

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 482, 485, and 489

[CMS-1599-P]

RIN 0938-AR53

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation

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) and other legislation. These proposed changes would be applicable to discharges occurring on or after October 1, 2013, 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, 2013.

We are proposing to update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) and implement certain statutory changes made by the Affordable Care Act. Generally, these proposed changes would be applicable to discharges occurring on or after October 1, 2013, unless otherwise specified in this proposed rule.

In addition, we are proposing 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 revised requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities (IPFs)) that are participating in Medicare.

We are proposing to update policies relating to the Hospital Value-Based Purchasing (VBP) Program and the Hospital Readmissions Reduction Program. In addition, we are proposing to revise the conditions of participation (CoPs) for hospitals relating to the administration of vaccines by nursing staff as well as the CoPs for critical access hospitals relating to the provision of acute care inpatient services.

DATES: Comment Period: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. EDT on June 25, 2013.

Application Deadline for GME FTE Resident Slots from Closed Hospital.

Applications from hospitals to receive GME FTE resident slots from a hospital's closure as described in section V.J.3.c. of the preamble of this proposed rule must be received, not postmarked, by 5 p.m. EST on July 25, 2013.

ADDRESSES: When commenting, please refer to file code CMS-1599-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. Electronically. You may submit electronic comments on this regulation at <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” and enter the file code CMS-1599-P to submit comments on this proposed rule.

2. By regular mail. You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1599-P,

P.O. Box 8011,

Baltimore, MD 21244-1850.

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

3. By express or overnight mail. You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1599-P,

Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

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

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

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

b. 7500 Security Boulevard,
Baltimore, MD 21244-1850.

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

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

For information on viewing public comments, see the beginning of the **Supplementary Information** section.

FOR FURTHER INFORMATION, CONTACT:

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

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

Mollie Knight, (410) 786-7948 and Bridget Dickensheets, (410) 786-8670, Market Basket for IPPS Hospitals and LTCHs 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.

Shaheen Halim, (410) 786-0641, 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.

Allison Lee, (410) 786-8691 and Jeffrey Buck, (410) 786-0407, Inpatient
Psychiatric Facility Quality Reporting Issues.

Sarah Fahrendorf, (410) 786-3112, Conditions of Participation (CoPs) for CAHs
Issues

Commander Scott Cooper, USPHS, (410) 786-9465, Hospital Conditions of
Participation (CoPs)—Pneumococcal Vaccine Issues

Jennifer Dupee, (410) 786-6537, and Jennifer Phillips, (410) 786-1023, Medical
Review Criteria for Hospital Inpatient Services under Medicare Part A

Ann Marshall, (410) 786-3059, Requirement for Physician Order for Payment of
Hospital Inpatient Services under Medicare Part A

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the
comment period are available for viewing by the public, including any personally
identifiable or confidential business information that is included in a comment. We post
all comments received before the close of the comment period on the following Web site

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

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

Electronic Access

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

Tables Available Only through the Internet on the CMS Web Site

In the past, a majority of the tables referred to throughout this preamble and in the Addendum to this proposed rule 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 will be available only through the Internet. The IPPS tables for this proposed rule are available only through the Internet on the CMS Web site at: <http://www.cms.hhs.gov/Medicare/medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>. Click on the link on the left side of the screen titled, “FY 2014 IPPS Proposed Rule Home Page” or “Acute Inpatient – Files for

Download”. The LTCH PPS tables for this FY 2014 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-1599-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
ALOS	Average length of stay
ALTHA	Acute Long Term Hospital Association
AMA	American Medical Association
AMGA	American Medical Group Association
AOA	American Osteopathic Association

APR DRG	All Patient Refined Diagnosis Related Group System
APRN	Advanced practice registered nurse
ARRA	American Recovery and Reinvestment Act of 2009, Pub. L. 111-5
ASCA	Administrative Simplification Compliance Act of 2002, Pub. L. 107-105
ASITN	American Society of Interventional and Therapeutic Neuroradiology
ATRA	American Taxpayer Relief Act of 2012, Pub. L. 112-240
BBA	Balanced Budget Act of 1997, Pub. L. 105-33
BBRA	Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Pub. L. 106-113
BIPA	Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Pub. L. 106-554
BLS	Bureau of Labor Statistics
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	<i>Clostridium difficile</i> -associated disease
CDC	Center for Disease Control and Prevention
CERT	Comprehensive error rate testing
CDI	<i>Clostridium difficile</i>
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, Pub. L. 99-272
COLA	Cost-of-living adjustment
CoP	[Hospital] condition of participation
CPI	Consumer price index
CRNA	Certified registered nurse anesthetist
CY	Calendar year
DACA	Data Accuracy and Completeness Acknowledgement
DPP	Disproportionate patient percentage
DRA	Deficit Reduction Act of 2005, Pub. L. 109-171
DRG	Diagnosis-related group
DSH	Disproportionate share hospital
ECI	Employment cost index

EDB	[Medicare] Enrollment Database
EHR	Electronic health record
EMR	Electronic medical record
FAH	Federation of 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
GAAP	Generally Accepted Accounting Principles
GAF	Geographic Adjustment Factor
GME	Graduate medical education
HAC	Hospital-acquired condition
HAI	Healthcare-associated infection
HBIPS	Hospital-based inpatient psychiatric services
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, Pub. L. 104-191
HIPC	Health Information Policy Council
HIS	Health information system
HIT	Health information technology
HMO	Health maintenance organization
HPMP	Hospital Payment Monitoring Program
HSA	Health savings account
HSCRC	[Maryland] Health Services Cost Review Commission
HSRV	Hospital-specific relative value
HSRVcc	Hospital-specific relative value cost center
HQA	Hospital Quality Alliance
HQI	Hospital Quality Initiative
ICD-9-CM	International Classification of Diseases, Ninth Revision, Clinical Modification
ICD-10-CM	International Classification of Diseases, Tenth Revision, Clinical Modification
ICD-10-PCS	International Classification of Diseases, Tenth Revision, Procedure Coding System
ICR	Information collection requirement

IGI	IHS Global Insight, Inc.
IHS	Indian Health Service
IME	Indirect medical education
I-O	Input-Output
IOM	Institute of Medicine
IPF	Inpatient psychiatric facility
IPFQR	Inpatient Psychiatric Facility Quality Reporting [Program]
IPPS	[Acute care hospital] inpatient prospective payment system
IRF	Inpatient rehabilitation facility
IQR	Inpatient Quality Reporting
IVR	Interactive voice response
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

MCV	Major cardiovascular condition
MDC	Major diagnostic category
MDH	Medicare-dependent, small rural hospital
MedPAC	Medicare Payment Advisory Commission
MedPAR	Medicare Provider Analysis and Review File
MEI	Medicare Economic Index
MGCRB	Medicare Geographic Classification Review Board
MIEA-TRHCA	Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006, Pub. L. 109-432
MIPPA	Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110-275
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173
MMEA	Medicare and Medicaid Extenders Act of 2010, Pub. L. 111-309
MMSEA	Medicare, Medicaid, and SCHIP Extension Act of 2007, Pub. L. 110-173
MRHFP	Medicare Rural Hospital Flexibility Program
MRSA	Methicillin-resistant <i>Staphylococcus aureus</i>
MSA	Metropolitan Statistical Area
MS-DRG	Medicare severity diagnosis-related group
MS-LTC-DRG	Medicare severity long-term care diagnosis-related group
NAICS	North American Industrial Classification System
NALTH	National Association of Long Term Hospitals

NCD	National coverage determination
NCHS	National Center for Health Statistics
NCQA	National Committee for Quality Assurance
NCVHS	National Committee on Vital and Health Statistics
NECMA	New England County Metropolitan Areas
NHSN	National Healthcare Safety Network
NOP	Notice of Participation
NQF	National Quality Forum
NTIS	National Technical Information Service
NTTAA	National Technology Transfer and Advancement Act of 1991 (Pub. L. 104-113)
NVHRI	National Voluntary Hospital Reporting Initiative
OACT	[CMS'] Office of the Actuary
OBRA 86	Omnibus Budget Reconciliation Act of 1986, Pub. L. 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
PS&R	Provider Statistical and Reimbursement [System]
PQRS	Physician Quality Reporting System
QIG	Quality Improvement Group, CMS
QIO	Quality Improvement Organization
RCE	Reasonable compensation equivalent
RHC	Rural health clinic
RHQDAPU	Reporting hospital quality data for annual payment update
RNHCI	Religious nonmedical health care institution
RPL	Rehabilitation psychiatric long-term care (hospital)
RRC	Rural referral center
RTI	Research Triangle Institute, International
RUCAs	Rural-urban commuting area codes

RY	Rate year
SAF	Standard Analytic File
SCH	Sole community hospital
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
TEFRA	Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97-248
TEP	Technical expert panel
TMA	TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007, Pub. L. 110-90
TPS	Total Performance Score
UHDDS	Uniform hospital discharge data set
VBP	[Hospital] Value Based Purchasing [Program]
VTE	Venous thromboembolism

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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 2014 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; and cancer hospitals. Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.
- Sections 123(a) and (c) of Pub. L. 106-113 and section 307(b)(1) of Pub. L. 106-554 (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of long-term care hospitals (LTCHs) described in section 1886(d)(1)(B)(iv) of the Act.

- Sections 1814(l), 1820, and 1834(g) of the Act, which specifies that payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services and that these payments are generally based on 101 percent of reasonable cost.
- Section 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)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case-mix.
- Section 1886(d)(4)(D) of the Act, which addresses certain hospital-acquired conditions (HACs), including infections. Section 1886(d)(4)(D) of the Act specifies that, by October 1, 2007, the Secretary was required to select, in consultation with the Centers for Disease Control and Prevention (CDC), at least two conditions that: (a) are high cost, high volume, or both; (b) are assigned to a higher paying MS-DRG when present as a secondary diagnosis (that is, conditions under the MS-DRG system that are CCs or MCCs); and (c) could reasonably have been prevented through the application of evidence-based guidelines. Section 1886(d)(4)(D) of the Act also specifies that the list of conditions may be revised, again in consultation with CDC, from time to time as long as the list contains at least two conditions. Section 1886(d)(4)(D)(iii) of the Act requires that hospitals, effective with discharges occurring on or after October 1, 2007, submit information on Medicare claims specifying whether diagnoses were present on admission

(POA). Section 1886(d)(4)(D)(i) of the Act specifies that effective for discharges occurring on or after October 1, 2008, Medicare no longer assigns an inpatient hospital discharge to a higher paying MS-DRG if a selected condition is not POA.

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

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

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

- 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, effective for discharges beginning on October 1, 2014.

- 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 3313 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(s)(4) of the Act, as added and amended by section 3401(f) and 10322(a) of the Affordable Care Act, respectively, which requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric

units. Under this program, known as the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, beginning with FY 2014, the Secretary must reduce any annual update to a standard Federal rate for discharges occurring during a fiscal year by 2.0 percentage points for any inpatient psychiatric hospital or psychiatric unit that does not comply with quality data submission requirements with respect to an applicable fiscal year.

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 Pub. L. 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 Pub. L. 110-90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Pub. L. 110-90.

While 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 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 are proposing a -0.8 percent recoupment adjustment to the

standardized amount in FY 2014. Although we are not proposing an additional prospective adjustment in FY 2014 for the cumulative MS-DRG documentation and coding effects through FY 2010, we are soliciting public comments as to whether any portion of the proposed -0.8 percent recoupment adjustment to the operating IPPS standardized amount should be reduced and instead applied as a prospective adjustment to the operating IPPS standardized amount (and hospital-specific rates) for the cumulative MS-DRG documentation and coding effect through FY 2010.

b. Proposed Refinement of the MS-DRG Relative Weight Calculation

Beginning in FY 2007, we implemented relative weights for DRGs based on cost report data instead of charge information. To address the issue of charge compression (the hospital practice of applying higher charges to lower cost items and applying lesser charges to higher cost items) when using cost report data to set the MS-DRG relative weights, in FYs 2009 and 2010, we created additional cost centers on the Medicare cost report to distinguish implantable devices from other medical supplies, MRIs and CT scans, respectively, from other radiology services, and cardiac catheterization from other cardiology services. As compared to previous years, we currently have a significant volume of hospitals completing all, or some, of these new cost centers on the Medicare cost report. In section II.E. of the preamble of this proposed rule, we provide various data analyses based on comparison of the FY 2014 relative weights computed using 15 cost-to-charge ratios (CCRs), as we have done in the past, and the FY 2014 relative weights computed using 19 CCRs, with distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization.

We believe that the analytic findings described in section II.E. of the preamble of this proposed rule support our original decision to break out and create new cost centers for implantable devices, MRIs, CT scans, and cardiac catheterization. Therefore, beginning in FY 2014, we are proposing 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.

c. Proposed Rebasement and Revision of the Hospital Market Baskets for Acute Care Hospitals

In section IV. of the preamble of this proposed rule, we are proposing to rebase and revise the acute care hospital operating and capital market baskets used to update IPPS payment rates. For both market baskets, we are proposing to update the base year cost weights from a FY 2006 base year to a FY 2010 base year. We also are proposing to recalculate the labor-related share using the proposed FY 2010-based hospital market basket, for discharges occurring on or after October 1, 2013. We would use the FY 2010-based market basket in developing the FY 2014 update factor for the operating and capital prospective payment rates and the FY 2014 update factor for the excluded hospital rate-of-increase limits. We also are setting forth the data sources used to determine the proposed revised market basket relative weights.

d. Reduction of Hospital Payments for Excess Readmissions

We are proposing a number of changes in policies to implement section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act, which establishes the Hospital Readmissions Reduction Program. The Hospital Readmissions Reduction

Program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. These conditions are acute myocardial infarction, heart failure, and pneumonia. For FY 2014, we are proposing additional exclusions to the three existing readmission measures (that is, the excess readmission ratio) that account for planned readmissions. We also are proposing additional readmission measures to be used in the payment determination for FY 2015. In addition, we are proposing that the readmissions payment adjustment factors for FY 2014 can be no more than a 2-percent reduction (there is a 1-percent cap in FY 2013), consistent with the statute. We are proposing a change in the methodology we use to calculate the readmissions payment adjustment factors to make it more consistent with the calculation of the excess readmission ratio.

e. 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 outlining payment details for the FY 2014 Hospital VBP Program. In addition, we are proposing numerous policies for the FY 2016 Hospital VBP Program, including measures, performance standards, and performance and baseline periods. We also are proposing a disaster/extraordinary circumstances waiver process, domain reclassification and weighting based on CMS' National Quality Strategy for the

FY 2017 Hospital VBP Program, and certain measures, performance and baseline periods, and performance standards for the FY 2017 through FY 2019 Programs.

f. Hospital-Acquired Condition (HAC) Reduction Program

In this proposed rule, we are proposing measures, scoring, and risk adjustment methodology to implement the FY 2015 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. 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.

g. Counting of Inpatient Days for Medicare Payment or Eligibility Purposes

In response to a comment we received on the FY 2013 IPPS/LTCH PPS final rule and consistent with the inpatient day counting rules for DSH as clarified in the FY 2010 IPPS/RV 2010 LTCH PPS final rule, we are proposing that patient days associated with maternity patients who were admitted as inpatients and were receiving ancillary labor and delivery services at the time the inpatient routine census is taken, regardless of whether the patient actually occupied a routine bed prior to occupying an ancillary labor and delivery bed and regardless of whether the patient occupies a “maternity suite” in which labor, delivery recovery, and postpartum care all take place in the same room, would be included in the Medicare utilization calculation. We understand that including labor and

delivery inpatient days in the Medicare utilization calculation invariably would reduce direct GME payments because direct GME payments are based, in part, on a hospital's Medicare utilization ratio and the denominator of that ratio, which includes the hospital's total inpatient days, would increase at a higher rate than the numerator of the ratio, which includes the hospital's Medicare inpatient days. However, because the Medicare utilization ratio is a comparison of a hospital's total Medicare inpatient days to its total inpatient days, we believe that revising the ratio to include labor and delivery days is appropriate because they are inpatient days and therefore should be counted as such. We are proposing to include labor and delivery days as inpatient days in the Medicare utilization calculation effective for cost reporting periods beginning on or after October 1, 2013.

h. 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. Currently, Medicare DSHs qualify for a DSH payment adjustment under a statutory formula that considers their Medicare utilization due to beneficiaries who also receive Supplemental Security Income benefits and their Medicaid utilization. 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 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 to implement these statutory changes.

i. Proposal Relating to Admission and Medical Review Criteria for Hospital Inpatient Services under Medicare Part A

To reduce uncertainty regarding the requirements for payments to hospitals and CAHs under Medicare Part A related to when a Medicare beneficiary should be admitted as a hospital inpatient, in this proposed rule, we are proposing to clarify the rules governing physician orders of hospital inpatient admissions for payment under Medicare Part A. We are proposing to clarify and specify in the regulations that an individual becomes an inpatient of a hospital, including a critical access hospital, pursuant to an order for inpatient admission by a physician or other qualified practitioner and, therefore, the order is required for payment of hospital inpatient services under Medicare Part A. We are proposing that hospital inpatient admissions spanning 2 midnights in the hospital would generally qualify as appropriate for payment under Medicare Part A. This would revise our guidance to hospitals and physicians relating to when hospital inpatient admissions are determined reasonable and necessary for payment under Part A. We also are proposing to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to offset the additional IPPS expenditures under this proposal by reducing the standardized amount,

the hospital-specific amount, and the Puerto Rico-specific standardized amount by 0.2 percent.

j. Proposed LTCH PPS Standard Federal Rate

In section VIII.A. of the preamble of this proposed rule, we present the proposed LTCH PPS standard Federal rate for FY 2014, which includes a proposed adjustment factor of 0.98734 for the second year of the 3-year phase-in of the permanent one-time adjustment to the standard Federal rate. In addition, under the LTCH Quality Reporting (LTCHQR) Program, the proposed annual update to the standard Federal rate will be reduced by 2 percentage points for LTCHs that fail to submit data for FY 2014 on specific measures under section 3004 of the Affordable Care Act.

k. Expiration of Certain Payment Rules for LTCH Services and Research on the Development of a Patient Criteria-Based Payment Adjustment under the LTCH PPS

In section VIII.D. of the preamble of this proposed rule, we note the expiration of the moratorium on the full implementation of the “25 percent threshold” payment adjustment to LTCHs under the LTCH PPS for cost reporting periods beginning on or after October 1, 2013.

In section VIII.E. of the preamble of this proposed rule, we describe the results of research being done by a CMS contractor, Kennell and Associates (Kennell) and its subcontractor, Research Triangle Institute, International (RTI), on the development of a payment adjustment under the LTCH PPS based on the establishment of LTCH patient criteria.

l. 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 make several changes to: (1) the measure set, including the removal of some measures, the refinement of some measures, and the adoption of several new measures; (2) the administrative processes; and (3) the validation methodologies. We also are proposing to allow hospitals the option of reporting the measures in four measure sets electronically for the FY 2016 payment determination. These proposed changes would improve the timeliness and efficiency of the Hospital IQR Program and begin the process of incorporating electronic reporting into the Hospital IQR Program.

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 2014 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 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 Pub. L. 110-90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Public L. 110-90.

While our actuaries estimate 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, we are proposing a -0.8 percent recoupment adjustment to the standardized amount in FY 2014. We estimate that this level of adjustment would recover \$0.96 billion in FY 2014, with approximately \$10.4 billion remaining to be addressed. We are not proposing any future adjustments at this time but note that if recoupment adjustments of approximately -0.8 percent are implemented in FYs 2014, 2015, 2016, and 2017, we estimate that the entire \$11 billion will be recovered by the end of the statutory 4-year timeline.

- **Proposed Refinement of the MS-DRG Relative Weight Calculation.** We refer readers to section VI.C. of Appendix A of this proposed rule for the overall IPPS operating impact, which includes the impact for the proposed refinement of the MS-DRG relative weight calculation. This proposed impact models payments to various hospital types using relative weights developed from 19 CCRs as compared to 15 CCRs. As with other proposed changes to the MS-DRGs, these proposed changes are to be implemented in a budget neutral manner.

- **Proposed Rebasing and Revision of the Hospital Market Baskets for Acute Care Hospitals.**

The proposed FY 2010-based IPPS market basket update (as measured by percentage increase) for FY 2014 is currently forecasted to be the same as the market basket update based on the FY 2006-based IPPS market basket at 2.5 percent (currently used under the IPPS). Therefore, we are projecting that there would be no fiscal impact on the IPPS operating payment rates in FY 2014 as a result of the proposed rebasing and revision of the IPPS market basket.

The proposed FY 2010-based IPPS capital input price index update (as measured by percentage increase) for FY 2014 is currently forecasted to be 1.2 percent, 0.2 percentage points lower than the update based on the FY 2006-based capital input price index. Therefore, we are projecting that there would be a fiscal impact of -\$16 million to the IPPS capital payments in FY 2014 as a result of this proposal (0.2 percentage points * annual capital IPPS payments of approximately \$8 billion).

In addition, we are proposing to update the labor-related share under the IPPS for FY 2014 based on the proposed FY 2010-based IPPS market basket, which would result in a labor-related share of 69.6 percent (compared to the FY 2013 labor-related share of 68.8) or 62 percent, depending on which results in higher payments to the hospital. For FY 2014, the proposed labor-related share for the Puerto Rico-specific standardized amount would be either 63.2 percent or 62 percent, depending on which results in higher payments to the hospital. We are projecting that there would be no impact on aggregate IPPS payments as a result of this proposal due to the statutory

requirement that any changes to the IPPS area wage adjustment (including the labor-related share) are adopted in a budget neutral manner.

- **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 2014, 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 0.98 (that is, or a 2-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, or approximately -\$175 million, in payments to hospitals for 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 2014 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 2014, and therefore the estimated amount available for value-based incentive payments for FY 2014 discharges, is approximately \$1.1 billion. We believe that the program's benefits will be seen in improved patient outcomes, safety, and in the patient's experience of care. We intend

to provide an updated analysis of the program's estimated dollar impact for the FY 2014 program year in the FY 2014 IPPS/LTCH PPS final rule. However, we cannot estimate these benefits in actual dollar and patient terms.

- **Implementation of the HAC Reduction Program for FY 2014.** We note that there is no payment impact for FY 2014 for implementing the HAC Reduction Program. 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 Appendix A of this proposed rule.

- **Counting of Inpatient Days in the Medicare Utilization Calculation.** We believe our proposal to include labor and delivery days as inpatient days in the Medicare utilization calculation would result in a savings of approximately \$15 million for FY 2014.

- **Changes 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 will be 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.

We are proposing that 75 percent of what otherwise would have been paid for Medicare DSH payments is adjusted to 88.8 percent of that 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 are adjusted to 66.6 percent (the product of 75 percent and 88.8 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 reduction of Medicare DSH payments and the inclusion of the additional payments will reduce payments overall by 0.9 percent as compared to Medicare DSH payments prior to the implementation of section 3133. The proposed additional payment costs have redistributive effects based on a hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that are estimated to receive Medicare DSH payments, and the payment amount is not tied to a hospital's discharges.

- **Proposal Relating to Admission and Medical Review Criteria for Hospital Inpatient Services under Medicare Part A.** In this proposed rule, we are making a proposal relating to admission and medical review criteria for hospital inpatient admissions under Medicare Part A. One aspect of this proposal is that hospital inpatient admissions spanning 2 midnights in the hospital would generally qualify as appropriate for payment under Medicare Part A. Our actuaries estimate that

the proposal would increase IPPS expenditures by approximately \$220 million due to an expected net increase in inpatient encounters. We are proposing to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to make a reduction of 0.2 percent to the standardized amount, the Puerto Rico standardized amount, and the hospital-specific payment rate to offset this estimated \$220 million in additional IPPS expenditures. We also are proposing to apply that 0.2 percent reduction to the capital Federal rates using our authority under section 1886(g) of the Act.

- **Hospital Inpatient Quality Reporting (IQR) Program.** We are proposing that hospitals participating in the Hospital IQR Program will have the option to report a subset of measures electronically in CY 2014 for the FY 2016 payment determination. Under this proposal, hospitals may choose to report the measures in four measure sets electronically or as chart-abstracted measures in CY 2014. For the FY 2016 payment determination, we also are proposing to remove seven chart-abstracted measures and one structural measure. We also are proposing to adopt five new claims-based measures for the FY 2016 payment determination and subsequent years. We are proposing, for the FY 2016 payment determination and subsequent years, to validate two additional chart-abstracted HAI measures: MRSA *bacteremia*, and *C. difficile*. We also are proposing to reduce the number of records used for HAI validation from 48 records per year to 36 records per year beginning with the FY 2015 payment determination. Finally, we are proposing to allow hospitals to submit patient charts for purposes of validation either in paper form or by means of electronic transmission. We believe the proposed

changes to the measure set, processes, and validation methodologies, the proposal for electronic submission of records for validation, as well as the proposal to allow hospitals to report certain measures electronically for the FY 2016 payment determination will result in improved program efficiency and begin the process of incorporating electronic reporting into the program. We estimate that the combination of these proposed changes and the reduction in measures mentioned above will reduce burden hours by 700,000 hours annually.

- **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 we are presenting in the preamble and Addendum of this proposed rule, including the proposed update to the standard Federal rate for FY 2014, the proposed changes to the area wage adjustment for FY 2014, and the proposed changes to short-stay outliers and high-cost outliers, would result in an increase in estimated payments from FY 2013 of approximately \$62 million (or 1.1 percent). Although we generally project an increase in proposed payments for all LTCHs in FY 2014 as compared to FY 2013, we expect rural LTCHs to experience slightly lower increases than the national average due to decreases in their wage index for FY 2014 compared to FY 2013. In addition, under current law, our moratoria on the full implementation of the “25-percent threshold” payment adjustment policy will expire for certain LTCHs for cost reporting periods beginning on or after October 1, 2013. These regulatory moratoria extended, for an additional year, the 5-year statutory moratorium on the application of the “25-percent threshold” payment adjustment policy as provided by

section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(a) and 10312(a) of the Affordable Care Act, which expired 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”) (77 FR 53483 through 53484, as amended by the FY 2013 IPPS/LTCH PPS correcting amendment (77 FR 63751 through 63753)), as explained in section VIII.D. of the preamble of this proposed rule. We estimate that the expiration of the regulatory moratoria will result in a reduction in payments of \$190 million to LTCHs. Overall, we estimate that the effect of the changes we are proposing for FY 2014 in conjunction with the expiration of the regulatory moratoria would result in a decrease in aggregate LTCH PPS payments in FY 2014 relative to FY 2013 of approximately -\$128 million (that is, the estimated increase of \$62 million plus the estimated reduction of \$190 million, as described above).

B. Summary

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

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

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

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

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

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

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

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

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. Through and including FY 2006, a Medicare-dependent, small rural hospital (MDH) received the higher of the Federal rate or the Federal rate plus 50 percent of the amount by which the Federal rate is exceeded by the higher of its FY 1982 or FY 1987 hospital-specific rate. As discussed below, for discharges occurring on or after October 1, 2007, but before October 1, 2013, an MDH will receive the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. (We note that the statutory provision for payments to MDHs expires at the end of FY 2013, that is, on September 30, 2013.) SCHs are the sole source of care in their areas, and MDHs are a major source of care for Medicare beneficiaries in their areas. Specifically, section

1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years). Both of these categories of hospitals are afforded this special payment protection in order to maintain access to services for beneficiaries.

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

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

2. Hospitals and Hospital Units Excluded from the IPPS

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

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

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

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act effective for cost reporting periods

beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123 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 October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS (73 FR 26797 through 26798).

4. Critical Access Hospitals (CAHs)

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

5. Payments for Graduate Medical Education (GME)

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

period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR Part 413.

C. Provisions of the Patient Protection and Affordable Care Act (Pub. L. 111-148), the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), and the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112-240)

The Patient Protection and Affordable Care Act (Pub. L. 111-148), enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), enacted on March 30, 2010, made a number of changes that affect the IPPS and the LTCH PPS. (Pub. L. 111-148 and Pub. L. 111-152 are collectively referred to as the "Affordable Care Act.") A number of the provisions of the Affordable Care Act affect the updates to the IPPS and the LTCH PPS and providers and suppliers. The provisions of the Affordable Care Act that were applicable to the IPPS and the LTCH PPS for FYs 2010, 2011, and 2012 were implemented in the June 2, 2010 **Federal Register** notice (75 FR 31118), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50042) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51476).

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 pursuant to sections 605 and 606 of Pub. L. 112-240 in a notice issued in the **Federal Register** on March 7, 2013 (78 FR 14689).

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 to implement, or continue in FY 2014 to implement, the following provisions (or portions of the following provisions) of the Affordable Care Act that are applicable to the IPPS, the LTCH PPS, and PPS-exempt cancer hospitals:

- Section 3001(a) of Pub. L. 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 Pub. L. 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 Pub. L. 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 Pub. L. 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 Pub. L. 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 Pub. L. 111-148, which modifies the methodologies for determining Medicare DSH payments and creates a new additional payment for uncompensated care.
- Section 3401 of Pub. L. 111-148, which provides for the incorporation of productivity adjustments into the market basket updates for IPPS hospitals and LTCHs.
- Section 10324 of Pub. L. 111-148, which provides for a wage adjustment for hospitals located in frontier States.
- Sections 3401 and 10319 of Pub. L. 111-148 and section 1105 of Pub. L. 111-152, which revise certain market basket update percentages for IPPS and LTCH PPS payment rates for FY 2014.
- Section 5506 of Pub. L. 111-148, which added a provision to the Act that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria up to the number of the closed hospital's FTE resident caps. The Secretary is directed to ensure that the aggregate number of FTE resident cap slots distributed is equal to the amount of slots in the closed hospital's direct GME and IME FTE resident caps, respectively.

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

In this proposed rule, we are proposing to implement or to make conforming changes to regulation text in accordance with the following provisions (or portions of the following provisions) of the American Taxpayer Relief Act of 2012 that are applicable to the IPPS:

- Section 605, which amended sections 1886(d)(12)(B), (C)(i), and (D) of the Act to extend changes to the payment methodology for the Medicare inpatient hospital payment adjustment for low-volume hospitals through September 30, 2013 (FY 2013). Beginning with FY 2014, the preexisting low-volume hospital qualifying criteria and payment adjustment, as implemented in FY 2005, will resume.

- Section 606(a), which amended sections 1886(d)(5)(G)(i) and (ii)(II) of the Act to extend the MDH program through September 30, 2013 (FY 2013), and section 606(b), which made conforming amendments to sections 1886(b)(3)(D)(i) and (iv) of the Act and amended section 13501(e)(2) of the Omnibus Budget Reconciliation Act of 1993 to permit hospitals to decline reclassification through FY 2013.

- Section 631, which amended section 7(b)(1)(B) of Pub. L. 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).

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 in FY 2014. We also are setting forth proposed changes relating to payments for IME costs and payments to certain hospitals that continue to be excluded from the IPPS and paid on a reasonable cost basis. In addition, in this proposed rule, we are setting forth proposed changes to the

payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2014.

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.
- Proposed application of the documentation and coding adjustment for FY 2014 resulting from implementation of the MS-DRG system.
- A discussion of the Research Triangle Institute, International (RTI) reports and recommendations relating to charge compression, including the proposal to calculate the MS-DRG relative weights using 19 CCRs.
- 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 2014.
- A discussion of the FY 2014 status of new technologies approved for add-on payments for FY 2013 and a presentation of our evaluation and analysis of the FY 2014 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Pub. L. 108-173, obtained in a town hall meeting).

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

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

- The proposed FY 2014 wage index update using wage data from cost reporting periods beginning in FY 2010.
- Analysis and implementation of the proposed FY 2014 occupational mix adjustment to the wage index for acute care hospitals, including the proposed application of the rural floor, the imputed rural floor calculated under the original and alternative methodologies, and the 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 2014 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 2014 hospital wage index.
- Determination of the labor-related share for the proposed FY 2014 wage index.

