core Based Statistical Areas (CBSAs) established by OMB. The current statistical areas used in FY 2014 were based on OMB standards published on December 27, 2000 (65 FR 82228) and Census 2000 data and Census Bureau population estimates for 2007 and 2008 (OMB Bulletin No. 10–02).

As stated in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27552) and final rule (78 FR 50586), on February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. In order to implement these changes for the IPPS, it is necessary to identify the new labor market area delineation for each county and hospital in the country. However, because the bulletin was not issued until February 28, 2013, with supporting data not available until later, and because the changes made by the bulletin and their ramifications needed to be extensively reviewed and verified, we were unable to undertake such a lengthy process before publication of the FY 2014 IPPS/LTCH PPS proposed rule and, thus, did not implement changes to the wage index for FY 2014 based on these new OMB delineations. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50586), we stated that we intended to propose changes to the wage index based on the new OMB delineations in this FY 2015 proposed rule. As discussed below, in this proposed rule, we are proposing to implement the new OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13–01, effective beginning with the FY 2015 IPPS wage index.

Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the proposed wage index for acute care hospitals for FY 2015 is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2010 and before October 1, 2011. The estimated impact of the updated wage data using the FY 2011 cost report data and the proposed new OMB labor market area delineations on hospital payments is isolated in Column 4 by holding the other payment parameters constant in this simulation. That is, Column 4 shows the proposed percentage change in payments when going from a model using the FY 2014 wage index, based on FY 2010 wage data, the labor-related share of 69.6 percent, under the new OMB delineations and having a 100-percent occupational mix adjustment applied, to a model using the proposed FY 2015 pre-reclassification wage index based on FY 2011 wage data with the proposed labor-related share of 69.6 percent, under the new OMB delineations, also having a 100-percent occupational mix adjustment applied, while holding other payment parameters such as use of the Version 32.0 MS–DRG GROUPER constant). The FY 2015 occupational mix adjustment is based on the CY 2010 occupational mix survey.

In addition, the column shows the impact of the application of the proposed wage budget neutrality to the proposed national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage index changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2015, we are proposing to calculate the wage budget neutrality factor to ensure that payments under updated wage data and the proposed labor-related share of 69.6 percent are budget neutral without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1.0. In other words, the wage budget neutrality is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The proposed wage budget neutrality factor is 1.000578, and the overall payment change is zero percent.

Column 4 shows the impacts of updating the wage data using FY 2011 cost reports. Overall, the new wage data and the proposed labor-related share, combined with the proposed wage budget neutrality adjustment, would lead to a 0.0 percent change for all hospitals as shown in Column 4.

In looking at the wage data itself, the national average hourly wage increased 1.9 percent compared to FY 2014. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the national 1.9 percent increase in average hourly wage. Of the 3,373 hospitals with wage data for both FYs 2014 and 2015, 1,644 or 48.7 percent would experience an average hourly wage increase of 1.9 percent or more.

The following chart compares the shifts in proposed wage index values for hospitals due to changes in the average hourly wage data for FY 2015 relative to FY 2014. Among urban hospitals, 11 would experience a decrease of more than 10 percent, with no urban hospital experiencing an increase of

more than 10 percent. One hundred twenty-one urban hospitals would experience an increase or decrease of at least 5 percent or more but less than or equal to 10 percent. Among rural hospitals, none would experience a decrease of more than 5 percent, but 5 rural hospitals would experience an increase of greater than 5 percent but less than or equal to10 percent. However, 803 rural hospitals would experience increases or decreases of less than or equal to 5 percent, while 2,325 urban hospitals would experience increases or decreases of less than or equal to 5 percent. One hundred eight urban and rural hospitals would not experience a change in their wage index. These figures reflect proposed changes in the ''pre-reclassified, occupational mix-adjusted wage index,'' that is, the proposed wage index before the proposed application of geographic reclassification, the proposed rural and imputed floors, the proposed out-migration adjustment, and other proposed wage index exceptions and adjustments. We note that this analysis was performed by applying the new OMB labor market area delineations to the FY 2015 proposed wage data and also by recomputing the FY 2014 final wage data to reflect the new OMB delineations. (We refer readers to sections III.G.2. through III.I. of the preamble of this proposed rule for a complete discussion of the exceptions and adjustments to the wage index.) We note that the proposed ''post-reclassified wage index'' or ''payment wage index,'' the proposed wage index that includes all such exceptions and adjustments (as reflected in Tables 2, 4A, 4B, 4C, and 4F of the Addendum to this proposed rule, which are available via the Internet on the CMS Web site) is used to adjust the proposed labor-related share of a hospital's standardized amount, either 69.6 percent or 62 percent, depending upon whether a hospital's wage index is greater than 1.0 or less than or equal to 1.0. Therefore, the proposed pre-reclassified wage index figures in the chart below may illustrate a somewhat larger or smaller change than would occur in a hospital's payment wage index and total payment.

The following chart shows the projected impact of changes in the average hourly wage data for urban and rural hospitals.

Percentage change in proposed area wage index values	Number of hospitals	
	Urban	Rural
Increase more than 10 percent	0	0
Increase more than 5 percent and less than or equal to 10 percent	29	5
Increase or decrease less than or equal to 5 percent	2,325	803
Decrease more than 5 percent and less than or equal to 10 percent	92	0
Decrease more than 10 percent	11	0
Unchanged	76	32

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 1.000578 and a proposed recalibration budget neutrality factor of 0.992938 (which is applied to the Puerto Rico-specific standardized amount and the hospital-specific rates). The product of the two proposed budget neutrality factors is the proposed cumulative wage and recalibration budget neutrality factor. The proposed cumulative wage and recalibration budget neutrality adjustment is 0.993512, or approximately 0.65 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 would result in a 0.0 percent change in payments.

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 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 2015 and the effects of the proposed adoption of the new OMB labor market area delineations on these reclassifications 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 proposed 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 purposes of this impact analysis, we are proposing to apply an adjustment of 0.991412 to ensure that the effects of the reclassifications under section 1886(d)(10) of the Act 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 geographic reclassification would increase payments to rural hospitals by an average of 1.8 percent. By region, all the rural hospital categories would experience increases in payments due to MGCRB reclassifications.

Table 9A listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site reflects the reclassifications for FY 2015.

f. Effects of the Proposed Rural and Imputed Floor, Including Application of Proposed 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 FYs 2011, 2012, 2013 and 2014 IPPS/LTCH PPS final rules, 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. The imputed floor, which is also included in the calculation of the budget neutrality adjustment to the wage index, was extended in FY 2012 for 2 additional years. In the past, only urban hospitals in New Jersey received the imputed floor. As discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53369), we established an alternative temporary methodology for the imputed floor, which resulted in an imputed floor for Rhode Island for FY 2013. For FY 2014, we extended the imputed rural floor, as calculated under the original methodology and the alternative methodology. For FY 2015, we are proposing to extend the imputed rural floor, as calculated under the original methodology and the alternative methodology. As a result, under this proposal, New Jersey, Rhode Island, and Delaware would receive an imputed floor, with 12 out of 64 hospitals in New Jersey receiving the imputed floor, 1 out of 6 hospitals in Delaware receiving the imputed floor and 4 out of 11 hospitals in Rhode Island receiving the imputed floor.

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. We have calculated a proposed FY 2015 rural floor budget neutrality factor to be applied to the wage index of 0.989455, which would reduce wage indexes by 1.1 percent.

Column 7 shows the projected impact of the proposed rural floor and imputed floor with the proposed national rural floor budget neutrality factor applied to the wage index based on the proposed new OMB labor market area delineations. The column compares the proposed post-reclassification FY 2015 wage index of providers before the rural floor and imputed floor adjustment and the proposed post-reclassification FY 2015 wage index of providers with the proposed rural floor and imputed floor adjustment based on the proposed new OMB labor market area delineations. Only urban

hospitals can benefit from the rural and imputed floors. Because the provision is budget neutral, all other hospitals (that is, all rural hospitals and those urban hospitals to which the adjustment is not made) would experience a decrease in payments due to the proposed budget neutrality adjustment that is applied nationally to their wage index.

We estimate that 441 hospitals benefit from the proposed rural and imputed floors while the remaining 2,947 IPPS hospitals in our model have their wage index reduced by the proposed rural floor budget neutrality adjustment of 0.989455 (or 1.1 percent). We project that, in aggregate, rural hospitals would experience a 0.3 percent decrease in payments as a result of the application of the proposed rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project hospitals located in urban areas would experience no change in payments because increases in payments by hospitals benefitting from the rural floor offset decreases in payments by nonrural floor urban hospitals whose wage index is downwardly adjusted by the proposed rural floor budget neutrality factor. Urban hospitals in the New England region can expect a 2.7 percent increase in payments primarily due to the application of the proposed rural floor in Massachusetts and Connecticut. Fifty-one urban providers in Massachusetts are expected to receive the proposed rural floor wage index value, including proposed rural floor budget neutrality, of 1.3383, increasing payments overall to Massachusetts by an estimated $158 million. 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, for the FY 2012 wage index, the rural floor for Massachusetts was established by the conversion of a CAH to an IPPS hospital that is geographically located in rural Massachusetts. The rural floor in Massachusetts continues to be set by the wage index of the hospital in rural Massachusetts that converted from CAH to IPPS status. We estimate that Massachusetts hospitals would receive approximately a 4.9 percent increase in IPPS payments due to the application of the rural floor in FY 2015.

Urban Puerto Rico hospitals are expected to experience a 0.0 percent change in payments as a result of the application of a proposed Puerto Rico rural floor with the application of the proposed Puerto Rico rural floor budget neutrality adjustment. We are proposing to apply a rural floor budget neutrality factor to the Puerto Rico-specific wage index of 0.991359 or −0.86 percent. The Puerto Rico-specific wage index adjusts the Puerto Rico-specific standardized amount, which represents 25 percent of payments to Puerto Rico hospitals. The increases in payments experienced by the urban Puerto Rico hospitals that benefit from a rural floor are offset by the decreases in payments by the nonrural floor urban Puerto Rico hospitals that have their wage indexes downwardly adjusted by the proposed rural floor budget neutrality adjustment. As a result, overall, urban Puerto Rico hospitals would experience a 0.0 percent change in payments due to the application of the proposed rural floor with rural floor budget neutrality.

There are 12 hospitals out of the 64 hospitals in New Jersey that benefit from the extension of the proposed imputed floor and would receive the proposed imputed floor wage index value under the new OMB labor market area delineations, including the proposed rural floor budget neutrality, of 1.0986 which we estimate would increase payments to those imputed floor hospitals by $17 million (the State, overall, would see a decrease in payments of approximately $5 million due the other hospitals in the State experiencing decreases in payments due to the rural floor budget neutrality adjustment). Four Rhode Island hospitals would benefit from the proposed imputed rural floor calculated under the alternative methodology and receive an additional $3.5 million (the State, overall, would receive an additional $1.6 million). One hospital in Delaware would benefit from the extension of the proposed imputed floor and would receive the proposed imputed floor wage index value under the new OMB labor market area delineations, and would receive an additional $25,000 (the State, overall, would experience a decrease in payments of $2.3 million).

In response to a public comment addressed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593), we are providing the payment impact of the proposed 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 proposed rural floor or imputed floor wage index for FY 2015 based on the proposed new OMB labor market area delineations. 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 based on the proposed new OMB labor market area delineations. The column compares the proposed post-reclassification FY 2015 wage index of providers before the proposed rural floor and imputed floor adjustment and the proposed post-reclassification FY 2015 wage index of providers with the proposed rural floor and imputed floor adjustment with the wage indexes calculated based on the proposed new OMB labor market area delineations. Column 4 displays the estimated payment amount that each State would gain or lose due to the application of the proposed rural floor and imputed floor with national budget neutrality. We will update our State-by-State rural floor budget neutrality impact analysis for the FY 2015 IPPS/LTCH PPS final rule.

FY 2015 IPPS Proposed Estimated Payments Due to Proposed Rural Floor and Imputed Floor With National Budget Neutrality

State	Number of hospitals (1)	Number of hospitals that would receive the proposed rural floor or imputed floor (2)	Percent change in payments due to application of proposed rural floor and imputed floor with budget neutrality (3)	Difference (in millions) (4)
Alabama	91	2	−0.5	−$8.5
Alaska	6	4	1.8	2.6
Arizona	56	8	−0.1	−2.3
Arkansas	45	0	−0.5	−5.4
California	308	184	2	196.3
Colorado	46	5	−0.1	−1.0
Connecticut	31	8	−0.3	−4.6
Delaware	6	1	−0.5	−2.3
Washington, DC	7	0	−0.6	−2.7
Florida	168	25	−0.3	−19.9
Georgia	106	0	−0.5	−13.1
Hawaii	12	1	−0.4	−1.2
Idaho	14	0	−0.4	−1.3

FY 2015 IPPS PROPOSED ESTIMATED PAYMENTS DUE TO PROPOSED RURAL FLOOR AND IMPUTED FLOOR WITH NATIONAL BUDGET NEUTRALITY—Continued

State	Number of hospitals (1)	Number of hospitals that would receive the proposed rural floor or imputed floor (2)	Percent change in payments due to application of proposed rural floor and imputed floor with budget neutrality (3)	Difference (in millions) (4)
Illinois	127	0	−0.6	−28.5
Indiana	91	5	−0.6	−13.1
Iowa	34	0	−0.3	−3.2
Kansas	53	0	−0.4	−4.1
Kentucky	65	1	−0.5	−7.9
Louisiana	100	3	−0.5	−7.0
Maine	20	0	−0.5	−2.5
Massachusetts	61	51	4.9	157.8
Michigan	95	0	−0.6	−24.1
Minnesota	51	0	−0.6	−10.4
Mississippi	64	0	−0.5	−5.5
Missouri	78	0	−0.5	−11.7
Montana	12	4	−0.3	−0.9
Nebraska	23	0	−0.5	−2.8
Nevada	24	19	1.6	10.9
New Hampshire	13	9	0.4	1.8
New Jersey	64	12	−0.1	−5.0
New Mexico	25	0	−0.4	−1.7
New York	163	0	−0.6	−48.9
North Carolina	87	0	−0.5	−16.7
North Dakota	6	1	−0.3	−0.8
Ohio	134	11	−0.5	−17.6
Oklahoma	86	2	−0.5	−5.8
Oregon	33	0	−0.6	−5.0
Pennsylvania	154	10	−0.5	−22.2
Puerto Rico	52	11	0	−0.1
Rhode Island	11	4	0.4	1.6
South Carolina	55	12	−0.1	−0.9
South Dakota	19	0	−0.4	−1.2
Tennessee	98	21	−0.3	−6.0
Texas	322	13	−0.5	−31.9
Utah	32	2	−0.5	−2.3
Vermont	6	0	−0.4	−0.8
Virginia	79	1	−0.5	−12.4
Washington	49	8	−0.2	−3.0
West Virginia	30	2	−0.4	−3.3
Wisconsin	65	1	−0.5	−8.8
Wyoming	11	0	−0.3	−0.4

g. Proposed Impact of the New OMB Delineations (Column 8)

Column 8 shows the effects of the proposed new OMB labor market area delineations. This column compares the payments under the proposed rural and imputed floor wage index with rural floor budget neutrality calculated under the new OMB delineations and the payments under the proposed rural and imputed floor wage index with budget neutrality calculated under the current OMB delineations. It does not reflect the proposed 3-year transition for hospitals that are currently located in urban counties that would become rural under the new OMB delineations and the 1-year transition to the new OMB delineations where the wage indexes are blended such that hospitals receive 50 percent of their wage index based on the new OMB delineations, and 50 percent of their wage index based on their current labor market area. Rather, it shows the proposed impact if the new OMB delineations were to be fully implemented for FY 2015. Approximately 666 hospitals have their wage index impacted due to the new OMB delineations. Urban and rural Middle Atlantic hospitals would experience the largest decreases in payments if the new OMB delineations were fully implemented for FY 2015, with payment decreases of 0.4 and 0.3 percent, respectively. Rural New England hospitals and Lugar hospitals would experience the largest increases in payments if the new OMB delineations were fully implemented for FY 2015 with payment increases of 0.4 percent and 0.6 percent, respectively.

h. Proposed Application of the CBSA Transition Wage Index With Budget Neutrality (Column 9)

As discussed earlier in this proposed rule, for FY 2015, we are proposing to use the most recent labor market area delineations issued by OMB but are proposing a transition period in certain circumstances. Specifically, we are proposing a 3-year transition for hospitals that are currently located in an urban county that would become rural under the new OMB labor market area delineations under which such hospitals would be assigned the urban wage index value of the CBSA in which they are physically located for FY 2014 for a period of 3 fiscal years (that is, for FYs 2015, 2016, and 2017). We also are proposing a 1-year blended wage index for all hospitals that would experience any decrease in their actual payment wage index (that is, a hospital's actual wage index used for payment, which accounts for all applicable effects of reclassification and redesignation) exclusively due to the proposed implementation of the new OMB labor market area delineations. We are proposing that a post-reclassified wage index with the rural and imputed floor applied would be

computed based on the hospital's FY 2014 CBSA (that is, using all of its FY 2014 constituent county/ies), and another post-reclassified wage index with the rural and imputed floor applied would be computed based on the hospital's new FY 2015 CBSA (that is, the FY 2015 constituent county/ies). We are proposing to compare these two wage indexes. If the proposed FY 2015 wage index with FY 2015 CBSAs would be lower than the proposed FY 2015 wage index with FY 2014 CBSAs, we are proposing that a blended wage index would be computed, consisting of 50 percent of each of the two wage indexes added together. We are proposing that this blended wage index would be the hospital's wage index for FY 2015. This proposed adjustment would only apply to hospitals that would experience a drop in their actual payment wage index exclusively due to the proposed implementation of the new OMB labor market area delineations. Hospitals that benefit from the new OMB labor market area delineations would receive their new wage index based on the new OMB labor market area delineations. We refer readers to section III.B. of the preamble to this proposed rule for a complete discussion on the transition wage indexes. Lastly, we are proposing to apply both the 3-year transition and 50/50 blended wage index adjustments in a budget neutral manner. We are proposing to make an adjustment to the standardized amount to ensure that the total payments, including the effect of the transition provisions, would equal what payments would have been if we would not be providing for these transitional wage indexes.

Column 9 shows the effects of the proposed adoption of the new OMB labor market area delineations, including the 3-year hold harmless provision for hospitals that are currently located in an urban county that would become rural under the new OMB delineations and the proposed 1-year transition to the new OMB delineations where the wage indexes are blended such that hospitals receive 50 percent of their wage index based on the new OMB delineations and 50 percent of their wage index based on their current labor market area. For FY 2015, we are proposing to apply both the 3-year transition and 50/50 blended wage index adjustments in a budget neutral manner, with a proposed budget neutrality factor of 0.998856 (or −0.1 percent) applied to the standardized amount to ensure that the total payments, including the effect of the transition provisions, would equal what payments would have been if we would not be providing for these transitional wage indexes. This column shows the payment impact of the proposed transitional wage index. For columns 1 through 8, the payment impacts and budget neutrality factors have been calculated under the new OMB labor market area delineations. Under the proposed 1-year transition to the new OMB delineations, hospitals that would have experienced a decrease in payments if the new OMB delineations had been fully implemented this year now would have those decreases alleviated due to the transition. Urban Middle Atlantic hospitals would experience a 0.4 percent increase in payments due to the proposed application of the transitional wage index with budget neutrality, while urban New England, South Atlantic, East North Central, West North Central, West South Central, Mountain and Pacific hospitals would experience a −0.1 percent change in payments due to the proposed transitional budget neutrality adjustment of −0.1 percent applied to the standard Federal rate.

i. Effects of the Application of the Proposed Frontier State Wage Index and Out-Migration Adjustment (Column 8)

This column shows the combined effects of the application of section 10324(a) of Affordable Care Act which requires that we establish a minimum post-reclassified wage-index of 1.00 for all hospitals located in ''frontier States,'' and the effects of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. These two wage index provisions are not budget neutral and increase payments overall by 0.1 percent compared to the provisions not being in effect.

The term ''frontier States'' is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, four States (Montana, North Dakota, South Dakota, and Wyoming) are considered frontier States and 46 hospitals located in those States will receive a frontier wage index of 1.0000. Nevada is also, by definition, a frontier State and was assigned a frontier floor value of 1.0000 for FY 2012, but since then and including in this proposed rule, its rural floor value has been greater than 1.0000 so it has not been subject to the frontier wage index. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $65 million or approximately 0.1 percent. Rural hospitals located in the Mountain region and urban hospitals located in the West North Central region would experience an increase in payments by 0.9 and 0.8 percent, respectively, because many of the hospitals located in this region are frontier State hospitals.

In addition, section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment 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. There are an estimated 244 providers that would receive the proposed out-migration wage adjustment in FY 2015. Rural hospitals generally qualify for the adjustment, resulting in a 0.2 percent increase in payments. This provision appears to benefit rural Middle Atlantic hospitals most in that they would experience a 0.2 percent increase in payments. This out-migration wage adjustment is also not budget neutral, and we estimate the impact of these providers receiving the out-migration increase to be approximately $47 million.

j. Effects of the Proposed Reductions Under the Hospital Readmissions Reduction Program (Column 11)

Column 11 shows our estimates of the effects of the proposed policies for reductions in payments under 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 for FY 2015, is based on a hospital's risk-adjusted readmission rate during a 3-year period for five applicable conditions: acute myocardial infarction, heart failure, pneumonia, total hip and total knee arthroplasty and chronic obstructive pulmonary disease. 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 the statute as 0.97 (or a 3.0 percent reduction) for FY 2015. A hospital's base operating DRG payment (that is, wage-adjusted DRG payment amount, as discussed in section IV.G. 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 2,623 hospitals would have their base operating DRG payments reduced by their hospital-specific readmissions adjustment, an increase from FY 2014, due to the proposed addition of new readmissions measures in the program. As a result, we estimate that the Hospital Readmissions Reduction Program would result in a 0.4 percent decrease, or approximately $422 million, in payments to hospitals overall for FY 2015 relative to no provision. We estimate that the Hospital Readmissions Reduction Program would result in a 0.2 percent decrease in payments relative to FY 2014.

Rural West South Central hospitals and hospitals with high Medicare utilization would experience the highest decreases of 0.8 and 0.7 percent, respectively. Puerto Rico hospitals would show a 0 percent change in payments because they are exempt from the provision.

k. Effects of the Proposed Changes to Medicare DSH Payments (Column 12)

Column 12 shows the effects of the proposed adjustments to Medicare DSH payments made under section 3133 of the Affordable Care Act. Under section 3133, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the former statutory formula for Medicare DSH payments. The remainder,

equal to an estimate of 75 percent of what otherwise formerly would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under age 65 who are uninsured and additional statutory adjustments, is available to make additional payments to each hospital that qualifies for Medicare DSH payments. Each Medicare DSH hospital will receive an additional payment based on its estimated share of the total amount of uncompensated care for all Medicare DSH hospitals. The reduction to Medicare DSH payments is not budget neutral.

For FY 2015, we are proposing that the amount to be distributed on the basis of uncompensated care, which is 75 percent of our estimate of what otherwise would have been paid in Medicare DSH payments (that is, Factor 1), be adjusted to 80.36 percent of that amount to reflect changes in the percentage of individuals under age 65 who are uninsured and additional statutory adjustments (that is, Factor 1 multiplied by Factor 2). For FY 2014, the uncompensated care payment was 75 percent of what otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 94.3 percent. Assuming DSH payments are constant, the proposed FY 2015 uncompensated care amount is approximately 10 percentage points less than the uncompensated care amount that we distributed for FY 2014. As a result, we project that compared to the empirically justified DSH payments and the uncompensated care payments made last year payments for FY 2015 would be reduced overall by 1.0 percent as compared to Medicare DSH payments made last year under the first year of the implementation of section 3133 of the Affordable Care Act. The proposed uncompensated care payment methodology has redistributive effects based on a Medicare DSH hospital's low income insured patient days (sum of Medicaid patient days and Medicare SSI patient days) relative to the Medicaid patient days and Medicare SSI patient days for Medicare DSH hospitals, and the payment amount is not tied to a hospital's discharges.

Urban Pacific hospitals would experience no change in DSH and uncompensated care payments relative to last year. Hospitals with low Medicare utilization (Medicare days are less than 25 percent of total inpatient day) would experience the largest decreases in payments compared to last year of −2.3 percent.

l. Effects of the Proposed Reductions Under the HAC Reduction Program (Column 13)

Column 13 shows the estimated effects of the proposed policies for reductions in payments under the HAC Reduction Program, established under section 3008 of the Affordable Care Act. Section 1886(p) of the Act, as added under section 3008(a) of the Affordable Care Act, establishes an adjustment to hospital payments for HACs effective for discharges beginning on October 1, 2014, and for subsequent program years. Beginning in FY 2015, hospitals scoring in the top quartile for the rate of HAC rate as compared to the national average will have their IPPS payments reduced by 1 percent for all discharges in that Federal fiscal year. We estimate that, under this proposal, 753 hospitals would be subject to the 1-percent reduction, and that overall payments would decrease approximately 0.3 percent or $330 million.

Government hospitals and teaching hospitals with more than 100 residents would experience the biggest decrease in payments under the HAC Reduction Program of −0.5 percent. Twenty-six percent of the government hospitals are estimated to be subject to the HAC reduction, while 53 percent of teaching hospitals with more than 100 residents are estimated to be subject to the HAC reduction for FY 2015. Puerto Rico hospitals are not included in the HAC Reduction Program; therefore, those hospitals would not experience a change in payments.

m. Effects of All Proposed FY 2015 Changes (Column 14)

Column 14 shows our estimate of the changes in payments per discharge from FY 2014 and FY 2015, resulting from all proposed changes reflected in this proposed rule for FY 2015. It includes combined effects of the previous columns in the table.

The proposed average decrease in payments under the IPPS for all hospitals is approximately 0.8 percent for FY 2015 relative to FY 2014. As discussed in section II.D. of the preamble of this proposed rule, this column includes the proposed FY 2015 documentation and coding recoupment adjustment of -0.8 percent on the national standardized amount as part of the recoupment required under section 631 of the ATRA. 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 proposed 2.7 percent market basket update, the proposed reduction of 0.4 percentage point for the multifactor productivity adjustment, and the 0.2 percentage point reduction under section 3401 of the Affordable Care Act. As described in Column 2, the proposed annual hospital update combined with the proposed documentation and coding recoupment adjustment would result in a 1.3 percent increase in payments in FY 2015 relative to FY 2014. Column 11 shows the estimated 0.4 percent decrease in payments due to the proposed reductions in payments under 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, which is an additional 0.2 percent decrease in payments under the Hospital Readmissions Reduction Program relative to FY 2014. Column 12 shows the estimated 1.0 percent decrease in Medicare DSH payments due to the changes made under section 3133 of the Affordable Care Act, which reduces Medicare DSH payments by 75 percent and redistributes the remainder, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under age 65 who are uninsured, to each hospital that qualifies for Medicare DSH payments as an uncompensated care payment based on the hospital's relative share of the total amount of uncompensated care. Column 13 shows the impact of the implementation of the HAC Reduction Program which would reduce payments by 0.3 percent overall. The impact of moving from our estimate of FY 2014 outlier payments, 5.79 percent, to the estimate of FY 2015 outlier payments, 5.1 percent, would result in a decrease of 0.7 percent in FY 2015 payments relative to FY 2014. Lastly, this column reflects the extension of MDH payment status for the first half of FY 2015, under Public Law 113–93, enacted on April 1, 2014. There also might 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 14 may not equal the sum of the estimated percentage changes described above.

Overall payments to hospitals paid under the IPPS are estimated to decrease by 0.8 percent for FY 2015. Much of the payment changes among the hospital categories is attributed to the proposed reduction in Medicare DSH payments and the redistribution of a portion of the Medicare DSH payments as an additional payment for hospitals' relative uncompensated care amounts. Hospitals in urban areas would experience a 0.9 percent decrease in payments per discharge in FY 2015 compared to FY 2014. Hospital payments per discharge in rural areas are estimated to decrease by 0.2 percent in FY 2015 due to lesser reductions in Medicare DSH and estimated outlier payments.

3. Impact Analysis of Table II

Table II presents the projected impact of the proposed changes for FY 2015 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2014 with the average payments per discharge for FY 2015, as calculated under our models. Therefore, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the proposed changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 14 of Table I.

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2015 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM

[Payments per discharge]

	Number of hospitals (1)	Estimated average FY 2014 payment per discharge (2)	Proposed estimated average FY 2015 payment per discharge (3)	All proposed FY 2015 changes (4)
All Hospitals	3,388	11,237	11,146	−0.8
By Geographic Location:				
Urban hospitals	2,542	11,629	11,529	−0.9
Large urban areas	1,395	12,398	12,285	−0.9
Other urban areas	1,147	10,696	10,611	−0.8
Rural hospitals	846	8,089	8,073	−0.2
Bed Size (Urban):				
0–99 beds	655	9,026	8,980	−0.5
100–199 beds	788	9,728	9,654	−0.8
200–299 beds	469	10,517	10,466	−0.5
300–499 beds	417	11,998	11,896	−0.9
500 or more beds	213	14,330	14,157	−1.2
Bed Size (Rural):				
0–49 beds	325	6,614	6,562	−0.8
50–99 beds	298	7,599	7,523	−1
100–149 beds	136	7,951	7,976	0.3
150–199 beds	50	8,898	8,891	−0.1
200 or more beds	37	9,850	9,913	0.6
Urban by Region:				
New England	120	12,805	12,699	−0.8
Middle Atlantic	324	12,927	12,855	−0.6
South Atlantic	406	10,454	10,339	−1.1
East North Central	397	10,856	10,748	−1
East South Central	153	10,086	9,935	−1.5
West North Central	162	11,373	11,321	−0.5
West South Central	385	10,670	10,522	−1.4
Mountain	159	11,891	11,797	−0.8
Pacific	384	14,704	14,673	−0.2
Puerto Rico	52	8,194	7,606	−7.2
Rural by Region:				
New England	22	11,024	11,000	−0.2
Middle Atlantic	57	8,118	8,070	−0.6
South Atlantic	132	7,714	7,666	−0.6
East North Central	115	8,263	8,315	0.6
East South Central	165	7,483	7,397	−1.1
West North Central	102	8,626	8,729	1.2
West South Central	168	7,064	6,931	−1.9
Mountain	61	9,111	9,245	1.5
Pacific	24	10,697	10,952	2.4
By Payment Classification:				
Urban hospitals	2,558	11,615	11,513	−0.9
Large urban areas	1,408	12,387	12,273	−0.9
Other urban areas	1,150	10,669	10,582	−0.8
Rural areas	830	8,270	8,270	0
Teaching Status:				
Nonteaching	2,352	9,312	9,262	−0.5
Fewer than 100 residents	792	10,966	10,891	−0.7
100 or more residents	244	16,538	16,317	−1.3
Urban DSH:				
Non-DSH	682	9,870	9,899	0.3
100 or more beds	1,591	12,067	11,939	−1.1
Less than 100 beds	366	8,354	8,247	−1.3
Rural DSH:				
SCH	388	7,587	7,597	0.1
RRC	212	9,035	9,057	0.2
100 or more beds	24	7,422	7,323	−1.3
Less than 100 beds	125	6,339	6,261	−1.2
Urban teaching and DSH:				
Both teaching and DSH	842	13,293	13,137	−1.2
Teaching and no DSH	133	11,107	11,166	0.5
No teaching and DSH	1,115	9,774	9,692	−0.8
No teaching and no DSH	468	9,287	9,308	0.2
Special Hospital Types:				

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2015 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued

[Payments per discharge]

	Number of hospitals (1)	Estimated average FY 2014 payment per discharge (2)	Proposed estimated average FY 2015 payment per discharge (3)	All proposed FY 2015 changes (4)
RRC	208	9,507	9,413	−1
SCH	324	8,856	9,035	2
MDH	154	6,800	6,485	−4.6
SCH and RRC	124	9,933	10,149	2.2
MDH and RRC	11	8,122	7,641	−5.9
Type of Ownership:				
Voluntary	1,925	11,370	11,296	−0.7
Proprietary	883	10,009	9,930	−0.8
Government	540	12,259	12,058	−1.6
Medicare Utilization as a Percent of Inpatient Days:				
0–25	445	15,819	15,431	−2.5
25–50	2,004	11,358	11,281	−0.7
50–65	718	9,019	9,005	−0.1
Over 65	131	7,424	7,317	−1.4
FY 2015 Reclassifications by the Medicare Geographic Classification Review Board:				
All Reclassified Hospitals	804	10,955	10,894	−0.6
Non-Reclassified Hospitals	2,584	11,344	11,242	−0.9
Urban Hospitals Reclassified	533	11,600	11,518	−0.7
Urban Nonreclassified Hospitals, FY 2015	1,965	11,664	11,557	−0.9
All Rural Hospitals Reclassified FY 2015	271	8,572	8,589	0.2
Rural Nonreclassified Hospitals FY 2015	511	7,511	7,483	−0.4
All Section 401 Reclassified Hospitals	48	9,810	9,825	0.2
Other Reclassified Hospitals (Section 1886(d)(8)(B))	66	7,724	7,543	−2.3
Specialty Hospitals:				
Cardiac Specialty Hospitals	15	12,351	12,561	1.7

H. Effects of Other Proposed Policy Changes

In addition to those proposed policy changes discussed above that we are able to model using our IPPS payment simulation model, we are proposing to make various other changes in this proposed rule. Generally, we have limited or no specific data available with which to estimate the impacts of these proposed changes. Our estimates of the likely impacts associated with these other proposed changes are discussed below.

1. Effects of Proposed Policy on MS–DRGs for Preventable 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.

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 2015	$28
FY 2016	30
FY 2017	33
FY 2018	36
FY 2019	38

In section IV.J. of the preamble of this proposed rule, we are proposing changes to the HAC Reduction Program for FY 2015. We refer readers to section I.H.6. of this Appendix A for a discussion of the impact of these proposed changes.

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 six applications for add-on payments for new

medical services and technologies for FY 2015, as well as the status of the new technologies that were approved to receive new technology add-on payments in FY 2014. As explained in the preamble to this proposed rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.I.4. of the preamble of this proposed rule, we have not yet determined whether any of the six applications we received for consideration for new technology add-on payments for FY 2015 will meet the specified criteria. Consequently, it is premature to estimate the potential payment impact of these six applications for any potential new technology add-on payments for FY 2015. We note that if any of the six applications are found to be eligible for new technology add-on payments for FY 2015, in the FY 2015 IPPS/LTCH PPS final rule, we would discuss the estimated payment impact for FY 2015.

In the preamble of this proposed rule, we are proposing to discontinue new technology add-on payments for DIFICID™ for FY 2015 because the technology will have been on the U.S. market for 3 years. We also are proposing to continue making new technology add-on payments for Voraxaze®, the Zenith® F.Graft, Kcentra™, the Argus® II Retinal Prosthesis System, and Zilver® PTX® Drug Eluting Peripheral Stent in FY 2015 because these technologies are still considered new. We note that new technology add-on payments per case are limited to the lesser of (1) 50 percent of the costs of the new technology or (2) 50 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case. Because it is difficult to predict the actual new technology add-on payment for each case, our estimates below are based on the increase in add-on payments for FY 2015 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment. For Voraxaze®, based on the applicant's estimate from FY 2013, we currently estimate that new technology add-on payments for Voraxaze® will increase overall FY 2015 payments by $6,300,000. For the Zenith® F. Graft, based on the applicant's estimate from FY 2013, we currently estimate that new technology add-on payments for the Zenith® F. Graft will increase overall FY 2014 payments by $4,085,750. For Kcentra™, based on the applicant's estimate from FY 2014, we currently estimate that new technology add-on payments for Kcentra™ will increase overall FY 2015 payments by $5,449,888. For the Argus® II Retinal Prosthesis System, based on the applicant's estimate from FY 2014, we currently estimate that new technology add-on payments for the Argus® II Retinal Prosthesis System will increase overall FY 2015 payments by $3,601,437. For the Zilver® PTX® Drug Eluting Peripheral Stent, based on the applicant's estimate from FY 2014, we currently estimate that new technology add-on payments for the Zilver® PTX® Drug Eluting Peripheral Stent will increase overall FY 2015 payments by $20,463,000.