3. Proposed Rebasing and Revision of the Hospital Market Baskets for Acute Care Hospitals

In section IV. of the preamble of this proposed rule, we are proposing to rebase and revise the acute care hospital operating and capital market baskets to be used in

developing the FY 2014 update factor for the operating and capital prospective payment rates and the FY 2014 update factor for the excluded hospital rate-of-increase limits. We also are setting forth the data sources used to determine the proposed revised market basket relative weights.

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

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

- Proposed changes to the inpatient hospital update for FY 2014, including incorporation of a productivity adjustment.
- 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 2014.
- The statutorily required IME adjustment factor for FY 2014.
- Proposed changes to the methodologies for determining Medicare DSH payments and proposals to implement the new additional payments for uncompensated care.
- Discussion of the extension of the MDH program through FY 2013.
- Proposed changes to the rules for payment adjustments under the Hospital Readmissions Reduction Program based on hospital readmission measures and the process for hospital review and correction of those rates.

- Proposed 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.

- Proposal for counting labor and delivery inpatient days in the calculation of Medicare utilization for direct GME purposes and for other inpatient days policy for payments and eligibility.

- Announcement of an additional closed hospital and redistribution of resident cap slots relating to direct GME and IME payments.

- Proposed clarifications of policies on payments for residents training in approved residency programs at CAHs.

- Announcement of the expiration of the inflation update freeze for high per resident amounts (PRAs).

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

- Extending the effective date of policies relating to hospital services furnished under arrangements.

- Proposed policy that medical review of inpatient admissions will include a presumption that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined by encounters crossing 2 midnights) in the hospital receiving medically necessary services.

5. Proposed FY 2014 Policy Governing the IPPS for Capital-Related Costs

In section VI. 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 2014 and other related proposed policy changes.

6. Proposed Changes to the Payment Rates for Certain Excluded Hospitals:

Rate-of-Increase Percentages

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

- Proposed changes to payments to certain excluded hospitals for FY 2014.
- Proposed changes to the conditions of participation (CoPs) relating to administration of pneumococcal vaccine and CAH payment for acute care inpatient services.

7. Proposed Changes to the LTCH PPS

In section VIII. 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 2014. We also note that the moratorium on the full implementation of the “25-percent threshold” payment adjustment will expire for certain cost reporting periods beginning on or after October 1, 2013. In addition, in this section, we describe the results of research being done by Kennell and Associates (Kennell) and its subcontractor, Research Triangle Institute, International (RTI), under a contract with CMS on the development of a payment adjustment under the LTCH PPS based on the establishment of LTCH patient criteria.

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.
- Proposed changes to the requirements under the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program.

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

In the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2014 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We are proposing to establish the threshold amounts for outlier cases. In addition, we address the proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2014 for certain hospitals excluded from the IPPS.

10. Determining Proposed Prospective Payment Rates for LTCHs

In the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2014 prospective standard Federal rate. We are proposing to establish the adjustments for wage levels, the labor-related

share, the cost-of-living adjustment, and high-cost outliers, including the fixed-loss amount, and the LTCH cost-to-charge ratios (CCRs) under the LTCH PPS.

11. 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, PCHs, and IPFs.

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

In Appendix B of this proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provide our recommendations of the appropriate percentage changes for FY 2014 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.

13. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2013 recommendations concerning hospital inpatient payment policies address the update

factor for hospital inpatient operating costs and capital-related costs under the IPPS, for hospitals and distinct part hospital units excluded from the IPPS. We address these recommendations in Appendix B of this proposed rule. For further information relating specifically to the MedPAC March 2013 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), and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53273).

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 2014 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 Pub. L. 110-90

In the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189), we adopted the MS-DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS-DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. (Currently, there are 751 MS-DRGs.) 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 Pub. L. 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 Pub. L. 110-90 required a documentation and coding adjustment of -0.9 percent, and we finalized that adjustment through rulemaking (73 FR 48447). The documentation and coding adjustments established in the FY 2008 IPPS final rule with comment period, which reflected the amendments made by Pub. L. 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 Pub. L. 110-90

a. Prospective Adjustment Required by Section 7(b)(1)(A) of Pub. L. 110-90

Section 7(b)(1)(A) of Pub. L. 110-90 requires that, if the Secretary determines that implementation of the MS-DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different than the prospective documentation and coding adjustments applied under section 7(a) of Pub. L. 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) Pub. L. 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 Pub. L. 110-90, section 7(b)(1)(B) of Pub. L. 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 Pub. L. 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 Pub. L. 110-90. That is, these adjustments are intended to recoup (or repay, in the case of underpayments) spending in excess of (or less than) spending that would have occurred had the prospective adjustments for changes in documentation and coding applied in FY 2008 and FY 2009 precisely matched the changes that occurred in those years. Pub. L. 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 Pub. L. 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/RV 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 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 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 Web page describes the file and provides directions and further detailed instructions for how to order.

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

Mailing address if using the U.S. Postal Service:

Centers for Medicare & Medicaid Services,

RDDC Account,

Accounting Division,

P.O. Box 7520,

Baltimore, MD 21207-0520.

Mailing address if using express mail:

Centers for Medicare & Medicaid Services,
OFM/Division of Accounting – RDDC,
7500 Security Boulevard, C3-07-11,
Baltimore, MD 21244-1850.

4. Prospective Adjustments for FY 2008 and FY 2009 Authorized by Section 7(b)(1)(A) of Pub. L. 110-90

In the FY 2010 IPPS/RV 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/RV LTCH PPS final rule for a detailed description of our proposal, responses to comments, and finalized policy. After analysis of the FY 2009 claims data for the FY 2011 IPPS/LTCH PPS final rule (75 FR 50057 through 50073), we found a total prospective documentation and coding effect of 1.054 percent. After accounting for the -0.6 percent and the -0.9 percent documentation and coding adjustments in FYs 2008 and 2009, we found a remaining documentation and coding effect of 3.9 percent. As we have discussed, an additional cumulative adjustment of -3.9 percent would be necessary to meet the requirements of section 7(b)(1)(A) of Pub. L. 110-90 to make an adjustment to the average standardized amounts in order to eliminate the full effect of the documentation and coding changes that do not reflect real changes in case-mix on future payments. Unlike section 7(b)(1)(B) of Pub. L. 110-90, section 7(b)(1)(A) does not specify when we must apply the prospective adjustment, but merely requires us to make an “appropriate” adjustment.

Therefore, as we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50061), we believe 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 year. Accordingly, we did not propose a prospective adjustment under section 7(b)(1)(A) of Pub. L. 110-90 for FY 2011 (75 FR 23868 through 23870). We note that, as a result, payments in FY 2011 (and in each future year until we 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 Pub. L. 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 will result in a continued accrual of unrecoverable overpayments, it was imperative that we implement a prospective adjustment for FY 2012, while recognizing CMS' continued desire to mitigate the effects of any significant downward adjustments to hospitals. Therefore, we implemented a -2.0 percent prospective adjustment to the standardized amount to partially eliminate the full effect of the documentation and coding changes that do not reflect real changes in case-mix on future payments.

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 Pub. L. 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 believe 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 years until a full adjustment is made.

We note again that delaying full implementation of the prospective portion of the adjustment required under section 7(b)(1)(A) of Pub. L. 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 Pub. L. 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 Pub. L. 110-90

As discussed in section II.D.3. of this preamble, section 7(b)(1)(B) of Pub. L. 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 Pub. L. 110-90. This determination must be based on a retrospective evaluation of claims data. Our actuaries estimated that

this 5.8 percentage point increase resulted in an increase in aggregate payments of approximately \$6.9 billion. Therefore, as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50062 through 50067), we determined that an aggregate adjustment of -5.8 percent in FYs 2011 and 2012 would be necessary in order to meet the requirements of section 7(b)(1)(B) of Pub. L. 110-90 to adjust the standardized amounts for discharges occurring in FYs 2010, 2011, and/or 2012 to offset the estimated amount of the increase in aggregate payments (including interest) in FYs 2008 and 2009.

It is often our practice to phase in rate adjustments over more than one year in order to moderate the effect on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, in the FY 2011 IPPS/LTCH PPS final rule, we made an adjustment to the standardized amount of -2.9 percent, representing approximately half of the aggregate adjustment required under section 7(b)(1)(B) of Pub. L. 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 Pub. L. 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 Pub. L. 110-90, and consistent with the discussion in the FY 2011 IPPS/LTCH PPS final rule, we completed the recoupment adjustment by implementing the remaining -2.9 percent adjustment, in addition to removing the effect of the -2.9 percent adjustment to the standardized amount finalized for FY 2011 (76 FR 51489 and 51498). 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 Pub. L. 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 Pub. L. 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 Pub. L. 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 Pub. L. 110-90.

Similar to the adjustments authorized under section 7(b)(1)(B) of Pub. L. 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 rates in one year would eventually be offset by a positive adjustment, once the necessary amount of overpayment is recovered.

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. In its March 2013 “Report to Congress: Medicare Payment Policy,” MedPAC estimates that a -2.4 percent adjustment made in FY 2014, and not removed until FY 2018, also would recover the required recoupment amount. It is often our practice to delay or phase in rate adjustments over more than one year, in order to moderate the effect on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, we are proposing a -0.8 percent recoupment adjustment to the standardized amount in FY 2014. We estimate that this level of adjustment will recover up to \$0.96 billion in FY 2014, with at least \$10.04 billion remaining to be recovered by FY 2017. 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 are not proposing specific adjustments for FYs 2015, 2016, or 2017 at this time. We believe that this level of adjustment for FY 2014 is a reasonable and fair approach that satisfies the requirements of the statute while mitigating extreme annual fluctuations in payment rates. 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. Additional Prospective Adjustments for the MS-DRG Documentation and Coding Effect through FY 2010 Authorized 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 if the Secretary determines such adjustments to be necessary for any subsequent fiscal years in order to eliminate the effect of coding or classification changes that do not reflect real changes in case-mix. After review of comments and recommendations received in a FY 2012 public comment letter from MedPAC (available on the Internet at:

http://www.medpac.gov/documents/06172011_FY12IPPS_MedPAC_COMMENT.pdf),

we analyzed claims data in FY 2010 to determine whether any additional adjustment would be appropriate to ensure that the introduction of MS-DRGs was implemented in a budget neutral manner. We analyzed FY 2010 data on claims paid through December 2011 using the same claims-based methodology as described in previous rulemaking (73 FR 43768 and 43775). We determined a total additional prospective documentation and coding effect of 0.8 percent through FY 2010 and found that this effect was present for both IPPS hospitals paid with the standardized amount and IPPS hospitals paid using their hospital-specific payment rates.

In the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27890), we proposed an additional -0.8 percent prospective adjustment to the standardized amount to account for this effect. We indicated that this additional prospective adjustment of -0.8 percent, when combined with the other prospective MS-DRG documentation and coding adjustments already made or proposed would eliminate the future effect of MS-DRG documentation and coding that did not reflect real changes in case-mix for discharges occurring through FY 2010. As discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53278 through

53280), numerous commenters objected to the CMS proposal to make an adjustment to account for payment increases due to MS-DRG documentation and coding that did not reflect real changes in case-mix for discharges occurring through FY 2010. Many commenters continued to assert that our estimates of documentation and coding were overstated, and could be explained by other factors. These commenters also focused on part of the analysis provided by MedPAC in its FY 2012 public comment letter indicating that a slightly smaller additional prospective adjustment of -0.55 percent rather than -0.8 percent might be required to offset the cumulative MS-DRG documentation and coding effect through FY 2010. Specifically, while MedPAC supported the overall methodology, it suggested that it was possible that changes in documentation and coding to optimize payments under the MS-DRG GROUPERS and weights may have resulted in slightly less than optimal payments under the FY 2007 GROUPEr and weights (the denominator of the documentation and coding change estimate). Many commenters requested that, given the MedPAC analysis, if CMS were to apply an additional prospective adjustment to the MS-DRG documentation and coding effect through FY 2010, it should subtract 0.25 percentage points from its estimate, for an adjustment of -0.55 percent.

After considering the public comments, we recognized that the issue of the estimate to use for the cumulative MS-DRG documentation and coding effect through FY 2010 may merit further consideration. Therefore, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53278 through 53280), we decided not to finalize the

proposed -0.8 percent adjustment to the standardized amount and the hospital-specific rate until more analysis could be completed.

CMS is continuing to consider whether MedPAC's recommendation that an adjustment to offset the cumulative documentation and coding effects through FY 2010 under section 1886(d)(3)(A)(vi) of the Act is appropriate and supported by a review of the claims data. After further consideration of the MedPAC analysis and the request by many public commenters, 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.

It is often our practice to delay or phase-in adjustments to mitigate negative financial impacts. Because we are proposing a -0.8 percent recoupment adjustment, as discussed in section II.D.6. of the preamble of this proposed rule, we are not proposing a prospective adjustment in FY 2014 for the cumulative MS-DRG documentation and coding effect through FY 2010. However, we are soliciting public comments as to whether any portion of the proposed -0.8 percent recoupment adjustment should be reduced and instead applied to a prospective adjustment for the cumulative MS-DRG documentation and coding effect through FY 2010. For example, we could apply a -0.25 percent recoupment adjustment, and a -0.55 prospective adjustment, for a total FY 2014 adjustment of -0.8 percent. Reducing the recoupment adjustment in FY 2014 would require relatively larger adjustments for FYs 2015, 2016, and/or 2017, but making a prospective adjustment of -0.55 percent would eliminate future payment increases due to MS-DRG documentation and coding that did not reflect real changes in case-mix for

discharges occurring through FY 2010. As we discuss above, because the documentation and coding effect through FY 2010 was found for both IPPS hospitals paid with the standardized amount and IPPS hospitals paid under their hospital-specific payment rate, if we were to apply a prospective adjustment to remove this effect, we also would apply such an adjustment to the hospital-specific payment rate, using the Secretary's broad authority under section 1886(d)(5)(I)(i) of the Act (77 FR 53276 through 53277).

Therefore, if we attribute a portion of the -0.8 percent adjustment for FY 2014 to the prospective adjustment, we also would make appropriate adjustments to the hospital-specific payment rates. Puerto Rico-specific rates would not be affected, as we previously found no significant additional MS-DRG documentation and coding effect for FY 2010 that would warrant any additional adjustment to the Puerto Rico-specific rate (77 FR 53279).

E. Proposed 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/LTCH PPS final rule (73 FR 48458 through 48467), in response to the RTI's recommendations concerning cost report refinements, we discussed our decision to pursue changes to the cost report to split the cost center for Medical Supplies Charged to Patients into one line for "Medical Supplies Charged to Patients" and another line for "Implantable Devices Charged to Patients." We acknowledged, as RTI had found, that charge compression occurs in several cost centers that exist on the Medicare cost report. However, as we stated in the FY 2009 IPPS/LTCH PPS final rule, we focused on the CCR for Medical Supplies and Equipment because RTI found that the

largest impact on the MS-DRG relative weights could result from correcting charge compression for devices and implants. In determining the items that should be reported in these respective cost centers, we adopted the commenters' recommendations that hospitals should use revenue codes established by the AHA's National Uniform Billing Committee to determine the items that should be reported in the "Medical Supplies Charged to Patients" and the "Implantable Devices Charged to Patients" cost centers. Accordingly, a new subscripted line 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 OPSS/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 OPSS 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 report 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/RV 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 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.

2. Discussion and Proposal for FY 2014

To calculate the proposed FY 2014 MS-DRG relative weights, we are proposing to continue our current methodology of using the two most recent data sources: the December 2012 update of the FY 2012 MedPAR file as the claims data source and the December 2012 update of FY 2011 HCRIS as the cost data source. We currently have 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. Specifically, using the December 2012 update of FY 2011 HCRIS, we were able to calculate a valid implantable device CCR for 2,285 IPPS hospitals, a valid MRI CCR for 1,402 IPPS hospitals, a valid CT scan CCR for 1,470 IPPS hospitals, and a valid cardiac catheterization CCR for 1,022 IPPS hospitals. 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.

We believe that there is a sufficient amount of data in the FY 2011 cost reports from which to generate a meaningful analysis of using distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. In addition, the corresponding charge data on hospital claims for implantable devices, MRIs, CT scans, and cardiac

catheterization are available in the FY 2012 MedPAR file. Therefore, we are providing various data analyses below based on comparison of the FY 2014 relative weights computed using 15 CCRs, as we have done in the past, and the FY 2014 relative weights computed using 19 CCRs, with distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. Specifically, rather than having a single CCR for “Supplies and Equipment” which includes low-cost supplies and high-cost implantable devices, a distinct CCR would be carved out of the “Supplies and Equipment” CCR, leaving one CCR for “Supplies” and one CCR for “Implantable Devices.” Regarding the Radiology CCR, which currently is comprised of general radiology ancillary services and MRIs and CT scans, the costs for MRIs and CT scans would be separated from general radiology, creating two distinct CCRs, one for MRIs and one for CT scans, respectively. Finally, by separating the costs of cardiac catheterization out of the CCR for general cardiology, a distinct CCR would be created for cardiac catheterization. Thus, by breaking out these 4 additional CCRs, the number of CCRs used to calculate the relative weights would increase from 15 to 19.

For comparison purposes, the following table shows the final FY 2013 CCRs, the potential FY 2014 CCRs computed with the existing 15 cost centers, and the potential FY 2014 CCRs computed with 19 cost centers, with 4 new CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization.

Group	Final FY 2013 15 CCRs	Potential FY 2014 15 CCRs	Potential FY 2014 19 CCRs
Routine days	0.514	0.502	0.502
Intensive days	0.442	0.423	0.423

Group	Final FY 2013 15 CCRs	Potential FY 2014 15 CCRs	Potential FY 2014 19 CCRs
Drugs	0.199	0.193	0.193
Supplies & Equipment	0.335	0.327	0.293
Implantable Devices	n/a	n/a	0.361
Therapy Services	0.370	0.355	0.355
Laboratory	0.143	0.133	0.133
Operating Room	0.238	0.225	0.225
Cardiology	0.145	0.134	0.132
Cardiac Catheterization	n/a	n/a	0.135
Radiology	0.136	0.128	0.170
MRI	n/a	n/a	0.091
CT Scans	n/a	n/a	0.045
Emergency Room	0.226	0.207	0.207
Blood	0.389	0.371	0.371
Other Services	0.397	0.399	0.399
Labor & Delivery	0.450	0.445	0.445
Inhalation Therapy	0.189	0.187	0.187
Anesthesia	0.109	0.120	0.120

In order to model the effects on the relative weights in medical MS-DRGs versus surgical MS-DRGs, we compared a set of relative weights calculated with 15 CCRs and 19 CCRs. Overall, if 19 CCRs are used to calculate the relative weights for FY 2014, relative weights for medical MS-DRGs would be expected to decrease by approximately 1.1 percent, and those for surgical MS-DRGs would be expected to increase by approximately 1.2 percent. In addition, as shown in the table below, at the MDC level, payments would increase by approximately 0.64 percent (0.39 + 0.25) within orthopedic and cardiac MDCs, with most of the reductions in payment resulting to the medical MS-DRGs in the nervous system, digestive system, and respiratory system MDCs.

MDC	Description	Estimated Percentage Change within MDC
08	Musculoskeletal System And Connective Tissue	0.39%
05	Circulatory System	0.25%
01	Nervous System	-0.16%
06	Digestive System	-0.10%
04	Respiratory System	-0.08%

The largest estimated increase in MS-DRG relative weights would likely occur for MS-DRGs associated with cardiac catheterization and implantable cardiac devices. The largest estimated reductions in MS-DRG relative weights would likely occur for MS-DRGs associated with traumatic head injury and concussion, which are high users of CT scanning and MRI services. We are including in the table below the top 10 (nonlabor and delivery) MS-DRGs that we predict would experience the largest increases and decreases in relative weights if 19 CCRs would be used as compared to 15 CCRs.

MS-DRGS THAT WOULD EXPERIENCE THE LARGEST DECREASE IN RELATIVE WEIGHT					
MS-DRG	Type	Title	Potential Relative Weight with 15 CCRs	Potential Relative Weights with 19 CCRs	Percentage Change
090	MED	Concussion without CC/MCC	0.7614	0.7013	-7.9%
084	MED	Traumatic Stupor & Coma, Coma >1 Hour without CC/MCC	0.9137	0.8516	-6.8%
087	MED	Traumatic Stupor & Coma, Coma <1 Hour without CC/MCC	0.7899	0.7369	-6.7%
965	MED	Other Multiple Significant Trauma without CC/MCC	1.0450	0.980	-6.1%

185	MED	Major Chest Trauma without CC/MCC	0.7281	0.6845	-6.0%
089	MED	Concussion with CC	0.9959	0.9366	-6.0%
123	MED	Neurological Eye Disorder	0.7355	0.6920	-5.9%
343	SURG	Appendectomy without Complicated Principal Diagnosis without CC/MCC	0.9880	0.9517	-5.7%
053	MED	Spinal Disorders & Injuries without CC/MCC	0.9355	0.8825	-5.7%
066	MED	Intracranial Hemorrhage or Cerebral Infarction without CC/MCC	0.8034	0.7579	-5.7%
MS-DRGS THAT WOULD EXPERIENCE THE LARGEST INCREASE IN RELATIVE WEIGHT					
454	SURG	Combined Anterior/Posterior Spinal Fusion with CC	7.6399	8.0563	5.5%
455	SURG	Combined Anterior/Posterior Spinal Fusion Without CC/MCC	5.9862	6.3133	5.5%
484	SURG	Major Joint & Limb Reattachment Procedure of Upper Extremity without CC/MCC	2.1211	2.2380	5.5%
225	SURG	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock without MCC	5.6298	5.9530	5.7%
223	SURG	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC	6.0956	6.4482	5.8%
458	SURG	Spinal Fusion Except Cervical with Spinal Curve/Malignant/Infection OR 9+ Fusion without CC/MCC	4.8794	5.1630	5.8%
245	SURG	AICD Generator Procedures	4.4627	4.7320	6.0%
849	MED	Radiotherapy	1.3423	1.4258	6.2%
946	MED	Rehabilitation without CC/MCC	1.1295	1.2024	6.5%
227	SURG	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC	5.2193	5.5714	6.7%

After computing the analyses described above by comparing both sets of MS-DRG relative weights computed with FY 2011 cost report data, we revisited RTI's July 2008 final report. We note that the impacts on relative weight and at the MDC level are generally consistent with those estimated by RTI in its modeling. RTI found that disaggregating the CCRs for medical supplies and devices would have the most impact on reducing charge compression, and that the largest impact was for MS-DRG 227. Similarly, as shown in the chart above, we estimate that the potential relative weight for MS-DRG 227 would experience the largest increase, 6.7 percent. Cardiac implants and spinal fusion procedures accounted for most of the 10 MS-DRGs with the largest incremental increases. In addition, RTI's July 2008 final report (pages 103 through 107) indicates that among the largest expected reductions are the MS-DRG relative weights for MS-DRGs associated with traumatic head injury and concussion, which are high users of CT scanning and MRI services. RTI's analyses were highly predictive for many of the MS-DRGs most sensitive to the effects of charge compression.

As we have stated in prior rulemaking (77 FR 53281 through 53283), once we determined that cost report data were available for analysis, we would propose, if appropriate, to use the distinct CCRs described above in the calculation of the MS-DRG relative weights. We believe that the analytic findings described above using the FY 2011 cost report data and FY 2012 claims data support our original decision to break out and create new cost centers for implantable devices, MRIs, CT scans, and cardiac catheterization, and we see no reason to further delay proposing to implement the CCRs of each of these cost centers. Therefore, beginning in FY 2014, we are proposing 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. We welcome public comments on this proposal and the impacts that it may have. We refer readers to section VI.C. of Appendix A of this proposed rule for the overall IPPS operating impact of this proposal, which models payments to various hospital types using relative weights developed from 19 CCRs as compared to 15 CCRs. In addition, each year, as part of the IPPS proposed rule and final rule, we issue Table 5, which lists all of the MS-DRGs and their relative weights. As part of this FY 2014 IPPS/LTCH PPS proposed rule, in addition to providing Table 5, which lists the proposed MS-DRGs and their relative weights using 19 CCRs (available on the CMS Web site at: http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp; click on the link on the left side of the screen titled “FY 2014 IPPS Proposed Rule Home Page” or “Acute Inpatient—Files for Download”), we are providing a separate table that lists all MS-DRGs and their relative weights if computed using 15 CCRs (available at the same CMS Web site cited above). These two formats will allow readers to compare our proposal to calculate the MS-DRG relative weights using 19 CCRs with the relative weights of MS-DRGs if computed using 15 CCRs.

F. Adjustment to MS-DRGs for Preventable Hospital-Acquired Conditions (HACs).

Including Infections

1. Background

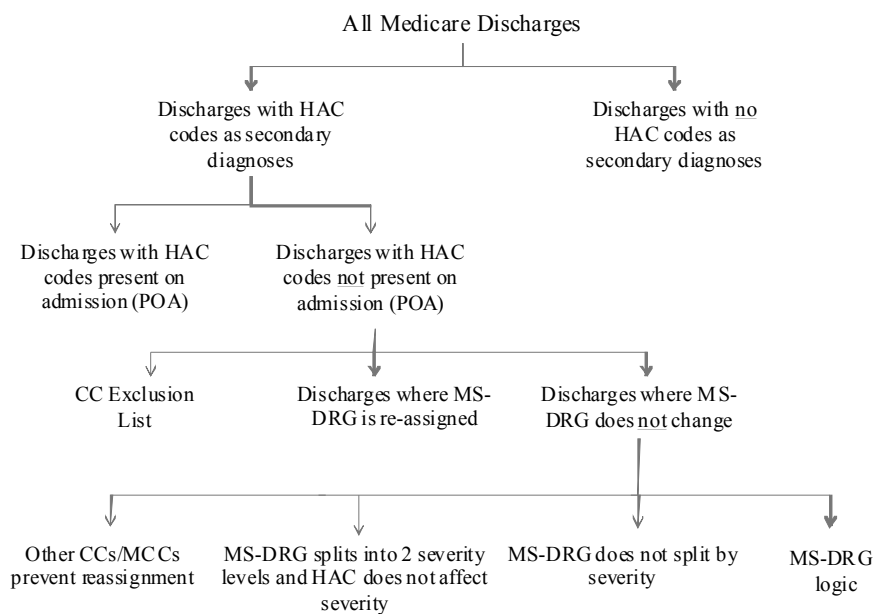
Section 1886(d)(4)(D) of the Act addresses certain hospital-acquired conditions (HACs), including infections. This provision is part of an array of Medicare tools that we are using to promote increased quality and efficiency of care. Under the IPPS, hospitals are encouraged to treat patients efficiently because they receive the same DRG payment for stays that vary in length and in the services provided, which gives hospitals an incentive to avoid unnecessary costs in the delivery of care. In some cases, conditions acquired in the hospital do not generate higher payments than the hospital would otherwise receive for cases without these conditions. To this extent, the IPPS encourages hospitals to avoid complications.

However, the treatment of certain conditions can generate higher Medicare payments in two ways. First, if a hospital incurs exceptionally high costs treating a patient, the hospital stay may generate an outlier payment. Because the outlier payment methodology requires that hospitals experience large losses on outlier cases before outlier payments are made, hospitals have an incentive to prevent outliers. Second, under the MS-DRG system that took effect in FY 2008 and that has been refined through rulemaking in subsequent years, certain conditions can generate higher payments even if the outlier payment requirements are not met. Under the MS-DRG system, there are currently 261 sets of MS-DRGs that are split into 2 or 3 subgroups based on the presence

or absence of a CC or an MCC. The presence of a CC or an MCC generally results in a higher payment.

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

Effective for discharges occurring on or after October 1, 2008, pursuant to the authority of section 1886(d)(4)(D) of the Act, Medicare no longer assigns an inpatient hospital discharge to a higher paying MS-DRG if a selected condition is not present on admission (POA). Thus, if a selected condition that was not POA manifests during the hospital stay, it is considered a HAC and the case is paid as though the secondary diagnosis was not present. However, even if a HAC manifests during the hospital stay, if any nonselected CC/MCC appears on the claim, the claim will be paid at the higher MS-DRG rate. In addition, Medicare continues to assign a discharge to a higher paying MS-DRG if a selected condition is POA. When a HAC is not POA, payment can be 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 IPSS 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 IPSS proposed rule (71 FR 24100) and final rule (71 FR 48051 through 48053); the FY 2008 IPSS proposed rule (72 FR 24716 through 24726) and final rule with comment period (72 FR 47200 through 47218); the FY 2009 IPSS proposed rule (73 FR 23547) and final rule (73 FR 48471); the FY 2010 IPSS/RV 2010 LTCH PPS proposed rule (74 FR 24106) and final rule (74 FR 43782); the FY 2011 IPSS/LTCH PPS proposed rule (75 FR 23880) and final rule (75 FR 50080); the FY 2012 IPSS/LTCH PPS

proposed rule (76 FR 25810 through 25816) and final rule (76 FR 51504 through 51522); and the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27892 through 27898) and final rule (77 FR 53283 through 53303). 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 discussed in the prior rulemaking cited above, 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, hospitals in Maryland operating under waivers, RNHCIs, and the Department of Veterans Affairs/Department of Defense hospitals, are exempt from POA reporting. We note that hospitals in Maryland operating under their waiver are not paid under the IPPS but rather are paid under the provisions of section 1814(b)(3) of the Act. This waiver applies to the amount paid to providers of services, and does not extend to billing requirements and other reporting requirements. In fact, hospitals in Maryland are

required to submit Medicare claims for Medicare payment and also to submit the same information on their Medicare claims as hospitals in other parts of the country paid under the IPPS. Therefore, we believe it is inappropriate to continue to exempt hospitals in Maryland from the POA indicator reporting requirement. Under current policy, hospitals in Maryland will continue to be exempt from the application of this HAC provision so long as they are not paid under the IPPS. However, we believe it is 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. (We refer readers to section V.I. of the preamble to this proposed rule for a discussion of our proposals to implement section 1886(p) of the Act.) Therefore, we are proposing that hospitals in Maryland operating under their waiver under section 1814(b)(3) of the Act will no longer be 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 are inviting public comment regarding this proposal.

As discussed in previous IPPS proposed and final rules, there are five POA indicator reporting options, as defined by the ICD-9-CM Official Guidelines for Coding and Reporting. Under the HAC policy, we treat HACs coded with “Y” and “W” indicators as POA and allow the condition on its own to cause an increased payment at the CC/MCC level. We treat HACs coded with “N” and “U” indicators as Not Present on Admission (NPOA) and do not allow the condition on its own to cause an increased payment at the CC/MCC level. We refer readers to the following rules for a detailed

discussion: the FY 2009 IPPS proposed rule (73 FR 23559) and final rule (73 FR 48486 through 48487); the FY 2010 IPPS/RV 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); and the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27893 through 27894) and final rule (77 FR 53284 through 53285).

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

Beginning on or after January 1, 2011, hospitals were required to begin reporting POA indicators using the 5010 electronic transmittal standards format. The 5010 format removes the need to report a POA indicator of “1” for codes that are exempt from POA reporting. We have issued CMS instructions on this reporting change as a One-Time Notification, Pub. No. 100-20, Transmittal No. 756, Change Request 7024, effective on August 13, 2010, which can be located at the following link on the CMS Web site:

http://www.cms.gov/manuals/downloads/Pub100_20.pdf.

In addition, as discussed elsewhere in section III.G.10. of the preamble of this proposed rule, the 5010 format allows the reporting and effective January 1, 2011, the processing of up to 25 diagnoses and 25 procedure codes. As such, it is necessary to report a valid POA indicator for each diagnosis code, including the principal and all secondary diagnoses up to 25.

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

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

At the March 5, 2012 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 current ICD-9-CM selected HACs has been translated into codes using the ICD-10-CM and ICD-10-PCS classification system. It was recommended that the public review this list of ICD-10-CM/ICD-10-PCS code translations of the current selected HACs available on the CMS Web site at: <http://www.cms.gov/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).” The above 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 encourage the public to submit comments on these translations through the HACs Web page using the CMS ICD-10-CM/PCS HAC Translation Feedback Mailbox that has been set up for this purpose under the Related Links section titled “CMS HAC Feedback.” The final HAC list translation from ICD-9-CM to ICD-10-CM/ICD-10-PCS will be subject to formal rulemaking.