3. Effects of Proposed Changes to List of MS–DRGs Subject to Postacute Care Transfer and DRG Special Pay Policy

In section IV.A. of the preamble of this proposed rule, we discuss proposed changes to the list of MS–DRGs subject to the postacute care transfer and DRG special payment policies. As reflected in Table 5 listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site, using criteria set forth in regulation at § 412.4, we evaluated MS–DRG charge, discharge, and transfer data to determine which MS–DRGs qualify for the postacute care transfer and DRG special pay policies. We note that we are making no proposal to change these payment policies in this FY 2015 proposed rule. We are proposing to change the status of certain MS–DRGs as a result of proposals to revise the MS–DRGs for FY 2015. We are proposing to change the status of five MS–DRGs to qualify for the postacute care transfer policy in FY 2015. One additional MS–DRG that qualified under the policy in FY 2014 does not qualify in FY 2015, and we are proposing to change the status accordingly. Finally, five MS–DRGs now qualify for the MS–DRG special pay policy in FY 2015 after not qualifying in FY 2014, and we are proposing to add them to the list of qualifying MS–DRGs. Column 4 of Table I in this Appendix A shows the effects of the proposed changes to the MS–DRGs and relative payment weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. The analysis and methods determining the proposed changes due to the MS–DRGs and relative payment weights accounts for and includes changes in MS–DRG postacute care transfer and special pay policy statuses. We refer readers to section I.G. of this Appendix for a more detailed discussion of payment impacts due to MS–DRG reclassification policies.

4. Effects of the Proposed Payment Adjustment for Low-Volume Hospitals for FY 2015

In section V.D. of the preamble to this proposed rule, we discuss the provisions of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) that extends for an additional year, through March 31, 2015, the temporary changes to the low-volume hospital definition and the methodology for determining the payment adjustment made by the Affordable Care Act for FYs 2011 and 2012, and extended through FY 2013 by the ATRA, and the first half of FY 2014 by the Pathway for SGR Reform Act (Pub. L. 113–67). Therefore, to qualify for the low-volume hospital payment adjustment for FY 2015 discharges occurring before April 1, 2015 under section 1886(d)(12) of the Act, a hospital must have less than 1,600 Medicare discharges and be located more than 15 miles from other IPPS hospitals. The payment adjustment for eligible low-volume hospital FY 2015 discharges occurring before April 1, 2015 is a continuous, linear sliding scale adjustment ranging from an additional 25 percent payment adjustment to qualifying hospitals with 200 or fewer Medicare discharges to no additional payment to hospitals with 1,600 or more Medicare discharges.

Beginning with FY 2015 discharges occurring on or after April 1, 2015, in accordance with section 1886(d)(12) of the Act, the low-volume hospital definition and payment adjustment methodology revert back to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act as amended by subsequent legislation. Therefore, effective for FY 2015 discharges occurring on or after April 1, 2015 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.

Based on FY 2013 claims data (December 2013 update of the MedPAR file), we estimate that approximately 600 hospitals will qualify as a low-volume hospital in FY 2014 and in FY 2015 for discharges occurring before April 1, 2015. With the statutory changes to the low-volume hospital payment adjustment, for FY 2015 discharges occurring on or after April 1, 2015, we estimate only approximately six hospitals will continue to qualify as a low-volume hospital. We project that the expiration of the temporary changes to the low-volume hospital definition and the payment adjustment methodology originally made by the Affordable Care Act and extended by subsequent legislation will result in a decrease in payments of approximately $343 million in FY 2015 as compared to the low-volume hospital payments in FY 2014. This estimate accounts for our projection of the six IPPS low-volume hospitals in FY 2014 that are expected to continue to receive a low-volume hospital payment adjustment of an additional 25 percent for FY 2015 discharges occurring on or after April 1, 2015.

5. Effects of Proposal Related to IME Medicare Part C Add-On Payments to SCHs Paid According to Their Hospital-Specific Rates

In section IV.E.2. of the preamble of this proposed rule, we discuss our proposal related to IME Medicare Part C add-on payments to SCHs that are paid according to their hospital-specific rates. Payments based on the Federal rate are based on the IPPS standardized amount and include all applicable IPPS add-on payments, such as outliers, DSH, and IME, while payments based on the hospital-specific rate include no add-on payments. The hospital-specific rate generally reflects the additional costs incurred by a teaching hospital for its Medicare Part A patients. However, the hospital-specific rate does not reflect the costs associated with Medicare Part C patients and there is no payment mechanism for SCHs paid based on their hospital-specific rate to receive the IME add-on payment for Medicare Part C patients. Accordingly, we are proposing to provide all SCHs that are subsection (d) teaching

hospitals, IME add-on payments for applicable discharges of Medicare Part C patients in accordance with section 1886(d)(11) of the Act, regardless of whether the SCH is paid based on the Federal rate or its hospital-specific rate; and that, for purposes of the comparison of payments based on the Federal rate and payments based on the hospital-specific rate under section 1886(d)(5)(D) of the Act, IME payments under section 1886(d)(11) of the Act for Medicare Part C patients will no longer be included as part of the Federal rate payment.

We estimate that the proposals at section IV.E.2. of the preamble of this proposed rule will result in an increase in payments to approximately 50 hospitals that are both SCHs or SCH/RRCs and teaching hospitals of approximately $5 million in FY 2015.

6. Effects of the Extension of the MDH Program for the First Half of FY 2015

In section V.G. of the preamble of this proposed rule, we briefly discuss the statutory extension of the MDH program through March 31, 2015, that is, through the first half of FY 2015, by section 106 of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93). Hospitals that qualify as MDHs receive the higher of operating IPPS payments made under the Federal standardized amount or the payments made under the Federal standardized amount plus 75 percent of the amount by which the hospital-specific rate (a hospital-specific cost-based rate) exceeds the Federal standardized amount. Based on the latest available data we have for 165 MDHs, we project that 98 MDHs will receive the blended payment (that is, the Federal standardized amount plus 75 percent of the amount by which the hospital-specific rate exceeds the Federal standardized amount) for the first half of FY 2015 (that is, for discharges occurring through March 31, 2015). We estimate that those hospitals will experience an overall increase in payments of approximately $56 million as compared to our previous estimates of payments to these hospitals for FY 2015 prior to the extension of the MDH program through March 31, 2015, by section 106 of Public Law 113–93.

7. Effects of Proposed Changes Under the FY 2015 Hospital Value-Based Purchasing (VBP) Program

Section 1886(o)(1)(B) of the Act directs the Secretary to make value-based incentive payments under the Hospital VBP Program to hospitals that meet performance standards during the performance period for discharges occurring on or after October 1, 2012. These incentive payments will be funded for FY 2015 through a reduction to the FY 2015 base operating DRG payment for each discharge of 1.50 percent, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2016 is 1.75 percent and for FY 2017 and subsequent years, it is 2 percent. We are required to ensure that the total amount available for value-based incentive payments is equal to the total amount of reduced payments for all hospitals for the fiscal year, as estimated by the Secretary.

We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547), the CY 2012 OPPS/ASC final rule with comment period (76 FR 74527 through 74547), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53567 through 53614), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50677 through 50707), and the CY 2014 OPPS/ASC final rule with comment period (78 FR 75120 through 75121) for further explanation of the details of the Hospital VBP Program.

We specifically refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53582 through 53592) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50678 through 50679), for discussions of the measures and other policies that we adopted for the FY 2015 and FY 2016 Hospital VBP Programs.

In section IV.I. of the preamble of this proposed rule, we estimate the available pool of funds for value-based incentive payments in the FY 2015 Hospital VBP Program, which, in accordance with section 1886(o)(7)(C)(iii) of the Act, will be 1.50 percent of base operating DRG payments, or a total of approximately $1.4 billion. This estimated available pool for FY 2015 is based on the historical pool of hospitals that were eligible to participate in the FY 2014 Hospital VBP Program and the payment information from the December 2013 update to the FY 2013 MedPAR file. We intend to provide an update to this estimate, which will be based on the March 2014 update to the FY 2013 MedPAR file, in the FY 2015 IPPS/LTCH PPS final rule.

The estimated impacts of the FY 2015 Hospital VBP Program by hospital characteristic, found in the table below, are based on historical TPSs. We used the FY 2014 Hospital VBP Program TPSs to calculate the proxy adjustment factors used for this impact analysis. These are the most recently available scores that hospitals were given an opportunity to review and correct. The proxy adjustment factors use estimated annual base operating DRG payment amounts derived from the December 2013 update to the FY 2013 MedPAR file. The proxy adjustment factors can be found in Table 16 associated with this proposed rule (available via the Internet on the CMS Web site).

The impact analysis shows that, for the FY 2015 Hospital VBP Program, the number of hospitals that would receive an increase in base operating DRG payment amount is slightly lower than the number of hospitals that would receive a decrease. Approximately 42 percent of hospitals would have a change in base operating DRG payment amount that is between −0.2 percent and +0.2 percent. Among urban hospitals, those in the New England, South Atlantic, East North Central, West North Central, and West South Central regions would have an increase, on average, in base operating DRG payment amount, and among rural hospitals, those in the New England and East North Central regions will have an increase, on average in base operating DRG payment amounts.

Both urban and rural hospitals in the Middle Atlantic, East South Central, Mountain, and Pacific regions and rural hospitals in the South Atlantic region would receive an average decrease in base operating DRG payment amount. As the percent of DSH payments increases, we see a decrease in base operating DRG payment amount, while as the Medicare utilization (MCR) percent increases, we see an increase in base operating DRG payment amount.

Nonteaching and teaching hospitals would have an average decrease in base operating DRG payment amount.

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNT CHANGES RESULTING FROM THE FY 2015 HOSPITAL VBP PROGRAM

	Number of hospitals	Average (%)
By Geographic Location:		
All Hospitals	2,728	−0.038
Large Urban	1,113	−0.021
Other Urban	910	−0.030
Rural Area	705	−0.074
Urban hospitals	*2,023*	*−0.025*
0–99 beds	307	0.025
100–199 beds	677	−0.043
200–299 beds	431	−0.032
300–499 beds	401	−0.033
500 or more beds	207	−0.010
Rural hospitals	*705*	*−0.074*
0–49 beds	161	−0.041
50–99 beds	296	−0.088
100–149 beds	148	−0.074

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNT CHANGES RESULTING FROM THE FY 2015 HOSPITAL VBP PROGRAM—Continued

	Number of hospitals	Average (%)
150–199 beds	55	−0.106
200 or more beds	45	−0.067
By Region:		
Urban By Region	2,023	−0.025
New England	112	0.059
Middle Atlantic	279	−0.076
South Atlantic	346	0.002
East North Central	350	0.052
East South Central	121	−0.043
West North Central	134	0.055
West South Central	248	0.003
Mountain	130	−0.085
Pacific	303	−0.154
Rural By Region	705	−0.074
New England	21	0.044
Middle Atlantic	64	−0.150
South Atlantic	136	−0.024
East North Central	114	0.036
East South Central	114	−0.018
West North Central	82	−0.052
West South Central	101	−0.177
Mountain	45	−0.299
Pacific	28	−0.247
By MCR Percent:		
0–25	260	−0.118
25–50	1,788	−0.033
50–65	605	−0.016
Over 65	46	0.003
BY DSH Percent:		
0–25	1,253	0.013
25–50	1,220	−0.063
50–65	141	−0.121
Over 65	114	−0.222
BY TEACHING STATUS:		
Teaching	933	−0.041
Non-Teaching	1,795	−0.036

As stated above, we intend to provide an updated impact analysis in the FY 2015 IPPS/LTCH PPS final rule. However, actual FY 2015 Hospital VBP Program TPSs would not be reviewed and corrected by hospitals until after the FY 2015 IPPS/LTCH PPS final rule has been published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2014 Hospital VBP Program will be used for the updated impact analysis. As noted above, the updated impact analysis for the final rule will reflect estimated annual base operating DRG payment amount changes based on the March 2014 update to the FY 2013 MedPAR file.

8. Effects of Proposed Changes to the HAC Reduction Program for FY 2015

In section IV.J. of the preamble of this proposed rule, we are establishing measures, scoring, and a risk adjustment methodology to implement the FY 2015 payment reduction under the HAC Reduction Program. Section 1886(p) of the Act, as added under section 3008(a) of the Affordable Care Act, establishes an adjustment to hospital payments for HACs, or a HAC Reduction program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce HACs, effective for discharges occurring on October 1, 2014 and for subsequent program years.

We note that hospitals will have a payment impact for the first time in FY 2015. For FY 2015, we are presenting the overall impact of the HAC Reduction Program provision along with other IPPS payment provision impacts in section I.G. of this Appendix A. The table and analyses that we are presenting below show the distributional effect of the measures and scoring system for the HAC Reduction Program included in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729).

For FY 2015, we note that we finalized a Total HAC Score methodology in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729) that assigns weights for Domain 1 and Domain 2 at 35 percent and 65 percent, respectively. Based on this methodology, the table below presents data on the proportion of hospitals, by structural characteristic, in the worst performing quartile based on the 35/65 weighting scheme.

The data for this simulation are derived from the AHRQ PSI results based on Medicare FFS discharges from July 2011 through June 2013, using version 4.5 of the AHRQ software, and CDC measure results were used based on Standard Infection Ratios (SIRs) calculated with data reported to the National Healthcare Safety Network for infections occurring between July 2012 and June 2013. To analyze the results by hospital characteristic, the FY 2014 impact file were used. Of the 3,337 hospitals included in this analysis, 3,298 hospitals were included for geographic location, region, DSH percent, and teaching status; 3,278 for ownership; and 3,205 for MCR percent. These differences in denominator are due to the source of the hospital characteristic data. This analysis does not include Maryland hospitals as Maryland hospitals are exempt by waiver from the HAC Reduction Program in FY 2015.

The percentage of hospitals for each characteristic (column 3) indicates the percent of hospitals in each level of characteristic. For example, with regard to geographic region, 39.4 percent of hospitals (or 1,301 hospitals) are characterized as large urban; 32.7 percent of hospitals (or 1,080 hospitals) are characterized as other urban; and 27.8 percent of hospitals (or 917 hospitals) are characterized as rural. The percentage of hospitals in the worst performing quartile (column 5) indicates the proportion of hospitals for each characteristic that would be penalized. For example, in regards to geographic location, 26.6 percent of hospitals (or 346 hospitals) characterized

as large urban would be subject to a payment adjustment; 22.8 percent of hospitals (or 246 hospitals) characterized as other urban would be subject to a payment adjustment; and 17.6 percent of hospitals (or 161 hospitals) characterized as rural would be subject to a payment adjustment.

With regard to geographic location of urban hospitals by bed size, 17.3 percent of hospitals (or 101 hospitals) characterized as urban hospitals with bed size of 0–99 beds would be subject to a payment adjustment; 21.1 percent of hospitals (or 152 hospitals) characterized as urban hospitals with bed size of 100–199 beds would be subject to a payment adjustment; 27.1 percent of hospitals (or 122 hospitals) characterized as urban hospitals with bed size of 200–299 beds would be subject to a payment adjustment; 27.1 percent of hospitals (or 71 hospitals) characterized as urban hospitals with bed size of 300–399 beds would be subject to a payment adjustment; 37.7 percent of hospitals (or 58 hospitals) characterized as urban hospitals with bed size of 400–499 beds would be subject to a payment adjustment; and 41.7 percent of hospitals (or 88 hospitals) characterized as urban hospitals with bed size of 500 or more beds would be subject to a payment adjustment.

With regard to geographical location of rural hospitals by bed size, 15.5 percent of hospitals (or 53 hospitals) characterized as rural hospitals with bed size of 0–49 beds would be subject to a payment adjustment; 20.6 percent of hospitals (or 66 hospitals) characterized as rural hospitals with bed size of 50–99 beds would be subject to a payment adjustment; 13.9 percent of hospitals (or 21 hospitals) characterized as rural hospitals with bed size of 100–149 beds would be subject to a payment adjustment; 15.3 percent of hospitals (or 9 hospitals) characterized as rural hospitals with bed size of 150–199 beds would be subject to a payment adjustment; and 26.7 percent of hospitals (or 12 hospitals) characterized as rural hospitals with bed size of 200 or more beds would be subject to a payment adjustment.

With regard to region of urban hospitals, 26.1 percent of hospitals (or 31 hospitals) characterized as urban in the New England region would be subject to a payment adjustment; 28.2 percent of hospitals (or 87 hospitals) characterized as urban in the Mid-Atlantic region would be subject to a payment adjustment; 24.0 percent of hospitals (or 89 hospitals) characterized as urban in the South Atlantic region would be subject to a payment adjustment; 23.4 percent of hospitals (or 90 hospitals) characterized as urban in the East North Central region would be subject to a payment adjustment; 22.4 percent of hospitals (or 32 hospitals) characterized as urban in the West South Central region would be subject to a payment adjustment; 20.5 percent of hospitals (or 33 hospitals) characterized as urban in the East North Central region would be subject to a payment adjustment; 19.6 percent of hospitals (or 71 hospitals) characterized as urban in the West South Central region would be subject to a payment adjustment; 35.8 percent of hospitals (or 57 hospitals) characterized as urban in the Mountain region would be subject to a payment adjustment; and 27.4 percent of hospitals (or 102 hospitals) characterized as urban in the Pacific region would be subject to a payment adjustment.

With regard to region of rural hospitals, 13.0 percent of hospitals (or 3 hospitals) characterized as rural in the New England region would be subject to a payment adjustment; 25.8 percent of hospitals (or 17 hospitals) characterized as rural in the Mid-Atlantic region would be subject to a payment adjustment; 15.1 percent of hospitals (or 24 hospitals) characterized as rural in the South Atlantic region would be subject to a payment adjustment; 21.2 percent of hospitals (or 25 hospitals) characterized as rural in the East North Central region would be subject to a payment adjustment; 13.9 percent of hospitals (or 23 hospitals) characterized as rural in the West South Central region would be subject to a payment adjustment; 19.2 percent of hospitals (or 20 hospitals) in the East North Central region would be subject to a payment adjustment; 14.7 percent of hospitals (or 26 hospitals) in the West South Central region would be subject to a payment adjustment; 24.7 percent of hospitals (or 18 hospitals) in the Mountain region would be subject to a payment adjustment; and 16.1 percent of hospitals (or 5 hospitals) in the Pacific region would be subject to a payment adjustment.

With regard to the DSH percent characteristic, 19.6 percent of hospitals (or 311 hospitals) characterized in the 0–24 DSH percent would be subject to a payment adjustment; 24.1 percent of hospitals (or 331 hospitals) characterized in the 25–49 DSH percent would be subject to a payment adjustment; 37.6 percent of hospitals (or 68 hospitals) characterized in the 50–64 DSH percent would be subject to a payment adjustment; and 27.2 percent of hospitals (or 43 hospitals) characterized in the 65 and over DSH percent would be subject to a payment adjustment.

With regard to the teaching status characteristic, 19.0 percent of hospitals (or 437 hospitals) characterized as nonteaching would be subject to a payment adjustment; 25.0 percent of hospitals (or 191 hospitals) characterized as fewer than 100 residents would be subject to a payment adjustment; and 52.7 percent of hospitals (or 125 hospitals) characterized as 100 or more residents would be subject to a payment adjustment.