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

5. Proposals Regarding Current HACs and Previously Considered Candidate HACs

We are not proposing to add or remove categories of HACs at this time. 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 III.F.5. of the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27892 through 27898) and the FY 2013

IPPS/LTCH PPS final rule (77 FR 53285 through 53292) for the HAC policy for FY 2013. In addition, readers may find updated information on evidence-based guidelines on the CMS Web site at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html.

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 healthcare 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/Hospital-Acquired_Conditions.html. Subsequent to this final report, RTI has been 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.

Updates to the guidelines will be made available to the public.

G. Proposed Changes to Specific MS-DRG Classifications

In this FY 2014 IPPS/LTCH PPS proposed rule, we are inviting public comment on each of the MS-DRG classification proposed changes described below, as well as our proposals to maintain certain existing MS-DRG classifications, which 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.

CMS encourages input from our stakeholders concerning the annual IPPS updates when that input is made available to us by early December of the year prior to the next annual proposed rule update. For example, to be considered for any updates or changes in FY 2014, comments and suggestions should have been submitted by early December 2012. The comments that were submitted in a timely manner are discussed below in this section.

1. Pre-Major Diagnostic Categories (Pre-MDCs): Heart Transplants and Liver Transplants

We received a request from an organization that represents transplant surgeons to eliminate the severity levels for the heart and liver transplants MS-DRGs. The MS-DRGs for heart transplants are: MS-DRG 001 (Heart Transplant or Implant of Heart Assist System with MCC) and MS-DRG 002 (Heart Transplant or Implant of Heart Assist System without MCC). The MS-DRGs for liver transplants are: MS-DRG 005 (Liver Transplant with MCC or Intestinal Transplant) and MS-DRG 006 (Liver Transplant without MCC). We received this comment during the comment period for the

FY 2013 IPPS/LTCH PPS proposed rule. We referred to this comment briefly in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53325), but we did not address the issue because we considered this comment outside of the scope of the proposed rule. However, we are addressing this issue in this FY 2014 proposed rule.

The commenter stated that there are no “uncomplicated” heart transplants or liver transplants, and indicated that all of these transplant procedures are highly complex, involving numerous complicating conditions, only some of which may be recognized by the MS-DRGs. The commenter expressed concern that the continued bifurcation of the MS-DRGs for heart and liver transplants will result in unsustainable payment for these cases that are assigned to the “without MCC” MS-DRGs 002 and 006. According to the commenter, in light of the relatively small number of Medicare patients involved and the significant cost variation involved, it would be preferable to eliminate the bifurcation of these procedures, thereby increasing the stability of the DRG weights for these procedures.

We examined claims data from the FY 2012 MedPAR file for heart and liver transplant cases assigned to MS-DRGs 001, 002, 005, and 006. The following table illustrates our findings:

MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 001	1,247	33.27	\$158,556
MS-DRG 002	284	18	\$97,932
MS-DRGs 001 and 002 - All cases	1,531	30.4	\$147,310
MS-DRG 005	828	19	\$66,746
MS-DRG 006	282	8.75	\$30,873

MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
MS-DRGs 005 and 006 - All cases	1,110	16.3	\$57,632

The data showed that the majority of the heart transplant cases, a total of 1,247, are assigned to MS-DRG 001, with average costs of approximately \$158,556 and an average length of stay of approximately 33.27 days. There were 284 cases assigned to MS-DRG 002, with average costs of approximately \$97,932 and an average length of stay of approximately 18 days.

This table shows that there are significant differences in average lengths of stay and average costs for the severity level for the heart transplant MS-DRGs that justify the existing split in MS-DRGs 001 and 002. If we were to combine the heart transplant cases in MS-DRGs 001 and 002 as suggested by the commenter, the payment for the majority of cases with an MCC would be lower.

The majority of the liver transplant cases, 828 cases, were assigned to MS-DRG 005, with average costs of approximately \$66,746 and an average length of stay of approximately 19 days. There were 282 cases assigned to MS-DRG 006, with average costs of approximately \$30,873 and an average length of stay of approximately 8.75 days. The data showed that there are significant differences in average costs and average lengths of stay in the severity levels for the liver transplant MS-DRGs. Again, if we were to combine all the liver transplant cases into one MS-DRG as requested by the commenter, the majority of the cases would receive lower payment.

Based on these findings, we believe that it would not be prudent to eliminate the severity levels for the heart and liver transplant MS-DRGs. Our clinical advisors concur with this analysis that two severity levels are justified for the heart and liver transplant MS-DRGs. Therefore, for FY 2014, we are not proposing to make any changes to the severity levels for heart and liver transplant MS-DRGs 001, 002, 005, and 006.

We are inviting public comments on this issue.

2. MDC 1 (Diseases and Disorders of the Nervous System): Tissue Plasminogen Activator (tPA) (rtPA) Administration Within 24 Hours Prior to Admission

During the comment period for the FY 2013 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 2013 IPPS/LTCH PPS final rule (77 FR 53325) that we would consider this issue in future rulemaking as part of our annual review process. The commenter requested that CMS conduct an analysis of diagnosis code V45.88 (Status post administration of tPA (rtPA) in a different facility within the last 24 hours prior to admission to current facility). Diagnosis code V45.88 was created for use beginning October 1, 2008, to identify patients who are given tissue plasminogen activator (tPA) at one institution and then transferred and admitted to a comprehensive stroke center for further care. This situation has been referred to as the “drip-and-ship” issue and was discussed at length in the FY 2009 IPPS proposed rule (73 FR 23563 through 23564) and final rule (73 FR 48493 through 48495), as well as the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23899 through 23900) and final rule (75 FR 50102 through 50106).

We refer readers to these previous discussions for detailed background information regarding this topic.

Similar to previous requests, according to the commenter, the concern at the receiving facilities is that the costs associated with [caring for] more complex stroke patients that receive tPA are much higher than the cost of the drug, presumably because stroke patients initially needing tPA have more complicated strokes and outcomes. However, because these patients do not receive the tPA at the second or transfer hospital, the receiving hospital will not be able to assign the case to one of the higher-weighted tPA stroke MS-DRGs when it admits these patients whose care requires the use of intensive resources. The MS-DRGs that currently include the diagnosis code for the use of tPA are: MS-DRG 061 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC); MS-DRG 062 (Acute Ischemic Stroke with Use of Thrombolytic Agent with CC); and MS-DRG 063 (Acute Ischemic Stroke with Use of Thrombolytic Agent without CC/MCC). These MS-DRGs have higher relative weights than the other MS-DRGs relating to stroke or cerebral infarction. The commenter requested an analysis of diagnosis code V45.88 to determine whether new claims data warrant any change in the MS-DRG structure.

For this proposed rule, we analyzed MedPAR claims data from FY 2012. We included claims for patient cases assigned to the following MS-DRGs:

- 061 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC)
- 062 (Acute Ischemic Stroke with Use of Thrombolytic Agent with CC)

- 063 (Acute Ischemic Stroke with Use of Thrombolytic Agent without CC/MCC)

- 064 (Intracranial Hemorrhage or Cerebral Infarction with MCC)

- 065 (Intracranial Hemorrhage or Cerebral Infarction with CC)

- 066 (Intracranial Hemorrhage or Cerebral Infarction without CC/ MCC).

Our data analysis included MS-DRGs 064, 065, and 066 because claims involving diagnosis code V45.88 also would be properly reported in the data for these MS-DRGs.

The following table reflects the results of our analysis of the MedPAR data in which diagnosis code V45.88 was reported as a secondary diagnosis for FY 2012.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 061 - All cases	3,369	7.48	\$18,556
MS-DRG 061 - Cases with secondary diagnosis code V45.88	140	7.51	\$19,008
MS-DRG 062 - All cases	5,277	4.92	\$12,935
MS-DRG 062 - Cases with secondary diagnosis code V45.88	179	5.03	\$13,317
MS-DRG 063 - All cases	1,709	3.45	\$10,363
MS-DRG 063 - Cases with secondary diagnosis code V45.88	48	3.15	\$9,372
MS-DRG 064 - All cases	64,095	6.30	\$11,654
MS-DRG 064 - Cases with secondary diagnosis code V45.88	955	7.06	\$14,432
MS-DRG 065 – All cases	101,011	4.29	\$7,414
MS-DRG 065 - Cases with secondary diagnosis code V45.88	1,259	4.91	\$9,471
MS-DRG 066 – All cases	56,620	2.92	\$5,414
MS-DRG 066 - Cases with secondary diagnosis code V45.88	493	3.28	\$6,682

Based on our review of the data for all of the cases in MS-DRGs 064, 065, and 066, compared to the subset of cases containing diagnosis code V45.88 as the secondary

diagnosis, we again concluded that the movement of cases with diagnosis code V45.88 as a secondary diagnosis from MS-DRGs 064, 065, and 066 to MS-DRGs 061, 062, and 063 is not warranted. We determined that the differences in the average lengths of stay and the average costs are too small to warrant an assignment to the higher-weighted MS-DRGs.

However, the data does reflect that the average costs for cases reporting diagnosis code V45.88 as a secondary diagnosis in MS-DRG 066 are more similar to the average costs of higher severity level cases in MS-DRG 065. Therefore, for FY 2014, we are proposing to move cases with diagnosis code V45.88 from MS-DRG 066 to MS-DRG 065, and to revise the title of MS-DRG 065 to reflect the patients status post tPA administration within 24 hours. The proposed revised MS-DRG title would be: MS-DRG 065 (Intracranial Hemorrhage or Cerebral Infarction with CC or tPA in 24 Hours).

We are inviting public comments on our proposal.

3. MDC 4 (Diseases and Disorders of the Ear, Nose, Mouth and Throat)

a. Endoscopic Placement of a Bronchial Valve

In response to the FY 2013 IPPS/LTCH PPS proposed rule, we received a request to modify the MS-DRG assignment for bronchial valve(s) insertion, which we considered to be outside of the scope of that proposed rule (77 FR 53325 through 53326). The requestor asked that cases in MS-DRGs 190, 191, and 192 (Chronic Obstructive Pulmonary Disease with MCC, with CC, and without MCC/CC, respectively) that involve insertion of a bronchial valve be assigned instead to MS-DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without MCC/CC, respectively). The

procedures are captured by procedure codes 33.71 (Endoscopic insertion or replacement of bronchial valve(s), single lobe) and 33.73 (Endoscopic insertion or replacement of bronchial valve(s), multiple lobes), which are considered nonoperating procedures and do not affect the MS-DRG assignment. When reported without any other operating room (OR) procedure code, the admission would be assigned to a medical MS-DRG.

The Spiration[®] IBV Valve System device, a bronchial valve, was approved for new technology add-on payments in the FY 2010 IPPS/RV 2010 LTCH PPS final rule (74 FR 43819 through 43823) with a maximum payment rate of \$3,437.50. In the FY 2012 IPPS/LTCH PPS final rule, the new technology add-on payments were discontinued for FY 2012 (76 FR 51575 through 51576). The bronchial valve device is used to place, via bronchoscopy, small, one-way valves into selected small airways in the lung in order to limit airflow into selected portions of lung tissue that have prolonged air leaks following surgery while still allowing mucus, fluids, and air to exit, and thereby reducing the amount of air that enters the pleural space. The device is intended to control prolonged air leaks following three specific surgical procedures: lobectomy, segmentectomy, or lung volume reduction surgery (LVRS). According to Spiration[®], an air leak that is present on postoperative day 7 is considered “prolonged” unless present only during forced exhalation or cough. In order to help prevent valve migration, there are five anchors with tips that secure the valve to the airway. The implanted valves are intended to be removed no later than 6 weeks after implantation.

New technology add-on payments were limited to cases involving prolonged air leaks following lobectomy, segmentectomy, and LVRS in MS-DRGs 163, 164, and 165

in the FY 2010 IPPS/RV 2010 LTCH PPS final rule (74 FR 43823). This limitation was based on the indications for use approved by the FDA in the FDA Humanitarian Device Exemption (HDE) approval process set forth in section 520(m) of the Federal Food, Drug & Cosmetic Act. A humanitarian use device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. Devices that receive HUD designation may be eligible for marketing approval, subject to certain restrictions, under an HDE application. To obtain marketing approval for an HUD, an HDE application must be submitted to the FDA. An HDE application is a premarket approval (PMA) application submitted to the FDA under 21 CFR 814.104 that seeks exemption from the PMA requirement under 21 CFR 814.20 demonstrating a reasonable assurance of effectiveness. A device that has received HUD designation may receive HDE approval if, among other things, the FDA determines that the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. In addition, the applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition (other than another device approved under an HDE application or a device under an approved Investigational Device Exemption), and that the device would not otherwise be available unless an HDE is granted. An approved HDE authorizes marketing of the HUD. However, an HUD

generally may be used in facilities only after prior approval by an Institutional Review Board (IRB).

FDA's approval of the HDE application limited the use of the Spiration[®] IBV Valve System device to cases involving prolonged air leaks following lobectomy, segmentectomy, or LVRS.

The requested MS-DRG change would initiate the same payment for chronic obstructive pulmonary disease (COPD) cases with a bronchial valve inserted without a major chest procedure as for cases where both a major chest procedure and a bronchial valve insertion were performed. The following table shows the COPD cases that involved the insertion of a bronchial valve as well as data on cases assigned to MS-DRGs 163, 164, and 165.

MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
COPD Cases			
MS-DRG 190 – All cases	133,566	5.07	\$7,815
MS-DRG 190 – Cases with procedure code 33.71	0	0	0
MS-DRG 190 – Cases with procedure code 33.73	2	14.0	\$47,034
MS-DRG 191 – All cases	129,231	4.18	\$6,245
MS-DRG 191 – Cases with procedure code 33.71	0	0	0
MS-DRG 191 – Cases with procedure code 33.73	0	0	0
MS-DRG 192 – All cases	93,507	3.32	\$4,776
MS-DRG 192 – Cases with procedure code 33.71	0	0	0
MS-DRG 192 – Cases with procedure code 33.73	0	0	0
Major Chest Procedures			

MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 163 – All cases	11,287	13.33	\$32,728
MS-DRG 164 – All cases	16,113	6.69	\$17,494
MS-DRG 165 – All cases	9,280	3.94	\$12,209

There were only two COPD cases that had bronchial valves inserted in MS-DRGs 190, 191, and 192. While the charges were high, these cases were assigned to the highest severity level MS-DRG (MS-DRG 190 with MCC). Given the small number of cases, it is not possible to determine if the high average costs were due to the bronchial valve insertion or to other factors such as other secondary diagnoses. The average length of stay for these two cases was approximately 14 days compared to approximately 5.07 days for all other cases within MS-DRG 190. Because the additional 10 days cannot be clinically attributed to the bronchial valve insertion, our clinical advisors have determined that other factors must have impacted these two cases.

Cases in MS-DRGs 163, 164, and 165 include those cases with a major chest procedure and those cases with both a major chest procedure as well as a bronchial valve insertion as discussed above. Our clinical advisors do not support moving COPD cases that have only a bronchial valve insertion and no other major chest procedure from MS-DRGs 190, 191, and 192 to MS-DRGs 163, 164, and 165. They do not believe the bronchial valve procedures are clinically similar to other major chest procedures that require significantly more resources to perform. Our clinical advisors point out that the limited circumstances where this procedure would be used led the sponsor to seek HDE approval from the FDA rather than a standard PMA. The indications for use approved by

the FDA are still limited to post-surgery. Our clinical advisors recommended that we not modify the MS-DRG logic so that COPD cases with bronchial valve insertions would be assigned to MS-DRGs 163, 164, and 165.

Given the limited number of cases for this procedure and the advice from our clinical advisors, we are not proposing any MS-DRG changes for bronchial valve(s) insertion for FY 2014. We also are not proposing to change the MS-DRG assignment for procedures involving bronchial valve(s) insertion (procedure codes 33.71 and 33.73) within MS-DRGs 190, 191, and 192.

We are inviting public comment on this issue.

b. Pulmonary Thromboendarterectomy (PTE) with Full Circulatory Arrest

We received a request from a university medical center to create a new MS-DRG or to reassign cases reporting a unique approach to pulmonary thromboendarterectomy (PTE) surgery performed with full cardiac arrest and hypothermia. The requestor asked that we move cases from MS-DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) to MS-DRGs 228, 229, and 230 (Other Cardiothoracic Procedures with MCC, with CC, and without CC/MCC, respectively). Currently, MS-DRGs 163, 164, and 165 are grouped within MDC 4 (Diseases and Disorders of the Respiratory System) while MS-DRGs 228, 229, and 230 are grouped within MDC 5 (Diseases and Disorders of the Circulatory System).

The requestor identified two conditions for which a pulmonary endarterectomy procedure is typically performed. These conditions are identified by ICD-9-CM diagnosis codes 415.19 (Other pulmonary embolism and infarction) and 416.2 (Chronic

pulmonary embolism). However, the requestor noted that diagnosis code 415.19 is usually associated with traditional PTE for acute pulmonary embolism while diagnosis code 416.2 is associated with the medical center's unique approach to PTE performed with full cardiac arrest and hypothermia.

Currently, there is not a specific ICD-9-CM procedure code to accurately describe PTE surgery performed with full cardiac arrest and hypothermia. Rather, a subset of existing ICD-9-CM procedure codes may be used to identify the various components involved in this unique approach to PTE surgery; for example, ICD-9-CM procedure codes 38.15 (Endarterectomy, other thoracic vessels); 39.61 (Extracorporeal circulation auxiliary to open heart surgery); 39.62 (Hypothermia (systemic) incidental to open heart surgery); and 39.63 (Cardioplegia). However, it is not clear if the requestor reports any of these codes or a combination of these codes to identify its unique approach to the procedure.

According to the requestor, its approach to PTE surgery is significantly different from traditional pulmonary endarterectomy procedures in terms of complexity, resource use, and the population for which the procedure is performed. The requestor noted that the surgery is "conducted under profound hypothermia and circulatory arrest which involves placing the patient on cardiopulmonary bypass and cooling the body to 20 degrees centigrade or lower." In addition, the requestor explained that "during this period of cooling and cardiac arrest, the heart is arrested and all of the patient's blood is removed from the body." Following this, circulation is stopped completely allowing for "optimal and extensive dissection of the pulmonary arteries and identification of an

endarterectomy plane which can be delicately incised into the deepest pulmonary vasculature.” The requestor further noted that “due to the complexity of the surgical technique, a very high degree of skill is required and the procedure is currently only performed by a handful of surgeons world-wide.” Lastly, the requestor stated the average operating time for a traditional PTE is approximately 3 to 4 hours compared to the university medical center’s approach to PTE, which averages approximately 10 to 12 hours.

We analyzed claims data from the FY 2012 MedPAR file for cases reporting a principal diagnosis code of 415.19 or a principal diagnosis code of 416.2 along with procedure codes 38.15, 39.61, 39.62, and 39.63. As displayed in the table below, there were a total of 11,287 cases in MS-DRG 163 with an average length of stay of approximately 13.33 days and average costs of approximately \$32,728. Using the combination of diagnosis and procedure codes as described above, the total number of cases found in MS-DRG 163 was 12, with average costs ranging from approximately \$46,959 to \$53,048 and an average length of stay ranging from approximately 13.50 days to 16.20 days. We acknowledge that the average length of stay and average costs for these cases are somewhat higher in comparison to the average lengths of stay and average costs of all the other cases in MS-DRG 163. However, the volume of cases was very low. The data reflect similar results for MS-DRG 164. Only 4 cases were identified in the analysis, with average costs ranging from approximately \$21,669 to \$37,447 and average lengths of stay ranging from approximately 7 days to 10 days.

In total, there were only 16 cases reflected in the data using the combination of diagnosis codes and proxy procedure codes. We believe there may be other factors contributing to the increased lengths of stay and costs. (We note that, there were no cases found for a principal diagnosis code of 415.19 with procedure code 38.15 only. There also were no cases found in MS-DRG 165 using the combination of diagnosis and procedure codes.)

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 163 - All cases	11,287	13.33	\$32,728
MS-DRG 163 - Cases with principal diagnosis code 415.19 with procedure code 38.15 and 39.61 or 39.62 or 39.63	4	13.50	\$46,959
MS-DRG 163 – Cases with principal diagnosis code 416.2 with procedure code 38.15 only	3	14.33	\$53,048
MS-DRG 163 – Cases with principal diagnosis code 416.2 with procedure code 38.15 and 39.61 or 39.62 or 39.63	5	16.20	\$50,393
MS-DRG 164 – All cases	16,113	6.69	\$17,494
MS-DRG 164 - Cases with principal diagnosis code 415.19 with procedure code 38.15 with 39.61 or 39.62 or 39.63	2	10.00	\$37,447
MS-DRG 164 - Cases with principal diagnosis code 416.2 with procedure code 38.15 only	0	0	0
MS-DRG 164 - Cases with principal diagnosis code 416.2 with procedure code 38.15 and 39.61 or 39.62 or 39.63	2	7.00	\$21,669

As stated in previous rulemaking discussion, the MS-DRG classification system on which the IPPS is based comprises a system of averages. As such, it is understood that, in any particular MS-DRG, it is not unusual for a small number of cases to demonstrate higher than average costs, nor is it unusual for a small number of cases to

demonstrate lower than average costs. Upon review of the MedPAR data, our clinical advisors agree that the current MS-DRG assignment for this unique procedure is appropriate.

We also analyzed claims data from the FY 2012 MedPAR file for MS-DRGs 228, 229, and 230 as illustrated below.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 228 - Other cardiothoracic procedures with MCC	1,643	13.26	\$46,758
MS-DRG 229 - Other cardiothoracic procedures with CC	1,841	7.77	\$30,432
MS-DRG 230 - Other cardiothoracic procedures without CC/MCC	506	5.08	\$25,068

ICD-9-CM procedure code 38.15 is designated as an operating room (OR) procedure code and currently groups to MS-DRGs 163, 164, and 165 in MDC 4 when either diagnosis code 415.19 or 416.2 are reported as the principal diagnosis. As diagnosis codes can only be assigned to one MDC within the GROUPER logic, it is not possible for a patient to have diagnosis code 415.19 or diagnosis code 416.2 reported along with procedure code 38.15 and grouped to MDC 5, which is where MS-DRGs 228, 229, and 230 are assigned.

Therefore, another aspect of this MS-DRG request involved the evaluation of moving ICD-9-CM diagnosis code 416.2 from MDC 4 to MDC 5. Our clinical advisors do not support moving diagnosis code 416.2 from MDC 4 to MDC 5 in order to accommodate this rare procedure performed by only a small number of physicians

worldwide. They pointed out that a basic change such as moving diagnosis code 416.2 from MDC 4 to MDC 5 would impact a large number of patients who do not undergo this procedure. It also would disrupt trend data from over 30 years of DRG and MS-DRG reporting. Given the very small number of potential cases, and the advice of our clinical advisors, we do not believe a MS-DRG modification is warranted at this time.

Therefore, we are not proposing to create a new MS-DRG or to reassign cases reporting this university medical center's approach to pulmonary thromboendarterectomy. We are inviting public comments on this issue.

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

a. Discharge/Transfer to Designated Disaster Alternative Care Site

We are proposing to add new patient discharge status code 69 (Discharged/transferred to a designated disaster alternative care site) to the MS-DRG GROUPER logic for MS-DRGs 280 (Acute Myocardial Infarction Discharged Alive with MCC), 281 (Acute Myocardial Infarction Discharged Alive with CC), and 282 (Acute Myocardial Infarction Discharged Alive without CC/MCC) to identify patients who are discharged or transferred to an alternative site that will provide basic patient care during a disaster response. As discussed in section II.G.7. of the preamble of this proposed rule, this new discharge status code is also being added to the Medicare Code Editor (MCE) software. We are inviting public comments on this proposal.

b. Discharges/Transfers With a Planned Acute Care Hospital Inpatient Readmission

We also are proposing to add 15 new discharge status codes to the MS-DRG GROUPER logic for MS-DRGs 280, 281, and 282 that will identify patients who are discharged with a planned acute care hospital inpatient readmission. As discussed in

section II.G.7. of the preamble of this proposed rule, these new discharge status codes are being proposed for addition to the MCE as well.

Shown in the table below are the current discharge status codes that are assigned to the GROUPER logic for MS-DRGs 280, 281, and 282, along with the proposed new discharge status codes and their titles.

Current Code	New Code	Title
01	81	Discharged to home or self care with a planned acute care hospital inpatient readmission
02	82	Discharged/transferred to a short term general hospital for inpatient care with a planned acute care hospital inpatient readmission
03	83	Discharged/transferred to a skilled nursing facility (SNF) with Medicare certification with a planned acute care hospital inpatient readmission
04	84	Discharged/transferred to a facility that provides custodial or supportive care with a planned acute care hospital inpatient readmission
05	85	Discharged/transferred to a designated cancer center or children's hospital with a planned acute care hospital inpatient readmission
06	86	Discharged/transferred to home under care of organized home health service organization with a planned acute care hospital inpatient readmission
21	87	Discharged/transferred to court/law enforcement with a planned acute care hospital inpatient readmission
43	88	Discharged/transferred to a federal health care facility with a planned acute care hospital inpatient readmission
61	89	Discharged/transferred to a hospital-based Medicare approved swing bed with a planned acute care hospital inpatient readmission
62	90	Discharged/transferred to an inpatient rehabilitation facility (IRF) including rehabilitation distinct part units of a hospital with a planned

Current Code	New Code	Title
		acute care hospital inpatient readmission
63	91	Discharged/transferred to a Medicare certified long term care hospital (LTCH) with a planned acute care hospital inpatient readmission
64	92	Discharged/transferred to a nursing facility certified under Medicaid but not certified under Medicare with a planned acute care hospital inpatient readmission
65	93	Discharged/transferred to a psychiatric distinct part unit of a hospital with a planned acute care hospital inpatient readmission
66	94	Discharged/transferred to a critical access hospital (CAH) with a planned acute care hospital inpatient readmission
70	95	Discharged/transferred to another type of health care institution not defined elsewhere in this code list with a planned acute care hospital inpatient readmission

We are inviting public comments on our proposal to add the above listed new discharge status codes to the GROUPER logic for MS-DRGs 280, 281, and 282.

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

a. Reverse Shoulder Procedures

We received a request to change the MS-DRG assignment for reverse shoulder replacement procedures which is captured with procedure code 81.88 (Reverse total shoulder replacement). The requestor did not suggest a specific new MS-DRG assignment, but requested that reverse shoulder replacement procedures be reassigned from MS-DRGs 483 and 484 (Major Joint/Limb Reattachment Procedure of, Upper

Extremities with CC/MCC and without CC/MCC, respectively) or that we create a new MS-DRG for reverse shoulder replacement procedures.

Biomechanically, the reverse shoulder devices move the center of rotation of the arm laterally and change the direction of the pull of the deltoid muscle, allowing the deltoid muscle to elevate the arm without functioning rotator cuff tendons. The requestor stated that the use of traditional total shoulder devices in patients with a nonfunctioning rotator cuff frequently leads to long-term complications and unsatisfactory functional results. Patients with damaged rotator cuffs or rotator cuff syndrome have poor outcomes with traditional shoulder replacement devices. The reverse shoulder replacement procedure was created to address the clinical needs for patients who would have poor outcomes with a traditional shoulder replacement. The requestor stated that reverse shoulder replacement devices were designed to provide a superior functionality and outcomes for patients with damaged rotator cuffs.

The requestor stated that the reverse shoulder replacement procedure is technically more complex and requires a higher level of expertise than traditional shoulder procedures and involves several issues that make the surgery more complex. Patients who have had prior rotator cuff surgery have anchors and scar tissue that must be surgically addressed. Often, there also are severe deformities that must be addressed in order to establish stability.

The requestor acknowledged that the reverse shoulder replacement procedure is an upper extremity procedure like other procedures assigned to MS-DRGs 483 and 484. These MS-DRGs include the longstanding total shoulder replacement procedures as well

as partial shoulder replacements. While the procedure is similar to other procedures in MS-DRGs 483 and 484, the requestor stated there are significant differences between the technical complexity and indications for usage from the other procedures. The requestor stated there are significant differences in resource usage and clinical coherence between longstanding approaches to shoulder replacement and other procedures assigned to MS-DRGs 483 and 484 and the reverse shoulder replacement procedure. The requestor stated not only was the resource consumption significantly higher, the individual supply costs for reverse shoulder replacement procedures were higher than the costs of other procedures assigned to MS-DRGs 483 and 484.

MS-DRGs 483 and 484 contain the following procedures:

- 81.73 (Total wrist replacement)
- 81.80 (Other total shoulder replacement)
- 81.81 (Partial shoulder replacement)
- 81.84 (Total elbow replacement)
- 81.88 (Reverse total shoulder replacement)
- 84.23 (Forearm, wrist, or hand reattachment)
- 84.24 (Upper arm reattachment).

As can be seen from this list, MS-DRGs 483 and 484 contain total and partial shoulder replacements, as well as replacement and attachment procedures on the wrist and upper arm. Both the newer shoulder replacement techniques as well as the longstanding shoulder replacement techniques are included in these MS-DRGs.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 483 – All cases	13,113	3.33	\$17,039
MS-DRG 483 – Cases with procedure code 81.88	5,690	3.30	\$19,023
MS-DRG 484 – All cases	21,073	2.01	\$14,448
MS-DRG 484 – Cases with procedure code 81.88	7,505	2.08	\$16,890

As the above table illustrates, the average costs for reverse total shoulder replacement are approximately \$2,000 higher than the average costs for all other procedures within MS-DRGs 483 and 484 and have similar average lengths of stays. While the average costs were higher, each MS-DRG has some cases that are higher and some cases that are lower than the average costs for the entire MS-DRG. We believe the average costs for the reverse shoulder replacement procedures are not inappropriately high compared to other procedures grouped within MS-DRGs 483 and 484. Therefore, the claims data do not support reassigning these cases or creating a new MS-DRG.

Our clinical advisors reviewed this issue and determined that the cases are appropriately assigned to MS-DRGs 483 and 484. As stated earlier, MS-DRGs 483 and 484 contain other types of shoulder replacements. Our clinical advisors believe it is appropriate to have all total shoulder replacement procedures within the same set of MS-DRGs. They do not believe it is appropriate to reassign those that use a different technique to accomplish the same goal, a total shoulder replacement. Therefore, our clinical advisors determined that this is an appropriate assignment for reverse shoulder replacement procedures from a clinical perspective. They also do not believe it is appropriate to move these cases to any other surgical, orthopedic MS-DRGs because of

differences in the clinical makeup of the other surgical orthopedic MS-DRGs. Our clinical advisors recommended not creating a new MS-DRG for reverse shoulder replacement procedures because they believe the procedures are appropriately assigned to MS-DRGs 483 and 484. Therefore, based on claims data and clinical analysis, we are not proposing to reassign these cases to any other MS-DRGs or to create a new MS-DRG.

Based on the claims data and our clinical analysis, we are not proposing to reassign cases reporting procedure code 81.88 from their current assignment to MS-DRGs 483 and 484 or to create a new MS-DRG. We are inviting public comments on this issue.

b. Total Ankle Replacement Procedures

In response to the FY 2013 IPPS/LTCH PPS proposed rule, we received a request to develop a new MS-DRG for total ankle replacements, which we considered to be outside the scope of that proposed rule (77 FR 53325). We are addressing this request as part of this FY 2014 IPPS/LTCH PPS proposed rule. The cases are captured by procedure code 81.56 (Total ankle replacement) and are assigned to MS-DRGs 469 and 470 (Major Joint Replacement or Reattachment of Lower Extremity with MCC and without MCC, respectively).

The commenter stated that total ankle procedures are much more clinically complex than total hip or total knee replacement procedures, which have their own distinct MS-DRGs. The commenter also stated that total ankle replacement is surgery that involves the replacement of the damaged parts of the three bones that make up the ankle joint, as compared to two bones in most other total joint procedures such as hip or

knee replacement. The commenter stated that average costs of total ankle replacements are higher than those for total knee and hip replacements. Therefore, a new MS-DRG should be created for total ankle replacements. As an alternative, the commenter suggested that these cases be reassigned to MS-DRG 469 even if the cases do not have an MCC as a secondary diagnosis.

MS-DRGs 469 and 470 include a variety of procedures of the lower extremities including the procedures listed below. This group of lower extremity joint replacement and reattachment procedures was developed because they were considered to be clinically cohesive and to have similar resource consumptions.

- 00.85 (Resurfacing hip, total, acetabulum and femoral head)
- 00.86 (Resurfacing hip, partial, femoral head)
- 00.87 (Resurfacing hip, partial, acetabulum)
- 81.51 (Total hip replacement)
- 81.52 (Partial hip replacement)
- 81.54 (Total knee replacement)
- 81.56 (Total ankle replacement)
- 84.26 (Foot reattachment)
- 84.27 (Lower leg or ankle reattachment)
- 84.28 (Thigh reattachment)

As the table below shows, there were 1,275 cases reporting total ankle replacements with 21 cases in MS-DRG 469 and 1,254 cases in MS-DRG 470. The 1,254 cases in MS-DRG 470 have higher costs than other cases in MS-DRG 470

(approximately \$17,242 compared to approximately \$13,984). The 21 cases in MS-DRG 469 had average costs of approximately \$23,360 compared to approximately \$21,186 in average costs for all cases within MS-DRG 469. While these procedures are higher in average costs than other procedures within the MS-DRGs, we point out that cases are grouped together based on similar clinical and resource criteria. Some cases will have average costs higher than the overall average costs for the MS-DRG, while other cases will have lower average costs. Total ankle replacements represent 0.3 percent of the total number of cases within MS-DRGs 469 and 470.

MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 469 – All cases	25,618	7.33	\$21,186
MS-DRG 469 – Cases with procedure code 81.56	21	6.81	\$23,360
MS-DRG 470 – All cases	390,518	3.37	\$13,984
MS-DRG 470 – Cases with procedure code 81.56	1,254	2.19	\$17,242
Total – All cases			416,136
Total – Cases with procedure code 81.56			1,275

Our clinical advisors reviewed this issue and determined that the total ankle replacements are appropriately classified within MS-DRGs 469 and 470. They do not support the commenter's contention that these cases are significantly more complex than knee and hip replacements. They believe that total ankle replacements are clinically consistent with other types of lower extremity joint replacements within MS-DRGs 469 and 470. Our clinical advisors do not support creating a new MS-DRG for total ankle replacements. After considering the results of examination of the claims data, the recommendations from our clinical advisors, and the small number of total ankle replacements, we are not proposing to create a new MS-DRG at this time.

We also examined the request to move all total ankle replacements to the highest severity level, MS-DRG 469, even when no secondary diagnosis on the MCC list was reported. Moving all total ankle replacements to MS-DRG 469 would lead to overpayments of approximately \$3,944 per case because the average costs of total ankle replacements in MS-DRG 470 was approximately \$17,242, while the average costs of all cases in MS-DRG 469 was approximately \$21,186. After considering the claims data as well as the input from our clinical advisors, we are not proposing that all total ankle procedures be assigned to MS-DRG 469 even when the case does not have an MCC reported as a secondary diagnosis. We believe the current MS-DRGs are appropriate for total ankle replacements.

We are not proposing to create a new total ankle replacement MS-DRG or to reassign all total ankle replacements to MS-DRG 469. We are proposing to maintain the current MS-DRG assignments for total ankle replacements. We are inviting public comment on our proposal.

6. MDC 15 (Newborns and Neonates with Conditions Originating in the Neonatal Period)

a. Persons Encountering Health Services for Specific Procedures, Not Carried Out

We received a request to evaluate the MS-DRG assignment of ICD-9-CM diagnosis codes V64.00 through V64.04, and V64.06 through V64.43 in MS-DRG 794 (Neonate with Other Significant Problems) under MDC 15. The requestor noted that the assignment of diagnosis code V64.05 (Vaccination not carried out because of caregiver refusal) was addressed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50111 through

50112). We removed diagnosis code V64.05 from MS-DRG 794 and added it to the “only secondary diagnosis” list for MS-DRG 795 (Normal Newborn). The requestor asked that we consider the reassignment of these diagnosis codes from MS-DRG 794 to MS-DRG 795. The codes under existing MS-DRG 794 include:

- V64.00 (Vaccination not carried out, unspecified reason)
- V64.01 (Vaccination not carried out because of acute illness)
- V64.02 (Vaccination not carried out because of chronic illness or condition)
- V64.03 (Vaccination not carried out because of immune compromised state)
- V64.04 (Vaccination not carried out because of allergy to vaccine or component)
- V64.06 (Vaccination not carried out because of patient refusal)
- V64.07 (Vaccination not carried out for religious reasons)
- V64.08 (Vaccination not carried out because patient had disease being vaccinated against)
- V64.09 (Vaccination not carried out for other reason)
- V64.1 (Surgical or other procedure not carried out because of contraindication)
- V64.2 (Surgical or other procedure not carried out because of patient’s decision)
- V64.3 (Procedure not carried out for other reasons)
- V64.41 (Laparoscopic surgical procedure converted to open procedure)
- V64.42 (Thoracoscopic surgical procedure converted to open procedure)
- V64.43 (Arthroscopic surgical procedure converted to open procedure).

In a newborn case with one of these diagnosis codes reported as a secondary diagnosis, the case would be assigned to MS-DRG 794. The commenter believed that these diagnosis codes, 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 diagnosis codes V64.00 through V64.04, and V64.06 through V64.3 should not continue to be assigned to MS-DRG 794, as there is no clinically usable information reported in those codes identifying significant problems. However, our clinical advisors recommend that diagnosis codes V64.41, V64.42, and V64.43, which identify that a surgical procedure converted to an open procedure, continue to be assigned to MS-DRG 794. These diagnosis codes may indicate a more significant encounter that required a surgical intervention.

Therefore, for FY 2014, we are proposing to reassign diagnosis codes V64.00 through V64.04, and V64.06 through V64.3 from MS-DRG 794 to MS-DRG 795. Diagnosis codes V64.00 through V64.04, and V64.06 through V64.3 would be added to the “only secondary diagnosis” list for MS-DRG 795. Diagnosis codes V64.41, V64.42, and V64.43 would continue to be assigned to MS-DRG 794. We are inviting public comments on this proposal.

b. Discharges/Transfers of Neonates with a Planned Acute Care Hospital Inpatient Readmission

We are proposing to add the patient discharge status codes shown in the table below to the MS-DRG GROUPER logic for MS-DRG 789 (Neonates, Died or

Transferred to Another Acute Care Facility) to identify neonates that are transferred to a designated facility with a planned acute care hospital inpatient readmission.

New Code	Title
82	Discharged/transferred to a short term general hospital for inpatient care with a planned acute care hospital inpatient readmission
85	Discharged/transferred to a designated cancer center or children's hospital with a planned acute care hospital inpatient readmission
94	Discharged/transferred to a critical access hospital (CAH) with a planned acute care hospital inpatient readmission

Currently, the GROUPER logic for MS-DRG 789 contains discharge status codes 02 (Discharged/transferred to a short term general hospital for inpatient care), 05 (Discharged/transferred to a designated cancer center or children's hospital), and 66 (Discharged/transferred to a critical access hospital (CAH)).

As discussed in section II.G.7. of the preamble of this proposed rule, these new discharge status codes are also being proposed for addition to the Medicare Code Editor (MCE). We are inviting public comments on our proposal.

7. 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.

a. Age Conflict Edit

We received a request to review three ICD-9-CM diagnosis codes currently listed under the age conflict edit within the MCE. The age conflict edit detects inconsistencies between a patient's age and any diagnosis on the patient's record. Specifically, the requestor recommended that CMS consider the removal of diagnosis codes 751.1 (Atresia and stenosis of small intestine), 751.2 (Atresia and stenosis of large intestine, rectum, and anal canal), and 751.61 (Biliary atresia) from the pediatric age conflict edit. Generally, diagnoses included in the list for the pediatric age conflict edit are applicable for ages 0 through 17.

The requestor noted that diagnosis code 751.1 was removed from the Integrated Outpatient Code Editor (IOCE) effective January 1, 2006. Our clinical advisors agree that patients described with any one of the above listed codes, although congenital anomalies, may require a revision procedure in adulthood. Therefore, we believe that the removal of these codes appears appropriate and also would be consistent with the IOCE.

We are inviting public comments on our proposal to remove diagnosis codes 751.1, 751.2, and 751.61 from the pediatric age conflict edit effective October 1, 2013.

b. Discharge Status Code Updates

To reflect changes in the UB-04 code set maintained by the National Uniform Billing Committee (NUBC), we are proposing to add the following new discharge status codes to the CMS GROUPER and the MCE logic effective October 1, 2013.

One of the new discharge status codes corresponds to an alternative care site. This alternative care site discharge status code is intended to identify patients being discharged or transferred to an alternative site that will provide basic patient care during a

disaster response. The new discharge status code is 69 (Discharged/transferred to a designated disaster alternative care site).

In addition, 15 new discharge status codes correspond with identifying planned acute care hospital inpatient readmissions. Shown below are the existing “base” discharge status codes and the new codes that will better identify patients who are discharged with a planned readmission.

Base Code	New Code	Title
01	81	Discharged to home or self care with a planned acute care hospital inpatient readmission
02	82	Discharged/transferred to a short term general hospital for inpatient care
03	83	Discharged/transferred to a skilled nursing facility (SNF) with Medicare certification with a planned acute care hospital inpatient readmission
04	84	Discharged/transferred to a facility that provides custodial or supportive care with a planned acute care hospital inpatient readmission
05	85	Discharged/transferred to a designated cancer center or children’s hospital with a planned acute care hospital inpatient readmission
06	86	Discharged/transferred to home under care of organized home health service organization with planned acute care hospital inpatient readmission
21	87	Discharged/transferred to court/law enforcement with a planned acute care hospital inpatient readmission
43	88	Discharged/transferred to federal health care facility with a planned acute care hospital inpatient readmission
61	89	Discharged/transferred to a hospital-based Medicare approved swing bed with a planned acute care hospital inpatient readmission
62	90	Discharged/transferred to an inpatient rehabilitation facility (IRF) including rehabilitation distinct part units of a hospital with a planned acute care hospital inpatient readmission
63	91	Discharged/transferred to a Medicare certified long term care hospital (LTCH) with a planned acute care hospital inpatient readmission
64	92	Discharged/transferred to a nursing facility certified under Medicaid but not certified under Medicare with a planned acute care hospital

Base Code	New Code	Title
		inpatient readmission
65	93	Discharged/transferred to a psychiatric distinct part unit of a hospital with a planned acute care hospital inpatient readmission
66	94	Discharged/transferred to a critical access hospital (CAH) with a planned acute care hospital inpatient readmission
70	95	Discharged/transferred to another type of health care institution not defined elsewhere in this code list with a planned acute care hospital inpatient readmission

We are inviting public comments on our proposal to add the above listed new discharge status codes to the GROUPER and the MCE logic effective October 1, 2013 (FY 2014).

8. 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 2014, 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.

In this proposed rule, we are proposing limited changes to the MS-DRG classifications for FY 2014, as discussed in sections II.G.2. and 5. of this preamble. In our review of these proposed changes, we did not identify any needed changes to the

surgical hierarchy. Therefore, in this proposed rule, we are not proposing any changes to the surgical hierarchy for Pre-MDCs and MDCs for FY 2014.

9. 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 2014

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

(1) No Proposed Revisions Based on Changes to the ICD-9-CM Diagnosis Codes for FY 2014

For FY 2014, there were no changes made to the ICD-9-CM coding system effective October 1, 2013, due to the partial code freeze. (We refer readers to section II.G.10. of the preamble of this proposed rule for a discussion of the ICD-9-CM coding system.)

(2) Suggested Changes to the MS-DRG Diagnosis Codes for FY 2014

(A) Coronary Atherosclerosis Due to Calcified Coronary Lesion

We received a request that we consider changing the severity levels for the following ICD-9-CM diagnosis code: 414.4 (Coronary atherosclerosis due to calcified coronary lesion). The requestor suggested that we change the severity level for diagnosis code 414.4 from a non-CC to an MCC.

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); and the FY 2013 final rule (77 FR 53315). 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.

The following chart shows the analysis of the MedPAR claims data for FY 2012 for ICD-9-CM diagnosis code 414.4.

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	1,390	1.58	2,174	2.31	2,001	3.11

We ran the above data as described in the FY 2008 IPSS 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 1.58. 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 2.31. 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 1.58 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 2.31 also does not support reclassifying this diagnosis code to an MCC. We also considered reclassifying the severity level of diagnosis code 414.4 to a CC; however, the C1 finding of 1.58 also does not support reclassifying the severity level to a CC. 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 or a CC. 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 comment on our proposal.

(B) Acute Cholecystitis Diagnosis Code

We received a comment recommending that we add diagnosis code 575.0 (Acute cholecystitis) to the CC Exclusion List when reported as a secondary diagnosis code with a principal diagnosis code 574.00 (Calculus of gallbladder with acute cholecystitis without mention of obstruction). We note that, there is an “excludes note” under diagnosis code 575.0 which excludes “that with cholelithiasis (574.00)”. Therefore, diagnosis codes 575.0 and 574.00 should not be reported on the same claim. However, the commenter stated that there may be double reporting.

Our clinical advisors agree with the commenter that diagnosis codes 575.0 and 574.00 capture the same clinical context. Therefore, we are proposing to add diagnosis code 575.0 to the CC Exclusion List when reported as a secondary diagnosis code with a principal diagnosis code 574.00. We are inviting public comments on our proposal.

(C) Chronic Total Occlusion (CTO) of Artery of the Extremities Diagnosis Code

We received a request to consider removing atherosclerosis and aneurysm codes from the CC Exclusion List for diagnosis code 440.4 (Chronic total occlusion of artery of the extremities). For FY 2013, we changed the designation of diagnosis code 440.4 from a non-CC level to a CC level. The CC Exclusion List for diagnosis code 440.4 includes the following diagnosis codes:

Diagnosis Code	Code Description
440.20	Atherosclerosis of native arteries of the extremities, unspecified
440.21	Atherosclerosis of native arteries of the extremities with intermittent claudication
440.22	Atherosclerosis of native arteries of the extremities with rest pain
440.23	Atherosclerosis of native arteries of the extremities with ulceration
440.24	Atherosclerosis of native arteries of the extremities with gangrene
440.29	Other atherosclerosis of native arteries of the extremities
440.30	Atherosclerosis of unspecified bypass graft of the extremities
440.31	Atherosclerosis of autologous vein bypass graft of the extremities
440.32	Atherosclerosis of nonautologous biological bypass graft of the extremities
440.4	Chronic total occlusion of artery of the extremities
441.00	Dissection of aorta, unspecified site
441.01	Dissection of aorta, thoracic
441.02	Dissection of aorta, abdominal
441.03	Dissection of aorta, thoracoabdominal
441.1	Thoracic aneurysm, ruptured
441.2	Thoracic aneurysm without mention of rupture
441.3	Abdominal aneurysm, ruptured
441.4	Abdominal aneurysm without mention of rupture

Diagnosis Code	Code Description
441.5	Aortic aneurysm of unspecified site, ruptured
441.6	Thoracoabdominal aneurysm, ruptured
441.7	Thoracoabdominal aneurysm, without mention of rupture
441.9	Aortic aneurysm of unspecified site without mention of rupture
442.0	Aneurysm of artery of upper extremity
442.2	Aneurysm of iliac artery
442.3	Aneurysm of artery of lower extremity
442.9	Aneurysm of unspecified site
443.22	Dissection of iliac artery
443.29	Dissection of other artery
443.81	Peripheral angiopathy in diseases classified elsewhere
443.82	Erythromelalgia
443.89	Other specified peripheral vascular diseases
443.9	Peripheral vascular disease, unspecified
444.01	Saddle embolus of abdominal aorta
444.09	Other arterial embolism and thrombosis of abdominal aorta
444.1	Embolism and thrombosis of thoracic aorta
444.21	Arterial embolism and thrombosis of upper extremity
444.22	Arterial embolism and thrombosis of lower extremity
444.81	Embolism and thrombosis of iliac artery
444.89	Embolism and thrombosis of other specified artery
444.9	Embolism and thrombosis of unspecified artery
445.01	Atheroembolism of upper extremity
445.02	Atheroembolism of lower extremity
445.81	Atheroembolism of kidney
445.89	Atheroembolism of other site
447.0	Arteriovenous fistula, acquired
447.1	Stricture of artery
447.2	Rupture of artery
447.5	Necrosis of artery
447.6	Arteritis, unspecified
447.70	Aortic ectasia, unspecified site
447.71	Thoracic aortic ectasia
447.72	Abdominal aortic ectasia
447.73	Thoracoabdominal aortic ectasia
449	Septic arterial embolism

Diagnosis code 440.4 is a CC except if one of the diagnosis codes listed above is reported as a principal diagnosis. If one of the diagnosis codes listed above is reported on a claim as a principal diagnosis and code 440.4 is reported as a secondary diagnosis, code 440.4 would not be counted as a CC. The commenter requested that we remove atherosclerosis codes 440.20 through 440.32, 443.22, 443.29, 443.81 through 443.9, and aneurysm codes 441.00 through 441.03, 441.1 through 441.7, 441.9, 442.0, 442.2, 442.3, and 442.9 from the CC Exclusion List for diagnosis code 440.4.

According to the commenter, aneurysm diagnoses are not closely related clinically to peripheral CTOs. Aneurysm physiology, clinical symptomology, and patient risk profile are fundamentally different than CTOs. Aneurysms result from the weakening of an artery wall and manifest in an out-pouched pocket of the lumen. Conversely, patients with CTOs present with extended segments of diseased and narrowed vessels and in most cases, complex lesions containing fibro-calcified plaques. The commenter stated that CTOs represent a high severity complication, which is not closely related to basic atherosclerosis.

Our clinical advisors agree with the commenter that the aneurysm and most of the atherosclerosis codes should be removed from the CC Exclusion List for diagnosis code 440.4. A case with a principal diagnosis of aneurysm with CTO adds substantial complexity and does not necessarily have the same immediate cause. A case with a principal diagnosis of atherosclerosis with CTO reported represents a more severe form of the disease and, therefore, is more complex. Our clinical advisors do not agree with the commenter that diagnosis codes 443.81 through 443.9 (Other and unspecified

peripheral vascular diseases) should be removed from the CC Exclusion List. These cases are more likely related to CTO and meet one of the principles for exclusion that we previously outlined above.

Therefore, for FY 2014, we are proposing to remove the following diagnosis codes from the CC Exclusion List for diagnosis code 440.4: atherosclerosis codes 440.20 through 440.32, 443.22, and 443.29, and aneurysm codes 441.00 through 441.03, 441.1 through 441.7, 441.9, 442.0, 442.2, 442.3, and 442.9. Diagnosis codes 443.81 through 443.9 would remain on the CC Exclusion List for diagnosis code 440.4. We are inviting public comments on this proposal.

For FY 2014, we are proposing changes to Table 6G (Additions to the CC Exclusion List) and Table 6H (Deletions from the CC Exclusion List). As we discussed earlier, we are not proposing changes to the severity level for diagnosis code 414.4. These tables, which contain codes that are effective for discharges occurring on or after October 1, 2013, are not being published in the Addendum to this proposed rule because of the length of the two tables. Instead, we are making them available through the Internet on the CMS Web site at: <http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>. Each of these principal diagnosis codes for which there is a CC exclusion is shown in Tables 6G and 6H with an asterisk, and the conditions that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis.

A complete updated MCC, CC, and Non-CC Exclusions List is available through the Internet on the CMS Web site at: <http://www.cms.hhs.gov/Medicare/Medicare-Fee->

[for-Service-Payment/AcuteInpatientPPS/index.html](http://www.cms.gov/Service-Payment/AcuteInpatientPPS/index.html). Beginning with discharges on or after October 1 of each fiscal year, the indented diagnoses are not recognized by the GROUPER as valid CCs for the asterisked principal diagnosis.

There are no new, revised, or deleted diagnosis codes for FY 2014. Therefore, there are no Tables 6A, 6C, and 6E published for FY 2014.

There are no proposed additions or deletions to the MS-DRG MCC List for FY 2014. There also are no proposed additions or deletions to the MS-DRG CC List for FY 2014. Therefore, there are no Tables 6I.1 through 6I.2 and 6J.1 through 6J.2 published for FY 2014.

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 30.0, is available on a CD for \$225.00. Version 31.0 of this manual, which will include the final FY 2014 MS-DRG changes, will be available on a CD for \$225.00. These manuals may be obtained by writing 3M/HIS at the following address: 100 Barnes Road, Wallingford, CT 06492; or by calling (203) 949-0303, or by obtaining an order form at the Web site: <http://www.3MHIS.com>. Please specify the revision or revisions requested.

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

Each year, we review cases assigned to former CMS DRG 468 (Extensive O.R. Procedure Unrelated to Principal Diagnosis), CMS DRG 476 (Prostatic O.R. Procedure

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

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

- 60.0 (Incision of prostate)
- 60.12 (Open biopsy of prostate)
- 60.15 (Biopsy of periprostatic tissue)
- 60.18 (Other diagnostic procedures on prostate and periprostatic tissue)

- 60.21 (Transurethral prostatectomy)
- 60.29 (Other transurethral prostatectomy)
- 60.61 (Local excision of lesion of prostate)
- 60.69 (Prostatectomy, not elsewhere classified)
- 60.81 (Incision of periprostatic tissue)
- 60.82 (Excision of periprostatic tissue)
- 60.93 (Repair of prostate)
- 60.94 (Control of (postoperative) hemorrhage of prostate)
- 60.95 (Transurethral balloon dilation of the prostatic urethra)
- 60.96 (Transurethral destruction of prostate tissue by microwave

thermotherapy)

- 60.97 (Other transurethral destruction of prostate tissue by other

thermotherapy)

- 60.99 (Other operations on prostate)

All remaining O.R. procedures are assigned to MS-DRGs 981 through 983 and 987 through 989, with MS-DRGs 987 through 989 assigned to those discharges in which

the only procedures performed are nonextensive procedures that are unrelated to the principal diagnosis.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 2014, we are not proposing to change the procedures assigned among these MS-DRGs.

a. Moving Procedure Codes from MS-DRGs 981 through 983 or MS-DRGs 987 through 989 into MDCs

We annually conduct a review of procedures producing assignment to MS-DRGs 981 through 983 (Extensive O.R. procedure unrelated to principal diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS-DRGs 987 through 989 (Nonextensive O.R. procedure unrelated to principal diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move procedure codes out of these MS-DRGs into one of the surgical

²The 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, and 2013, 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), and in the FY 2013 final rule (77 FR 53321).

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 2014, 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 2014, 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.1. through 6. of this preamble, we are not proposing to add any diagnosis or procedure codes to MDCs for FY 2014.

11. Proposed Changes to the ICD-9-CM Coding System, Including Discussion of the Replacement of the ICD-9-CM Coding System with the ICD-10-CM and ICD-10-PCS Systems in FY 2014

a. ICD-9-CM Coding System

The ICD-9-CM is a coding system currently used for the reporting of diagnoses and procedures performed on a patient. In September 1985, the ICD-9-CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co chaired by the National Center for Health Statistics (NCHS), the Centers for Disease Control and Prevention, and CMS, charged with maintaining and updating the ICD-9-CM system. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the ICD-9-CM to reflect newly developed procedures and technologies and newly identified diseases. The Committee is

also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The Official list of valid ICD-9-CM diagnosis and procedure codes can be found on the CMS Web site at:

<http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.html>. The NCHS has lead responsibility for the ICD-9-CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD-9-CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

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

The Committee presented proposals for coding changes for implementation in FY 2014 at a public meeting held on September 19, 2012, and finalized the coding

changes after consideration of comments received at the meetings and in writing by November 16, 2012. There were no changes to the ICD-9-CM coding system for FY 2014. There were no new, revised or deleted diagnosis or procedure codes for FY 2014.

The Committee held its 2013 meeting on March 5, 2013. Any new codes for which there was consensus of public support and for which complete tabular and indexing changes will be made by May 2013 will be included in the October 1, 2013 update to ICD-9-CM. Any code revisions that were discussed at the March 5, 2013 Committee meeting but that could not be finalized in time to include them in the tables listed in section VI. of the Addendum to this proposed rule will be included in Table 6B, which is listed in section VI. of the Addendum to the final rule and available via the Internet on the CMS Web site, and will be marked with an asterisk (*).

For FY 2014, there were no changes to the ICD-9-CM coding system due to the partial code freeze or for new technology. Therefore, there are no new, revised, or deleted diagnosis codes and no new, revised, or deleted procedure codes that are usually announced in Tables 6A (New Diagnosis Codes), 6B (New Procedure Codes), 6C (Invalid Diagnosis Codes), 6D (Invalid Procedure Codes), 6E (Revised Diagnosis Code Titles), and 6F (Revised Procedure Codes). Therefore, there are no Tables 6A through 6F published as part of this proposed rule for FY 2014. We note that, there may be ICD-9-CM coding changes finalized after this proposed rule based on public comments that we receive after the March 5, 2013 ICD-9-CM Coordination and Maintenance Committee meeting. If there are changes, we will include these changes in the final rule.

Copies of the minutes of the procedure codes discussions at the Committee's September 19, 2012 meeting and March 5, 2013 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 19, 2012 meeting and March 5, 2013 meeting are found at: <http://www.cdc.gov/nchs/icd.htm>. These Web sites also provide detailed information about the Committee, including information on requesting a new code, attending a Committee meeting, and timeline requirements and meeting dates.

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

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

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

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

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

The ICD-9-CM Coordination and Maintenance Committee holds its meetings in the spring and fall in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the ICD-9-CM

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

A discussion of this timeline and the need for changes are included in the December 4-5, 2005 ICD-9-CM Coordination and Maintenance Committee 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 Pub. L. 108-173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to

describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD-9-CM Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the requester at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. The participants at the meeting and those reviewing the Committee meeting summary report are provided the opportunity to comment on this expedited request. All other topics are considered for the October 1 update. Participants at the Committee meeting are encouraged to comment on all such requests. There were no requests approved for an expedited April 1, 2013 implementation of an ICD-9-CM code at the September 19, 2012 Committee meeting. Therefore, there were no new ICD-9-CM codes implemented on April 1, 2013.

Current 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>. Information on ICD-9-CM diagnosis codes, along with the Official ICD-9-CM Coding Guidelines, can be found on the Web site at: <http://www.cdc.gov/nchs/icd9.htm>. Information on new, revised, and deleted ICD-9-CM codes is also provided to the AHA for publication in the Coding Clinic for ICD-9-CM. AHA also distributes information to publishers and software vendors.

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

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

b. Code Freeze

The International Classification of Diseases, 10th Revision (ICD-10) coding system applicable to hospital inpatient services was to be implemented on October 1, 2013, as described in the Health Insurance Portability and Accountability Act

of 1996 (HIPAA) Administrative Simplification: Modifications to Medical Data Code Set Standards to Adopt ICD-10-CM and ICD-10-PCS final rule (74 FR 3328 through 3362, January 16, 2009). However, the Secretary of Health and Human Services issued a final rule that delays, from October 1, 2013, to October 1, 2014, the compliance date for the International Classification of Diseases, 10th Edition diagnosis and procedure codes (ICD-10). The final rule, 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>.

The ICD-10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) for inpatient hospital procedure coding, as well as the Official ICD-10-CM and ICD-10-PCS Guidelines for Coding and Reporting. In the January 16, 2009 ICD-10-CM and ICD-10-PCS final rule (74 FR 3328 through 3362), there was a discussion of the need for a partial or total freeze in the annual updates to both ICD-9-CM and ICD-10-CM and ICD-10-PCS codes. The public comment addressed in that final rule stated that the annual code set updates should cease 1 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 Pub. L. 108-173. There were to be no updates to ICD-9-CM on October 1, 2014, as the

system would no longer be a HIPAA standard and, therefore, no longer be used for reporting.

- On October 1, 2015, one year after the implementation of ICD-10, regular updates to ICD-10 will begin.

The ICD-9-CM Coordination and Maintenance Committee announced that it would continue to meet twice a year during the freeze. At these meetings, the public will be encouraged to comment on whether or not requests for new diagnosis and procedure codes should be created based on the need to capture new technology and new diseases. Any code requests that do not meet the criteria will be evaluated for implementation within ICD-10 on or after October 1, 2015, once the partial freeze is ended.

Complete information on the partial code freeze and discussions of the issues at the Committee meetings can be found on the ICD-9-CM Coordination and Maintenance Committee Web site at:

<http://www.cms.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, are 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>.

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

CMS is currently processing all 25 diagnosis codes and 25 procedure codes submitted on electronic hospital inpatient claims. Prior to January 1, 2011, hospitals

could submit up to 25 diagnoses and 25 procedures. However, CMS' system limitations allowed for the processing of only the first 9 diagnosis codes and 6 procedure codes. We discussed this change in processing claims in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127), in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25843), in a correction notice issued in the **Federal Register** on June 14, 2011 (76 FR 24633), and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51553). As discussed in these prior rules, CMS undertook an expansion of our internal system capability so that we are able to process up to 25 diagnoses and 25 procedures on hospital inpatient claims as part of the HIPAA ASC X12 Technical Reports Type 3, Version 005010 (Version 5010) standards system update. We recognize the value of the additional information provided by this coded data for multiple uses such as for payment, quality measures, outcome analysis, and other important uses. We will continue to process up to 25 diagnosis codes and 25 procedure codes when received on the 5010 format.

d. ICD-10 MS-DRGs

In response to the FY 2011 IPPS/LTCH PPS proposed rule, we received comments on the creation of the ICD-10 version of the MS-DRGs, which will be implemented at the same time as ICD-10 (75 FR 50127 and 50128). As we stated earlier, the Secretary of Health and Human Services has delayed the compliance date of ICD-10 from October 1, 2013 to October 1, 2014 (77 FR 54664). While we did not propose an ICD-10 version of the MS DRGs in the FY 2011 IPPS/LTCH PPS proposed rule, we noted that we have been actively involved in converting our current MS-DRGs from ICD-9-CM codes to ICD-10 codes and sharing this information through the ICD-9-CM

Coordination and Maintenance Committee. We undertook this early conversion project to assist other payers and providers in understanding how to go about their own conversion projects. We posted ICD-10 MS-DRGs based on Version 26.0 (FY 2009) of the MS-DRGs. We also posted a paper that describes how CMS went about completing this project and suggestions for others to follow. All of this information can be found on the CMS Web site at: <http://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-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 at:

<http://cms.hhs.gov/Medicare/Coding/ICD10/ICD10-MS-DRG-Conversion-Project.html>.

To make the review of Version 28 R1 updates easier for the public, we also made available pilot software on a CD ROM that could be ordered through the National Technical Information Service (NTIS). A link to the NTIS ordering page was provided on the CMS ICD-10 MS-DRG Web page. We stated that we believed that, by providing the ICD-10 MS-DRG Version 28 R1 Pilot Software (distributed on CD ROM), the public would be able to more easily review and provide feedback on updates to the ICD-10 MS-DRGs. We discussed the updated ICD-10 MS-DRGs Version 28 R1 at the September 14, 2011 ICD-9-CM Coordination and Maintenance Committee meeting. We encouraged the public to continue to review and provide comments on the ICD-10 MS-DRGs so that CMS could continue to update the system.

In FY 2012, we prepared the ICD-10 MS-DRGs Version 29.0, based on the FY 2012 MS-DRGs (Version 29.0) that we finalized in the FY 2012 IPPS/LTCH PPS final rule. We posted a Definitions Manual of ICD-10 MS-DRGs Version 29.0 on our ICD-10 MS-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 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 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 can be found 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 30.0 computer software should facilitate additional review of the ICD-10 MS-DRGs conversion.

We provided information on a study conducted on the impact on 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) and converted to the ICD-10 MS-DRGs Version 27.0. The study estimated the impact on aggregate payment to hospitals and the distribution of payments across hospitals. The impact of the conversion from ICD-9-CM to ICD-10 on Medicare MS-DRG hospital payments was estimated using 2009 Medicare data. The study found a hospital payment increase of 0.05 percent using the ICD-10 MS-DRGs Version 27.0.