With regard to the urban teaching and DSH characteristic, 34.2 percent of hospitals (or 277 hospitals) characterized as teaching and DSH would be subject to a payment adjustment; 22.1 percent of hospitals (or 29 hospitals) characterized as teaching and no DSH would be subject to a payment adjustment; 20.4 percent of hospitals (or 206 hospitals) characterized as no teaching and DSH would be subject to a payment adjustment; 18.6 percent of hospitals (or 80 hospitals) characterized as no teaching and no DSH would be subject to a payment adjustment; and 17.6 percent of hospitals (or 161 hospitals) characterized as nonurban would be subject to a payment adjustment.

With regard to the type of ownership characteristic, 23.3 percent of hospitals (or 441 hospitals) characterized as voluntary would be subject to a payment adjustment; 19.5 percent of hospitals (or 167 hospitals) characterized as proprietary would be subject to a payment adjustment; and 26.8 percent of hospitals (or 141 hospitals) characterized as government would be subject to a payment adjustment.

With regard to the MCR percent characteristic, 37.7 percent of hospitals (or 147 hospitals) characterized in the 0–24 MCR percent would be subject to a payment adjustment; 23.2 percent of hospitals (or 458 hospitals) characterized in the 25–49 MCR percent would be subject to a payment adjustment; 15.9 percent of hospitals (or 113 hospitals) characterized in the 50–64 MCR percent would be subject to a payment adjustment; and 10.8 percent of hospitals (or 14 hospitals) characterized in the 65 and over MCR percent would be subject to a payment adjustment.

PROPORTION OF HOSPITALS IN THE WORST PERFORMING QUARTILE (>75 PERCENTILE) OF THE TOTAL HAC SCORE BY HOSPITAL CHARACTERISTIC

Hospital characteristic			Hospitals in the worst performing quartile	
Characteristic	Number of hospitals	Percent *	Number of hospitals	Percent
By Geographic Location:				
All Hospitals:				
Large Urban **	1,301	39.4	346	26.6
Other Urban	1,080	32.7	246	22.8
Rural	917	27.8	161	17.6
Urban Hospitals:				
0–99 beds	584	24.5	101	17.3

PROPORTION OF HOSPITALS IN THE WORST PERFORMING QUARTILE (>75 PERCENTILE) OF THE TOTAL HAC SCORE BY HOSPITAL CHARACTERISTIC—Continued

Hospital characteristic			Hospitals in the worst performing quartile	
Characteristic	Number of hospitals	Percent *	Number of hospitals	Percent
100–199 beds	720	30.2	152	21.1
200–299 beds	450	18.9	122	27.1
300–399 beds	262	11.0	71	27.1
400–499	154	6.5	58	37.7
500 or more beds	211	8.9	88	41.7
Rural Hospitals:				
0–49 beds	341	37.2	53	15.5
50–99 beds	321	35.0	66	20.6
100–149 beds	151	16.5	21	13.9
150–199 beds	59	6.4	9	15.3
200 or more beds	45	4.9	12	26.7
By Region:				
Urban by Region:				
New England	119	3.6	31	26.1
Mid-Atlantic	308	9.3	87	28.2
South Atlantic	371	11.2	89	24.0
East North Central	385	11.7	90	23.4
West South Central	143	4.3	32	22.4
East North Central	161	4.9	33	20.5
West South Central	363	11.0	71	19.6
Mountain	159	4.8	57	35.8
Pacific	372	11.3	102	27.4
Rural by Region:				
New England	23	0.7	3	13.0
Mid-Atlantic	66	2.0	17	25.8
South Atlantic	159	4.8	24	15.1
East North Central	118	3.6	25	21.2
West South Central	166	5.0	23	13.9
East North Central	104	3.2	20	19.2
West South Central	177	5.4	26	14.7
Mountain	73	2.2	18	24.7
Pacific	31	0.9	5	16.1
By DSH Percent:				
0–24	1,588	48.2	311	19.6
25–49	1,371	41.6	331	24.1
50–64	181	5.5	68	37.6
65 and over	158	4.8	43	27.2
By Teaching Status:				
Non-teaching	2,297	69.6	437	19.0
Fewer than 100 residents	764	23.2	191	25.0
100 or more residents	237	7.2	125	52.7
By Urban Teaching and DSH:				
Teaching and DSH	811	24.6	277	34.2
Teaching and no DSH	131	4.0	29	22.1
No teaching and DSH	1,010	30.6	206	20.4
No teaching and no DSH	429	13.0	80	18.6
Non-urban	917	27.8	161	17.6
By Type of Ownership:				
Voluntary	1,893	57.7	441	23.3
Proprietary	858	26.2	167	19.5
Government	527	16.1	141	26.8
By MCR Percent:				
0–24	390	12.2	147	37.7
25–49	1,976	61.7	458	23.2
50–64	709	22.1	113	15.9
65 and over	130	4.1	14	10.8

* Percents may not sum to 100 due to rounding.
** Large urban hospitals are hospitals located in large urban areas (populations over 1 million).

9. Effects of Proposed Policy Changes Relating to Payments for Direct GME and IME

Under section IV.K.2. of the preamble of this proposed rule, we discuss our proposal to simplify and streamline the timing of CMS's policies related to when the FTE resident caps, the 3-year rolling average, and the IRB ratio cap would become effective for new teaching hospitals, by stating that the FTE resident caps, rolling average, and IRB ratio cap would be effective simultaneously, beginning with the applicable hospital's cost reporting period that precedes the start of the 6th program year of the first new program started. We are proposing that this policy regarding the effective dates of the FTE residency caps, rolling average, and IRB ratio cap for FTE residents in new programs would

be consistent with the methodology for calculation of the FTE resident caps as described in the FY 2013 IPPS/LTCH PPS final rule, and implemented at 42 CFR 413.79(e)(1) and (3). That is, this proposal is effective for urban hospitals that have not yet had FTE resident caps established under § 413.79(e)(1), and for rural hospitals, on or after October 1, 2012. This proposal would reduce the amount of time that the new programs would be exempt from the FTE resident caps by several months, depending on the cost reporting period of the new teaching hospital. However, depending on the length of new programs started and the point during the 5-year growth period in which new programs are started, there may also be some gain and loss for hospitals in terms of the amount of time that the FTEs in the new programs would be exempt from the rolling average and the IRB ratio cap. In either case, the estimate of possible savings or cost of this proposal is less than $5 million a year and therefore, is negligible.

In section IV.K.3.a. of the preamble of this proposed rule, we discuss our proposals related to the effect of new OMB labor market area delineations on certain teaching hospitals training residents in rural areas. Under existing regulations a new teaching hospital has 5 years from when it first begins training residents in its first new program to grow its cap. If the teaching hospital is a rural teaching hospital, it can continue to receive permanent cap adjustments even after the initial 5-year cap-building period ends if it trains residents in a new program. As a result of OMB redesignations, some teaching hospitals may be redesignated from being located in a rural area to an urban area, thereby losing their ability to increase their caps again after their initial 5-year cap-building period. If a rural hospital had started training residents in the new program while it was rural and was redesignated as urban before the end of the 5-year cap-building period, we are proposing that effective for cost reporting periods beginning on or after October 1, 2014, it can continue growing that program(s) for the remainder of the cap-building period and receive a permanent cap adjustment for that new program(s). Once the cap-building period for the new program(s) that was started while the hospital was still rural expires, the teaching hospital that has been redesignated as urban will no longer be able to receive any additional permanent cap adjustments.

In section IV.K.3.b. of the preamble of this proposed rule, we discuss our proposal related to a redesignated hospital's participation in a rural track program. Under existing regulations, if an urban hospital rotates residents to a separately accredited rural track program at a rural site(s) for more than one-half of the duration of the program, the urban hospital may receive an adjustment to its cap for training those FTE residents, referred to as the rural track FTE limitation. We are proposing that any time a rural hospital participating in a rural track is in an area redesignated by OMB as urban after residents started training in the rural track and during the period that is used to calculate the urban hospital's rural track FTE limitation, the urban hospital may still receive a cap adjustment for that rural track. We also are proposing that if the rural hospital participating in the rural track is in an area redesignated as urban, the redesignated urban hospital can continue to be considered a rural hospital for purposes of the rural track for up to 2 years. However, within those 2 years, either the rural hospital that has been redesignated as urban must reclassify as rural under § 412.103 for purposes of IME payment only, or the urban hospital must find a new geographically rural site to participate as the rural site for purposes of the rural track and must be training FTE residents at that new site, in order for the urban hospital to receive payment under § 413.79(k)(1) or (k)(2) for the rural track program after the 2-year period ends.

We estimate that the proposals discussed under IV.K.3.a. and b. of the preamble of this proposed rule would have a very minimal, if any, impact on Medicare expenditures. These proposals would only be applied to, at the most, very few hospitals (if any at all) and would only apply once every 10 years as a result of OMB changes in labor market area delineations due to a recent Census.

In sections IV.K.5.a. and b. of the preamble of this proposed rule, we are proposing some changes to the current application process for and awarding of cap slots from closed hospitals under section 5506 of the Affordable Care Act that would be effective for hospital closures announced on or after October 1, 2014. We are proposing an alternative interpretation of the statutory provision at section 5506(d) of the Affordable Care Act, which provides that the Secretary give consideration to the effect of the permanent awarding of slots under section 5506 of the Affordable Care Act to any temporary cap adjustments to a hospital received under § 413.79(h) of the regulations to ensure that there be no duplication of FTE cap slots. Currently, when applying this statutory provision for no duplication of FTE slots, we look at all of the hospitals that are receiving temporary cap adjustments to train displaced residents and all of the hospitals that are applying for a permanent increase in caps under section 5506 when determining the effective date for slots permanently awarded to hospitals under Ranking Criterion One and Ranking Criteria Three through Eight. In this proposed rule, we are proposing to interpret the statutory language at section 5506(d) in a manner that would permit us to apply the concept of ensuring no duplication of FTE resident slots on a hospital-by-hospital basis, such that if a hospital is both receiving a temporary cap adjustment under § 413.79(h) and is applying under section 5506 for permanent cap slots, it will not be able to receive a permanent cap adjustment until the displaced residents graduate. However, if a hospital is applying under section 5506 for permanent cap slots and did not receive a temporary cap adjustment under § 413.79(h), that hospital will not have to wait until displaced residents that are training at another hospital graduate to be awarded any permanent cap slots under section 5506. We estimate that this proposal could result in a slight increase in Medicare expenditures in a rare event a section 5506 cap adjustment may be provided to one hospital before a temporary cap adjustment expires at another hospital. However, we are unable to estimate whether this will occur with any future hospital closures where section 5506 is applied because we do not know how many, if any, residents will be displaced. Furthermore, we believe that any temporary duplicate payment would be a rare occurrence as most hospitals that are receiving a temporary cap adjustment under § 413.79(h) will also receive a permanent cap adjustment under section 5506. In this instance the hospital would only be able to receive the permanent cap adjustment once the temporary cap adjustment expires in which case there would be no duplication of FTE resident slots.

In addition, under section IV.K.5.c. of the preamble of this proposed rule, we are proposing to revise the ranking criteria used to award slots under section 5506. First, we are proposing to no longer allow hospitals to apply for cap relief, which is included under current Ranking Criterion Eight. This proposed change would mean that hospitals would be awarded slots under section 5506 for taking over a closed hospital's residency training program, having participated with a closed hospital in a Medicare GME affiliated group, taking over part of a closed hospital's program, expanding or starting a new geriatrics program, expanding or starting a new primary care or general surgery program, and expanding or starting a new nonprimary care or nongeneral surgery program. Second, Ranking Criterion One currently applies to hospitals that are assuming (or have assumed) an entire program from the hospital that closed. We are proposing to revise this Ranking Criterion to provide priority to a hospital whose FTE resident caps were erroneously reduced by CMS under section 5503 of the Affordable Care Act, contrary to the specific statutory exception at section 1886(h)(8)(A)(i)(I) of the Act, and the CMS Central Office is made aware of the error prior to the posting of this proposed rule. We do not believe there is any cost associated with these proposals because we would be assigning all of the closed hospital's slots, only the specific hospital awarded the slots may change.

10. Effects of Implementation of Rural Community Hospital Demonstration Program

In section IV.L. 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.L. of the preamble of this proposed rule, in the IPPS final rules for each of the previous 10 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 across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that ''aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration . . . was not implemented'' but does not identify the range across which aggregate payments must be held equal.

We are proposing to adjust the national IPPS rates according to the methodology set forth elsewhere in this proposed rule. The proposed adjustment to the national IPPS rates to account for estimated demonstration cost for FY 2014 for the 7 ''pre-expansion'' participating hospitals that are currently participating in the demonstration and the 15 additional hospitals participating as a result of the expansion of the demonstration under the Affordable Care Act is $53,673,008. In addition, in this proposed rule, we are proposing to add to the adjustment of the national IPPS rates the amount by which the actual costs of the demonstration for FY 2008 (as shown in the finalized cost reports for cost reporting periods beginning in FY 2008 for the hospitals that participated in the demonstration during FY 2008) exceed the budget neutrality offset amount that was finalized in the FY 2008 IPPS final rule ($10,389,771). Thus, we are proposing that the resulting total ($64,062,779) would be the amount for which an adjustment to inpatient rates for FY 2015 would be calculated. We also are proposing that if settled cost reports for all of the demonstration hospitals that participated in the applicable fiscal year (FY 2009, 2010, or 2011), are made available prior to the FY 2015 IPPS/LTCH PPS final rule, we would incorporate into the FY 2015 budget neutrality offset amount any additional amounts by which the final settled costs of the demonstration for the year (FY 2009, 2010, or 2011) exceeded the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule.

11. Effects of Proposed Changes Related to Reclassification as Rural for CAHs

In section VI.C.2. of the preamble of this proposed rule, we discuss our proposals relating to reclassifications of CAHs as a result of the proposed adoption of the new OMB labor market area delineations. A facility is eligible for designation as a CAH only if it is either physically located in a rural area or has been reclassified as rural under 42 CFR 412.103. CAHs can be affected by the recent OMB labor market area delineations because facilities that are currently participating as CAHs that were previously located in rural areas may now be located in urban areas as a result of the new delineations. Previously, in both in the FY 2005 IPPS final rule and the FY 2010 IPPS/LTCH PPS final rule, we revised the regulations to give currently participating CAHs 2 years, from the effective date of the earlier OMB designations, to reclassify as rural facilities. However, these regulation changes were specific to a particular timeframe. As we are proposing implementation of the latest OMB labor market area delineations in this proposed rule, we are proposing that, effective October 1, 2014, currently participating CAHs that are located in an area that has been redesignated from rural to urban under the new delineations will again be treated as rural for 2 years from the date the new OMB delineations are implemented. An affected CAH would have 2 years from the date the redesignation becomes effective to reclassify as rural and thereby retain its CAH status. If a CAH fails to reclassify within those 2 years, it can no longer participate in Medicare as a CAH. However, unlike in previous years when the regulation changes were specific to a particular timeframe, the change that we are proposing to the regulations is not specific to a particular timeframe but would also apply to future OMB labor market area delineations. We estimate that this proposal will have little or no impact on Medicare expenditures because we expect that virtually all of the affected CAHs will be granted rural status by the State in which they are located and, therefore, will be able to apply for reclassification as rural under § 412.103 in order to retain their CAH status.

12. Effects of Proposed Revision of the Requirements for Physician Certification of CAH Inpatient Services

In section VI.C.3. of the preamble of this proposed rule, we discuss the statutory requirement for physician certification of CAH inpatient services. For inpatient CAH services to be payable under Medicare Part A, section 1814(a)(8) of the Act requires that a physician certify that the individual may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the CAH. These statutory requirements are addressed in the regulations at 42 CFR 424.15. In order to provide CAHs with greater flexibility in meeting this certification requirement, we are proposing to amend the regulations governing the timing of the 96-hour certification requirement at § 424.15(b) such that physician certification is required no later than 1 day before the date on which the claim for payment for the inpatient CAH service is submitted. We also are proposing to revise § 424.11(d)(5) to remove the phrase ''or critical access hospital inpatient''. We do not believe there is any significant impact on Medicare expenditures associated with these proposed changes because we are simply proposing to provide CAHs with additional flexibility in meeting the statutory requirement. The underlying statutory requirement itself is unchanged.

13. Effects of Proposed Changes Relating to Administrative Appeals by Providers and Judicial Review for Appropriate Claims in Provider Cost Reports

In section VIII. of the preamble to this proposed rule, we discuss our proposal to require a provider to include an appropriate claim for an item in its Medicare cost report with the penalty for the failure to do so being the preclusion of payment for the item in the notice of program reimbursement (NPR) issued by the fiscal intermediary and in any decision or order issued by a reviewing entity in an administrative appeal filed by the provider. The proposal also would revise the Medicare provider appeals regulations by eliminating the requirement that a provider must include an appropriate claim for an item in its Medicare cost report in order to meet the dissatisfaction requirement for Provider Reimbursement Review Board jurisdiction and would make technical corrections to the provider reimbursement appeals regulations to conform the regulations to the statute. There is no impact to the provider resulting from these proposed provisions.

I. Effects of Proposed Update to the Reasonable Compensation Equivalent (RCE) Limits for Compensation for Physician Services Provided in Providers

In section VI.B. of the preamble of this proposed rule, we discuss our proposal to update and revise the methodology used to calculate the reasonable compensation equivalent (RCE) limits for compensation for physician services provided in providers, in accordance with our regulations at 42 CFR 415.70(f)(2). For CY 2015, we estimate that 59 cancer and children's hospitals and 46 IPPS teaching hospitals would be subject to the RCE limits. We estimate the costs associated with the updated RCE limits for CY 2015 to be approximately $40 million. We do not expect this proposed RCE limit update to impact a significant number of small, rural entities; therefore, a full impact analysis is not required.

J. Effects of Proposed Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented below, we used data from the December 2013 update of the FY 2013 MedPAR file and the December 2013 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 2013 update of the most recently available hospital cost report data (FYs 2011 and 2012) 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.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each proposed change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the December 2013 update of the FY 2013 MedPAR file, we simulated payments under the capital IPPS for FY 2014 and FY 2015 for a comparison

of total payments per case. Any short-term, acute care hospitals not paid under the general IPPS (for example, 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 2015 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 will increase by 0.5 percent in both FYs 2014 and 2015.
- We estimate that Medicare discharges will be approximately 12.2 million in FY 2014 and 12.6 million in FY 2015.
- 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 1.5 percent for FY 2015.
- In addition to the proposed FY 2015 update factor, the proposed FY 2015 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality adjustment factor of 0.9957 and a proposed outlier adjustment factor of 0.9374. As discussed in section VI.C. of the preamble of this proposed rule, we are not proposing to make an additional MS–DRG documentation and coding adjustment to the capital IPPS Federal rates for FY 2015.