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 updated paper is posted on 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 will provide additional information to the public who are evaluating the conversion of the MS-DRGs to ICD-10 MS-DRG.

We will continue to work with the public to explain how we are approaching the conversion of MS-DRGs to ICD-10 and will post drafts of updates as they are developed for public review. The final version of the ICD-10 MS-DRGs will be implemented at the same time as ICD-10 and will be subject to notice and comment rulemaking. In the meantime, we will provide extensive and detailed information on this activity through the ICD-9-CM Coordination and Maintenance Committee.

H. Recalibration of the Proposed FY 2014 MS-DRG Relative Weights

1. Data Sources for Developing the Proposed Relative Weights

In developing the proposed FY 2014 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 2012 MedPAR data used in this proposed rule include discharges occurring on October 1, 2011, through September 30, 2012, based on bills received by CMS through December 31, 2012, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which are under a waiver from the IPPS under section 1814(b)(3) of the Act). The FY 2012 MedPAR file used in calculating the proposed relative weights includes data for approximately 10,364,125 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, 2012 update of the FY 2012 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 2014 also excludes claims with claim type values not equal to “60.” The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. Normally, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. Specifically, we used cost report data from the December 31, 2012 update of the FY 2011 HCRIS for calculating the proposed FY 2014 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 proposing to calculate the relative weights based on 19 CCRs, instead of the 15 CCRs previously used. The methodology we used to calculate the proposed FY 2014 MS-DRG cost-based relative weights based on claims data in the FY 2012 MedPAR file and data from the FY 2011 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2014 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 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 2011 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 92.7 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. For FY 2014, as explained in section II.E.2. of the preamble of this proposed rule, we are proposing to calculate the relative weights using 19 cost centers instead of the 15 cost centers previously used in calculating the FY 2013 relative weights. In calculating the FY 2014 relative weights, we also are proposing to continue to remove claims of providers with more than five blank cost centers from the dataset used to calculate the relative weights. (We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53326) for the edit threshold related to FY 2013 and prior fiscal years). In recent years, this trim kept approximately 96 percent of IPPS providers in the MedPAR file upon which we base our relative weight calculations. (For examples of our FYs 2012 and 2013 relative weight calculations, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51558) and the FY 2013 IPPS/LTCH PPS final rule 77 FR 53326).) However, under the proposal presented in this proposed rule to add 4 cost centers to the relative weight calculations, this trim kept approximately 92.7 percent of the IPPS providers in the MedPAR file upon which we base our proposed FY 2014 relative weight calculations.

Although this trim is now removing a greater percentage of providers' claims from the relative weight calculations than were previously removed, we believe that it is appropriate to propose to continue to remove providers' claims that do not have charges

greater than zero in more than five cost centers. We believe that this proposal is appropriate because we are not introducing new costs into the relative weight calculation; we are only proposing to make use of more refined, granular costs by breaking out implantable devices from the Supplies and Equipment CCR, MRIs and CT scans from the Radiology CCR, and cardiac catheterization from the Cardiology CCR. Furthermore, because we are proposing to make use of more refined cost report data for these cost centers, we believe that it is also appropriate to edit the claims with a more refined threshold. We are inviting public comments on the proposal to trim the data used in our relative weight calculations.

- 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 2011 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. (We note that we have made several changes to the table, most importantly, to remove the columns listing the cost centers from the CMS Form 2552-96 cost reports. Because we are proposing to use data from FY 2011 cost reports, which were filed on the CMS Form 2552-10, the columns referencing the CMS Form 2552-96 cost report are no longer relevant. We also have updated and refined the table to reflect the proposed 19 CCRs, instead of the current 15, and we have made some minor corrections to revenue codes and cost report cost centers that are grouped with each CCR.)

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

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
	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

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field	Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Drugs	Pharmacy Charges	025X, 026X and 063X	Intravenous Therapy	C 1 C5 64	C 1 C6 64	D3 HOS C2 64
					C 1 C7 64	
			Drugs Charged To Patient	C 1 C5 73	C 1 C6 73	D3 HOS C2 73
					C 1 C7 73	

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
Supplies and Equipment	Medical/Surgical Supply Charges	0270, 0271, 0272, 0273, 0274, 0277, and 0621, 0622, 0623	Medical Supplies Charged to Patients	C 1 C5 71	C 1 C6 71	D3 HOS C2 71
					C 1 C7 71	
	Durable Medical Equipment Charges	0290, 0291, 0292 and 0294-0299	DME-Rented	C 1 C5 96	C 1 C6 96	D3 HOS C2 96
					C 1 C7 96	
	Used Durable Medical Charges	0293	DME-Sold	C 1 C5 67	C 1 C6 97	D3 HOS C2 97
					C 1 C7 97	

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
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	D3_HOS_C2_67

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field	Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
					C 1 C7 67	
	Speech Pathology Charges	044X and 047X	Speech Pathology	C 1 C5 68	C 1 C6 68	D3 HOS C2 68
					C 1 C7 68	
Inhalation Therapy	Inhalation Therapy Charges	041X and 046X	Respiratory Therapy	C 1 C5 65	C 1 C6 65	D3 HOS C2 65
					C 1 C7 65	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field	Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Operating Room	Operating Room Charges	036X	Operating Room	C 1 C5 50	C 1 C6 50 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

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field	Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Anesthesia	Anesthesia Charges	037X	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	D3 HOS C2 59

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field	Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
					C 1 C7 59	
Laboratory	Laboratory Charges	030X, 031X, and 075X	Laboratory	C 1 C5 60	C 1 C6 60	D3_HOS_C2_60
					C 1 C7 60	
			PBP Clinic Laboratory Services	C 1 C5 61	C 1 C6 61	D3_HOS_C2_61
					C 1 C7 61	
		074X, 086X	Electro-encephalography	C 1 C5 70	C 1 C6 70	D3_HOS_C2_70

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field	Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
					C 1 C7 70	
Radiology	Radiology Charges	032X, 040X	Radiology - Diagnostic	C 1 C5 54	C 1 C6 54	D3 HOS C2 54
					C 1 C7 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	D3 HOS C2 56
					C 1 C7 56	

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
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
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	D3_HOS_C2_91

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field	Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
					C 1 C7 91	
Blood and Blood Products	Blood Charges	038x	Whole Blood & Packed Red Blood Cells	C 1 C5 62	C 1 C6 62	D3 HOS C2 62
					C 1 C7 62	
	Blood Storage / Processing	039x	Blood Storing, Processing, & Transfusing	C 1 C5 63	C 1 C6 63	D3 HOS C2 63
					C 1 C7 63	

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field	Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
Other Services	Other Service Charge	0002-0099, 022X, 023X, 024X, 052X, 053X				
		055X-060X, 064X-070X, 076X-078X, 090X-095X and 099X				
	Renal Dialysis	0800X	Renal Dialysis	C 1 C5 74	C 1 C6 74	D3 HOS C2 74
	ESRD Revenue Setting Charges	080X and 082X-088X			C 1 C7 74	
			Home Program Dialysis	C 1 C5 94	C 1 C6 94	D3 HOS C2 94

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field	Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
					C 1 C7 94	
	Outpatient Service Charges	049X	ASC (Non Distinct Part)	C 1 C5 75	C 1 C6 75	D3 HOS C2 75
	Lithotripsy Charge	079X			C 1 C7 75	
			Other Ancillary	C 1 C5 76	C 1 C6 76	D3 HOS C2 76
					C 1 C7 76	
	Clinic Visit Charges	051X	Clinic	C 1 C5 90	C 1 C6 90	D3 HOS C2 90
					C 1 C7 90	

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
			Observation beds	C_1_C5_92.01	C_1_C6_92.01	D3_HOS_C2_92.01
					C_1_C7_92.01	
	Professional Fees Charges	096X, 097X, and 098X	Other Outpatient Services	C_1_C5_93	C_1_C6_93	D3_HOS_C2_93
					C_1_C7_93	
	Ambulance Charges	054X	Ambulance	C_1_C5_95	C_1_C6_95	D3_HOS_C2_95
					C_1_C7_95	
			Rural Health Clinic	C_1_C5_88	C_1_C6_88	D3_HOS_C2_88

Cost Center Group Name (19 total)	MedPAR Charge Field	Revenue Codes contained in MedPAR Charge Field	Cost Report Line Description	Cost from HCRIS (Worksheet C, Part 1, Column 5 and line number) Form CMS-2552-10	Charges from HCRIS (Worksheet C, Part 1, Column 6 & 7 and line number) Form CMS-2552-10	Medicare Charges from HCRIS (Worksheet D-3, Column & line number) Form CMS-2552-10
					C 1 C7 88	
			FQHC	C 1 C5 89	C 1 C6 89	D3 HOS C2 89
					C 1 C7 89	

3. Development of National Average CCRs

We developed the national average CCRs as follows:

Using the FY 2011 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 2014 cost-based relative weights were then normalized by an adjustment factor of 1.6122128377 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 2014 are as follows:

Group	CCR
Routine Days	0.502
Intensive Days	0.423
Drugs	0.193
Supplies & Equipment	0.293
Implantable Devices	0.361
Therapy Services	0.355
Laboratory	0.133
Operating Room	0.225
Cardiology	0.132
Cardiac Catheterization	0.135
Radiology	0.170
MRIs	0.091
CT Scans	0.045
Emergency Room	0.207
Blood and Blood Products	0.371
Other Services	0.399
Labor & Delivery	0.445
Inhalation Therapy	0.187
Anesthesia	0.120

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 2014 proposed rule, we are proposing to use that same case threshold in recalibrating the proposed MS-DRG weights for FY 2014. Using data from the FY 2012 MedPAR file, there were 7 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 2014, because we do not have sufficient MedPAR data to set accurate and stable cost weights for these low-volume MS-DRGs,

we are proposing to compute weights for the low-volume MS-DRGs by adjusting their FY 2013 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
789	Neonates, Died or Transferred to Another Acute Care Facility	FY 2013 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate	FY 2013 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
791	Prematurity with Major Problems	FY 2013 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
792	Prematurity without Major Problems	FY 2013 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
793	Full-Term Neonate with Major Problems	FY 2013 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
794	Neonate with Other Significant Problems	FY 2013 FR weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
795	Normal Newborn	FY 2013 FR 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 2014, 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/RV 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 2013 IPPS/LTCH PPS final rule contains the final thresholds that will be used to evaluate applications for new technology add-on payments for FY 2014. We refer

readers to the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY-2013-IPPS-Final-Rule-Home-Page.html> for a complete viewing of Table 10 from the FY 2013 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 Pub. L. 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 Pub. L. 108-173, add-on payments for new medical services or technologies for FY 2005 and later years have not been subjected to budget neutrality.

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

for their new medical service or technology by July 1 of each year prior to the beginning of the fiscal year that the application is being considered.

The Council on Technology and Innovation (CTI) at CMS oversees the agency's cross-cutting priority on coordinating coverage, coding and payment processes for Medicare with respect to new technologies and procedures, including new drug therapies, as well as promoting the exchange of information on new technologies between CMS and other entities. The CTI, composed of senior CMS staff and clinicians, was established under section 942(a) of Pub. L. 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 2015 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-](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html)

[Payment/AcuteInpatientPPS/newtech.html](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 2015, the Web site also will post the tracking forms completed by each applicant.

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

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Pub. L. 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 2014 prior to publication of this FY 2014 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on November 23, 2012 (77 FR 70163 through 70165), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on February 5, 2013. 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 2014 new medical service and technology add-on payment applications before the publication of this FY 2014 proposed rule.

Approximately 60 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 over the Internet and received very positive feedback from the public on use of this option. We are considering no longer holding an in-person town hall meeting in Baltimore, MD, and instead holding a virtual town hall meeting that would be live-streamed on the Internet. We are inviting public comments on the possibility of holding a virtual town hall meeting instead of an in-person town hall

meeting in Baltimore, MD. Four of the five FY 2014 applicants presented information on their technologies, including a discussion of data reflecting the substantial clinical improvement aspect of the technology. We considered each applicant's presentation made at the town hall meeting, as well as written comments submitted on the applications that were received by the due date of February 26, 2013, in our evaluation of the new technology add-on payment applications for FY 2014 in this proposed rule.

In response to the published notice and the new technology town hall meeting, we received written comments regarding applications for FY 2014 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 "substantial clinical improvement." As explained above and in the **Federal Register** notice announcing the new technology town hall meeting (77 FR 70163 through 70165), the purpose of the new technology town hall meeting was specifically to discuss the substantial clinical improvement criterion in regard to pending new technology applications for FY 2014. 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 2014 Status of Technologies Approved for FY 2013 Add-On Payments

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

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

The AutoLITT™ received a 510(k) FDA clearance in May 2009. The AutoLITT™ is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 1064 nm lasers. The AutoLITT™ may be used in patients with glioblastoma multiforme brain tumors. The applicant stated in its application and through supplemental information that, due to required updates, the technology was actually introduced to the market in December 2009. After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the AutoLITT™ and consideration of the public comments we received in response to the FY 2011 IPPS/LTCH PPS proposed rule, including the additional analysis of clinical data and supporting information submitted by the applicant, we approved the AutoLITT™ for new technology add-on payments for FY 2011. In the FY 2013 IPPS/LTCH PPS

proposed rule (77 FR 27935 through 27936), based on the original information provided by the applicant, we believed that the newness date for the AutoLITT™ began in December 2009. However, as summarized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53345 through 53346), the applicant submitted a public comment (in response to the FY 2013 proposed rule) demonstrating that the AutoLITT™ was first available on May 11, 2010. The manufacturer explained that some of the sterile disposable products were not released from quarantine until May 11, 2010, which prevented the AutoLITT™ from being used prior to May 11, 2010. Therefore, the manufacturer asserted that the first time the AutoLITT™ was available on the market was May 11, 2010. As a result of this information, we continued to make new technology add-on payments for the AutoLITT™ in FY 2013. (We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on this issue).

Consistent with the applicant's clinical trial, the add-on payment is intended only for use of the device in cases of glioblastoma multiforme. Therefore, we limited the new technology add-on payment to cases involving the AutoLITT™ in MS-DRGs 025 (Craniotomy and Endovascular Intracranial Procedures with Major Complications or Comorbidities (MCC)), 026 (Craniotomy and Endovascular Intracranial Procedures with Complications or Comorbidities (CC)), and 027 (Craniotomy and Endovascular Intracranial Procedures without CC or MCC). Cases involving the AutoLITT™ that are eligible for the new technology add-on payment are identified by assignment to MS-DRGs 025, 026, and 027 with a procedure code of 17.61 (Laser interstitial thermotherapy of lesion or tissue of brain under guidance) in combination with a

principal diagnosis code that begins with a prefix of 191 (Malignant neoplasm of brain). We note that using the procedure and diagnosis codes above and restricting the add-on payment to cases that map to MS-DRGs 025, 026, and 027 is consistent with information provided by the applicant, which demonstrated that cases of the AutoLITT™ would only map to MS-DRGs 025, 026, and 027. Procedure code 17.62 (Laser interstitial thermotherapy of lesion or tissue of head and neck under guidance) does not map to MS-DRGs 025, 026, or 027 under the GROUPER software and, therefore, is ineligible for new technology add-on payment.

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

The new technology add-on payment regulations provide that “a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD-9-CM code assigned to the new 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 the AutoLITT™, as stated above, we consider the beginning of the newness period for the device to commence when the AutoLITT™ was first available on May 11, 2010. Because the 3-year anniversary date of the AutoLITT™ entry onto the market will expire May 11, 2013, which is prior to the beginning of FY 2014, we are proposing to discontinue new technology add-on payments for the AutoLITT™ for FY 2014. We are inviting public comments on this proposal.

b. 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 ($\$22,500 \times 4$). 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)). 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 Voraxaze[®] is still within the 3-year newness period, we are proposing to

continue new technology add-on payments for this technology for FY 2014. We are inviting public comments on this proposal.

c. 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 x 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 FY 2013 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)). 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 DIFICID™, as stated above, we 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 DIFICID™ will occur in the second half of the fiscal year (after April 1, 2014), we are proposing to continue new technology add-on payments for DIFICID™ for FY 2014. We are inviting public comments on this proposal.

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

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

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 Zenith[®] F. Graft is still within the 3-year newness period, we are proposing to continue new technology add-on payments for this technology for FY 2014. We are inviting public comments on this proposal.

4. FY 2014 Applications for New Technology Add-On Payments

We received five applications for new technology add-on payments for FY 2014.

a. 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.

The applicant expects to receive FDA approval for Kcentra™ in the second quarter of 2013. The technology is not described by any current ICD-9-CM procedure codes. The applicant applied for a new ICD-9-CM procedure code for consideration at the March 5, 2013 ICD-9-CM Coordination and Maintenance Committee Meeting. More information on this request 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>. We note that any final

decisions on new codes approved at the March 5, 2013 ICD-9-CM Coordination and Maintenance Committee meeting will be included in the ICD-9-CM code addendum posted on the CMS Web site in June 2013 at:

<http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/addendum.html>. In addition, code revisions that were discussed at the March 5, 2013 ICD-9-CM Coordination and Maintenance Committee meeting but that could not be finalized in time to include them in the tables for this proposed rule will be included in the appropriate table for the final rule (the tables for both the proposed rule and the final rule are available via the Internet on the CMS Web site).

We note that we are concerned that Kcentra™ may be substantially similar to FFP and/or Vitamin K therapy. If so, Kcentra™ would not meet the newness criterion because costs associated with FFP and/or Vitamin K therapy are already reflected within the MS-DRGs. In the FY 2010 IPPS/RV 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantial 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, we believe that both FFP and Kcentra™ use the same mechanism of action of **Vitamin K dependent coagulation to reverse the anti-coagulation effects of warfarin**. With respect to the second criterion, we believe that cases involving both FFP and Kcentra™ would be assigned to the same MS-DRGs. Finally, with respect to the third criterion, we believe that both technologies treat the same disease and patient population. Specifically, the patient population for both Kcentra™ and FFP are patients with an acquired coagulation factor deficiency due to warfarin and who are experiencing a severe bleed. Delay of treatment of these patients can lead to an increase in complications as well as an increase of the severity of the bleed. Although FFP needs to thaw for a couple of hours before it can be administered (thus delaying treatment) compared to Kcentra™, which can be used instantly, we believe that both Kcentra™ and FFP treat the same patient population. Based on evaluation of the similarity criteria, it appears that Kcentra™ is substantially similar to FFP. Therefore, Kcentra™ may not be considered “new” for purposes of new technology add-on payments. We are inviting public comments regarding whether Kcentra™ is substantially similar to existing technologies and whether Kcentra™ meets the newness criterion.

According to the applicant, the technology is eligible to be used across all MS-DRGs. To demonstrate that it meets the cost criterion, the applicant searched the FY 2011 MedPAR file (across all MS DRGs) for cases reporting a primary or secondary diagnosis of E934.2 (Adverse events due to anticoagulants), V58.61 (Long term (current) use of anticoagulants), or 964.2 (Poisoning by anticoagulants) in combination with

procedure code 99.07 (Transfusion of the serum). The applicant believed that this combination identified cases that suggest the use of a Vitamin K antagonist therapy as well as a major bleed.

The applicant found 66,749 cases across all MS-DRGs and noted that 18 percent of all cases would map to MS-DRGs 377 (Gastrointestinal Hemorrhage with MCC), 378 (Gastrointestinal Hemorrhage with CC), and 379 (Gastrointestinal Hemorrhage without CC/MCC), while the top 20 MS-DRGs would account for 41 percent of all cases. The applicant standardized charges (for all 66,749 cases) and removed charges for FFP therapy, which equated to a case-weighted average standardized charge per case of \$49,748. The applicant calculated a case-weighted threshold of \$46,068 across all MS-DRGs. The applicant asserted that the average case-weighted standardized charge per case without including charges for Kcentra™ exceeded the case-weighted threshold of \$46,068. Therefore, the applicant maintained that it meets the cost criterion. We are inviting public comments regarding whether Kcentra™ meets the cost criterion, particularly with regard to the assumptions and methodology used in the applicant's analysis.

With regard to substantial clinical improvement, according to the applicant, Kcentra™ is the first prothrombin complex concentrate (PCC) that will be FDA-approved for rapid warfarin reversal in patients experiencing an acute major bleed. The manufacturer maintained that Kcentra™ represents a substantial clinical improvement in the treatment of patients with acute severe bleeding who require immediate reversal of their Vitamin K antagonist (VKA) therapy by (1) providing a rapid, beneficial resolution

of the patient's blood clotting factor deficiency, (2) decreasing the risk of exposure to blood borne pathogens, and (3) reducing the rate of transfusion-associated complications.

The applicant cited its pivotal study (a noninferior, randomized clinical trial)³ and noted that Kcentra™ was able to reverse the effects of warfarin to a target International Normalized Ratio (INR) of less than or equal to 1.3 within 30 minutes in 62 percent of patients compared to less than 10 percent success for plasma. Also, serum levels of the key coagulant and anti-thrombotic proteins were normalized in less than an hour with Kcentra™, but remained depressed with plasma for hours.

The applicant also explained that Kcentra™ undergoes a dedicated pathogen removal process and plasma does not. The applicant asserted that this drastically reduces the risk of transmitting both known and unknown blood borne pathogens. The applicant cited a retrospective analysis of scientific publications⁴ on the use of Kcentra™ in the European Union (EU), including the pharmacovigilance database from 1996 through 2008. The applicant noted that an estimated 350,000 patients have been treated with Kcentra™ (known as Beriplex in the EU) with no cases of viral transmission.

The applicant also stated that, in the United States, blood suppliers follow a strict set of regulations for screening and testing the blood supply, but these tests and donor questionnaires do not account for emerging pathogens that could contaminate the blood supply. The applicant explained that parasitic infections and diseases (such as babesiosis

³ Sarode R, et al., Efficacy and Safety of a Four Factor Prothrombin Complex Concentrate in Patients on Vitamin K Antagonists Presenting with Major Bleeding: A Randomized, Plasma Controlled, Phase IIIb Study. *Circulation*. Submitted October 31, 2012. Copy to be provided upon acceptance.

⁴ Hanke A, et al., Efficacy and Long-Term Safety of a Pasteurized Nanofiltrated Prothrombin Complex Concentrate (BERIPLEX® P/N), 2009, *J Thromb Haemost*, Vol. 7 (Suppl.2) PP-WE-697.

and Chaga's disease) have already been documented in U.S. patients as a result of transfusion. However, there is no screening test to date for some of these parasitic infections and diseases. The applicant believed that the multi-step manufacturing process for Kcentra™, including heat treatment and nanofiltration, reduces the risk of transmitting such infections and diseases.

The applicant also noted that another benefit of Kcentra™ is the ability to rapidly prepare and administer the product in an emergency situation. In addition to the benefit of room temperature storage, Kcentra™ can be rapidly reconstituted. In the clinical study, the applicant found that the average administration time for Kcentra™ was less than 30 minutes. However, the applicant stated, other treatments such as FFP and intravenous Vitamin K therapies act slowly, and FFP can be difficult to use. The applicant explained that FFP therapy requires blood-type matching, usually requires thawing, and is often located away from the point of care. The applicant also cited a study⁵ that demonstrated the median time from time of diagnosis to plasma infusion was 90 minutes, which did not include time to infuse the plasma which can take hours.

The applicant further noted that essential blood coagulation factors in one vial of Kcentra™ are approximately 25 times more concentrated than the equivalent plasma dose. According to the applicant, this translated to an infusion volume that was 87 percent greater in the plasma group of patients as seen in the pivotal study. The applicant explained that high transfusion volumes of treatments such as FFP therapy can lead to transfusion-associated circulator overload (TACO). According to the applicant, when

⁵ Goldstein, Joshua N., et al., Timing of Fresh Frozen Plasma Administration and Rapid Correction of Coagulopathy in Warfarin-Related Intracerebral Hemorrhage, *Stroke* 37.1 (2006):151-155.

TACO occurs, acute left ventricular failure may occur resulting in shortness of breath, tachypnea (rapid breathing), and other harmful effects.

Finally, the applicant noted that Kcentra™ is the standard of care in the new guidelines issued by the American College of Chest Physicians (ACCP). In addition, the applicant noted that the American Association of Blood Banks (AABB) stated that plasma should no longer be used to reverse warfarin in bleeding patients when specific factor concentrates are available.

In conclusion, the applicant maintained that Kcentra™ represents a substantial clinical improvement over existing technologies. We are inviting public comments regarding whether Kcentra™ meets the substantial clinical improvement criterion.

We note, if Kcentra™ were to be approved for new technology add-on payments, we do not believe such payments would be available with respect to discharges for which the hospital receives an add-on payment for 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 blood clotting factor to Medicare beneficiaries who have hemophilia and are hospital inpatients are paid separately from the IPPS. (For information on how the 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-](http://cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf)

[Guidance/Guidance/Manuals/Downloads/clm104c03.pdf](http://cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf).) If Kcentra™ is approved by FDA as a blood clotting factor, we believe that it may be eligible for clotting factor add-on payments when administered to Medicare beneficiaries with hemophilia. CMS would make an add-on payment for Kcentra™ for such discharges in accordance with our policy for payment of blood clotting factor, and it 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 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 point out that new technology add-on payments are based on the operating costs per case relative to the prospective payment rate as described in 42 CFR 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.

If Kcentra™ were to be approved for new technology add-on payments, we believe that hospitals may only receive that add-on payment for discharges where Kcentra™ is an operating cost of inpatient hospital services. In other words, we do not believe a hospital could 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 could be eligible for a new technology add-on payment because Kcentra™ would not be excluded from the operating costs of inpatient hospital services. Therefore, we do not believe that discharges where the hospital receives a clotting factor add-on payment are eligible for a new technology add-on payment for the blood clotting factor.

To summarize, we believe it would be inappropriate to make an add-on payment for new technology for a blood clotting factor when a blood clotting factor add-on payment has been made. We welcome public comment on our proposal to only make new technology add-on payments for Kcentra™ in cases when it is included in the

operating costs of inpatient hospital services (that is, when no add-on payment is made for clotting factor).

b. 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. There are no existing ICD-9-CM or ICD-10-CMS/PCS codes for the implantation of a retina prosthesis. The applicant applied for three new ICD-9-CM procedure codes for consideration at the March 5, 2013 ICD-9-CM Coordination and Maintenance Committee meeting. More information on this request 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>. We note that any final decisions on new codes approved at the March 5, 2013 Coordination and Maintenance Committee meeting will be included in the ICD-9-CM code addendum posted on the CMS Web site in June 2013 at:

<http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/addendum.html>. In addition, code revisions that were discussed at the March 5, 2013 Committee meeting but that could not be finalized in time to include them in the tables for this proposed rule will be included in the appropriate table in the final rule (the tables for both the proposed rule and the final rule are made available via the Internet on the CMS Web site). We are inviting public comments on whether the Argus[®] II System meets the newness criterion.

With regard to the cost criterion, the applicant identified all discharges from claims in the FY 2011 MedPAR file for MS-DRGs 116 (Intraocular Procedures with CC/MCC) and 117 (Intraocular Procedures without CC/MCC) with the presence of ICD-9-CM procedure code 14.73 (Anterior vitrectomy), or 14.74 (Posterior vitrectomy). (We note that because no procedure code exists for this technology, these cases would include patients that are not eligible for or would not otherwise receive this technology.) The applicant found 199 cases (47.6 percent of all cases) in MS-DRG 116 and 219 cases (52.3 percent of all cases) in MS-DRG 117. This resulted in an average charge per case of \$40,957 for MS-DRG 116 and \$20,621 for MS-DRG 117, equating to a case-weighted average charge per case of \$24,011.

The applicant then standardized the charges using the FY 2011 final rule impact file and converted the cost of the device to a charge by dividing the operating costs by a CCR of 0.50 (which equates to a 100 percent markup). Although the applicant submitted data related to the estimated cost of the Argus[®] II System, the applicant noted that the cost of the technology was proprietary information. The applicant then added the charges related to the device to the case-weighted average standardized charge per case and

determined a final case-weighted average standardized charge per case of \$311,180. Using the FY 2014 Table 10 thresholds, the case-weighted threshold for MS-DRGs 116 and 117 was \$30,328 (all calculations above were performed using unrounded numbers). Because the final case-weighted average standardized charge per case for the applicable MS-DRGs exceed the case-weighted threshold amount, the applicant maintained that the Argus[®] II System would meet the cost criterion.

We note that, although we cannot disclose the cost of the technology, the device is very costly. Because of its high costs, the technology would easily exceed the case-weighted threshold. In addition, because of the high cost of the device it is likely that claims with the device would receive an outlier payment. The applicant anticipates that approximately 65 Argus[®] II Systems will be sold in FY 2014, of which approximately 50 systems would be provided to Medicare patients. The target disease population is extremely limited as required and supported by the HDE application. Most patients for whom this technology is indicated may be eligible for Medicare based on their age or a disability that is associated with profound blindness.

We also note that these types of procedures are often performed in the outpatient setting. We are concerned that if new technology add-on payments were to be approved, this would serve as a financial incentive to inappropriately shift utilization from an outpatient to an inpatient setting, although medical review may result in very few of these cases being paid as inpatient hospital services if the patient can be appropriately treated as an outpatient. We continue to emphasize that it is critical that physicians use their clinical judgment in determining the medical necessity of an inpatient admission and

stress that care should be provided in the appropriate setting. We are inviting public comments on whether the Argus[®] II System meets the cost criterion, particularly based on the assumptions and methodology used in the applicant's analysis. We also have general concerns relating to the descriptions of the medical necessity of performing this procedure on an inpatient basis. Therefore, we are inviting public comments to further our understanding regarding whether approving new technology add-on payments for the Argus[®] II System would create a financial incentive that would shift utilization inappropriately from an outpatient to an inpatient setting.

With regard to the substantial clinical improvement criterion, the Argus[®] II System is intended to provide electrical stimulation of the retina to induce visual perception in blind patients with the indication of severe to profound RP with bare or no light perception in both eyes. According to the applicant, an estimated 1 in 3,037 Americans suffers from RP, and the incidence of people with severe to profound RP is significantly lower. According to the applicant, the need for treatments for RP is high, given the impact of loss of vision.

According to the applicant, numerous experimental research programs are currently underway to slow, stop, or reverse the progress of RP, including gene therapy, tissue and cell transplants, and some pharmacologic neuroprotection therapies. However, these approaches so far have had fairly limited success in treating RP patients, and some approaches are intended for an extremely small segment of the RP population. Currently there are no other approved treatments for patients with severe to profound RP.

Therefore, the Argus[®] II device treats a patient population that has no other treatment options.

The applicant submitted the results of a clinical trial to demonstrate substantial clinical improvement. This clinical trial enrolled 30 patients. The median age of patients was 57.9 years at the time of implantation and the range was 28 to 77 years of age. Thirty percent of the patients were female, and 70 percent were male. All of the patients had bare or no light perception in both eyes. Fourteen of the patients were Medicare eligible. As part of the methods for the study, the applicant stated that while working within the framework of clinical trials for other ophthalmic devices, the manufacturer and its team of scientific advisors selected or designed several tests that would address the main elements of the system that should be assessed for these types of devices--visual function (that is, how the eye as an organ works [for example, visual acuity]), functional vision (that is, how the patient performs in vision-related activities of daily living), and quality of life. The endpoints that were selected provided a mixture of objective and subjective data. The study design was strengthened by the fact that controlled observations could be obtained by performing assessments with the Argus[®] II System “on” and “off” (that is, control was available at each time point).