2. Results

We used the actuarial model described above to estimate the potential impact of our proposed changes for FY 2015 on total capital payments per case, using a universe of 3,388 hospitals. As described above, the individual hospital payment parameters are taken from the best available data, including the December 2013 update of the FY 2013 MedPAR file, the December 2013 update to the PSF, and the most recent cost report data from the December 2013 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2014 and estimated total payments per case for FY 2015 based on the proposed FY 2015 payment policies. Column 2 shows estimates of payments per case under our model for FY 2014. Column 3 shows estimates of payments per case under our model for FY 2015. Column 4 shows the total percentage change in payments from FY 2014 to FY 2015. The change represented in Column 4 includes the proposed 1.5 percent update to the capital Federal rate and other proposed changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2015 are expected to increase as compared to capital payments per case in FY 2014. This expected increase is due primarily to the approximately 0.9 percent increase in the proposed capital Federal rate for FY 2015 as compared to the FY 2014 capital Federal rate. Overall, across all hospitals, the proposed changes to the GAFs are expected to have no net effect on capital payments. However, regionally, the effects of the proposed changes to the GAFs on capital payments are consistent with the projected changes in payments due to proposed changes in the wage index (and proposed policies affecting the wage index) as shown in Table I in section I.G. of this Appendix.

Overall, there is an increase in capital payments per case due to the effects of proposed changes to the MS–DRG reclassifications and recalibrations, with more of this increase expected for urban hospitals. However, this increase is offset by projected changes in outlier payments, with rural areas expected to experience more of this offset.

The net impact of these proposed changes is an estimated 1.2 percent change in capital payments per case from FY 2014 to FY 2015 for all hospitals (as shown below in Table III).

The geographic comparison shows that, on average, with the exception of hospitals in the Rural Mountain area, most hospitals are expected to experience an increase in capital IPPS payments per case in FY 2015 as compared to FY 2014. As we stated above, these expected increases are primarily due to the proposed increase in the capital Federal rate. Capital IPPS payments per case for hospitals in ''large urban areas'' are expected to have an estimated increase of 1.4 percent, while hospitals in rural areas, on average, are expected to experience a 0.7 percent increase in capital payments per case from FY 2014 to FY 2015. Capital IPPS payments per case for ''other urban hospitals'' are estimated to increase 1.2 percent. The primary factor contributing to the difference in the proposed projected increase in capital IPPS payments per case for urban hospitals as compared to rural hospitals is the proposed increase in capital payments to urban hospitals due to proposed changes to the MS–DRG relative weights. This projected increase is slightly lower for rural hospitals.

The comparisons by region show that the estimated increases in capital payments per case from FY 2014 to FY 2015 in urban areas range from a 2.0 percent increase for the Pacific urban region to a 0.8 percent increase for the East South Central urban region, and a 0.6 percent increase for the Puerto Rico urban region. For rural regions, the Pacific rural region is expected to experience the largest increase in capital IPPS payments per case of 1.9 percent, while the Mountain rural region is the only region projected to have a decrease in capital payments per case, 0.1 percent, compared to FY 2014 payments per case. Unlike most other urban and rural regions where proposed changes in the GAFs contribute to a projected decrease in capital payments, the proposed changes in the GAFs contribute to an expected increase in capital IPPS payments per case for the Pacific urban and rural regions. A larger than average decrease in capital payments per case for the Mountain rural area due to the proposed change in outliers offset the projected increases to that area's capital payments per case in FY 2015 compared to FY 2014.

Hospitals of all types of ownership (that is, voluntary hospitals, government hospitals, and proprietary hospitals) are estimated to experience an increase in capital payments per case from FY 2014 to FY 2015. The proposed increase in capital payments for proprietary hospitals is estimated at 1.2 percent; for voluntary hospitals, at 1.3 percent. Government hospitals are estimated to experience a 1.1 percent increase in capital payments per case from FY 2014 to FY 2015.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2015. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this proposed rule for FY 2015, we show the average capital payments per case for reclassified hospitals for FY 2015. Urban reclassified hospitals are expected to experience an increase in capital payments of 1.5 percent, whereas for urban nonreclassified hospitals, the expected increase is 1.2 percent. The estimated percentage increase for rural reclassified hospitals is 0.7 percent, and for rural nonreclassified hospitals, the estimated percentage increase is 0.3 percent. Other reclassified hospitals (that is, hospitals reclassified under section 1886(d)(8)(B) of the Act) are expected to experience the largest increase (2.2 percent) in capital payments from FY 2014 to FY 2015.

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE

[FY 2014 payments compared to FY 2015 payments]

	Number of hospitals	Average FY 2014 payments/case	Average FY 2015 payments/case	Change
By Geographic Location:				
All hospitals	3,388	848	859	1.2
Large urban areas (populations over 1 million)	1,395	936	948	1.4
Other urban areas (populations of 1 million or fewer)	1,147	817	827	1.2
Rural areas	846	577	581	0.7
Urban hospitals	2,542	882	893	1.3
0–99 beds	655	728	732	0.5
100–199 beds	788	761	770	1.2
200–299 beds	469	810	821	1.4
300–499 beds	417	902	915	1.4
500 or more beds	213	1,056	1,070	1.3
Rural hospitals	846	577	581	0.7
0–49 beds	325	470	473	0.6
50–99 beds	298	534	537	0.5
100–149 beds	136	575	579	0.7
150–199 beds	50	640	645	0.8
200 or more beds	37	704	711	0.9
By Region:				
Urban by Region	2,542	882	893	1.3
New England	120	974	985	1.2
Middle Atlantic	324	946	963	1.7
South Atlantic	406	796	805	1.1
East North Central	397	848	856	0.9
East South Central	153	758	764	0.8
West North Central	162	876	887	1.3
West South Central	385	816	824	0.9
Mountain	159	906	916	1.1
Pacific	384	1,111	1,133	2.0
Puerto Rico	52	406	408	0.6
Rural by Region	846	577	581	0.7
New England	22	802	812	1.2
Middle Atlantic	57	562	569	1.3
South Atlantic	132	550	551	0.2
East North Central	115	601	606	0.8
East South Central	165	530	534	0.7
West North Central	102	613	617	0.6
West South Central	168	511	513	0.5
Mountain	61	651	650	−0.1
Pacific	24	742	756	1.9
Puerto Rico	0	0	0	0.0
By Payment Classification:				
All hospitals	3,388	848	859	1.2
Large urban areas (populations over 1 million)	794	879	889	1.1
Other urban areas (populations of 1 million or fewer)	1,764	882	894	1.4
Rural areas	830	588	591	0.5
Teaching Status:				
Non-teaching	2,352	722	730	1.1
Fewer than 100 Residents	792	831	841	1.3
100 or more Residents	244	1,196	1,213	1.4
Urban DSH:				
100 or more beds	1,591	902	914	1.3
Less than 100 beds	366	635	639	0.8
Rural DSH:				
Sole Community (SCH/EACH)	388	521	524	0.6
Referral Center (RRC/EACH)	212	649	653	0.6
Other Rural:				
100 or more beds	24	548	546	−0.3
Less than 100 beds	125	459	461	0.4
Urban teaching and DSH:				
Both teaching and DSH	842	980	993	1.3
Teaching and no DSH	133	884	897	1.6
No teaching and DSH	1,115	754	763	1.3
No teaching and no DSH	468	791	798	0.9
Rural Hospital Types:				
Non special status hospitals	2,576	882	893	1.2
RRC/EACH	197	717	730	1.8
SCH/EACH	325	619	624	0.8
SCH, RRC and EACH	125	704	710	0.9

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE—Continued

[FY 2014 payments compared to FY 2015 payments]

	Number of hospitals	Average FY 2014 payments/case	Average FY 2015 payments/case	Change
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY2015 Reclassifications:				
All Urban Reclassified	533	883	896	1.5
All Urban Non-Reclassified	1,858	890	901	1.2
All Rural Reclassified	271	615	620	0.7
All Rural Non-Reclassified	379	541	543	0.3
Other Reclassified Hospitals (Section 1886(d)(8)(B))	60	574	587	2.2
Type of Ownership:				
Voluntary	1,925	861	872	1.3
Proprietary	883	770	779	1.2
Government	540	886	895	1.1
Medicare Utilization as a Percent of Inpatient Days:				
0–25	445	1,069	1,082	1.3
25–50	2,004	865	876	1.3
50–65	718	704	713	1.2
Over 65	131	560	565	0.9

K. Effects of Proposed Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule, we set forth the proposed annual update to the payment rates for the LTCH PPS for FY 2015. In the preamble of this proposed rule, 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, there are 422 LTCHs included in this impacts analysis, which includes data for 91 nonprofit (voluntary ownership control) LTCHs, 288 proprietary LTCHs, and 43 LTCHs that are government-owned and operated. (We note that although there are currently approximately 435 LTCHs, for purposes of this impact analysis, we excluded the data of all inclusive rate providers and the LTCHs that are paid in accordance with demonstration projects, consistent with the development of the proposed FY 2015 MS–LTC–DRG relative weights (discussed in section VII.B.3.c. of the preamble of this proposed rule)). In the impact analysis, we used the proposed payment rate, factors, and policies presented in this proposed rule, including the proposed 2.1 percent annual update for LTCHs that submit quality data in accordance with section 1886(m)(5)(C) of the Act, which is based on the full estimated increase of the LTCH PPS market basket and the reductions required by sections 1886(m)(3) and (m)(4) of the Act, the proposed final year of the phase-in of a one-time prospective adjustment factor of 0.98734 (approximately −1.3 percent), the proposed update to the MS–LTC–DRG classifications and relative weights, the proposed update to the wage index values, including the proposed implementation of the new OMB delineations, and labor-related share, and the best available claims and CCR data to estimate the change in payments for FY 2015. (As discussed in section VII.C. of the preamble of this proposed rule, in accordance with section 1886(m)(5)(C) of the Act, for LTCHs that fail to submit quality data, the proposed annual update to the LTCH PPS standard Federal rate is reduced by 2.0 percentage points in FY 2015.)

The standard Federal rate for FY 2014 is $40,607.31 for LTCHs that submit quality data in accordance with the requirements of section 1886(m)(5)(C) of the Act. For FY 2015, we are proposing to establish a standard Federal rate of $40,943.51 for LTCHs that submit quality data in accordance with the requirements of section 1886(m)(5)(C) of the Act, which reflects the proposed 2.1 percent annual update to the standard Federal rate, and the proposed area wage budget neutrality factor of 1.0002034 to ensure that the proposed changes in the wage index, including the proposed implementation of the new OMB delineations, and labor-related share do not influence aggregate payments, and the proposed final year of the phase-in of a one-time prospective adjustment factor of 0.98734. For LTCHs that fail to submit data for the LTCHQR Program, in accordance with section 1886(m)(5)(C) of the Act, we are proposing to establish a standard Federal rate of $40,141.47. This reduced standard Federal rate reflects the proposed updates described above in addition to a 2.0 percentage point to the annual update for failure to submit data to the LTCHQR Program. We note that the proposed factors described above to determine the proposed FY 2015 standard Federal rate are applied to the FY 2014 Federal standard rate set forth under § 412.523(c)(3)(ix)(A) (that is, $40,607.31).

Based on the best available data for the 422 LTCHs in our database, we estimate that the proposed annual update to the standard Federal rate for FY 2015, including the reduced updated for LTCHs that fail to submit quality data in accordance with the requirements of the LTCHQR Program (discussed in section V.A.2. of the Addendum to this proposed rule) and the proposed changes to the area wage adjustment for FY 2015 (discussed in section V.B. of the Addendum to this proposed rule), in addition to an estimated decrease in HCO payments would result in an increase in estimated payments from FY 2014 of approximately $44 million. Based on the 422 LTCHs in our database, we estimate that the FY 2015 LTCH PPS payments would be approximately $5.594 billion, as compared to estimated FY 2014 LTCH PPS payments of approximately $5.550 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 approximate $44 million for the projected increase in estimated aggregate proposed LTCH PPS payments from FY 2014 to FY 2015 does not reflect changes in LTCH admissions or case-mix intensity in estimated LTCH PPS payments, which also will affect overall payment changes.

The projected 0.8 percent increase in estimated proposed payments per discharge from FY 2014 to FY 2015 is attributable to several factors, including the proposed 2.1 percent annual update to the standard Federal rate (or 0.1 percent annual update for LTCHs that failed to submit data under the requirements of the LTCHQR Program), a proposed one-time prospective adjustment factor for FY 2015 of 0.98734 (approximately −1.3 percent), and projected decreases in estimated HCO payments. Although the net effect of the proposed 2.1 percent annual update and the approximate −1.3 percent proposed one-time prospective adjustment factor is approximately 0.8 percent (that is, 2.1 percent −1.3 percent = 0.8 percent), Table IV (column 6) shows the estimated change attributable solely to the proposed

annual update to the standard Federal rate (2.1 percent for LTCHs that submit quality data under the requirements of the LTCHQR Program and 0.1 percent for LTCHs that failed submit quality data under the requirements of the LTCHQR Program), including a proposed one-time prospective adjustment factor for FY 2015 under the final year of the phase-in (approximately 1.3 percent), is projected to result in an increase of 0.7 percent in payments per discharge from FY 2014 to FY 2015, on average, for all LTCHs. In addition to the proposed 2.1 percent annual update for FY 2015 (or 0.1 percent annual update for LTCHs that failed to submit data under the LTCHQR Program), and a proposed −1.3 percent one-time prospective adjustment factor for FY 2015, this estimated increase in aggregate LTCH PPS payments of 0.7 percent shown in column 6 of Table IV also includes estimated payments for SSO cases that are paid using special methodologies that are not affected by the annual update to the standard Federal rate. Therefore, for some hospital categories, the projected increase in payments based on the proposed standard Federal rate is slightly less than the net effect of the proposed 2.1 percent annual update and the approximate −1.3 percent proposed one-time prospective adjustment factor (or 0.8 percent) for FY 2015. Because we are proposing to apply an area wage level budget neutrality factor to the standard Federal rate, the proposed annual update to the wage data, including the proposed implementation of the new OMB delineations, and labor-related share does not impact the increase in aggregate 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 2015 based on the most recent available data and the proposed adoption of the new OMB labor market area delineations. Under our proposal to adopt the new OMB delineations, we are proposing a transitional blended wage index for FY 2015 for LTCH's that would have a lower wage index value under those delineations, as discussed in section VII.D.2. of the preamble of this proposed rule. Therefore, this column reflects the proposed blended wage index that is calculated as a 50/50 blend of the wage index under the current CBSA designations and the wage index under the new OMB delineations under our proposed transitional wage index policy. In addition, we are proposing a slight increase to the labor-related share from 62.537 percent to 62.571 percent under the LTCH PPS for FY 2015, based on the most recent available data on the relative importance of the labor-related share of operating and capital costs based on the FY 2009-based LTCH-specific market basket. We also are proposing to apply an area wage level budget neutrality factor of 1.0002034, which increases the proposed standard Federal rate by approximately 0.02 percent. Therefore, the proposed changes to the wage data, including the proposed adoption of the new OMB delineations, and labor-related share do not result in a change in estimated aggregate LTCH PPS payments.

Table IV below shows the impact of the proposed payment rate and the proposed policy changes on LTCH PPS payments for FY 2015 presented in this proposed rule by comparing estimated FY 2014 payments to estimated FY 2015 payments. The projected increase in payments from FY 2014 to FY 2015 of 0.8 percent is attributable to the impacts of the proposed change to the standard Federal rate (0.7 percent in Column 6) and the effect of the estimated slight decrease in proposed payments for HCO cases (0.1 percent) and an estimated increase in payments for SSO cases (0.2 percent). We currently estimate total HCO payments are projected to decrease slightly from FY 2014 to FY 2015 in order to ensure that the estimated HCO payments would be 8 percent of the total estimated LTCH PPS payments in FY 2015. An analysis of the most recent available LTCH PPS claims data (that is, FY 2013 claims data from the December 2013 update of the MedPAR file) indicates that the FY 2014 HCO threshold of $13,314 (as established in the FY 2014 IPPS/LTCH PPS final rule) may result in HCO payments in FY 2015 that are slightly above the estimated 8 percent. Specifically, we currently estimate that HCO payments would be approximately 8.1 percent of the estimated total LTCH PPS payments in FY 2014. We estimate that the impact of the slight decrease in HCO payments would result in approximately a 0.1 percent decrease in estimated payments from FY 2014 to FY 2015, on average, for all LTCHs. Furthermore, in calculating the estimated HCO payments for FYs 2014 and 2015, 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 approximately 0.2 percent relative to last year. The net result of these projected changes in HCO and SSO payments in FY 2015 is an estimated change in aggregate payments of 0.1 percent. We note that estimated payments for all SSO cases comprise approximately 12 percent of the estimated total LTCH PPS payments, and estimated payments for HCO cases comprise approximately 8 percent of the estimated total FY 2015 LTCH PPS payments. Payments for HCO cases are based on 80 percent of the estimated cost of the case above the HCO threshold, while the majority of the payments for SSO cases (approximately 60 percent) are based on the estimated cost of the case.

In addition to the projected increase in LTCH PPS payments per discharge of approximately $44 million (0.8 percent) from FY 2014 to FY 2015, as shown in Table IV below, we also estimate that the net effect of the projected impact of certain other proposed LTCH PPS policy changes (that is, the reinstatement of the moratorium on the full implementation of the ''25-percent policy'' payment adjustment; the reinstatement of the moratorium on the development of new LTCHs and LTCH satellite facilities and additional LTCH beds; the proposed revision of the ''greater than 3-day interruption of stay'' policy; the proposed revocation of on-site discharges and readmissions policy; and the proposed payment adjustment for ''subclause (II)'' LTCHs) would result in a $14 million decrease in aggregate LTCH PPS payments in FY 2015. The individual impact of these proposed policy changes are discussed in greater detail below in section I.K.3.b. of this Appendix.

As we discuss in detail throughout this proposed rule, based on the most recent available data, we believe that the provisions of this proposed rule relating to the LTCH PPS 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 0.7 percent increase in estimated payments per discharge for FY 2015 as compared to FY 2014 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 22 rural LTCHs in our database (out of 422 LTCHs) for which complete data were available.

The estimated increase in LTCH PPS payments from FY 2014 to FY 2015 for rural LTCHs (0.7 percent) is slightly less than the national average increase (0.8 percent). The estimated increase in LTCH PPS payments from FY 2014 to FY 2015 for rural LTCHs is primarily due to the proposed increase to the standard Federal rate. However, rural LTCHs are experiencing slightly lower increases than the national average due to decreases in their wage index for FY 2015 compared to FY 2014.

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.K.1. of this Appendix, we project an increase in aggregate LTCH PPS payments per discharge in FY 2015 relative to FY 2014 of approximately $44 million based on the 422 LTCHs in our database. In addition, as discussed below in section I.K.3.b. of this Appendix, we also estimate that the net effect of the projected impact of certain other proposed LTCH PPS policy changes would result in a $14 million decrease in aggregate LTCH PPS payments in FY 2015.

b. Impact of Certain Proposed LTCH PPS Policy Changes

(1) Proposed Reinstatement of the Moratorium on the Full Implementation of the ''25-Percent Policy'' Payment Adjustment (§ 412.534 and § 412.536) and Proposed Reinstatement of the Moratorium on the

Development of New LTCHs and LTCH Satellites and Additional LTCH beds (§ 412.23(e) and §§ 412.23(e)(6) and (7))

Section 1206(b) of Public Law 113–67 provides for the retroactive reinstatement and extension, for an additional 4 years, of the moratorium on the full implementation of the 25-percent threshold payment adjustment (referred to as the ''25-percent policy'' payment adjustment) established under section 114(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. As discussed in section VII.E. of the preamble of this proposed rule, we are proposing to reinstate this payment adjustment retroactively for LTCH cost reporting periods beginning on or after July 1, 2013 or October 1, 2013, as applicable under the regulations at § 412.534 and § 412.536.

Section 1206(b)(2) of Public Law 113–67, as amended by section 112(b) of the Protecting Access to Medicare Act of 2–14 (Pub. L. 113–93), provides for moratoria on the establishment of new LTCHs and LTCH satellite facilities and on bed increases in LTCHs effective for the period beginning April 1, 2014, and ending September 30, 2017. This statutory provision also provides specific exceptions to the moratorium on the establishment of new LTCHs and LTCH satellites. We are proposing to implement this policy under the regulations at § 412.23(e) and §§ 412.23(e)(6) and (7), respectively. For additional details, refer to section VII.G. of the preamble of this proposed rule.

Our Office of the Actuary projects that the reinstatement of ''25-percent policy'' adjustment policy would result in approximately a $120 million increase in aggregate LTCH PPS payments in FY 2015. In addition, our Office of the Actuary projects that the portion of the moratoria on the establishment of new LTCHs and LTCH satellite facilities and additional LTCH beds that would occur during FY 2015 is estimated to result in approximately a $30 million reduction in aggregate LTCH PPS payments in FY 2015. Therefore, we project our proposed implementation of both of these statutory provisions would result in approximately a $90 million increase in aggregate LTCH PPS payments in FY 2015.

(2) Proposed Revision of the ''Greater than 3-Day Interruption of Stay'' Policy (§ 412.531) and Proposed Revocation of On-Site Discharges and Readmissions Policy (§ 412.532)

The LTCH greater than 3-day interruption of stay policy under § 412.531 is a payment adjustment that is applied when during the course of an LTCH hospitalization, a patient is discharged to an inpatient acute care hospital, an IRF, or a SNF for treatment or services not available at the LTCH for a specified period followed by readmittance to the same LTCH. Specifically, under this policy, we established specific fixed-day thresholds, which apply to the days away from the LTCH, depending upon the intervening provider. If the stay is an ''interrupted stay,'' that is, the patient returned to the LTCH within the threshold number of days, payment for both ''halves'' of the LTCH discharge is ''bundled,'' and Medicare makes one payment based on the second date of discharge. As discussed in section VII.F. of the preamble of this proposed rule, we are proposing to revise the fixed-day thresholds under the ''greater than 3-day interruption of stay policy'' to apply a uniform 30-day threshold as an ''acceptable standard'' for determining a linkage between an index discharge and a readmission.

As also discussed in section VII.F. of the preamble of this proposed rule, we also are proposing to remove the discharge and readmission requirement specified in the regulations under § 412.532 (referred to as the ''5-percent payment threshold''). Under the ''5-percent payment threshold'' policy, if an LTCH (or a LTCH satellite facility) directly readmits more than 5 percent of its total Medicare inpatients discharged from an ''on-site facility'' (for example, a co-located acute care hospital, an IRF, or a SNF, or a in the case of a LTCH satellite facility, that is co-located with an LTCH), all such discharges to the co-located ''on-site facility'' and the readmissions to the LTCH are treated as one discharge for that cost reporting period, and, as such, one LTCH PPS payment is made on the basis of each patient's initial principal diagnosis.

We estimate that the proposed revision to the greater than 3-day interruption of stay policy under § 412.531 would result in a reduction in aggregate LTCH PPS payments of approximately $130 million for FY 2015, if the proposal to apply a uniform 30-day threshold is finalized. We also estimate that the proposed discontinuation of the ''5-percent payment threshold'' policy would result in an increase of approximately $20 million in aggregate LTCH PPS payments in FY 2015. Accordingly, our Office of the Actuary projects that, together, these proposed policy revisions are estimated to decrease aggregate LTCH PPS payments in FY 2015 by approximately $110 million.

(3) Proposed Payment Adjustment for ''Subclause (II)'' LTCHs (proposed § 412.526)

Section 1206(d) of Public Law 113–67 requires the Secretary to evaluate payments and regulations governing ''hospitals which are classified under subclause (II) of subsection (d)(1)(B)(iv)''. In addition, based on the result of such evaluations, the statute authorizes the Secretary to adjust the payment rates for this type of hospital and to adjust regulations governing a subclause (II) LTCH that otherwise apply to subclause (I) LTCHs. As discussed in section VII.H. of the preamble of this proposed rule, under new § 412.526, we are proposing to apply a payment adjustment under the LTCH PPS to a subclause (II) LTCH beginning in FY 2015 that would result in payments to this type of LTCH resembling those under the reasonable cost TEFRA payment system model. Our Office of the Actuary projects that, if the proposed payment adjustment for ''subclause (II)'' LTCHs is finalized, it would increase aggregate LTCH PPS payments in FY 2015 by approximately $6 million.

c. Impact on Providers

The basic methodology for determining a per discharge LTCH PPS payment is set forth under § 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, a COLA for LTCHs located in 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 2015, it is necessary to estimate payments per discharge for FY 2014 using the rates, factors (including the FY 2014 GROUPER (Version 31.0), and relative weights and the policies established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50753 through 50760 and 51002). It is also necessary to estimate the payments per discharge that would be made under the proposed LTCH PPS rates and factors, and GROUPER (proposed Version 32.0) for FY 2015 (as discussed in section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule). These estimates of FY 2014 and FY 2015 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 2014 payments to estimated FY 2015 payments (on a per discharge basis) for each category of LTCHs. We are proposing to establish a standard Federal rate for FY 2015 of $40,943.51 (for LTCHs that submit quality data under the requirements of the LTCHQR Program), which includes the proposed 2.1 percent annual update, the proposed area wage budget neutrality factor of 1.0002304, and a proposed one-time prospective adjustment to the standard Federal rate for FY 2015 of 0.98734 (approximately -1.3 percent). For LTCHs that fail to submit data to the LTCH Quality Reporting Program, we are proposing to establish a standard Federal rate for FY 2015 of $40,141.47 that includes a 2.0 percentage point reduction applied to the proposed annual update under the requirements of section 1886(m)(5)(C) of the Act in addition to the other proposed adjustments noted above.

Hospital groups were based on characteristics provided in the OSCAR data, FY 2010 through FY 2012 cost report data in HCRIS, and PSF data. Hospital groups included the following:

- Location: large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

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 2013 MedPAR file to estimate payments for FY 2014 and to estimate payments for FY 2015 for 422 LTCHs. We believe that the discharges based on the FY 2013 MedPAR data for the 422 LTCHs in our database, which includes 288 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 2013 MedPAR files. For modeling estimated LTCH PPS payments for FY 2014, we used the FY 2014 standard Federal rate (that is, $40,607.31 for LTCHs that submit quality data under the requirements of the LTCHQR Program and $39,808.74 for LTCHs that failed to submit quality data under the requirements of the LTCHQR Program) used to make payments for LTCH discharges occurring on or after October 1, 2013 through September 30, 2014).

For modeling estimated proposed LTCH PPS payments for FY 2015, we used the proposed FY 2015 standard Federal rate of $40,943.51 (for LTCHs that submit quality data under the requirements of the LTCHQR Program), which includes a proposed one-time prospective adjustment of 0.98734 for FY 2015 for the final year of the 3-year phase-in. For LTCHs that we project to have failed to submit the requisite quality data for FY 2015 under the LTCH Quality Reporting Program, we used the proposed FY 2015 standard Federal rate of $40,141.47, which reflects the 2.0 percentage points reduction required by section 1886(m)(5)(C)of the Act. The proposed FY 2015 standard Federal rates also include the proposed application of an area wage level budget neutrality factor of 1.0002034 (as discussed in section V.B.5. of the Addendum to this proposed rule). Furthermore, in modeling estimated LTCH PPS payments for both FY 2014 and FY 2015 in this impact analysis, we applied the FY 2014 and the proposed FY 2015 adjustments for area wage levels and the proposed COLA for LTCHs located in Alaska and Hawaii. Specifically, we adjusted for differences in area wage levels in determining estimated FY 2014 payments using the current LTCH PPS labor-related share of 62.537 percent (78 FR 50995 through 50996) and the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2014 IPPS/LTCH PPS final rule (which are available via the Internet on the CMS Web site. We also applied the FY 2014 COLA factors shown in the table in section V.C. of the Addendum to that final rule (78 FR 50997 through 50998) to adjust the FY 2014 nonlabor-related share (37.463 percent) for LTCHs located in Alaska and Hawaii. Similarly, we adjusted for differences in area wage levels in determining the estimated FY 2015 payments using the proposed FY 2015 LTCH PPS labor-related share of 62.571 percent and the proposed FY 2015 wage index values, including the proposed 50/50 blended wage index, determined from the proposed wage index values presented in Tables 12A through 12D listed in section VI. of the Addendum to this proposed rule (and available via the Internet). We also applied the proposed FY 2015 COLA factors shown in the table in section V.C. of the Addendum to this proposed rule to the proposed FY 2015 nonlabor-related share (37.429 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 2015, we applied an inflation factor of 4.7 percent (determined by OACT) to estimate the costs of each case using the charges reported on the claims in the FY 2013 MedPAR files and the best available CCRs from the December 2013 update of the PSF. Furthermore, in modeling estimated LTCH PPS payments for FY 2015 in this impact analysis, we used the proposed FY 2015 fixed-loss amount of $15,730 (as discussed in section V.D. of the Addendum to this proposed rule).

These impacts reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from FY 2014 to FY 2015 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 2014 (as described above).
- The fifth column shows the estimated payment per discharge for FY 2015 (as described above).
- The sixth column shows the percentage change in estimated payments per discharge from FY 2014 to FY 2015 due to the proposed annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this proposed rule), including the proposed 2.0 percentage point reduction to the update to the standard Federal rate for LTCHs that fail to submit data to the LTCHQR Program and the final year of the phase-in of a one-time prospective adjustment factor for FY 2015.
- The seventh column shows the percentage change in estimated payments per discharge from FY 2014 to FY 2015 for proposed changes to the area wage level adjustment (that is, the proposed wage indexes, including the proposed implementation of the new OMB delineations, and proposed labor-related share), including the proposed application of an area wage level budget neutrality factor, (as discussed in section V.B. of the Addendum to this proposed rule. This column includes the proposed wage index calculated as a 50/50 blend of the wage index under the current CBSA designations and the wage index under the new OMB delineations under our proposed transitional wage index policy for the proposed implementation of the new OMB delineations.
- The eighth column shows the percentage change in estimated payments per discharge from FY 2014 (Column 4) to FY 2015 (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 2015

[Estimated FY 2014 Payments Compared to Estimated FY 2015 Payments]

LTCH classification	Number of LTCHs	Number of LTCH PPS cases	Average FY 2014 LTCH PPS payment per case	Average FY 2015 LTCH PPS payment per case [1]	Percent change in estimated payments per discharge from FY 2014 to FY 2015 for the proposed annual update to the federal rate [2]	Percent change in estimated payments per discharge from FY 2014 to FY 2015 for proposed changes to the area wage level adjustment with proposed budget neutrality [3]	Percent change in payments per discharge from FY 2014 to FY 2015 for all proposed changes [4]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
ALL PROVIDERS	422	137,897	$40,247.74	$40,567.74	0.7	0	0.8
BY LOCATION:							
RURAL	22	5,691	35,633.63	35,893.55	0.8	−0.2	0.7
URBAN	400	132,206	40,446.36	40,768.95	0.7	0	0.8
LARGE	200	76,347	42,694	43,082	0.7	0.1	0.9
OTHER	200	55,859	37,375	37,608	0.7	−0.2	0.6

TABLE IV—IMPACT OF PROPOSED PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR FY 2015—Continued

[Estimated FY 2014 Payments Compared to Estimated FY 2015 Payments]

LTCH classification	Number of LTCHs	Number of LTCH PPS cases	Average FY 2014 LTCH PPS payment per case	Average FY 2015 LTCH PPS payment per case [1]	Percent change in estimated payments per discharge from FY 2014 to FY 2015 for the proposed annual update to the federal rate [2]	Percent change in estimated payments per discharge from FY 2014 to FY 2015 for proposed changes to the area wage level adjustment with proposed budget neutrality [3]	Percent change in payments per discharge from FY 2014 to FY 2015 for all proposed changes [4]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
BY PARTICIPATION DATE:							
BEFORE OCT. 1983	16	5,200	37,560.33	38,297.27	0.7	0.8	2
OCT. 1983–SEPT. 1993	44	16,796	43,706.56	44,005.21	0.7	−0.2	0.7
OCT. 1993–SEPT. 2002	181	62,686	39,413.76	39,694.92	0.7	−0.1	0.7
OCTOBER 2002 and AFTER	181	53,215	40,401.05	40,732.81	0.7	0.1	0.8
BY OWNERSHIP TYPE:							
VOLUNTARY	91	21,887	41,091.65	41,428.06	0.7	0.1	0.8
PROPRIETARY	288	104,450	39,975.38	40,291.47	0.7	0	0.8
GOVERNMENT	43	11,560	41,110.80	41,435.10	0.7	0.1	0.8
BY REGION:							
NEW ENGLAND	14	6,948	36,681.66	37,478.17	0.7	1.1	2.2
MIDDLE ATLANTIC	29	8,522	42,608.78	43,311.85	0.7	1.1	1.7
SOUTH ATLANTIC	61	18,561	42,577.65	42,756.02	0.7	−0.3	0.4
EAST NORTH CENTRAL	70	20,072	42,055.63	42,256.47	0.7	−0.1	0.5
EAST SOUTH CENTRAL	31	8,940	39,632.87	39,809.48	0.7	−0.5	0.4
WEST NORTH CENTRAL	26	6,446	39,279.06	39,620.34	0.7	0.1	0.9
WEST SOUTH CENTRAL	134	48,191	35,731.94	36,001.75	0.7	−0.2	0.8
MOUNTAIN	32	6,775	43,403.32	43,675.91	0.7	−0.1	0.6
PACIFIC	25	13,442	50,149.94	50,643.35	0.7	0.1	1
BY BED SIZE:							
BEDS: 0–24	24	2,593	35,165.11	35,370.96	0.8	−0.2	0.6
BEDS: 25–49	200	47,183	39,176.76	39,479.06	0.7	0	0.8
BEDS: 50–74	117	37,486	40,905.58	41,253.12	0.7	0.1	0.8
BEDS: 75–124	45	22,044	42,299.43	42,677.61	0.7	0.2	0.9
BEDS: 125–199	22	15,353	39,223.11	39,498.04	0.7	−0.1	0.7
BEDS: 200 +	14	13,238	40,969.52	41,252.44	0.7	−0.2	0.7

[1] Estimated FY 2015 LTCH PPS payments based on the proposed payment rate and factor changes presented in the preamble of and the Addendum to this proposed rule.

[2] Percent change in estimated payments per discharge from FY 2014 to FY 2015 for the proposed annual update to the standard Federal rate and the proposed one-time prospective adjustment factor for FY 2015 as discussed in section V.A.2. of the Addendum to this proposed rule.

[3] Percent change in estimated payments per discharge from FY 2014 to FY 2015 for proposed changes to the area wage level adjustment under § 412.525(c) (as discussed in section V.B. of the Addendum to this proposed rule).

[4] Percent change in estimated payments per discharge from FY 2014 LTCH PPS (shown in Column 4) to FY 2015 LTCH PPS (shown in Column 5), including all of the proposed changes to the rates and factors presented in the preamble of 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 proposed 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 422 LTCHs, we have prepared the following summary of the impact (as shown above in Table IV) of the proposed LTCH PPS payment rate and policy changes presented in this proposed rule. The impact analysis in Table IV shows that estimated payments per discharge are expected to increase 0.8 percent, on average, for all LTCHs from FY 2014 to FY 2015 as a result of the proposed payment rate and policy changes presented in this proposed rule, including an estimated slight decrease in HCO payments. This estimated 0.8 percent increase in LTCH PPS payments per discharge from the FY 2014 to FY 2015 for all LTCHs (as shown in Table IV) was determined by comparing estimated FY 2015 LTCH PPS payments (using the proposed payment rates and factors discussed in this proposed rule) to estimated FY 2014 LTCH PPS payments (as described above in section I.L.1. of this Appendix).

We are proposing to establish a standard Federal rate of $40,943.51 (or a standard Federal rate of $40,141.47 for LTCHs that failed to submit data under the requirements of the LTCHQR Program) for FY 2015. Specifically, we are proposing to update the standard Federal rate for FY 2015 by 2.1 percent, which is based on the latest estimate of the proposed LTCH PPS market basket increase (2.7 percent), the proposed reduction of 0.4 percentage point for the MFP adjustment, and the 0.2 percentage point reduction consistent with sections 1886(m)(3) and (m)(4) of the Act. For LTCHs that fail to submit quality data under the requirements of the LTCHQR Program, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction is applied to the proposed annual update to the standard Federal rate. In addition, we are proposing to apply a one-time prospective adjustment factor for FY 2015 of 0.98734 (approximately −1.3 percent) to the standard Federal rate for the final year of the 3-year phase-in.

We noted earlier in this section that, for most categories of LTCHs, as shown in Table IV (Column 6), the payment increase due to the proposed 2.1 percent annual update to the standard Federal rate and the proposed application of a one-time prospective adjustment for FY 2015 of approximately −1.3 percent for the final year of the 3-year phase-in is projected to result in approximately a 0.7 percent decrease in estimated payments per discharge for all LTCHs from FY 2014 to FY 2015.