According to the applicant, there were no unexpected adverse events. Non-serious adverse events represented the majority of events. The safety review concluded that the Argus[®] II System has a reasonable safety profile for an ophthalmic device that requires vitreoretinal surgery to implant. In addition, the applicant noted that the device can be extracted and is reversible. The Argus[®] II System provided all 30 patients with

benefit as measured by high-contrast visual function tests. The applicant stated that the degree of benefit varied from patient to patient and provided the following results:

- All subjects were able to see visual percepts when the Argus[®] II System was electrically activated.
- On the Square Localization Test (that is, object localization), patients (on average) performed better with the system “on” rather than “off” at all follow-up time points. At 24 months, on average, patients missed the target by approximately 50 pixels with the system “on” versus approximately 250 pixels with the system “off”.
- On the Direction of Motion Test, which tested the patients’ ability to determine the direction of a moving bar, patients had higher mean accuracy with the system “on” than they did with the system “off” at all follow-up time points, indicating that the Argus[®] II System improved their performance on a spatial vision task. At 24 months, the mean response error was approximately 60° with the system “on” versus more than 80° with the system “off”. According to the applicant, this is nearly the error expected by chance.
- On the Grating Visual Acuity Test, which assessed the patients’ visual acuity using the principles of acuity charts designed for extremely low vision patients, 27 percent of the patients were able to score on the scale (between 1.6 and 2.9 log MAR) at least once with the system “on”, while none of the Argus[®] II patients were able to score on the scale with the system “off.”
- A large number of patients were able to recognize large letters and numbers with the system “on” (but not with the system “off”), and some of the patients were able

to read short words. The median percent correct with the system “on” was approximately 50 percent higher than with the system “off.”

- The trial also measured objectively-scored functional vision tests. The patients performed better with the Argus[®] II System “on” versus “off” on orientation and mobility tests (finding a door and following a line) and on functional vision tasks (sorting white, black, and grey socks, following an outdoor sidewalk, and determining the direction of a person walking by).

- Analysis of the Functional Low-vision Observer Rated Assessment (FLORA) results showed that three-quarters of the patients received a positive benefit in terms of well-being and/or functional vision, while none of the patients experienced a negative effect.

We note that we are concerned that the study did not have pre-specified endpoints and changed measurements mid trial. In addition, we are concerned about the reliability of the measures used for the tests and the inconsistency of the results across different patients, which lead us to question the long-term benefits associated with this device. We are inviting public comments on whether the Argus[®] II System meets the substantial clinical improvement criterion, specifically in regard to the measures used in the study and the lack of pre-specified endpoints.

We received two comments on the Argus[®] II System during the town hall meeting’s public comment period. These comments are summarized below.

Comment: Several commenters supported approving the Argus[®] II System for new technology add-on payments. One commenter, a society of retina specialists, stated

that the Argus[®] II System is the first and only approved treatment in the United States for patients suffering from severe to profound cases of retinitis pigmentosa with bare or no light perception in both eyes. The commenter explained that while the Argus[®] II System does not restore vision, it provides visual information that can range, depending on the patient, from light detection to form detection. The commenter asserted that, for patients with bare or no light perception, even limited restoration of vision can make a substantial difference, restoring a patient's ability to visually connect and interact with others and providing greater independence.

Another commenter, a foundation for supporting blindness, stated that it is essential that CMS is progressive in making therapies like the Argus[®] II System accessible for these patients who have no other treatment alternatives. The commenter recommended approving the Argus[®] II System for new technology add-on payments. The commenter noted that for patients with rare retinal diseases like retinitis pigmentosa, the Argus[®] II System represents the first approved breakthrough to help restore sight and improve quality of life.

Response: We appreciate the commenters' support. We considered these comments presented during the town hall meeting's public comment period in the development of this proposed rule. As stated above, we are inviting additional public comments on whether the Argus[®] II System meets the substantial clinical improvement criterion, specifically in regard to the measures used in the study and the lack of pre-specified endpoints.

c. Responsive Neurostimulator (RNS[®]) System

NeuroPace, Inc. submitted an application for new technology add-on payments for FY 2014 for the use of the RNS[®] System. 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 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[®] 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 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 or helpful for 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 with medically intractable partial onset seizures. The applicant anticipates FDA premarket approval of the RNS[®] System in the second quarter of 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 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 was possible for 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 the technology because the technology is an elective procedure.

The applicant submitted two analyses to demonstrate that it 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 standardized charge. The applicant maintained that this analysis best represents the anticipated charges for the technology because it is based on actual cases treated with this technology. The applicant analyzed 163 claims from 28 hospitals participating in the clinical trial. Five claims from one site 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 charge per case for these 158 claims was \$54,961.

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, the applicant inflated each claim using the Consumer Price Index for Inpatient Hospital Services (CPI-IP) to inflate the data to the same period. Specifically, because the publicly available FY 2011 MedPAR data do not identify the month of the discharge on inpatient claims but 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 2012 CPI-IP. Specifically, the applicant used the following assumptions:

FY 2011 Calendar Quarter	Midpoint of Quarter	CPI IP	Percent Change to August 2012
Q4 2010	Nov-10	227.186	9.54%
Q1 2011	Feb-11	232.933	6.84%
Q2 2011	May-11	235.567	5.64%
Q3 2011	Aug-11	237.219	4.91%
Most recent as of application	Aug-12	248.856	

Source as cited by applicant: Bureau of Labor Statistics' Web site, accessed October 15, 2012; 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 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 in 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 0.50 CCR used in the applicant's analyses.

Using this approach, the applicant added the anticipated hospital charge for the implantable RNS[®] System to the inflated average standardized charge per case and determined a final inflated average standardized charge per case of \$121,990. Although the applicant submitted data related to the estimated cost of the RNS[®] System, the applicant noted that the cost of the technology was proprietary information. Using the FY 2014 Table 10 thresholds, the threshold for MS-DRG 024 is \$78,039. Because the final inflated average standardized charge per case of \$121,990 for MS-DRG 024 exceeds the threshold amount, the applicant maintained that the RNS[®] System would meet the cost criterion.

In the second analysis, which the applicant characterizes as supplementary, the applicant searched the FY 2011 MedPAR file for cases reporting the combination of ICD-9-CM procedures codes 02.93 (Implantation or replacement of intracranial neurostimulator lead(s)) and 86.95 (Insertion or replacement of multiple array neurostimulator pulse generator, not specified as rechargeable), or the combination of ICD-9-CM procedures codes 02.93 (Implantation or replacement of intracranial neurostimulator lead(s)) and 01.20 (Cranial implantation or replacement of neurostimulator pulse generator) that mapped to MS-DRG 024.

The applicant found 565 claims 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 565 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 implementation of leads only. The applicant contacted two hospitals that reported claims where total covered charges were less than the charges for a full DBS system, and the hospitals confirmed that their claims represented lead implantation alone. Therefore, for this second analysis, the applicant included all of the cases in MS-DRG 024 reported with a combination of ICD-9-CM procedures codes 02.93 and 86.95 and all of the cases in MS-DRG 024 reported with 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 485 claims from 130 providers met these criteria and that these data represented claims from the fourth calendar quarter of 2010 through the third calendar quarter of 2011, or FY 2011. Based on this assumption, the applicant calculated an average charge per case of \$60,955. The applicant then removed DBS charges from the average charge per case. The applicant estimated charges for DBS and maintained that the average cost for a DBS system was \$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 DBS of \$51,958. After removing DBS charges, the applicant standardized charges and then inflated the charges to the current period using the same methodology in the first analysis. The applicant then added charges for the RNS[®] System and determined a final inflated average standardized charge per case of \$118,408. As noted above,

although the applicant submitted data that related to the estimated cost of the RNS[®] System, the applicant noted that the cost of the technology was proprietary information. Using the FY 2014 Table 10 thresholds, the threshold for MS-DRG 024 is \$78,039. Because the final inflated average standardized charge per case of \$118,408 for MS-DRG 024 exceeds the threshold amount, the applicant maintained that the RNS[®] System would meet the cost criterion.

Under either analysis, the applicant maintained that the final inflated average standardized charge per case would exceed the 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 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 who fail treatment with antiepileptic medications, or fail VNS therapy and are ineligible for respective surgery due to the extent and/or location of the seizure, or patients who do not elect surgery. According to the applicant, the RNS[®] System clinical trials provide Class I evidence that treatment with the RNS[®] System substantially reduces disabling seizures in patients 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 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 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; 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 with 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 1 or 2 seizure foci who have failed 2 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 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 compares 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 patients in the applicant's study 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 due to the relatively young age of the majority of 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. The applicant did provide the following comparison of VNS to the RNS[®] System:

Key Differences Between the RNS[®] System and DBS and VNS Systems

	RNS[®] System	Deep Brain Stimulator	Vagus Nerve Stimulator
Type of stimulation	Closed loop: responsive	Open loop: scheduled	
Stimulation time/day	About 5 minutes		
Stimulation target	Cortical; varies according to seizure focus	Deep brain nuclei	Ascending vagus nerve
Neurostimulator	Cranially implanted	Subcutaneously (pectorally) implanted	
Programming changes	According to clinical and electrographic response	According to clinical response	
Information from device	Device data, detections, stimulations and electrocorticograms	Device data	

	RNS® System	Deep Brain Stimulator	Vagus Nerve Stimulator
Physician data review	At time of programming as well as online access to stored data	At time of programming	

Because the applicant included claims with DBS 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 two comments on the RNS® System during the town hall meeting's public comment period. These comments are summarized below.

Comment: One commenter stated that it looked forward to the RNS® System's commercial availability and encouraged CMS to approve the RNS® System for new technology add-on payments. The commenter noted that the benefits of the RNS® System therapy include a significant reduction in seizure frequency and severity, and for some patients, extended periods of seizure freedom. The commenter asserted that this reduction in seizure frequency improves over time and is sustained over several years of

follow-up, and can result in improved cognition and a better quality of life. The commenter added that, most impressively, these positive results were achieved with no chronic side effects from stimulation. The commenter also noted that a significant number of these individuals are eligible for Medicare due to their disability.

Another commenter stated that the pivotal trial findings, in both the blinded period and the open-label period, have provided compelling support for what had previously been an only theoretical concept for non-ablative intervention. The commenter explained that those patients with seizure foci in eloquent areas or with hi-hippocampal seizure onset, the most difficult patient cohort to address, have been well-suited to RNS and often substantially benefited from this intervention. The commenter noted that in the functional and stereotactic neurosurgical community, the most exciting and compelling advances have arisen from those non-resective strategies by which maladaptive pathophysiology and its symptoms have been ameliorated by targeted electrical stimulation and neural function preserved with the NeuroPace experience--the most compelling in epilepsy.

The commenter concluded with the following: the RNS[®] System has had a remarkable and reassuring safety track record; the surgery for its implementation is comparable to that of deep brain stimulation system placement; the permanent and serious morbidity have been extremely low and the serious and life-threatening risks associated with medically intractable epilepsy, in comparison, are generally underappreciated and substantially higher.

Response: We appreciate the commenters' support. We considered these comments presented during the town hall meeting's public comment period 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.

d. 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). We are inviting public comments regarding how the Zilver[®] PTX[®] meets the newness criterion.

With regard to the cost criterion, the applicant believed that cases of superficial femoral arteries typically map to MS-DRGs 252 (Other Vascular Procedures with MCC), 253 (Other Vascular Procedures with CC), and 254 (Other Vascular Procedures without CC/MCC). The applicant searched the FY 2010 MedPAR file for cases reporting procedure code of 39.90 (Insertion of non-drug-eluting peripheral vessel stents) in combination with a diagnosis code of 440.20 (Atherosclerosis of the extremities, unspecified), 440.21 (Atherosclerosis of the extremities, with intermittent claudication), 440.22 (Atherosclerosis of the extremities with rest pain), 440.23 (Atherosclerosis of the extremities with ulceration), or 440.24 (Atherosclerosis of the extremities with gangrene). The applicant noted that the Zilver[®] PTX[®] is available in an 80 mm size and is approved for lesions in native vascular disease of the above-the-knee femoropopliteal arteries having reference vessel diameter from 4 mm to 9 mm and total lesion lengths up to 140 mm per limb. The applicant further noted that bare metal stents typically are available up to lengths of 200 mm. Therefore, in order to target cases eligible for the Zilver[®] PTX[®], the applicant believed it was only appropriate to target those cases with one or two bare metal stents. The applicant was able to identify the amount of stents used per claim by searching for ICD-9-CM procedure codes 00.45 (Insertion of one vascular stent) and 00.46 (Insertion of two vascular stents). The applicant submitted two methodologies: one

with cases that received one bare metal stent and the other with cases that received one or two bare metal stents.

Under the first methodology (one bare metal stent), the applicant found 2,062 cases (or 19.7 percent of all cases) in MS-DRG 252, 3,385 cases (or 32.3 percent of all cases) in MS-DRG 253, and 5,019 cases (or 48 percent of all cases) in MS-DRG 254. The average charge per case was \$89,194 for MS-DRG 252, \$67,965 for MS-DRG 253, and \$46,539 for MS-DRG 254, equating to a case-weighted average charge per case of \$60,855.

The case-weighted average charge per case above does not include charges related to the Zilver[®] PTX[®]. Therefore, it is first necessary to remove the amount of charges related to the non-drug-eluting peripheral vessel stent and replace them with charges related to the Zilver[®] PTX[®]. The applicant multiplied the use of the single stent used per case by the average market price for non-drug-eluting peripheral vessel stents and then converted the cost of the stents used per case to a charge by dividing the results by the hospital-specific CCR (from the FY 2010 IPPS impact file). The applicant removed the appropriate amount of charges per case and then standardized the charges per case.

Because the applicant used FY 2010 MedPAR data, it was necessary to inflate the charges from FY 2010 to FY 2013. Using data from the Bureau of Labor Statistics Consumer Price Index, the applicant inflated the average standardized charge per case with an inflation factor of 7 percent. To determine the amount of Zilver[®] PTX[®] stents per case, instead of using the amount of stents used per case based on the ICD-9-CM

codes above, the applicant used an average of 1.9 stents per case based on the Zilver[®] PTX[®] Global Registry Clinical Study⁶. The applicant believed that it is appropriate to use data from the clinical study (to determine the average amount of stents used per case) rather than the actual data from the claims because the length of a non-drug-eluting peripheral vessel stent typically ranges from 80mm to 120 mm, while the length of the Zilver[®] PTX[®] is 80 mm (which could cause a variance in the actual amount of stents used per case when using the Zilver[®] PTX[®]). The applicant then multiplied the average of 1.9 stents used per case by the future market price for the Zilver[®] PTX[®] and then converted the cost of the stents used per claim to a charge by dividing the results by the hospital-specific CCR (from the FY 2010 IPPS impact file). The applicant then added the amount of charges related to the Zilver[®] PTX[®] to the inflated average standardized charge per case and determined a final inflated case-weighted average standardized charge per case of \$58,419. Although the applicant submitted data that related to the estimated cost of the Zilver[®] PTX[®], the applicant noted that the cost of the technology was proprietary information. Using the FY 2014 Table 10 thresholds, the case-weighted threshold for MS-DRGs 252, 253, and 254 was \$54,547 (all calculations above were performed using unrounded numbers). Because the final inflated case-weighted average standardized charge per case for the applicable MS-DRGs exceeded the case-weighted threshold amount, the applicant maintained that the Zilver[®] PTX[®] would meet the cost criterion.

⁶ Dake, M.D., Ansel, G.M., Jaff, M.R., Ohki, T., Saxon, R.R., Smouse, H.B., Zeller, T., Roubin, G.S., Burket, M.W., Khatib, Y., Snyder, S.A., Ragheb, A.O., White, J.K., Machan, L.S.(2011), Paclitaxel-eluting stents show superiority to balloon angioplasty and bare metal stents in femoropopliteal disease: twelve-month zilver PTX randomized study results. *Circulation Cardiovascular Interventions*, published online September 27, 2011, 495-504.

The applicant used the same methodology above to demonstrate that it meets the cost criterion with the only difference being that it included cases that used one or two bare metal stents instead of just one bare metal stent. Using this methodology, the applicant determined a final inflated case-weighted average standardized charge per case of \$62,455. Using the FY 2014 Table 10 thresholds, the case-weighted threshold for MS-DRGs 252, 253, and 254 was \$54,474 (all calculations above were performed using unrounded numbers). Because the final inflated case-weighted average standardized charge per case for the applicable MS-DRGs exceeded the case-weighted threshold amount, the applicant maintained that the Zilver[®] PTX[®] would meet the cost criterion.

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

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

The applicant cited a 479-patient, multicenter, multinational randomized controlled trial that compared the Zilver[®] PTX[®] to balloon angioplasty⁷; an additional component of the study allowed a direct comparison of the Zilver[®] PTX[®] to a bare (uncoated) metal Zilver[®] stent. Patients were randomized to treatment with the Zilver[®] PTX[®] stent (treatment group) or with PTA (control group). Recognizing that balloon angioplasty may not be successful acutely, the trial design mandated provisional stent placement immediately after failure of balloon angioplasty in instances of acute PTA failure. Therefore, patients with suboptimal (failed) PTA underwent a secondary randomization to stenting with either Zilver[®] PTX[®] or bare Zilver stents. This secondary randomization allows evaluation of the Zilver[®] PTX[®] stent compared to a bare metal stent. The primary safety endpoint of the randomized controlled study was “Event-Free Survival” (EFS), defined as “freedom from the major adverse events of death, target lesion revascularization, target limb ischemia requiring surgical intervention or surgical repair of the target vessel, and freedom of worsening systems as described by the Rutherford classification by 2 classes or to class 5 or 6.” The primary effectiveness endpoint was primary patency (defined as a less than 50 percent re-narrowing). We note that we are concerned that other endpoints such as walking, walking speed, and climbing were not considered as primary endpoints to demonstrate the effectiveness of the Zilver[®] PTX[®].

⁷ Dake, M.D., Ansel, G.M., Jaff, M.R., Ohki, T., Saxon, R.R., Smouse, H.B., Zeller, T., Roubin, G.S., Burket, M.W., Khatib, Y., Snyder, S.A., Ragheb, A.O., White, J.K., Machan, L.S. (2011), Paclitaxel-eluting stents show superiority to balloon angioplasty and bare metal stents in femoropopliteal disease: twelve-month Zilver PTX randomized study results. *Circulation Cardiovascular Interventions*, published online September 27, 2011, 495-504

According to the applicant, the Zilver[®] PTX[®] had an EFS of 90.4 percent compared to balloon angioplasty, which had an EFS of 83.9 percent, at 12 months demonstrating that the Zilver[®] PTX[®] is as safe or safer than balloon angioplasty. The applicant further stated that this benefit was maintained at 24 months. In addition, the applicant noted that the Zilver[®] PTX[®] demonstrated a 50-percent reduction in restenosis rates compared to angioplasty and a 20-percent reduction compared to bare metal stents. The 12-month patency rate for the Zilver[®] PTX[®] was 82.7 percent, which compared favorably to the balloon angioplasty patency rate of 32.7 percent. In the provisional stenting arm of the study, which allowed a direct comparison of the Zilver[®] PTX[®] and a bare metal stent, the Zilver[®] PTX[®] primary patency exceeded the bare metal stent patency by nearly 20 percent (87.3 percent versus 72.3 percent at 12 months). The applicant stated that these differences are significant, as they result in a substantial clinical improvement compared to angioplasty and bare metal stenting, with patients being spared a recurrence of their leg pain and the need to be admitted to the hospital for repeat procedures on these treated lesions. The applicant also submitted 3 years of follow-up data, which the applicant maintained support that the Zilver[®] PTX[®] is more effective in maintaining primary patency.⁸

The applicant also cited a prospective, multicenter, multinational, 787-patient single arm study on the Zilver[®] PTX[®] that demonstrated similar safety and effectiveness results consistent with those from the pivotal randomized controlled study above. The applicant cited an EFS for the Zilver[®] PTX[®] of 89.0 percent and an 86.2 percent primary patency rate. According to the applicant, these results confirm the safety and

⁸ Dake, MD., VIVA 2012, October 10, 2012; Las Vegas, Nevada.

effectiveness of the Zilver[®] PTX[®], and compare favorably to current results for angioplasty and bare metal stenting. The applicant further stated that these results also demonstrate a 67 to 81 percent relative reduction in Target Lesion Revascularization (the need to retreat an already treated lesion that has restenosed, resulting in a recurrence of symptoms) rates compared to recently published results of contemporary bare metal stents.⁹

We also are concerned that on April 24, 2013, the FDA announced that, based on its investigation into a small number of complaints that the delivery system of the device had separated at the tip of the inner catheter, Cook Medical has initiated a nationwide/global voluntary recall of its Zilver[®] PTX[®] Drug Eluting Peripheral Stent.

We refer readers to

<http://www.fda.gov/Safety/Recalls/ucm349421.htm?source=govdelivery> for more information regarding this announcement.

We are inviting public comments regarding whether the Zilver[®] PTX[®] meets the substantial clinical improvement criterion. We note that we did not receive any public comments on the Zilver[®] PTX[®] during the new technology town hall meeting's public comment period.

⁹ Dake, M. D., Scheinert, D., Tepe, G., Tessarek, J., Fanelli, F., Bosiers, M., et al., (2011). Nitinol stents with polymer-free paclitaxel coating for lesions in the superficial femoral and popliteal arteries above the knee: Twelve-month safety and effectiveness results from the Zilver PTX single-arm clinical study. *Journal of Endovascular Therapy*, 18(5), 613-623.

e. MitraClip[®] System

Abbott Vascular submitted an application for new technology add-on payments for the MitraClip[®] System for FY 2014. The MitraClip[®] System is a transcatheter mitral valve 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 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 mitral valve as the heart contracts. If the amount of blood that leaks back into the mitral valve is minimal then intervention is usually not necessary. However, if the amount of blood 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 mitral regurgitation can lead to heart failure and death. The American College of Cardiology (ACC) and the American Heart Association (AHA) issued practice guidelines in 2006 recommending intervention for moderate-severe or severe MR (3+ to 4+). The applicant stated that the MitraClip[®] System is intended "for patients with symptomatic, significant mitral regurgitation who have been determined by a cardiac surgeon to be too high risk for open mitral valve surgery and in whom existing co-morbidities would not preclude the expected benefit from correction of the mitral regurgitation."

The MitraClip[®] System performs percutaneous mitral valve repair. The applicant noted that the MitraClip[®] 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.^{10,11,12,13,14} 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. As a result, when the suture is placed in the middle of the valve, the valve will have a functional double orifice during diastole, thus the alternate name for the procedure “Double Orifice Repair.”

With regard to the newness criterion, the manufacturer submitted a Premarket Approval (PMA) application in support of obtaining FDA approval for the MitraClip[®] System. 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. On March 20, 2013, a meeting was held by the Circulatory System Devices Panel of the Medical Devices Advisory Committee of the FDA to discuss, make recommendations, and vote on information related to the PMA application for the MitraClip[®] System. Specifically, the Committee was charged with determining if the

¹⁰Maisano, F., et al., The double-orifice technique as a standardized approach to treat mitral regurgitation due to severe myxomatous disease: surgical technique, *Eur J Cardiothorac Surg*, 2000, 17(3): p. 201-5.

¹¹ Maisano, F., et al., The edge-to-edge technique: a simplified method to correct mitral insufficiency, *Eur J Cardiothorac Surg*, 1998, 13(3): p. 240-5; discussion 245-6.

¹² Totaro, P., et al., Mitral valve repair for isolated prolapse of the anterior leaflet: an 11-year follow-up, *Eur J Cardiothorac Surg*, 1999, 15(2): p. 119-26.

¹³ Umana, J.P., et al., "Bow-tie" mitral valve repair: an adjuvant technique for ischemic mitral regurgitation, *Ann Thorac Surg*, 1998, 66(5): p. 1640-6.

¹⁴ Alfieri, O. and F. Maisano, An effective technique to correct anterior mitral leaflet prolapse, *J Card Surg*, 1999, 14(6): p. 468-70.

data presented by the applicant demonstrated a reasonable assurance of safety and effectiveness. We refer readers to the following FDA Web site for additional detailed information and meeting materials regarding the MitraClip[®] System

<http://www.fda.gov/AdvisoryCommittees/Calendar/ucm339809.htm>. In addition, a summary of the March 20, 2013 meeting can be located on the following FDA Web site <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/UCM345235.pdf>. We are inviting public comments regarding how the MitraClip[®] System meets the newness criterion.

With regard to the cost criterion, the applicant conducted four separate analyses. The applicant noted that while ICD-9-CM procedure code 35.97 groups 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[®] has demonstrated that it is extremely rare for a patient to receive stents concurrently with the MitraClip[®] procedure. The applicant further cited the FY 2013 IPPS/LTCH PPS final rule (77 FR 55308) 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 MitraClip® meet the incremental cost thresholds provided in Table 10 for those MS-DRGs.

The applicant included two analyses that utilize the FY 2011 MedPAR file and two analyses of hospital UB-04 claims data from the EVEREST II Continued Access Study that were collected during FY 2012. Below is a summary of the applicant's four data analyses, including the methodology and the findings for each.

- Analysis 1: The applicant searched the FY 2011 MedPAR file for cases reporting procedure code 35.97 that mapped to MS-DRGs 250 and 251. According to the applicant, this search yielded actual MitraClip® procedures that were performed in an IDE study setting where hospitals obtained the MitraClip® System at a reduced investigational price; the applicant stated that it is likely that hospitals did not bill at all for the investigational device or submitted billed charges that were significantly less than the actual device acquisition costs (we refer readers to the explanation below). The applicant found 39 cases in MS-DRG 250 (29 percent of all cases), and 94 cases in MS-DRG 251 (71 percent of all cases), which resulted in a case-weighted average charge per case of \$97,918. The applicant then standardized the charges using the FY 2011 final rule impact file and inflated the standardized charges using two different inflation factors.

The first approach used a factor of 4.6 percent, which was based on data from the U.S. Department of Labor's Bureau of Labor Statistics non-seasonally adjusted Consumer Price Index for All Urban Consumers between January 2011 and January 2013. This resulted in an inflated case-weighted average standardized charge per case of \$79,346. The second approach used a factor of 18.6 percent based on the growth in charges between 2009 and 2011 in MS-DRGs 250 and 251 and adjusting for case-mix year over year. This resulted in an inflated case-weighted average standardized charge per case of \$89,986. The applicant noted that both approaches used to determine the inflated case-weighted average standardized charge per case were calculated without any adjustments to reflect the reduced investigational price or inadequate hospital billing.

In order to determine if hospitals adequately billed for the device, the applicant analyzed the cost of the device on each claim by summing the charges that map to the 15 CMS IPPS cost centers (77 FR 53340). The applicant then calculated the standardized cost for this subset of charges by multiplying the standardized charges in each cost center by the CMS national CCR for each cost center in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53340). The applicant asserted that, whereas all hospitals in the study were charged a uniform investigational price for the MitraClip[®] System, this analysis confirmed that some hospitals did not bill at all for the device or charged substantially less than the actual hospital acquisition cost, which is likely due to the investigational status of the technology. The applicant explained that the mean total standardized costs in the "Supplies and Equipment" cost center in the FY 2011 MedPAR file for MitraClip[®] cases were remarkably low for MS-DRGs 250 and 251, respectively. According to the

applicant, the mean total standardized costs in the “Supplies and Equipment” cost center reflect only 50 percent of the actual MitraClip[®] System costs not inclusive of other supply and equipment costs associated with the MitraClip[®] procedure and hospital stay. Therefore, the applicant believed that Analysis 1 severely underestimated the actual hospital costs.

Using the FY 2014 Table 10 thresholds, the case-weighted threshold for MS-DRGs 250 and 251 was \$63,097 (all calculations above were performed using unrounded numbers). Because the inflated case-weighted average standardized charge per case for the applicable MS-DRGs for both approaches discussed above exceeds the case-weighted threshold amount, the applicant maintained that the MitraClip[®] System would meet the cost criterion.

- Analysis 2: The second analysis is identical to the first analysis (the applicant searched the FY 2011 MedPAR file for cases reporting procedure code 35.97 that mapped to MS-DRGs 250 and 251) except that the applicant excluded hospital claims that either did not include any charge for the device-dependent procedure or included a charge that was significantly less than the actual device acquisition cost. The applicant believed that these exclusions would provide more accurate data on the costs associated with the MitraClip[®] procedure in the IDE study when hospitals obtained the MitraClip[®] System at a reduced investigational price. The applicant explained that it included only those cases where the standardized charge for the “Supplies and Equipment” cost center, reduced by each hospital’s average hospital-wide CCR (rather than using CMS national CCRs for each cost center), was greater than \$10,000, which is lower than the acquisition

cost for the MitraClip[®] System. The applicant stated that this analysis reflects a conservative but more appropriate estimate of the actual costs incurred by the hospitals during the clinical trial than the first analysis.

Using the methodology above, the applicant found 12 cases in MS-DRG 250 (22 percent of all cases) and 43 cases in MS-DRG 251 (78 percent of all cases), which resulted in a case-weighted average charge per case of \$112,434. The applicant then standardized the charges using the FY 2011 final rule impact file and inflated the standardized charges using two different inflation factors. The first approach used a factor of 4.6 percent, which was based on data from the U.S. Department of Labor's Bureau of Labor Statistics non-seasonally adjusted Consumer Price Index for All Urban Consumers between January 2011 and January 2013. This resulted in an inflated case-weighted average standardized charge per case of \$97,289. The second approach used a factor of 18.6 percent based on the growth in charges between 2009 and 2011 in MS-DRGs 250 and 251 and adjusting for case-mix year over year. This resulted in an inflated case-weighted average standardized charge per case of \$110,335.

Using the FY 2014 Table 10 thresholds, the case-weighted threshold for MS-DRGs 250 and 251 was \$61,896 (all calculations above were performed using unrounded numbers). Because the inflated case-weighted average standardized charge per case for the applicable MS-DRGs for both charge inflation approaches discussed above exceeds the case-weighted threshold amount, the applicant maintained that the MitraClip[®] System would meet the cost criterion.

- Analysis 3: Because the first two analyses sought only to estimate standardized charges for the MitraClip[®] procedure in an investigational setting with a reduced price for the device, the applicant submitted two additional analyses using hospital charges in a commercial setting and a commercial device price. Rather than using MedPAR data, the applicant utilized hospital UB-04 claims collected from the ongoing EVEREST II Continued Access Study in addition to claims from compassionate-use cases. The applicant stated that patient characteristics and charges for both of these cases were not significantly different.

The applicant analyzed 98 claims from 21 sites (for discharges on or after October 1, 2011 through discharges on or before September 30, 2012 (FY 2012 claims data)) and excluded 18 cases because the cases either did not map to MS-DRGs 250 or 251, or the patient was below the age of 65 years. Of these remaining 80 cases, 17 mapped to MS-DRG 250 (21.3 percent of all cases) and 63 mapped to MS-DRG 251 (78.8 percent of all cases), which resulted in a case-weighted average charge per case of \$112,509. The case-weighted average charge per case above includes clinical trial charges related to the MitraClip[®] System, which does not reflect the full commercial charge for the MitraClip[®] System. Therefore, the applicant removed the amount of clinical trial charges related to the MitraClip[®] System. The applicant then standardized the charges using the FY 2012 final rule impact file and inflated the standardized charges using the two different approaches described in the first and second analyses (an inflation factor of 4.6 percent and 18.6 percent, respectively).

The applicant then added commercial charges for the device to the inflated standardized charges (for both charge inflation approaches). Although the applicant submitted data that related to the estimated cost of the MitraClip® System, the applicant noted that the cost of the technology was proprietary information. To compute the commercial charges for the MitraClip® System, the applicant took the European commercial price of the MitraClip® System, converted the cost to U.S. dollars by multiplying the amount by an exchange rate of 1.38, and then divided the result by the “Supplies and Equipment” cost center CCR (in the FY 2013 IPPS/LTCH PPS final rule) of 0.335. This resulted in an inflated case-weighted average standardized charge per case of \$129,019 and \$132,372 under the first and second charge inflation approaches, respectively.

Using the FY 2014 Table 10 thresholds, the case-weighted threshold for MS-DRGs 250 and 251 was \$61,805 (all calculations above were performed using unrounded numbers). Because the inflated case-weighted average standardized charge per case for the applicable MS-DRGs for both charge inflation approaches exceeds the case-weighted threshold amount, the applicant maintained that the MitraClip® System would meet the cost criterion.

- Analysis 4: The fourth analysis was similar to the third analysis. However, instead of basing commercial charges on the European commercial price, the applicant used the anticipated U.S. commercial price to determine the commercial charges for the device. Similar to above, the applicant determined a case-weighted average charge per case of \$112,509. The applicant then removed the clinical trial charges related to the

MitraClip[®] System (for each claim), standardized the charges using the FY 2012 final rule impact file, and inflated the standardized charges using both charge inflation approaches discussed above.