In addition, our estimate of the proposed changes in payments due to the proposed update 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 may increase by less than 0.8 percent for certain hospital categories due to the proposed annual update to the standard Federal rate and the proposed application of the final phase of the one-time prospective adjustment for FY 2015.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 4 percent of all LTCH 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 2014 to FY 2015 for all hospitals is 0.8 percent for all proposed changes. For rural LTCHs, the percent change for all proposed changes is estimated to be a 0.7 percent increase, while for urban LTCHs, we estimate the increase would be 0.8 percent. Large urban LTCHs are projected to experience an increase of 0.9 percent in estimated payments per discharge from FY 2014 to FY 2015, while other urban LTCHs are projected to experience an increase of 0.6 percent in estimated payments per discharge from FY 2014 to FY 2015, as shown in Table IV.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) Before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) October 2002 and after. Based on the most recent available data, the categories of LTCHs with the largest percentage of LTCH cases (approximately 45 percent) are in hospitals that began participating in the Medicare program between October 1993 and September 2002, and they are projected to experience a 0.7 percent increase in estimated payments per discharge from FY 2014 to FY 2015, as shown in Table IV.

Approximately 4 percent of LTCHs began participating in the Medicare program before October 1983, and these LTCHs are projected to experience a higher than average percent increase (2.0 percent) in estimated payments per discharge from FY 2014 to FY 2015, as shown in Table IV. Approximately 10 percent of LTCHs began participating in the Medicare program between October 1983 and September 1993. These LTCHs are projected to experience a 0.7 percent increase in estimated payments from FY 2014 to FY 2015. LTCHs that began participating in the Medicare program after October 1, 2002, which treat approximately 39 percent of all LTCH cases, are projected to experience a 0.8 percent increase in estimated payments from FY 2014 to FY 2015.

(3) Ownership Control

LTCHs are grouped into three categories based on ownership control type: Voluntary, proprietary, and government. Based on the most recent available data, approximately 22 percent of LTCHs are identified as voluntary (Table IV). The majority (nearly 68 percent) of LTCHs are identified as proprietary while government-owned and operated LTCHs represent about 10 percent of LTCHs. Based on ownership type, each category of LTCHs is expected to experience the average increase in payments of 0.8 percent in estimated payments per discharge from FY 2014 to FY 2015.

(4) Census Region

Estimated payments per discharge for FY 2015 are projected to increase for LTCHs located in all regions in comparison to FY 2014. 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 New England and Middle Atlantic regions (2.2 percent and 1.7 percent, respectively as shown in Table IV). The estimated percent increase in payments per discharge from FY 2014 to FY 2015 for those regions is largely attributable to the proposed changes in the area wage level adjustment.

In contrast, LTCHs located in the South Atlantic and East South Central regions are projected to experience the smallest increase in estimated payments per discharge from FY 2014 to FY 2015. The lower than national average estimated increase in payments of 0.4 percent 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. Most bed size categories are projected to receive either a slightly higher or slightly lower than average increase in estimated payments per discharge from FY 2014 to FY 2015. We project that small LTCHs (0–24 beds) would experience a 0.6 percent increase in payments, mostly due to decreases in the area wage level adjustment, while large LTCHs (200+ beds) would experience a 0.7 percent increase in payments. LTCHs with between 75 and 124 beds are expected to experience an above average increase in payments per discharge from FY 2014 to FY 2015 (0.9 percent).

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 2015 relative to FY 2014 of approximately $44 million (or approximately 0.8 percent) for the 422 LTCHs in our database.

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.

L. Effects of Proposed Requirements for Hospital Inpatient Quality Reporting (IQR) Program

In section IX.A. of the preamble of this proposed rule, we discuss our proposed requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for the FY 2017 payment determination. We are proposing to remove a total of 20 measures from the Hospital IQR Program for the FY 2016 payment determination and subsequent years, which begins in the CY 2015 reporting period. The first five measures are: (1) AMI–1 Aspirin at arrival (NQF #0132); (2) AMI–3 ACEI/ARB for left ventricular systolic dysfunction (NQF #0137); (3) AMI–5 Beta-blocker prescribed at discharge (NQF #0160); (4) SCIP INF–6 Appropriate Hair Removal; and (5) Participation in a systematic database for cardiac surgery (NQF #0113). Of those, the first four measures are currently suspended. The fifth measure was recommended by the MAP for removal because it is ''topped-out.'' We believe that an additional 15 chart-abstracted measures are ''topped out,'' based on the previously adopted criteria, and we are proposing to remove them from the FY 2017 payment determination and subsequent years measure set. However, we are proposing to retain the electronic clinical quality measure version of 10 of these chart-abstracted measures for Hospital IQR Program reporting as discussed in section IX.A.7.f. of the preamble of this proposed rule.

We also are proposing to add one chart-abstracted measure in this proposed rule: Severe sepsis and septic shock: management bundle (NQF #0500).

We are proposing to incorporate refinements for several measures for the FY 2017 payment determination and subsequent years that were previously adopted in the Hospital IQR Program. These refinements have either arisen out of the NQF endorsement maintenance process, or during our internal efforts to harmonize measure approaches. The measure refinements include the following: (1) Refining the planned readmission algorithm for all seven readmission measures included in the Hospital IQR Program; (2) modifying the hip/knee readmission and complication measure cohorts to exclude index admissions with a secondary fracture diagnosis; and (3) modifying the hip/knee complication measure to not count as complications coded as ''present on admission'' (POA) during the index admission. We do not anticipate any hospital burden associated with these revisions, as each is based on claims submitted by hospitals for payment purposes.

Information is not available to determine the precise number of hospitals that would not meet the requirements to receive the full annual percentage increase for the FY 2017 payment determination. Historically, an average of 100 hospitals that participate in the Hospital IQR Program do not receive the full annual percentage increase in any fiscal year. We anticipate that because of the new requirements we are proposing for reporting for the FY 2017 payment determination, the number of hospitals not receiving the full annual percentage increase may be higher than average. The highest number of hospitals failing to meet program requirements was approximately 200 after the introduction of new NHSN reporting requirements. If the number of hospitals failing does increase because of proposed new requirements, we anticipate that over the long run, this number will decline as hospitals gain more experience with these requirements.

As discussed in section XIII.B.6. of the preamble of this proposed rule, we estimate that our proposals for the adoption and removal of measures will result in an overall decrease of 5.86 million hours or 1,775 hours per hospital. The table below describes the hospital burden associated with the Hospital IQR Program requirements.

BURDEN IMPACT OF PROPOSED HOSPITAL IQR PROGRAM REQUIREMENTS FOR FY 2017

Hospital IQR program requirement	Number of hospitals impacted	Burden per hospital for previously finalized requirements	Burden per hospital for all requirements as proposed (continuing, removed, added)	Net change in burden per hospital
Chart-abstracted and structural measures, forms	3,300	1,291 hours	963 hours	−328 hours.
Review reports for claims-based measures	3,300	4 hours	4 hours	0.
Reporting of voluntary electronic clinical quality measures (E–CQM) in place of chart-abstracted measures.	Unknown	−570 hours	−554 hours	16 hours.
Validation templates	Up to 600	144 hours	144 hours	0.
E–CQM validation test	Up to 100	0	16 hours	16 hours.
Validation charts photocopying	Up to 600	$8,640	$8,496	$−144.

We estimate that the total burden associated with the proposed voluntary electronic clinical quality measure reporting option will be similar to the burden outlined for hospitals in the Medicare EHR Incentive Program Stage 2 final rule (77 FR 53968 through 54162). However, by allowing hospitals to submit data for a maximum of 16 measures that could be used to satisfy partial requirements for both programs, each hospital that participates in the voluntary electronic quality measure reporting option could realize a reduction in burden of up to approximately 554 hours. To achieve a savings of 554 hours, we made the following assumptions. We assumed an average annual collection burden for 164 chart-abstracted measures (in Stroke, VTE, ED, and PC–01 topic areas) to be a combined 582 hours annually per hospital over 4 quarters. We estimate that each quarter, each hospital will need approximately 2 hours and 40 minutes (10 minutes per measure) to process and submit measures results electronically per quarter. This equates to 10 hours and 40 minutes annually. Because the remaining 12 electronic clinical quality measures submitted to the Hospital IQR Program would not replace any chart-abstracted reporting requirements, there would be an extra 2 hours per quarter per hospital in burden (8 hours total), with no commensurate savings.

In the FY 2014 IPPS/LTCH PPS final rule, hospitals were permitted to meet Hospital IQR program requirements for these 16 measures by submitting data electronically for a single quarter (78 FR 50811 through 50819) for the FY 2016 payment determination. Moreover, there were no options for submitting 12 additional measures. Therefore, we estimate that savings for hospitals choosing to submit all optional measures electronically for the FY 2016 payment determination would have been about 579 hours (582 hours minus 2 hours and 40 minutes). The net burden of the proposal for the FY 2017 payment determination compared with the policy finalized for the FY 2016 payment determination is an additional 16 hours for a hospital choosing to submit all possible required and optional measures electronically.

M. Effects of Proposed Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program for FY 2017

In section IX.B. of the preamble of this proposed rule, we discuss our proposed policies for the quality data reporting program for PPS-exempt cancer hospitals (PCHs), which we refer to as the PCHQR Program. The PCHQR Program is authorized under section 1866(k) of the Act, which was added by section 3005 of the Affordable Care Act.

In this proposed rule, we are proposing that PCHs submit data on one additional measure beginning with the FY 2017 program which, if finalized, would increase the total number of measures in the FY 2017 PCHQR measure set to 19 measures. We also are proposing to update the specifications for the five previously finalized clinical process/oncology care measures to require PCHs to report all-patient data for each of these measures, and to adopt a new sampling methodology that PCHs can use to report these measures. Furthermore, we are proposing to require PCHs to submit population and sample size counts for these measures. We also are proposing to give PCHs a choice of one of two reporting options to report the clinical process/oncology care, SCIP, and clinical process/cancer specific treatment measures.

The impact of the proposed requirements for the PCHQR program is expected to be minimal overall because some PCHs are already submitting previously adopted quality measure data to CMS. As a result, these PCHs are familiar with our IT infrastructure and programmatic operations. In addition to fostering transparency and facilitating public reporting, we believe our proposed requirements introduce minimal burden while increasing quality of care. We further believe that these requirements outweigh any burden.

One expected effect of the PCHQR Program is to keep the public informed of the quality of care provided by PCHs. We will publicly display quality measure data collected under the PCHQR Program as required under the Act. These data will be displayed on the *Hospital Compare* Web site. The goals of making these data available to the public in a user-friendly and relevant format, include, but are not limited to: (1) Allowing the public to compare PCHs in order to make informed health care decisions regarding care setting; and (2) providing information about current trends in health care. Furthermore, PCHs can use their own health care quality data for many purposes such as in risk management programs, health care acquired infection prevention programs, and research and development activities, among others.

N. Effects of Proposed Requirements for the Long-Term Care Hospital Quality Reporting (LTCHQR) Program for FY 2015 Through FY 2018

In section IX.C. of the preamble of this proposed rule, we discuss the implementation of section 1886(m)(5) of the Act, which was added by section 3004(a) of the Affordable Care Act. Section 1886(m)(5) of the Act provides that, for rate year 2014 and each subsequent year, any LTCH that does not submit data to the Secretary in accordance with section 1886(m)(5)(C) of the Act shall receive a 2-percentage point reduction to the annual update to the standard Federal rate for discharges for the hospital during the applicable fiscal year. 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 annual percentage increase in any fiscal year as a result of failure to submit data under the LTCHQR Program. Information is not available to determine the precise number of LTCHs that would not meet the requirements to receive the full annual percentage increase for the FY 2016 payment determination. At the time that this analysis was prepared, 8 of the 442 active Medicare-certified LTCHs did not receive the full annual percentage increase for the FY 2014 payment determination. We believe that a majority of LTCHs will continue to collect and submit data for the FY 2015 payment determination and subsequent years because they will continue to view the LTCHQR Program as an important step in improving the quality of care patients receive in the LTCHs. We believe that the burden associated with the LTCHQR Program is the time and effort associated with data collection. There are approximately 442 LTCHs currently reporting quality data to CMS.

In this proposed rule, we are retaining seven previously finalized measures, proposing revisions to two previously finalized measures, and are proposing three additional quality measures for inclusion in the LTCHQR Program. In section IX.C.7. of the preamble of this proposed rule, we are proposing three new quality measures for inclusion in the LTCHQR Program affecting the FY 2018 payment determination and subsequent years: (1) Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function; (2) Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support; and (3) National Healthcare Safety Network (NHSN) Ventilator-Associate Event (VAE) Outcome Measure.

Six of the previously adopted and newly proposed measures either will or would be collected via the NHSN. In section IX.C.7.b. of the preamble of this proposed rule, we are proposing to collect the NHSN VAE Outcome Measure. Normally, we would only discuss the burden associated with those measures that are being proposed in any given rule. Because we have access to information that now indicates our previous calculations for the CAUTI, CLABSI, MRSA, and CDI were incorrect (we estimated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50959 through 50964) that LTCHs would submit six infection events per month for each of these measures), we offer below the recalculation of the associated burden. Based on submissions to the NHSN, we now estimate that each LTCH will execute approximately 7 NHSN submissions per month; 1 MRSA event; 1 CDI event; 2 CLABSI events; 3 CAUTI events (84 events per LTCH annually). This equates to a total of approximately 37,128 submissions of events to the NHSN from all LTCHs per year (includes CAUTI, CLABSI, MRSA, and CDI). The CDC estimated the public reporting burden of the collection of information for each measure to include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. MRSA and CDI events are estimated to require an average of 15 minutes per response (10 minutes of clinical (RN) time, and 5 minutes of clerical (Medical Record or Healthcare Information Technician). CAUTI is estimated to require an average of 29 minutes per response, and CLABSI events are estimated to require an average of 32 minutes per response. In addition, each LTCH must also complete a Patient Safety Monthly Reporting Plan estimated at 35 minutes per Plan and a Denominator for Specialty Care Area, which is estimated at 5 hours per month. Based on this estimate, we expect each LTCH would expend 8.6 hours per month for each LTCH, 103.2 hours annually for each LTCH, or 45,614.4 annually for all LTCHs reporting to the NHSN.

In addition, each LTCH must submit the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431), which the CDC estimates will take 10 minutes annually per LTCH, or an additional 73.66 hours for all LTCH annually. In total, the burden we have recalculated for all previously finalized measures (including CAUTI, CLABSI, MRSA, CDI, HCP, Patient Safety Monthly Reporting plan, and Denominator for Specialty Care Area) will equal 103.4 hours annually per LTCH or 45,072.8 hours for all LTCHs annually.

For the newly proposed VAE measure, which will also be reported by LTCHs through the CDC's NHSN, the CDC estimates that each LTCH will submit 1 VAE per month, which will require approximately 22 minutes of clinical time per response. This equates to 22 minutes per LTCH monthly, 4.4 hours per LTCH annually, and 1,944.8 hours for all LTCHs annually. According to the US Bureau of Labor and Statistics, the mean hourly wage for a registered nurse (RN) is $33.1 [191]; the mean hourly wage for a medical records and health information technician is $16.81. However, in order to account for overhead and fringe benefits, we have double the mean hourly wage, making it $66.26 for an RN, and $33.62 for a Medical Record or Health Information Technician. We estimate that the annual cost per each LTCH for the previously finalized measures, for which we have recalculated burden (including CAUTI, CLABSI, MRSA, CDI, HCP, Patient Safety Monthly Reporting plan, and Denominator for Specialty Care Area) to be $6,770.10 and that the total yearly cost to all LTCHs for the submission of data to NHSN would be $2,992,384.20. We estimate that the total cost for the newly proposed VAE measure would be $291.54 per LTCH annually, or $128,860.68 for all LTCHs annually.

The All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals is a Medicare claims-based measure; because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe there will be no additional impact.

The remaining five measures will be collected utilizing the LTCH CARE Data Set. The burden estimates associated with OMB control number 0938–1163 estimate that each LTCH has an impact data collection burden of 243.24 hours or $6,755.84 associated with collection of the LTCH CARE Data Set, which includes the following three measures: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678); Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680), and the Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).

We also are proposing to use the LTCH CARE Data Set to report the two additional proposed measures, Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support; and Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function for the FY 2018 payment determination and subsequent years. In addition, the LTCH CARE Data Set will be used to report the previously finalized measure. We estimate the additional elements for two newly proposed measures will take 13.5 minutes of nursing/clinical staff time to report data for Admission assessment and 13 minutes of nursing/clinical staff time to report data for Discharge assessment, for a total of 26.5 minutes. In accordance with OMB control number 0920–0666, we estimate 202,050 discharges from all LTCHs annually, with an additional burden of 26.5 minutes. This would equate to 89,238.75 total hours or 201.9 hours per LTCH. We believe this work will be completed by RN staff. As previously noted, per the US Bureau of Labor and Statistics, the mean hourly wage for a registered nurse (RN) is $33.13.[192] However, in order to account for

[191] According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Registered Nurse is $31.48. See: *http://www.bls.gov/ooh/healthcare/registered-nurses.htm.* Fringe benefits are calculated at a rate of 36.25 percent in accordance with OMB Circular A–76, Attachment C, Table C.1. After adding the fringe benefits, the total hourly cost for an RN is $42.89.

[192] According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Registered Nurse is $31.48. See: *http://www.bls.gov/ooh/healthcare/registered-nurses.htm.* Fringe benefits are calculated at a rate of 36.25 percent in accordance with OMB Circular A–76, Attachment C, Table C.1. After adding the fringe benefits, the total hourly cost for an RN is $42.89.

overhead and fringe benefits, we have double the mean hourly wage, making it $66.26 for an RN. The total cost related to the two newly proposed functional status measures referenced above is estimated at $13,377.89 per LTCH annually, or $5,913,027.38 for all LTCHs annually.

Lastly, we are proposing to validate data submitted on the LTCH CARE Data Set by requesting portions of 1,300 patient charts from 260 LTCHs submitted during CY 2015 be copied and mailed to a CMS validation contractor. We estimate the total submission for each chart to be no more than 270 pages in length. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53269), we estimated the appropriate cost for sending charts under the Hospital IQR Program to be 12 cents per page in accordance with our photocopying payment methodology (68 FR 67955). We believe that the costs would be the same under the LTCHQR Program because we would use the same photocopying payment methodology. Each chart also will require approximately $4.00 shipping. Two hundred seventy pages at a rate of $0.12 per page with a $4.00 shipping cost would be $36.40 per chart. We estimate the total cost of sending charts selected for validation to be $36.40 multiplied by 1,300 charts for a total of $47,320.