The applicant then added commercial charges for the device to the inflated standardized charges (for both charge inflation approaches). As mentioned above, although the applicant submitted data that related to the estimated cost of the MitraClip[®] System, the applicant noted that the cost of the technology was proprietary information. To compute the commercial charges for the MitraClip[®] System, the applicant used the anticipated U.S. commercial price of the MitraClip[®] System and divided the amount by the “Supplies and Equipment” cost center CCR (in the FY 2013 IPPS/LTCH PPS final rule) of 0.335. This resulted in an inflated case-weighted average standardized charge per case of \$136,183 and \$139,535 under the first and second charge inflation approaches, respectively.

Using the FY 2014 Table 10 thresholds, the case-weighted threshold for MS-DRGs 250 and 251 was \$61,805 (all calculations above were performed using unrounded numbers). Because the inflated case-weighted average standardized charge per case for the applicable MS-DRGs for both charge inflation approaches exceeds the case-weighted threshold amount, the applicant maintained that the MitraClip[®] System would meet 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 four analyses.

The applicant asserted that the MitraClip[®] System meets the substantial clinical improvement criterion. 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 with severe MR who are too high risk for surgery and receiving palliative medical management.

The applicant further stated that although many of the patients who are refused surgery die in the intervening months to years, the economic burden to the healthcare system of mitral regurgitation in elderly patients not deemed suitable for conventional open chest surgery is considerable. The applicant noted that the vast majority of such patients are repeatedly hospitalized, often with prolonged lengths of in-hospital stays, and, even when returned to the community, they consume additional resources from the primary care and social services. The applicant asserted that the quality of life enjoyed by these patients is also poor and their mortality rates are high. The applicant cited the 2012 European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS) clinical practice guideline for valvular heart disease, which recommended that the MitraClip[®] procedure be considered in high surgical risk patients with symptomatic severe secondary MR.

The applicant also stated that it would meet the substantial clinical improvement criterion based on clinical studies that have consistently shown that the MitraClip[®] procedure leads 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, health-related quality of life and reductions in heart-failure related hospitalizations, and significantly lower mortality than predicted surgical mortality.

The applicant cited clinical data from the EVEREST II High Risk Study¹⁵ and from the EVEREST II Continued Access Study/Registry (REALISIM)¹⁶. The applicant also cited clinical data from a high risk cohort of patients (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 surgery; and (2) patients within the EVEREST II Continued Access Study/Registry who were too high risk for surgery using identical eligibility inclusion criteria.

In addition to the published clinical experience from the EVEREST studies, the applicant cited data on the use of the MitraClip[®] 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[®] device group of the ACCESS-EU post-approval clinical trial in Europe. The European use of the MitraClip[®] device is focused on patients who are too high risk for surgery and patients are selected for therapy using a multi-disciplinary “heart team” approach.

The applicant stated that published reports of the MitraClip[®] procedure have consistently demonstrated a significant reduction in MR that is durable out to 1, 2, and 3

¹⁵ 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. *JACC* 2012;59:130-139.

¹⁶ Feldman et al., Percutaneous Repair or Surgery for Mitral Regurgitation. *NEJM* 2011;364:1395-1406.

years. The applicant cited the EVEREST II High Risk Study, which demonstrated that the MitraClip[®] procedure successfully reduced MR for high-risk patients with results durable out to 2 years. The applicant also noted that the proportion of patients with significant MR (MR grade $\geq 3+$) was reduced from 99 percent at baseline to 22 percent at 1 year follow-up ($p < 0.0001$). The applicant further noted that reduction of MR was also associated with significant improvements in left ventricular dimensions including LV end diastolic and systolic volumes ($p < 0.0001$) consistent with positive ventricular remodeling.

According to the applicant, the most recent available data from the EVEREST II High Risk Cohort submitted to the FDA for high-risk patients demonstrated a significant reduction in severe MR from 86 percent at baseline to 13 percent at 2 years ($p < 0.0001$), improvements in LV dimensions and volumes sustained at 2 years, and a 48-percent reduction in rates of heart failure-related hospitalizations between the baseline and the 12-month follow-up period after the MitraClip[®] procedure ($p < 0.0001$).

The applicant noted that patients treated with MitraClip[®] reported substantial clinical improvements in NYHA functional class from baseline at both 1 and 2 year followup. The applicant explained that the NYHA classification system assigns patients into one of four categories representing the extent of heart failure based on how much they are limited during physical activity. In the EVEREST II High-Risk Cohort, the applicant stated that the proportion of patients with NYHA class III/IV representing marked or severe limitations in activity was significantly reduced from 82 percent at

baseline to 17 percent at 1 year ($p < 0.0001$). The applicant noted that these results also have been consistently shown in multiple other published studies.

Based on data from the EVEREST II High Risk Cohort, the applicant cited additional data demonstrating that the MitraClip[®] treatment is associated with clinically and statistically significant improvements in general health-related quality of life. The applicant explained that the RAND SF-36 health survey, a quality of life instrument, demonstrated similar physical and mental component scores after 30 days and 1 year. In addition, the applicant stated that the MitraClip[®] is associated with lower than predicted mortality rates at 30 days as measured by the Society for Thoracic Surgery (STS) Mortality Risk Score. Also, mortality at 1 year is favorable when (1) comparing the MitraClip[®] to published literature^{17,18,19,20,21,22,23} and (2) comparing MitraClip[®] mortality to a high-risk concurrent control group of patients treated with medical management.

¹⁷ Mirabel M, Iung B, Baron G, et al. What are the characteristics of patients with severe, symptomatic, mitral regurgitation who are denied surgery? *Eur Heart J*. 2007 Jun;28(11):1358-65.

¹⁸ Patel JB, Borgeson DD, Barnes ME, Rihal CS, Daly RC, Redfield MM.: Mitral regurgitation in patients with advanced systolic heart failure. *J Card Fail*. 2004 Aug;10(4):285-91.

¹⁹ Trichon BH, Felker GM, Shaw LK, Cabell CH, O'Connor CM: Relation of frequency and severity of mitral regurgitation to survival among patients with left ventricular systolic dysfunction and heart failure, *Am J Cardiol*. 2003 Mar 1. 91(5):538-43.

²⁰ Bursi F, Enriquez-Sarano M, Nkomo VT, Jacobsen SJ, Weston SA, Meverden RA, Roger VL: Heart failure and death after myocardial infarction in the community: the emerging role of mitral regurgitation. *Circulation*. 2005 Jan 25;111(3):295-301.34.

²¹ Grigioni F, Enriquez-Sarano M, Zehr KJ, Bailey KR, Tajik AJ: Ischemic mitral regurgitation: long-term outcome and prognostic implications with quantitative Doppler assessment. *Circulation*. 2001 Apr 3;103(13):1759-64.

²² Koelling TM, Aaronson KD, Cody RJ, Bach DS, Armstrong WF: Prognostic significance of mitral regurgitation and tricuspid regurgitation in patients with left ventricular systolic dysfunction, *Am Heart J*. 2002 Sep;144(3):524-9.

²³ Cioffi G, Tarantini L, De Feo S, Pulignano G, Del Sindaco D, Stefanelli C, Di Lenarda A, Opasich C.: Functional mitral regurgitation predicts 1-year mortality in elderly patients with systolic chronic heart failure. *Eur J Heart Fail*. 2005 Dec;7(7):1112-7.

In conclusion, the applicant cited data from the ACCESS-EU study as presented at the European Society of Cardiology Congress in August 2012, which demonstrated improvement in disease-specific quality of life measures including the Minnesota Living with Heart Failure Questionnaire and Six Minute Walk Test.

We note that, similar to the FDA, as referenced above, we are concerned that the applicant performed post hoc analyses on a different patient population and revised the initial indication for use for the MitraClip[®] after learning that the FDA expressed concern regarding the PMA based on insufficient data resulting from the initial indication for use and patient population in the EVEREST II RCT. As we discuss below, data results from 2 years of the EVEREST II RCT also demonstrated that surgery reduced mitral regurgitation more than the percutaneous MitraClip[®] System. However, both the surgical patients and the MitraClip[®] patients showed comparable results for improved left ventricular function, NYHA functional class, and quality of life. Subsequent to this trial, the applicant conducted a retrospective review of registry data to support the revised indication for use. This retrospective analysis involved pooling two registry data sets (the EVEREST II High Risk Registry (HRR) and the REALISM HRR Continued Access Protocol (CAP)) in a post hoc manner, which resulted in major design flaws and data interpretation limitations. The pooled registry data sets were referred to as the Integrated High Surgical Risk Cohort.

We note that, the EVEREST II HRR and the REALISM HRR CAP were not intended to be used as pivotal data sets. The applicant was previously informed by the FDA that without positive pivotal trial results, the PMA application could not be

approved based on the data results of the EVEREST II RCT by itself. Therefore, the FDA suggested the additional studies (the EVEREST II HRR and the REALISM HRR CAP) to complement the randomized study and, therefore, could be considered adjunctive to the EVEREST II RCT.

In our review of the clinical trials' data, we agree with the FDA regarding the following key points:

- 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 what the appropriate target population for the MitraClip[®] System is because clinical trials conducted by the applicant included patients with both functional and degenerative mitral regurgitation, which makes it difficult to determine which group of patients may benefit more or less from the technology. For example, in a subgroup analysis of the EVEREST II RCT, authors concluded that older patients and those patients with functional mitral regurgitation 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 mitral regurgitation more than the percutaneous MitraClip[®] System. However, both the surgical patients and the MitraClip[®] System's patients 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 also with regard to the appropriate target population for this technology.

We received nine comments on the MitraClip® System during the town hall meeting's public comment period. These comments are summarized below.

Comment: Several commenters expressed support for new technology add-on payments for the MitraClip® System and recommended that the technology be reassigned from MS-DRGs 250 and 251 (Percutaneous Cardiovascular Procedure without Coronary Artery Stent or AMI with and without MCC, respectively) to MS-DRGs 216, 217, 218, 219, 220, and 221 (Cardiac Valve and Other Major Cardiothoracic Procedure with and without Cardiac Catheterization with MCC, CC, and without CC/MCC, respectively).

Response: We appreciate the commenters' support. However, we note that we did not request public comments nor propose to make any changes to the MS-DRG classification for the MitraClip® System. Because these comments are outside the scope of the new technology add-on payment application included in this proposed rule, we are not providing a complete summary of and response to these comments. We encourage the commenters to review the process for submitting comments regarding MS-DRG classifications as outlined in section II.G. of the preamble of this proposed rule.

Comment: Several commenters stated that they supported the application for new technology add-on payments for the MitraClip® System because it is a novel technology utilizing the transcatheter approach to repair the mitral valve and has demonstrated

substantial clinical improvement. According to the commenters, the technology is intended to be used for high-risk patients who do not have other treatment options available due to the severity of their mitral regurgitation and other comorbidities, such as heart failure. The commenters noted that the percutaneous MitraClip[®] System results in significant improvement in quality of life for this group of patients for whom conventional surgery is contraindicated.

One commenter stated that another benefit of the MitraClip[®] System is that it offers patients with all forms of mitral regurgitation the opportunity to receive treatment much earlier, thereby resulting in improved cardiac function, reduced heart failure, and increased savings to the healthcare system.

Another commenter expressed support for the MitraClip[®] System and noted that surgery for this high-risk patient population is not a viable alternative and neither are the currently available medical therapy options, as evidenced by the readmission rates for congestive heart failure exacerbations in this group of patients. This commenter also noted that the MitraClip[®] device has proven to reduce the degree of mitral regurgitation as shown in a number of high-risk patient registries and clinical trials. The commenter further noted that savings could be realized with the reductions in readmissions for heart failure exacerbations for this group of patients.

One commenter indicated that the MitraClip[®] System meets the substantial clinical improvement criterion because it offers nonoperative patients a device that could “potentially revolutionize management of nonsurgical patients with severe mitral regurgitation.” Another commenter stated that the MitraClip[®] System “represents a

landmark in our ability to perform mitral valve surgeries with less risk.” This commenter further stated that the “MitraClip[®] joins TAVR (Transcatheter aortic valve replacement) and TPVI (Transcatheter pulmonary valve implantation) as new percutaneous surgical therapies for patients with valvular heart disease who are not candidates for traditional valve replacement or repair.”

Another commenter noted that the MitraClip[®] System has shown substantial clinical improvement in patients considered too high risk for surgery as demonstrated by the EVEREST II cohort, including improvement in patients NYHA functional class, reduced hospitalizations, and improved left ventricular function.

Response: We appreciate the commenters’ support. We have considered these comments received during the town hall meeting’s public comment period in this proposed rule. As stated above, we are inviting additional public comments on whether the MitraClip[®] System meets the substantial clinical improvement criterion, particularly in comparison to other surgical therapies such as mitral valve repair or replacement, and also with regard to the appropriate target population for this technology.

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

A. Background

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts “for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.” 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 2014 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 2014 is discussed in section **II.B.** of the Addendum to this proposed rule.

As discussed below in section III.H. of this preamble, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the

provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The proposed budget neutrality adjustment for FY 2014 is discussed in section **II.A.4.b.** of the Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are proposing to apply beginning October 1, 2013 (the FY 2014 wage index) appears under section III.F. of the preamble of this proposed rule.

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

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we define hospital labor market areas based on the Core-Based Statistical Areas (CBSAs) established by OMB. The current statistical areas 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 plans to announce new area delineations based on new standards adopted in 2010

(75 FR 37246) and the 2010 Census of Population and Housing data. 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 provides 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 order to implement these changes for the IPPS, it is necessary to identify the new area designation 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, there are new CBSAs, urban counties that become rural, rural counties that become urban, and existing CBSAs that have been split apart. In addition, the effect of the new designations on various hospital reclassifications, the outmigration 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 considered regarding the effects of the new designations 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 must be extensively reviewed and verified, we were unable to undertake such a lengthy process before publication of this FY 2014 proposed rule. By the time the bulletin was issued, the FY 2014 IPPS proposed rule was in the advanced stages of development. We had already developed the FY 2014 proposed wage index based on the previous OMB definitions. We note that, in June 2003, OMB announced changes resulting from the 2000 Census, and at that time, CMS proposed and implemented the changes during the following year's rulemaking cycle for FY 2005. Although OMB published the data earlier than June this year, we still are in essentially the same situation as we were in 2003 because the data are not available in time to be incorporated into this year's rulemaking cycle. To allow for sufficient time to assess the new changes and their ramifications, we intend to propose changes to the wage index based on the newest CBSA changes in the FY 2015 proposed rule. We refer readers to the FY 2005 IPPS final rule (69 FR 49026 through 49034) for those interested in learning about the issues we may need to address next year in proposing to implement the latest OMB update for FY 2015, and some of the policy decisions that we may consider making.

C. Worksheet S-3 Wage Data for the Proposed FY 2014 Wage Index

The proposed FY 2014 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2010 (the FY 2013 wage indices were based on data from cost reporting periods beginning during FY 2009).

1. Included Categories of Costs

The proposed FY 2014 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 2013, the proposed wage index for FY 2014 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as SNF services, home health services, costs related to

GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The proposed FY 2014 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 indices applicable to other providers, such as SNFs, home health agencies (HHAs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indices for non-IPPS providers, other than for LTCHs. Such comments should be made in response to separate proposed rules for those providers.

D. Verification of Worksheet S-3 Wage Data

The wage data for the proposed FY 2014 wage index were obtained from Worksheet S-3 of the Medicare cost report for cost reporting periods beginning on or after October 1, 2009, and before October 1, 2010. For wage index purposes, we refer to cost reports during this period as the “FY 2010 cost report,” the “FY 2010 wage data,” or

the “FY 2010 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 36, Sections 3605.2 and 3605.3 for Form CMS-2552-96 and Chapter 40, Sections 4005.2 through 4005.4 for Form CMS-2552-10. Hospitals with cost reporting periods beginning on or after October 1, 2009 and before May 1, 2010 reported FY 2010 data on Form CMS-2552-96. Hospitals with cost reporting periods beginning on or after May 1, 2010 and before October 1, 2010 reported FY 2010 data on the new Form CMS-2552-10. The data file used to construct the wage index includes FY 2010 data submitted to us as of March 1, 2013. 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 fiscal intermediaries/MACs to revise or verify data elements that result in specific edit failures. For the proposed FY 2014 wage index, we identified and excluded 44 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 2014 wage index. We instructed fiscal intermediaries/MACs to complete their data verification of questionable data elements and to transmit any changes to the wage data no later than April 10, 2013. We intend that all unresolved data elements will be resolved by the date the FY 2014 final rule is issued. The revised data will be reflected in the FY 2014 IPPS final rule.

In constructing the proposed FY 2014 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2010, 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 4 hospitals that converted to CAH status on or after February 14, 2012, the cut-off date for CAH exclusion from the FY 2013 wage index, and through and including February 14, 2013, the cut-off date for CAH exclusion from the FY 2014 wage index. After removing hospitals with aberrant data and hospitals that converted to CAH status, the proposed FY 2014 wage index is calculated based on 3,427 hospitals.

For the proposed FY 2014 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 2013 wage index (77 FR 53366). Table 2 containing the proposed FY 2014 wage index associated with this proposed rule (available on the CMS Web site) includes separate wage data for the campuses of six multicampus hospitals (two additional multicampus hospitals have been added to the wage index calculation for FY 2014).

E. Method for Computing the Proposed FY 2014 Unadjusted Wage Index

The method used to compute the proposed FY 2014 wage index without an occupational mix adjustment follows the same methodology that we used to compute the FY 2012 final wage index without an occupational mix adjustment (76 FR 51591 through

51593) and which we discussed and used for the FY 2013 final wage index without an occupational mix adjustment (77 FR 53366 through 53367).

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, 2009, through April 15, 2011, 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 2014. The factors used to adjust the hospital’s data were based on the midpoint of the cost reporting period, as indicated below.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment Factor
10/14/2009	11/15/2009	1.02682
11/14/2009	12/15/2009	1.02490
12/14/2009	01/15/2010	1.02299
01/14/2010	02/15/2010	1.02116
02/14/2010	03/15/2010	1.01941
03/14/2010	04/15/2010	1.01768
04/14/2010	05/15/2010	1.01591
05/14/2010	06/15/2010	1.01412
06/14/2010	07/15/2010	1.01235
07/14/2010	08/15/2010	1.01064
08/14/2010	09/15/2010	1.00898
09/14/2010	10/15/2010	1.00738
10/14/2010	11/15/2010	1.00584
11/14/2010	12/15/2010	1.00434
12/14/2010	01/15/2011	1.00288
01/14/2011	02/15/2011	1.00143

After	Before	Adjustment Factor
02/14/2011	03/15/2011	1.00000
03/14/2011	04/15/2011	0.99860

For example, the midpoint of a cost reporting period beginning January 1, 2010, and ending December 31, 2010, is June 30, 2010. An adjustment factor of 1.01235 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 2013 IPPS/LTCH PPS final rule, the proposed FY 2014 national average hourly wage (unadjusted for occupational mix) is \$38.2384. The proposed FY 2014 Puerto Rico overall average hourly wage (unadjusted for occupational mix) is \$16.4873.

F. Proposed Occupational Mix Adjustment to the Proposed FY 2014 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 2014 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 2013 IPPS/LTCH PPS final rule (77 FR 53367 through 53368), the occupational mix adjustment to the FY 2013 wage index was based on data collected on the 2010 Medicare Wage Index Occupational Mix Survey (Form CMS-10079 (2010)). For the FY 2014 wage index, we are proposing to again use occupational mix data collected on the 2010 survey to compute the occupational mix adjustment for FY 2014. We are including data for 3,188 hospitals that also have wage data included in the proposed FY 2014 wage index.

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

As stated earlier, section 304(c) of Pub. L. 106-554 amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. We used occupational mix data collected on the 2010 survey to compute the occupational mix adjustment for FY 2013 and the proposed FY 2014 wage index associated with this proposed rule. We also plan to use the 2010 survey data for the FY 2015 wage index. 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 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 is pending OMB review, and is available on the CMS Web site at: <http://www.cms.hhs.gov/PaperworkReductionActof1995> by clicking on “PRA Listings.” (The OMB control number for this collection of information is 0938-0907.) Hospitals are required to submit their completed 2013 surveys to their fiscal intermediaries/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 2014

For FY 2014, we are proposing to calculate the occupational mix adjustment factor using the same methodology that we used for the FY 2012 and FY 2013 wage indices (76 FR 51582 through 51586, and 77 FR 53367 through 53368, respectively). As a result of applying this methodology, the proposed FY 2014 occupational mix adjusted national average hourly wage is \$38.2094. The proposed FY 2014 occupational mix adjusted Puerto Rico-specific average hourly wage is \$16.5300.

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 2014 wage index. For the FY 2010 survey, the response rate was 91.7 percent. In the proposed FY 2014 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 wage index desk review process. We will review these data for future analysis and consideration of potential penalties for noncompliant hospitals.

G. Analysis and Implementation of the Proposed Occupational Mix Adjustment and the Proposed FY 2014 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 this preamble, for FY 2014, we are proposing to apply the proposed occupational mix adjustment to 100 percent of the proposed FY 2014 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 2014 wage index results in a proposed national average hourly wage of \$38.2094 and a proposed Puerto-Rico specific average hourly wage of \$16.5300. After excluding data of hospitals that either submitted aberrant data that failed critical edits, or that do not have FY 2010 Worksheet S-3, Parts II and III, cost report data for use in calculating the proposed FY 2014 wage index, we calculated the proposed FY 2014 wage index using the occupational mix survey data from 3,188 hospitals. Using the Worksheet S-3, Parts II and III, cost report data of 3,427 hospitals and occupational mix survey data from 3,188 hospitals represents a 93.0 percent survey response rate. The proposed FY 2014 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
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Occupational Mix Nursing Subcategory	Proposed Average Hourly Wage
National RN	37.432120148
National LPN and Surgical Technician	21.773706724
National Nurse Aide, Orderly, and Attendant	15.327583858
National Medical Assistant	17.213605923
National Nurse Category	31.811167234

The proposed national average hourly wage for the entire nurse category as computed in Step 5 of the occupational mix calculation is \$31.811167234. 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 43.44 percent, and the national percentage of hospital employees in the all other occupations category is 56.56 percent. At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 21.9 percent in one CBSA, to a high of 62.0 percent in another CBSA.

We compared the proposed FY 2014 occupational mix adjusted wage indices for each CBSA to the proposed unadjusted wage indices for each CBSA. As a result of applying the proposed occupational mix adjustment to the wage data, the proposed wage index values for 204 (52.2 percent) urban areas and 32 (66.7 percent) rural areas would

increase. One hundred and eighteen (30.2 percent) urban areas would increase by 1 percent or more, and 4 (1.02 percent) urban areas would increase by 5 percent or more. Thirteen (27.1 percent) rural areas would increase by 1 percent or more, and no rural areas would increase by 5 percent or more. However, the proposed wage index values for 186 (47.6 percent) urban areas and 16 (33.3 percent) rural areas would decrease. Seventy-nine (20.2 percent) urban areas would decrease by 1 percent or more, and 1 urban area would decrease by 5 percent or more (0.26 percent). Seven (14.6 percent) rural areas would decrease by 1 percent or more, and no rural areas would decrease by 5 percent or more. The largest positive impacts are 6.61 percent for an urban area and 2.66 percent for a rural area. The largest negative impacts are 5.28 percent for an urban area and 3.17 percent for a rural area. One urban area's wage index, but no rural area wage indices, would remain unchanged by application of the proposed occupational mix adjustment. These results indicate that a larger percentage of rural areas (66.7 percent) would benefit from the proposed occupational mix adjustment than would urban areas (52.2 percent). However, approximately one-third (33.3 percent) of rural CBSAs would still experience a decrease in their proposed wage indices as a result of the proposed occupational mix adjustment.

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

a. Proposed Rural Floor

Section 4410(a) of Pub. L. 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 Pub. L. 111-148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor. In the proposed FY 2014 wage index associated with this proposed rule and available on the CMS Web site, we estimated that 434 hospitals would receive an increase in their FY 2014 proposed wage index due to the application of the rural floor.

b. Proposed Imputed Floor

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 three times, the last of which was adopted in the FY 2013 IPPS/LTCH PPS final rule and is set to expire on September 30, 2014 (we refer readers to the discussion in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53368 through 53369) and to our regulations at 42 CFR 412.64(h)(4)). There are currently two all-urban States, New Jersey and Rhode Island, that have a range of wage indices assigned to hospitals in the State, including through reclassification or redesignation (we refer readers to discussions of geographic reclassifications and redesignations in section III.H. of this preamble). However, as we explain below, the method as of FY 2012 for computing the imputed floor, which we will refer to as 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 (that is, New Jersey and Rhode Island) as well as the average of the ratios of lowest-to-highest CBSA wage indices of those all-urban States. We compared the State's own ratio to the average ratio for all-urban States and whichever is higher was multiplied by the highest CBSA wage index value in the State--the product of which established the imputed floor for the State. Rhode Island has only one CBSA (Providence-New Bedford-Fall River, RI-MA); therefore, Rhode Island's own ratio equals 1.0, and its imputed floor was equal to its original CBSA wage index value. Conversely, New Jersey has 10 CBSAs. Because the average ratio of New Jersey and Rhode Island was higher than New Jersey's own ratio, the original 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), for the FY 2013 wage index, the final year of the extension of the imputed floor policy under § 412.64(h)(4), we did not make any changes to the original methodology and we finalized a proposed alternative, temporary methodology for computing the imputed floor wage index to address the concern that the then-current imputed floor methodology guaranteed a benefit for one all-urban State with multiple wage indices but could not benefit the other. The alternative methodology for calculating the imputed floor was established using data from the application of the rural floor policy for FY 2013. 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 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 would then be increased by this factor, the result of which established the State's alternative imputed floor. We refer to this methodology as the alternative methodology. We also adopted a policy that, for discharges on or after October 1, 2012, and before October 1, 2013, the minimum wage index value for the State is the higher of the value determined under the original methodology or the value computed using the alternative methodology. We amended § 412.64(h)(4) of the regulations to add new paragraph (vi) to incorporate the finalized alternative methodology policies, and to make conforming references in paragraph (v).

We stated that we intended to further evaluate the need, applicability, and methodology for the imputed floor before the September 30, 2013 expiration of the imputed floor policy and address these issues in the FY 2014 proposed rule. For FY 2014, we are proposing to extend the imputed floor policy (both the original methodology and the alternative methodology) for one additional year, through September 30, 2014, while we continue to explore potential wage index reforms. We are proposing to revise the regulations at § 412.64(h)(4) to reflect the proposed 1-year extension. We are inviting public comments regarding the 1-year extension of the imputed floor.

The wage index and impact tables associated with this FY 2014 proposed rule that are available on the CMS Web site include the application of the proposed imputed floor policy at § 412.64(h)(4) and a proposed national budget neutrality adjustment for the proposed rural floor (which includes the proposed imputed floor). There are 35 hospitals in New Jersey that would receive an increase in their FY 2014 wage index due to the imputed floor policy. The proposed wage index and impact tables for this proposed rule also reflect the application of the alternative methodology for computing the imputed floor, which will benefit four hospitals in Rhode Island.

c. Proposed Frontier Floor

Section 10324 of Pub. L. 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). Forty-six hospitals would receive the frontier floor value of 1.0000 for their proposed FY 2014 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 2014 rural floor value of 1.1503 is greater than 1.0000, and therefore no Nevada hospitals would receive a frontier floor value for their proposed FY 2014 wage index.

The areas affected by the proposed rural, imputed, and frontier floor policies for the proposed FY 2014 wage index are identified in Table 4D associated with this proposed rule and available on the CMS Web site.

3. Proposed FY 2014 Wage Index Tables

The proposed wage index values for FY 2014 (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.

Tables 3A and 3B, available on the CMS Web site, list the 3-year average hourly wage for each labor market area before the redesignation or reclassification of hospitals based on FYs 2008, 2009, and 2010 cost reporting periods. Table 3A lists these data for urban areas, and Table 3B lists these data for rural areas. In addition, Table 2, which is available on the CMS Web site, includes the adjusted average hourly wage for each hospital from the FY 2008 and FY 2009 cost reporting periods, as well as the FY 2010 period used to calculate the proposed FY 2014 wage index. The 3-year averages are calculated by dividing the sum of the dollars (adjusted to a common reporting period using the method described previously) across all 3 years, by the sum of the hours. If a hospital is missing data for any of the previous years, its average hourly wage for the 3-year period is calculated based on the data available during that period. The proposed average hourly wages in Tables 2, 3A, and 3B, which are available on the CMS Web site, include the proposed occupational mix adjustment. The proposed wage index values in Tables 4A, 4B, 4C, and 4D also include the proposed national rural 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.

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 2014, and the policies for the effects of hospitals' reclassifications and redesignations on the wage index, are the same as those discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596). Also, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under 42 CFR 412.103. Hospitals

that are geographically located in States without any rural areas are ineligible to apply for rural reclassification pursuant to 42 CFR 412.103.

2. FY 2014 MGCRB Reclassifications

a. FY 2014 Reclassification Requirements and Approvals

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

At the time this proposed rule was developed, the MGCRB had completed its review of FY 2014 reclassification requests. Based on such reviews, there were 332 hospitals approved for wage index reclassifications by the MGCRB for FY 2014. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2014, hospitals reclassified during FY 2012 or FY 2013 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications. There were 249 hospitals approved for wage index reclassifications in FY 2012, and 192 hospitals approved for wage index reclassifications in FY 2013. Of all the hospitals approved for reclassification for FY 2012, FY 2013, and FY 2014, based upon the review at the time of this proposed rule, 773 hospitals are in a reclassification status for FY 2014.

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 2014 will be incorporated into the wage index values published in the FY 2014 IPPS/LTCH PPS final rule. These changes affect not only the wage index value for specific geographic areas, but also the wage index value redesignated/reclassified hospitals receive; that is, whether they receive the wage index that includes the data for both the hospitals already in the area and the redesignated/reclassified hospitals. Further, the wage index value for the area from which the hospitals are redesignated/reclassified may be affected.

b. Applications for Reclassifications for FY 2015

Applications for FY 2015 reclassifications are due to the MGCRB by September 3, 2013 (the first working day of September 2013). 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 mentioned in section III.B. of the preamble of this proposed rule, although OMB has issued revisions on February 28, 2013 to its area delineations, we are not proposing to adopt those revisions for the FY 2014 wage index, and we will not be adopting the revisions before the September 3, 2013 deadline for

applications for the FY 2015 wage index. Therefore, hospitals must apply for reclassifications based on the delineations we are using for FY 2014. Applications and other information about MGCRB reclassifications may be obtained, beginning in mid-July 2013, via the Internet on the CMS Web site at:

[http://www.cms.gov/Regulations-and-Guidance/Review-](http://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/index.html?redirect=/MGCRB/02_instructions_and_applications.asp)

[Boards/MGCRB/index.html?redirect=/MGCRB/02_instructions_and_applications.asp](http://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/index.html?redirect=/MGCRB/02_instructions_and_applications.asp), or by calling the MGCRB at (410) 786-1174. The mailing address of the MGCRB is: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244-2670.

3. Redesignations of Hospitals under Section 1886(d)(8)(B) of the Act

Section 1886(d)(8)(B) of the Act requires us to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the MSA if certain criteria are met. Effective beginning FY 2005, we use OMB's 2000 CBSA standards and the Census 2000 data to identify counties in which hospitals qualify under section 1886(d)(8)(B) of the Act to receive the wage index of the urban area. (We note that, as mentioned in section III.B. of the preamble of this proposed rule, although OMB has issued revisions on February 28, 2013, to its area delineations based on 2010 census data, we are not proposing to adopt these revisions for the FY 2014 wage index.) Hospitals located in these counties have been known as "Lugar" hospitals and the counties themselves are often referred to as "Lugar" counties. The FY 2014 chart with the listing of the rural counties containing the hospitals designated as urban under section 1886(d)(8)(B) of the Act is available via the Internet on the CMS Web site.