In summary, the total cost for all previously finalized HAI and vaccination measures (CAUTI, CLABSI, MRSA, CDI, HCP, Patient Safety Monthly Reporting plan, and Denominator for Specialty Care Area) reported through the CDC's NHSN, that we have recalculated based on new information regarding the number of infection events reported by LTCHs per month, is $6,770.10 per LTCH annually, or $2,992,384.20 for all LTCHs annually. The total cost per LTCH for the three newly proposed measures in this proposed rule (Functional Outcome Measure: Change in Mobility among Inpatients requiring Ventilator Support, Percent of LTCH Inpatients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function, and Ventilator-Associated Events) is $13,669.43 per LTCH annually, or $6,041,886.06 for all LTCHs annually. The total cost for the 260 LTCHs selected under our newly proposed data accuracy validation policy is $47,320, which would be paid by CMS.

O. Effects of Proposals Regarding Electronic Health Record (EHR) Incentive Program and Hospital IQR Program

In sections IX.D. of the preamble of this proposed rule, we discuss proposed requirements for the EHR Incentive Program. We are proposing to align the Medicare EHR Incentive Program reporting and submission timelines for clinical quality measures for eligible hospitals and CAHs with the Hospital IQR Program's reporting and submission timelines.

We have determined that the electronic submission of aggregate-level data using QRDA–III will not be feasible in 2015 for eligible hospitals and CAHs under the Medicare EHR Incentive Program. We are proposing to continue, for FY 2015, the policy we adopted for FY 2014 for eligible hospitals and CAHs submitting CQMs under the Medicare EHR Incentive Program. For FY 2015, eligible hospitals and CAHs would be able to electronically submit using a method similar to the 2012 and 2013 EHR Incentive Program electronic reporting pilot for eligible hospitals and CAHs, which used QRDA–I (patient-level data). Eligible hospitals and CAHs that are beyond their first year of meaningful use may continue to report aggregate CQM results through attestation. We also are clarifying our policy on zero denominators and the case threshold exemption for clinical quality measures.

We do not believe that our proposals to align the Medicare EHR Incentive program reporting and submission timelines for clinical quality measures with the Hospital IQR Program's reporting and submission timelines and to allow the electronic submission of QRDA–I (patient-level data) for eligible hospitals and CAHs to electronic submit CQMs under the Medicare EHR Incentive Program will have a significant impact.

P. Effects of Proposed Revision of Regulations Governing Use and Release of Medicare Advantage Risk Adjustment Data

Under section X. of the preamble of this proposed rule, we are proposing to revise the existing regulations at § 422.310(f) to broaden the specified uses of risk adjustment data in order to strengthen program management and increase transparency in the MA program and to specify the conditions for release of risk adjustment data to entities outside of CMS. We are proposing to revise the regulations to specify four additional purposes for which CMS may use or release risk adjustment data submitted by MA organizations: (1) To conduct evaluations and other analysis to support the Medicare program (including demonstrations) and to support public health initiatives and other health care-related research; (2) for activities to support the administration of the Medicare program; (3) for activities conducted to support program integrity; and (4) for purposes explicitly permitted by other laws. In addition, the existing regulations do not specify conditions for release by CMS of risk adjustment data submitted by MA organizations. Therefore, we are proposing to add regulatory language to address CMS' release of such data to non-CMS entities.

We have determined that the proposed regulatory amendments do not impose any mandatory costs on entities that may choose, under this proposal, to request data files from CMS for their research analyses or other purposes listed in the proposal. Requesting data from CMS is at the discretion of the requester. Therefore, we have determined that there are not any economically significant effects of the proposed provisions. We also have determined that the proposed regulatory amendments would not impose a burden on the entity requesting data files.

Q. Effects of Proposed Changes to Enforcement Provisions for Organ Transplant Centers

Under section XI. of the preamble of this proposed rule, we discuss our proposals to expand and clarify the current organ transplant regulation as it relates to a transplant program's ability to request approval for participation in Medicare based on mitigating factors, the timelines for such review, and potential System Improvement Agreements that may allow a transplant program to improve outcomes and avert Medicare termination when outcomes have not met CMS requirements. Our proposals also would allow for consideration of factors such as innovative practice in the field of organ transplantation, and for potential mitigating factors consideration of a transplant program's outcomes using Bayesian methodology for calculating outcomes for patient death and graft failure.

These proposals will not have a significant effect on Medicare and Medicaid programs as it will allow organ transplant programs to continue to participate in Medicare if approved based on mitigating factors or during the time established in the Systems Improvement Agreement. There is an added benefit to patients who receive transplants, and to the Medicare program, when a transplant program improves patient and graft survival through completion of a system Improvement Agreement. However, sufficient data are not currently available to quantify the added benefit of System Improvement Agreements or innovative practices. Therefore, we project only that the cost impact of the proposals to the Medicare and Medicaid programs would be negligible.

Historical data reflect that between the date the transplant regulation was codified in 2007 and August 2013, CMS rendered a final determination for 129 organ transplant programs that applied for Medicare approval based on mitigating factors. Of the 129 transplant programs, 20 terminated Medicare participation. An additional 33 transplant programs averted Medicare termination by successful completion of a Systems Improvement Agreement and resulting substantial improvement in patient and graft survival. The remaining programs were approved for mitigating factors based on improved outcomes (without needing a System Improvement Agreement), special circumstances, or came into compliance with CMS requirements during the mitigating factors review period. We estimate the cost associated with the application for mitigating factors at $10,000. This is based on the salary for the transplant administrator to prepare the documents for the application during the 30-day timeframe allotted. The cost does not represent any increase from what is anticipated in the existing transplant regulation related to mitigating factors. For transplant programs that enter into a Systems Improvement Agreement, the estimated cost to the transplant program is $200,000 to $250,000 based on reports from programs that have completed such Agreements in the past. Both a mitigating factors review and completion of a System Improvement Agreement are voluntary acts on the part of a hospital that maintains a transplant program. Since the 2007 effective date of the CMS regulation, only one hospital has elected not to file a mitigating factors review after being cited by CMS for a condition-level deficiency for patient outcomes or clinical experience, and few hospitals have declined a CMS offer to complete a System

Improvement Agreement. Therefore, we conclude that the costs involved in these activities are much lower for the hospital compared with other alternatives, such as filing an appeal and incurring the legal costs of that appeal.

Our proposals would not have a significant impact on a substantial number of small businesses or other small entities. Nor would they have a significant impact on small rural hospitals.

II. Alternatives Considered

This proposed rule contains a range of proposed policies. It also provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

III. 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 decrease of 0.8 percent in operating payments. As discussed in section I.G. of this Appendix, we estimate that proposed operating payments will decrease by approximately $864 million in FY 2015 relative to FY 2014. However, when we account for the impact of the changes in Medicare DSH payments and the impact of the new additional payments based on uncompensated care in accordance with section 3133 of the Affordable Care Act, based on estimates provided by the CMS Office of the Actuary, consistent with our policy discussed in section IV.F. of the preamble of this proposed rule, we estimate that operating payments would decrease by approximately $30 million relative to FY 2014. In addition, we estimate a savings of $28 million associated with the proposed HACs policies in FY 2015, which is an additional $2 million in savings as compared to FY 2014. We estimate that the expiration of the expansion of low-volume hospital payments for discharges beginning on April 1, 2015, under the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) will result in a decrease in payments of approximately $343 million relative to FY 2014. We estimate that the continuation of certain new technology add-on payments for FY 2015 will increase spending by approximately $7 million. Finally, we estimate that the proposed policies related to validation, including submission of and payment for secure electronic versions of medical information for validation for the FY 2017 payment determination and subsequent years, as described in the ICRs for the Hospital IQR Program in section XII.B.6. of the preamble of this proposed rule, will result in a cost savings to CMS of approximately $0.5 million. These estimates, combined with our estimated decrease in FY 2015 operating payment of −$30 million, result in an estimated decrease of approximately $367 million for FY 2015. We estimate that hospitals will experience a 1.2 percent increase in capital payments per case, as shown in Table III of section I.I. of this Appendix. We project that there will be a $126 million increase in capital payments in FY 2015 compared to FY 2014. The proposed cumulative operating and capital payments would result in a net decrease of approximately $241 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 2015. In the impact analysis, we are using the proposed rates, factors, and policies presented in this proposed rule, including proposed updated wage index values and relative weights, and the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2015. Accordingly, based on the best available data for the 423 LTCHs in our database, we estimate that FY 2015 LTCH PPS payments will increase approximately $44 million relative to FY 2014 as a result of the proposed payment rates and factors presented in this proposed rule. In addition, we estimate that net effect of the projected impact of certain other proposed LTCH PPS policy changes (that is, the reinstatement of the moratorium on the full implementation of the ''25 percent threshold'' payment adjustment as discussed in section VII.E. of the preamble of this proposed rule; the reinstatement of the moratorium on the development of new LTCHs and LTCH satellite facilities and additional LTCH beds as discussed in section VII.G. of the preamble of this proposed rule; the proposed revision of the ''greater than 3-day interruption of stay'' policy as discussed in section VII.F. of the preamble of this proposed rule; the proposed revocation of onsite discharges and readmissions policy as discussed in section VII.H. of the preamble of this proposed rule; and the proposed payment adjustment for ''subclause (II)'' LTCHs as discussed in section VII.I. of the preamble of this proposed rule) is estimated to result in a reduction in LTCH PPS payments of approximately $14 million. The impact analysis of the proposed payment rates and factors presented in this proposed rule under the LTCH PPS, in conjunction with the estimated payment impacts of certain other proposed LTCH PPS policy changes would result in a net increase of $30 million to LTCH providers. Additionally, we present the costs to LTCHs associated with the completion of the proposed data for the LTCHQR Program at $6.08 million or approximately $3.11 million more than FY 2014.

IV. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table V below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the proposed changes to the IPPS presented in this proposed rule. All expenditures are classified as transfers to Medicare providers.

The savings to the Federal Government associated with the policies in this proposed rule are estimated at $241 million.

TABLE V—ACCOUNTING STATEMENT: CLASSIFICATION OF PROPOSED ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2014 TO FY 2015

Category	Transfers
Annualized Monetized Transfers	−$241 million.
From Whom to Whom	Federal Government to IPPS Medicare Providers.

B. LTCHs

As discussed in section I.L. of this Appendix, the impact analysis of the proposed payment rates and factors presented in this proposed rule under the LTCH PPS, As discussed in section I.L. of this Appendix, the impact analysis of the proposed payment rates and factors presented in this proposed rule under the LTCH PPS, in conjunction with the estimated payment impacts of certain other proposed LTCH PPS policy changes (that is, the reinstatement of the moratorium on the full implementation of the ''25-percent threshold'' payment adjustment; the reinstatement of the moratorium on the development of new LTCHs and LTCH satellite facilities and increase in the number of LTCH beds; the proposed revision of the ''greater than 3-day interruption of stay'' policy; the proposed revocation of onsite discharges and readmissions policy; and the proposed payment adjustment for ''subclause (II)'' LTCHs), is projected to result in an increase in estimated aggregate LTCH PPS payments in FY 2015 relative to FY 2014 of approximately $30 million based on the data for 423 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table VI below, we have prepared an accounting

statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to the 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 payment rates and factors and other provisions presented in this proposed rule based on the data for the 423 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs). Lastly, we present the costs to LTCHs associated with the completion of the proposed data for the LTCHQR Program at $6.08 million or approximately $3.11 million more than FY 2014.

The cost to the Federal Government associated with the proposed policies for LTCHs in this proposed rule is estimated at $30 million.

TABLE VI—ACCOUNTING STATEMENT: CLASSIFICATION OF PROPOSED ESTIMATED EXPENDITURES FROM THE FY 2014 LTCH PPS TO THE FY 2015 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	$30 million.
From Whom to Whom	Federal Government to LTCH Medicare Providers.
Category	**Costs**
Annualized Monetized Costs for LTCHs to Submit Quality Data	$3.11 million.

V. 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 $7.0 million to $35.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 36 of the Table of Small Business Size Standards for NAIC 622 found on the SBA Web site at: *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.*)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We believe that the provisions of this proposed rule relating to acute care hospitals 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.L. of this Appendix. 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. Any public comments that we receive and our responses will be presented in the final rule.

VI. 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.)

VII. 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 2014, that threshold level is approximately $141 million. This proposed rule will not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

VIII. 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 MDHs, 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 2015, 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 2015

A. Proposed FY 2015 Inpatient Hospital Update

As discussed in section IV.B of the preamble to this proposed rule, for FY 2015, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a 33⅓ percent reduction to three-fourths of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful electronic health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to an adjustment

based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment), and an additional reduction of 0.2 percentage point as required by section 1886(b)(3)(B)(xii) of the Act. 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 2015 adjustment of 0.2 percentage point may result in the applicable percentage increase being less than zero.

Based on the most recent data available for this FY 2015 proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to base the proposed FY 2015 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Insight, Inc.'s (IGI's) first quarter 2014 forecast of the FY 2010-based IPPS market basket rate-of-increase with historical data through fourth quarter 2013, which is estimated to be 2.7 percent. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.B.1. of the preamble of this FY 2015 IPPS/LTCH PPS proposed rule, we are proposing a multifactor productivity (MFP) adjustment (the 10-year moving average of MFP for the period ending FY 2015) of 0.4 percent. Therefore, based on IGI's first quarter 2014 forecast of the FY 2010-based IPPS market basket, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount. Below we provide a table summarizing the four proposed applicable percentage increases.

FY 2015	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Market Basket Rate-of-Increase	2.7	2.7	2.7	2.7
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.675	−0.675
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−0.675	0.0	−0.675
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.4	−0.4	−0.4	−0.4
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.2	−0.2	−0.2	−0.2
Proposed Applicable Percentage Increase Applied to Standardized Amount	2.1	1.425	1.425	0.75

B. Proposed Update for SCHs and MDHs for FY 2015

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2015 applicable percentage increase in the hospital-specific rate for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS).

As discussed in section IV.G. of the preamble of this proposed rule, section 1106 of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), enacted on December 26, 2013, extended the MDH program from the end of FY 2013 through the first half of FY 2014 (that is, for discharges occurring before April 1, 2014). Subsequently, section 106 of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93), enacted on April 1, 2014, further extended the MDH program through the first half of FY 2015 (that is, for discharges occurring before April 1, 2015). Prior to the enactment of Public Law 113–67, the MDH program was to be in effect through the end of FY 2013 only. The MDH program expires for discharges beginning on April 1, 2015, under current law. Accordingly, the proposed update of the hospital-specific rates for FY 2015 for MDHs will apply in determining payments for FY 2015 discharges occurring before April 1, 2015.

As mentioned above, the update to the hospital specific rate for SCHs and MDHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are proposing the same four possible applicable percentage increases in the table above to the hospital-specific rate applicable to SCHs and MDHs.

C. Proposed FY 2015 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 for FY 2015

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and America Samoa). Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under the provisions of § 413.40, which also use section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. We are proposing that the FY 2015 rate-of-increase percentage to be applied to the target amount for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa would be the percentage increase in the IPPS operating market basket. For this proposed rule, the current estimate of the FY 2015 IPPS operating market basket percentage increase is 2.7 percent.

E. Proposed Update for LTCHs for FY 2015

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this proposed rule, we are proposing to establish an update to the LTCH

PPS standard Federal rate for FY 2015 based on the full LTCH PPS market basket increase estimate (for this proposed rule, estimated to be 2.7 percent), subject to an adjustment based on changes in economy-wide productivity and an additional reduction required by sections 1886(m)(3)(A)(ii) and (m)(4)(E) of the Act. In accordance with the LTCHQR Program under section 1886(m)(5) of the Act, we are proposing to reduce the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. The MFP adjustment described in section 1886(b)(3)(B)(xi)(ii) of the Act is currently estimated to be 0.4 percent for FY 2015. In addition, section 1886(m)(3)(A)(ii) of the Act requires that any annual update for FY 2015 be reduced by the ''other adjustment'' at section 1886(m)(4)(E) of the Act, which is 0.2 percentage point. Therefore, based on IGI's first quarter 2014 forecast of the FY 2015 LTCH PPS market basket increase, we are proposing an annual update to the LTCH PPS standard Federal rate of 2.1 percent (that is, the current proposed FY 2015 estimate of the market basket rate-of-increase of 2.7 percent less an adjustment of 0.4 percentage point for MFP and less 0.2 percentage point). Accordingly, we are proposing to apply an update factor of 1.021 in determining the LTCH PPS standard Federal rate for FY 2015. For LTCHs that fail to submit quality data for FY 2015, we are proposing an annual update to the LTCH PPS standard Federal rate of 0.1 percent (that is, the proposed annual update for FY 2015 of 2.1 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying an update factor of 1.001 in determining the LTCH PPS standard Federal rate for FY 2015. Furthermore, we are proposing an adjustment for the final year of the 3-year phase-in of the 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) in FY 2015, consistent with current law.

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update equal to 3.25 percent for FY 2015. MedPAC's rationale for this update recommendation is described in more detail below. As mentioned above, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending the four possible applicable percentage increases to the standardized amount listed in the table under section II. of this Appendix B. We are recommending that the same applicable percentage increases apply to SCHs and MDHs. For the Puerto Rico-specific standardized amount, we are recommending an update of 2.1 percent.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa of 2.7 percent.

For FY 2015, consistent with policy set forth in section VII. of the preamble of this proposed rule, we are recommending an update of 2.1 percent (that is, the current FY 2015 estimate of the LTCH PPS market basket rate-of-increase of 2.7 percent less a proposed adjustment of 0.4 percentage point for MFP and less 0.2 percentage point) to the LTCH PPS standard Federal rate.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2014 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 3.25 percent concurrent with changes to the outpatient prospective payment system and with initiating change to the LTCH PPS. We refer the reader to the March 2014 MedPAC report, which is available for download at *www.medpac.gov* for a complete discussion on this recommendation. MedPAC expects Medicare margins to remain low in 2014. 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.

Response: With regard to MedPAC's recommendation of an update to the hospital inpatient rates equal to 3.25 percent, for FY 2015, 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 2015 applicable percentage increase. Therefore, we are proposing an applicable percentage increase for FY 2015 of 2.1 percent, provided the hospital submits quality data and is a meaningful EHR user, consistent with these statutory requirements.

We note that, because the operating and capital prospective payment systems remain separate, we are continuing to use separate updates for operating and capital payments. The proposed update to the capital rate is discussed in section III. of the Addendum to this proposed rule.

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