4. 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 2014 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.)

5. 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 V.E. 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 the requisite number of days from the publication of the proposed rule²⁴) to automatically waive its urban status for the 3-year period for which its out-migration adjustment is effective. That is, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the adjustment. Thus, under the procedural change, a Lugar hospital that requests to waive its urban status in order to receive the rural wage index in addition to the out-migration adjustment would be deemed to have accepted the out-migration adjustment and agrees to be treated as rural for the duration of its 3-year eligibility period, unless, prior to its second or third year of eligibility, the hospital explicitly notifies CMS in writing, within the required period (generally 45 days from the publication of the proposed rule), that it instead elects to return to its deemed urban status and no longer wishes to accept the out-migration adjustment.

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

²⁴ Hospitals generally have 45 days from publication of the proposed rule to request an out-migration adjustment in lieu of the section 1886(d)(8) deemed urban status.

I. Proposed FY 2014 Wage Index Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with the broad discretion granted to the Secretary under section 1886(d)(13) of the Act, as added by section 505 of Pub. L. 108-173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the “out-migration” adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index. The proposed FY 2014 out-migration adjustment is based on the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment. (We refer readers to a full discussion of the adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) 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 2014 wage index.

J. Process for Requests for Wage Index Data Corrections

The preliminary, unaudited Worksheet S-3 wage data and occupational mix survey data files for the proposed FY 2014 wage index were made available on October 3, 2012, 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_2014_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 new file does not alter the current wage index process or schedule. We notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and the scheduling of the Hospital Open Door forums at the CMS Web site at: <http://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/index.html>.

In a memorandum dated October 19, 2012, we instructed all fiscal intermediaries/MACs to inform the IPPS hospitals they service of the availability of the wage index data files and the process and timeframe for requesting revisions (including the specific deadlines listed below). We also instructed the fiscal intermediaries/MACs to advise hospitals that these data were also made available directly through their representative hospital organizations.

If a hospital wished to request a change to its data as shown in the October 3, 2012 wage and occupational mix data files, the hospital was to submit corrections along with complete, detailed supporting documentation to its fiscal intermediary/MAC by December 10, 2012. (We note that this date was originally December 3, 2012. However, in a memorandum dated October 25, 2012, we instructed all fiscal intermediaries/MACs to inform the IPPS hospitals they service that we extended the deadline to December 10, 2012.) 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 October 19, 2012 memorandum referenced above.

In the October 19, 2012 memorandum, we also specified that a hospital requesting revisions to its occupational mix survey data was to copy its record(s) from the CY 2010 occupational mix preliminary files posted to the CMS Web site in October, highlight the revised cells on its spreadsheet, and submit its spreadsheet(s) and complete documentation to its fiscal intermediary/MAC no later than December 10, 2012.

The fiscal intermediaries/MACs notified the hospitals by mid-February 2013 of any changes to the wage index data as a result of the desk reviews and the resolution of the hospitals' early-December revision requests. The fiscal intermediaries/MACs also submitted the revised data to CMS by mid-February 2013. CMS published the proposed wage index public use files that included hospitals' revised wage index data on February 21, 2013. Hospitals had until March 4, 2013, to submit requests to the fiscal intermediaries/MACs for reconsideration of adjustments made by the fiscal

intermediaries/MACs as a result of the desk review, and to correct errors due to CMS' or the fiscal intermediary's (or, if applicable, the MAC's) mishandling of the wage index data. Hospitals also were required to submit sufficient documentation to support their requests.

After reviewing requested changes submitted by hospitals, fiscal intermediaries/MACs were required to transmit any additional revisions resulting from the hospitals' reconsideration requests by April 10, 2013. The deadline for a hospital to request CMS intervention in cases where the hospital disagreed with the fiscal intermediary's (or, if applicable, the MAC's) policy interpretations was April 17, 2013.

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_2014_Wage_Index_Home_Page.html.

Table 2 contains each hospital's adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2010 data used to construct the proposed FY 2014 wage index. We note that the hospital average hourly wages shown in Table 2 only reflect changes made to a hospital's data that were transmitted to CMS by March 4, 2013.

We will release the final wage index data public use files in early May 2013 on the Internet at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY_2014_Wage_Index_Home_Page.html. The May 2013 public use files are

made available solely for the limited purpose of identifying any potential errors made by CMS or the fiscal intermediary/MAC in the entry of the final wage index data that resulted from the correction process described above (revisions submitted to CMS by the fiscal intermediaries/MACs by April 10, 2013). If, after reviewing the May 2013 final public use files, a hospital believes that its wage or occupational mix data are incorrect due to a fiscal intermediary/MAC or CMS error in the entry or tabulation of the final data, the hospital should send a letter to both its fiscal intermediary/MAC and CMS that outlines why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). CMS and the fiscal intermediaries (or, if applicable, the MACs) must receive these requests no later than June 3, 2013.

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

After the release of the May 2013 wage index data files, changes to the wage and occupational mix data will only be made in those very limited situations involving an error by the fiscal intermediary/MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the fiscal intermediary/MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by fiscal intermediaries or the MACs on or before April 10, 2013.

- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the February 21, 2013 wage index public use files.
- Requests to revisit factual determinations or policy interpretations made by the fiscal intermediary or the MAC or CMS during the wage index data correction process.

Verified corrections to the wage index data received timely by CMS and the fiscal intermediaries or the MACs (that is, by June 3, 2013) will be incorporated into the final wage index in the FY 2014 IPPS/LTCH PPS final rule, which will be effective October 1, 2013.

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 2014 payment rates. Accordingly, hospitals that do not meet the procedural deadlines set forth above will not be afforded a later opportunity to submit wage index data corrections or to dispute the fiscal intermediary's (or, if applicable, the MAC's) decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines set forth above will not be permitted to challenge later, before the Provider Reimbursement Review Board, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections.

Again, we believe the wage index data correction process described above provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the fiscal intermediary's (or, if applicable, the MAC's)

attention. Moreover, because hospitals have access to the final wage index data by early May 2013, they have the opportunity to detect any data entry or tabulation errors made by the fiscal intermediary or the MAC or CMS before the development and publication of the final FY 2014 wage index by August 2013, and the implementation of the FY 2014 wage index on October 1, 2013. 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 3, 2013, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our existing regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) the fiscal intermediary or the MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, “before the beginning of the fiscal year” means by the June 3 deadline for making corrections to the wage data for the following fiscal year’s wage index. This provision is not available to a hospital seeking to revise another hospital’s data that may be affecting the requesting hospital’s wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS Web site prior to publishing both the proposed and final IPPS rules, and the fiscal intermediaries or the MACs notify hospitals directly of any wage index data changes

after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 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 fiscal intermediary (or, if applicable, the MAC) or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the fiscal intermediary (or, if applicable, the MAC) and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the June 3, 2013 deadline for the FY 2014 wage index); and (3) CMS agreed before October 1 that the fiscal intermediary (or, if applicable, the MAC) or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the June 3, 2013 deadline), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the fiscal intermediary's (or, if applicable, the MAC's) mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or

implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; and it can only be used for the current Federal fiscal year. In 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 judicial decision reverses a CMS denial of a hospital's wage index data revision request.

K. Labor-Related Share for the Proposed FY 2014 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 Pub. L. 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 Pub. L. 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 results in a higher payment.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43850 through 43857), we rebased and revised the IPPS market basket and the labor-related share, using FY 2006 as the base year. The labor-related share for FY 2010 through FY 2013 is 68.8 percent.

For FY 2014, as described in section IV. of the preamble of this proposed rule, we are proposing to rebase and revise the IPPS market basket using FY 2010 as the base year. Using the proposed FY 2010-based IPPS market basket, we also are proposing to recalculate the labor-related share for discharges occurring on or after October 1, 2013. As discussed in Appendix A of this proposed rule, we are proposing this revised and rebased labor-related share in a budget neutral manner. However, consistent with section 1886(d)(3)(E) of the Act, we are not taking 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. As described in section IV. of the preamble of this proposed rule, we are proposing to include in the labor-related share 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 as measured in the proposed IPPS market basket, as based on FY 2010. Therefore, for FY 2014, we are proposing to use a labor-related share of 69.6 percent for discharges occurring on or after October 1, 2013. Tables 1A and 1B, which are published in section VI. of the Addendum to this proposed rule and are available via the Internet, reflect this proposed labor-related share. We note that section 403 of Pub. L. 108-173 amended sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this employment "would result in lower payments to a hospital than would otherwise be made." Therefore, for FY 2014, for all IPPS hospitals whose wage indices are less than 1.0000, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals whose wage indices are greater than 1.0000, for FY 2014, we are proposing to apply the wage index to a 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 2010 IPPS/RV 2010 LTCH PPS final rule (74 FR 43850 through 43856), we also rebased and revised the labor-related share for the Puerto Rico-specific standardized amounts using FY 2006 as a base year. We finalized a labor-related share for the Puerto Rico-specific standardized amounts for FY 2010 through FY 2013 of 62.1 percent. As described in section IV. of the preamble of this proposed rule, for FY 2014, we also are proposing to rebase and revise the labor-related share for the Puerto Rico-specific standardized amounts using FY 2010 as a base year. For FY 2014, we are proposing a labor-related share for the Puerto Rico-specific standardized amounts of 63.2 percent for discharges occurring on or after October 1, 2013. Consistent with our methodology for determining the national labor-related share, we added the Puerto Rico-specific relative weights for wages and salaries, employee benefits, contract labor, with the national proportion of costs for the labor-related portion of professional fees, administrative and facilities support services, and all other labor-related services to determine the labor-related share. Puerto Rico hospitals are paid based on 75 percent of the national standardized amounts and 25 percent of the Puerto Rico-specific standardized amounts. For FY 2014, we are proposing that the labor-related share of a hospital's Puerto Rico-specific rate will 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 2014, we will 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 will result in higher payments. Conversely, a

hospital with a Puerto Rico-specific wage index of less than 1.0 for FY 2014 will be paid using the Puerto Rico-specific labor-related share of 62 percent of the Puerto Rico-specific rates because the lower labor-related share will result in higher payments. The proposed Puerto Rico labor-related share of 63.2 percent for FY 2014 is reflected in Table 1C, which is published in section VI. of the Addendum to this proposed rule and available via the Internet.

IV. Proposed Rebasing and Revision of the Hospital Market Baskets for Acute Care Hospitals

A. Background

Effective for cost reporting periods beginning on or after July 1, 1979, we developed and adopted a hospital input price index (that is, the hospital market basket for operating costs). Although “market basket” technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term “market basket” as used in this document refers to the hospital input price index.

The percentage change in the market basket reflects the average change in the price of goods and services hospitals purchase in order to provide inpatient care. We first used the market basket to adjust hospital cost limits by an amount that reflected the average increase in the prices of the goods and services used to provide hospital inpatient care. This approach linked the increase in the cost limits to the efficient utilization of resources.

Since the inception of the IPPS, the projected change in the hospital market basket has been the integral component of the update factor by which the prospective payment rates are updated every year. An explanation of the hospital market basket used to develop the prospective payment rates was published in the **Federal Register** on September 1, 1983 (48 FR 39764). We also refer readers to the FY 2010 IPPS/RV 2010

LTCH PPS final rule (74 FR 43843) in which we discussed the most recent previous rebasing of the hospital input price index.

The hospital market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

The index itself is constructed in three steps. First, a base period is selected (in this proposed rule, we are proposing to use FY 2010 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called “cost weights” or “expenditure weights.” Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a “price proxy.” In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to provide hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a hospital hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the hospital, but would not be factored into the price change measured by a fixed-weight hospital market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights.

Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care between base periods. We last rebased the hospital market basket cost weights effective for FY 2010 (74 FR 43843), with FY 2006 data used as the base period for the construction of the market basket cost weights.

B. Rebasing and Revising the IPPS Market Basket

The terms “rebasing” and “revising,” while often used interchangeably, actually denote different activities. “Rebasing” means moving the base year for the structure of costs of an input price index (for example, in this proposed rule, we are proposing to shift the base year cost structure for the IPPS hospital index from FY 2006 to FY 2010).

“Revising” means changing data sources, or price proxies, used in the input price index.

As published in the FY 2006 IPPS final rule (70 FR 47387), in accordance with section 404 of Pub. L. 108-173, CMS determined a new frequency for rebasing the hospital

market basket. We established a rebasing frequency of every 4 years and, therefore, for the FY 2014 IPPS update, we are proposing to rebase and revise the IPPS market basket. We are inviting public comments on our proposed methodology discussed below.

1. Development of Cost Categories and Weights

a. Medicare Cost Reports

The major source of expenditure data for developing the rebased and revised hospital market basket cost weights is the FY 2010 Medicare cost reports. These FY 2010 Medicare cost reports are for cost reporting periods beginning on and after October 1, 2009 and before October 1, 2010. We are proposing to use FY 2010 as the base year because we believe that the FY 2010 Medicare cost reports represent the most recent, complete set of Medicare cost report data available for IPPS hospitals. As was done in previous rebasings, these cost reports are from IPPS hospitals only (hospitals excluded from the IPPS and CAHs are not included) and are based on IPPS Medicare-allowable operating costs. IPPS Medicare-allowable operating costs are costs that are eligible to be paid for under the IPPS. For example, the IPPS market basket excludes home health agency (HHA) costs as these costs would be paid under the HHA PPS and, therefore, these costs are not IPPS Medicare-allowable costs.

We are proposing to obtain seven major expenditures or cost categories for the FY 2010 IPPS market basket from the Medicare cost reports--the same as in the FY 2006-based hospital market basket: wages and salaries, employee benefits, contract labor, pharmaceuticals, professional liability insurance (malpractice), blood and blood products, and a residual "all other." The proposed cost weights that were obtained

directly from the Medicare cost reports are reported in Table IV01. We are proposing to then supplement these Medicare cost report cost weights with information obtained from other data sources to derive the proposed IPPS market basket cost weights.

Table IV01.--Major Cost Categories and Their Respective Cost Weights As Calculated Directly from the Medicare Cost Reports

Major Cost Categories	FY 2006-Based Market Basket	Proposed FY 2010-Based Market Basket
Wages and salaries	45.156	45.819
Employee benefits	11.873	12.713
Contract labor	2.598	1.806
Professional Liability Insurance (Malpractice)	1.661	1.330
Pharmaceuticals	5.380	5.402
Blood and blood products	1.078	1.069
All other	32.254	31.861

From FY 2006 to FY 2010, the wages and salaries and employee benefits cost weights as calculated directly from the Medicare cost reports increased by approximately 0.7 and 0.8 percentage point, respectively, while the contract labor cost weight decreased by 0.8 percentage point. As we did for the FY 2006-based IPPS market basket (74 FR 43847), we are proposing to allocate contract labor costs to the wages and salaries and employee benefits cost weights based on their relative proportions for employed labor under the assumption that contract labor costs are comprised of both wages and salaries and employee benefits. The contract labor allocation proportion for wages and salaries is equal to the wages and salaries cost weight as a percent of the sum of the wages and salaries cost weight and the employee benefits cost weight. Using the FY 2010 Medicare cost report data, this percentage is 78.3 percent; therefore, we are proposing to allocate approximately 78.3 percent of the contract labor cost weight to the

wages and salaries cost weight. Table IV02 shows the wages and salaries and employee benefit cost weights after contract labor allocation for both the FY 2006-based IPPS market basket and the proposed FY 2010-based IPPS market basket.

Table IV02.--Wages and Salaries and Employee Benefits Cost Weights After Contract Labor Allocation

Major Cost Categories	FY 2006-Based Market Basket	Proposed FY 2010-Based Market Basket
Wages and salaries	47.213	47.233
Employee benefits	12.414	13.105

After the allocation of contract labor, the proposed FY 2010-based wages and salaries cost weight is relatively similar to the FY 2006-based wages and salaries cost weight while the proposed FY 2010-based employee benefits cost weight increased 0.7 percentage point. This is primarily a result of an increase in benefits costs relative to wages and salaries costs from the Medicare cost report data for employed workers; in 2006, the ratio of the employee benefits cost weight to the wages and salaries cost weight was 26.3 percent while in 2010, this ratio increased to 27.8 percent.

b. Other Data Sources

In addition to the data from the Medicare cost reports, the other data source we are proposing to use to develop the FY 2010-based IPPS market basket cost weights is the 2002 Benchmark Input-Output (I-O) Tables created by the Bureau of Economic Analysis (BEA), U.S. Department of Commerce. We are proposing to use the 2002 BEA Benchmark I-O data to disaggregate the “all other” (residual) cost category (31.861 percent) into more detailed hospital expenditure category shares. The BEA

Benchmark I–O accounts provide the most detailed information on the goods and services purchased by an industry, which allows for a more detailed disaggregation of expenses in the market basket for which we can then proxy the appropriate price inflation.

The BEA Benchmark I-O data are generally scheduled for publication every 5 years. The most recent data available are for 2002. BEA also produces Annual I-O estimates; however, the 2002 Benchmark I-O data represent a much more comprehensive and detailed set of data that are derived from the 2002 Economic Census. In the FY 2010 IPPS/RV 2010 LTCH PPS final rule (74 FR 43845), we used the 2002 Benchmark I-O data (aged to FY 2006) for the FY 2006-based IPPS market basket, to be effective for FY 2010. Because BEA has not yet released new Benchmark I–O data, and we believe the data to be comprehensive and complete as indicated above, we are currently proposing to use the 2002 Benchmark I–O data in the FY 2010-based IPPS market basket.

Therefore, instead of using the less detailed, less accurate Annual I-O data, we are proposing to age the 2002 Benchmark I-O data forward to FY 2010. The methodology we are proposing to use to age the data forward involves applying the annual price changes from the respective price proxies to the appropriate cost categories. We repeat this practice for each year. We also are proposing that, if more recent BEA benchmark I-O data for 2007 is released between the proposed and final rule with sufficient time to incorporate such data into the final rule, we would incorporate these data into the FY

2010-based IPPS market basket for the final rule. The 2007 BEA I-O data is expected to be released in the summer of 2013.

The “all other” cost category expenditure shares are determined as being equal to each category’s proportion to total “all other” expenditures based on the aged 2002 Benchmark I–O data. For instance, if the cost for telephone services represented 10 percent of the sum of the “all other” Benchmark I–O hospital expenditures, telephone services would represent 10 percent of the “all other” cost category of the proposed IPPS market basket.

Following publication of the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, and in an effort to provide greater transparency, we posted on the CMS market basket Web page at: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html> an illustrative spreadsheet that shows how the detailed cost weights in the proposed rule (that is, those not calculated using Medicare cost reports) were determined using the 2002 Benchmark I-O data. As stated above, we are proposing to use the 2007 Benchmark BEA I-O data if available before the final rule with sufficient time to incorporate such data into the final rule. We would use the same methodology as described above in determining the detailed weights in the “all other” cost weight.

2. Cost Category Computation

As stated previously, for the proposed FY 2010-based market basket we are proposing to use data from the Medicare cost reports to derive seven major cost categories. We are proposing the same detailed cost categories as the FY 2006-based

IPPS market basket. Also, we are not proposing to change our definition of the labor-related share. As discussed in more detail below and similar to the previous rebasing, we classify a cost category as labor-related and include it in the labor-related share if the cost category is defined as being labor-intensive and its cost varies with the local labor market.

3. Selection of Price Proxies

After computing the FY 2010 cost weights for the proposed IPPS market basket, it was necessary to select appropriate wage and price proxies to reflect the rate of price change for each expenditure category. We are proposing to use the same price proxies that were used in the FY 2006-based IPPS market basket. A discussion of our rationale for selecting these price proxies can be found in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43845).

With the exception of the proxy for professional liability insurance (PLI), all the proxies we are proposing are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

- **Producer Price Indexes--Producer Price Indexes (PPIs)** measure price changes for goods sold in markets other than the retail market. PPIs are preferable price proxies for goods and services that hospitals purchase as inputs because PPIs better reflect the actual price changes encountered by hospitals. For example, we are proposing to use a PPI for prescription drugs, rather than the Consumer Price Index (CPI) for prescription drugs, because hospitals generally purchase drugs directly from a wholesaler. The PPIs that we are proposing to use measure price changes at the final stage of production.

- Consumer Price Indexes--Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by the typical consumer. Because they may not represent the price faced by a producer, we are proposing to use CPIs only if an appropriate PPI is not available, or if the expenditures are more like those faced by retail consumers in general rather than by purchasers of goods at the wholesale level. For example, the CPI for food purchased away from home is proposed to be used as a proxy for contracted food services.

- Employment Cost Indexes--Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. Appropriately, they are not affected by shifts in employment mix.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. Availability means that the proxy is publicly available. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. We believe the proposed PPIs, CPIs, and ECIs selected meet these criteria.

Table IV03 below sets forth the proposed FY 2010-based IPPS market basket, including the cost categories and their respective weights and price proxies. For

comparison purposes, the corresponding FY 2006-based IPPS market basket cost weights also are listed. A summary outlining the choice of the various proxies follows the table.

Table IV03.—Proposed FY 2010-Based IPPS Hospital Market Basket Cost Categories, Cost Weights, and Price Proxies Compared to FY 2006-Based IPPS Market Basket Cost Weights

Cost Categories	FY 2006-Based Hospital Market Basket Cost Weights	Proposed FY 2010-Based Hospital Market Basket Cost Weights	Proposed FY 2010-Based Hospital Market Basket Price Proxies
1. Compensation	59.627	60.338	--
A. Wages and Salaries ¹	47.213	47.233	ECI for Wages and Salaries, Civilian Hospital Workers
B. Employee Benefits ¹	12.414	13.105	ECI for Benefits, Civilian Hospital Workers
2. Utilities	2.180	2.246	--
A. Fuel, Oil, and Gasoline	0.418	0.447	PPI for Petroleum Refineries
B. Electricity	1.645	1.666	PPI for Commercial Electric Power
C. Water and Sewage	0.117	0.133	CPI-U for Water & Sewerage Maintenance
3. Professional Liability Insurance	1.661	1.330	CMS Professional Liability Insurance Premium Index
4. All Other	36.533	36.086	--
A. All Other Products	19.473	19.458	--
(1.) Pharmaceuticals	5.380	5.402	PPI for Pharmaceuticals for Human Use, Prescription
(2.) Food: Direct Purchases	3.982	4.206	PPI for Processed Foods & Feeds

Cost Categories	FY 2006-Based Hospital Market Basket Cost Weights	Proposed FY 2010-Based Hospital Market Basket Cost Weights	Proposed FY 2010-Based Hospital Market Basket Price Proxies
(3.) Food: Contract Services	0.575	0.578	CPI-U for Food Away From Home
(4.) Chemicals ²	1.538	1.529	Blend of Chemical PPIs
(5.) Blood and Blood Products	1.078	1.069	PPI for Blood and Organ Banks
(6.) Medical Instruments	2.762	2.577	PPI for Medical, Surgical, and Personal Aid Devices
(7.) Rubber and Plastics	1.659	1.637	PPI for Rubber & Plastic Products
(8.) Paper and Printing Products	1.492	1.507	PPI for Converted Paper & Paperboard Products
(9.) Apparel	0.325	0.299	PPI for Apparel
(10.) Machinery and Equipment	0.163	0.151	PPI for Machinery & Equipment
(11.) Miscellaneous Products	0.519	0.503	PPI for Finished Goods less Food and Energy
B. Labor-related Services	9.175	9.249	--
(1.) Professional Fees: Labor-related	5.356	5.500	ECI for Compensation for Professional and Related Occupations
(2.) Administrative and Support Services ³	0.626	0.619	ECI for Compensation for Office and Administrative Services
(3.) All Other: Labor-Related Services	3.193	3.130	ECI for Compensation for Private Service Occupations

Cost Categories	FY 2006-Based Hospital Market Basket Cost Weights	Proposed FY 2010-Based Hospital Market Basket Cost Weights	Proposed FY 2010-Based Hospital Market Basket Price Proxies
C. Nonlabor-Related Services	7.885	7.379	--
(1.) Professional Fees: Nonlabor-Related	4.074	3.687	ECI for Compensation for Professional and Related Occupations
(2.) Financial Services	1.281	1.239	ECI for Compensation for Financial Activities
(3.) Telephone Services	0.627	0.597	CPI-U for Telephone Services
(4.) Postage	0.963	0.956	CPI-U for Postage
(5.) All Other: Nonlabor-Related Services	0.940	0.900	CPI-U for All Items less Food and Energy
Total	100.000	100.000	--

Note: Detail may not add to total due to rounding.

¹Contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents.

²To proxy the “chemicals” cost category, we used a blended PPI composed of the PPI for industrial gas manufacturing, the PPI for other basic inorganic chemical manufacturing, the PPI for other basic organic chemical manufacturing, and the PPI for soap and cleaning compound manufacturing. For more detail about this proxy, see the FY 2010 IPPS/R Y 2010 LTCH PPS final rule (74 FR 43845).

³We note that this cost category in the FY 2006-based IPPS market basket was “Administrative and Business Support Services.” We changed the name slightly to be more clear what type of costs are included in this cost category, but we did not change the classification of which costs are included in the category.

As stated above, we are proposing to use the same price proxies used in the FY 2006-based IPPS market basket. A rationale for selecting these price proxies can be found in the FY 2010 IPPS/R Y 2010 LTCH PPS final rule (74 FR 43845). The price proxies we are proposing were selected to most closely match the costs included in each of the cost categories of the proposed FY 2010-based IPPS market basket. As discussed

above, we are proposing that, if the 2007 Benchmark I-O data become available between the proposed and final rule with sufficient time to incorporate such data into the final rule, we would incorporate this data into the FY 2010-based IPPS market basket for the final rule. As a result, to the extent the incorporation of the 2007 Benchmark I-O data results in a different composition of costs included in a particular cost category, we are proposing that we may choose to revise that specific price proxy to ensure that the costs included in each detailed cost category are best aligned with the associated price proxy. Below is a list of the price proxies we are proposing for the FY 2010-based IPPS market basket.

a. Wages and Salaries

We are proposing to use the ECI for Wages and Salaries for Hospital Workers (All Civilian) (BLS series code CIU1026220000000I) to measure the price growth of this cost category.

b. Employee Benefits

We are proposing to use the ECI for Employee Benefits for Hospital Workers (All Civilian) to measure the price growth of this cost category.

c. Fuel, Oil, and Gasoline

We are proposing to use the PPI for Petroleum Refineries (BLS series code PCU324110324110) to measure the price growth of this cost category.

d. Electricity

We are proposing to use the PPI for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category.

e. Water and Sewage

We are proposing to use the CPI for Water and Sewerage Maintenance (All Urban Consumers) (BLS series code CUUR0000SEHG01) to measure the price growth of this cost category.

f. Professional Liability Insurance

We are proposing to proxy price changes in hospital professional liability insurance premiums (PLI) using percentage changes as estimated by the CMS Hospital Professional Liability Insurance Premium Index. To generate these estimates, we collect commercial insurance premiums for a fixed level of coverage while holding nonprice factors constant (such as a change in the level of coverage). This method is also used to proxy PLI price changes in the Medicare Economic Index (75 FR 73268).

g. Pharmaceuticals

We are proposing to use the PPI for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This is the same proxy that was used in the FY 2006-based IPPS market basket, although BLS since changed the naming convention for this series.

h. Food: Direct Purchases

We are proposing to use the PPI for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category.

i. Food: Contract Services

We are proposing to use the CPI for Food Away From Home (All Urban Consumers) (BLS series code CUUR0000SEFV) to measure the price growth of this cost category.

j. Chemicals

We are proposing to use a blended PPI composed of the PPI for Industrial Gas Manufacturing (NAICS 325120) (BLS series code PCU325120325120P), the PPI for Other Basic Inorganic Chemical Manufacturing (NAICS 325180) (BLS series code PCU32518–32518–), the PPI for Other Basic Organic Chemical Manufacturing (NAICS 325190) (BLS series code PCU32519–32519), and the PPI for Soap and Cleaning Compound Manufacturing (NAICS 325610) (BLS series code PCU32561–32561–).

k. Blood and Blood Products

We are proposing to use the PPI for Blood and Organ Banks (BLS series code PCU621991621991) to measure the price growth of this cost category.

l. Medical Instruments

We are proposing to use the PPI for Medical, Surgical, and Personal Aid Devices (BLS series code WPU156) to measure the price growth of this cost category.

m. Rubber and Plastics

We are proposing to use the PPI for Rubber and Plastic Products (BLS series code WPU07) to measure price growth of this cost category.

n. Paper and Printing Products

We are proposing to use the PPI for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category.

o. Apparel

We are proposing to use the PPI for Apparel (BLS series code WPU0381) to measure the price growth of this cost category.

p. Machinery and Equipment

We are proposing to use the PPI for Machinery and Equipment (BLS series code WPU11) to measure the price growth of this cost category.

q. Miscellaneous Products

We are proposing to use the PPI for Finished Goods Less Food and Energy (BLS series code WPUSOP3500) to measure the price growth of this cost category.

r. Professional Fees: Labor-Related and Professional Fees: Nonlabor-Related

We are proposing to use the ECI for Compensation for Professional and Related Occupations (Private Industry) (BLS series code CIU2010000120000I) to measure the price growth of these cost categories.

s. Administrative and Facilities Support Services

We are proposing to use the ECI for Compensation for Office and Administrative Support Services (Private Industry) (BLS series code CIU2010000220000I) to measure the price growth of this category.

t. All Other: Labor-Related Services

We are proposing to use the ECI for Compensation for Service Occupations (Private Industry) (BLS series code CIU2010000300000I) to measure the price growth of this cost category.

u. Financial Services

We are proposing to use the ECI for Compensation for Financial Activities (Private Industry) (BLS series code CIU201520A000000I) to measure the price growth of this cost category.

v. Telephone Services

We are proposing to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category.

w. Postage

We are proposing to use the CPI for Postage (BLS series code CUUR0000SEEC01) to measure the price growth of this cost category.

x. All Other: Nonlabor-Related Services

We are proposing to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category.

Table IV04 compares both the historical and forecasted percent changes in the FY 2006-based IPPS market basket and the proposed FY 2010-based IPPS market basket.

Table IV04.--FY 2006-Based and Proposed FY 2010-Based Prospective Payment Hospital Operating Index Percent Change, FY 2008 through FY 2016

Fiscal Year (FY)	FY 2006-Based IPPS Market Basket Operating Index Percent Change	Proposed FY 2010-Based IPPS Market Basket Operating Index Percent Change
Historical data:		
FY 2008	4.0	4.0
FY 2009	2.6	2.6
FY 2010	2.1	2.1
FY 2011	2.7	2.7
FY 2012	2.2	2.2
Average FYs 2008-2012	2.7	2.7
Forecast:		
FY 2013	2.2	2.2
FY 2014	2.5	2.5
FY 2015	2.7	2.7
FY 2016	3.0	3.0
Average FYs 2013-2016	2.6	2.6

Source: IHS Global Insight, Inc., 1st Quarter 2013.

The differences between the FY 2006-based and the proposed FY 2010-based IPPS market basket increases are minimal. While the percent changes differ slightly, when rounded to the nearest tenth, the updates based on the FY 2006-based and the proposed FY 2010-based IPPS market baskets are the same.

4. Labor-Related Share

Under section 1886(d)(3)(E) of the Act, the Secretary estimates from time to time the proportion of payments 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 proportion of hospitals’ costs that are attributable to wages and wage-related costs as the “labor-related share.”

The labor-related share is used to determine the proportion of the national PPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are *labor intensive* and *vary with the local labor market*. Because of this approach, we are proposing to include in the labor-related share 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, as we did in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43850). Consistent with previous rebasings, the "all other: labor-related services" cost category is mostly comprised of building maintenance and security services (including, but not limited to, commercial and industrial machinery and equipment repair, nonresidential maintenance and repair, and investigation and security services). Because these services tend to be labor-intensive and are mostly performed at the hospital facility (and, therefore, unlikely to be purchased in the national market), we believe that they meet our definition of labor-related services.

Similar to the FY 2006-based IPPS market basket, we are proposing that the professional fees: labor-related cost category includes expenses associated with advertising and a proportion of legal services, accounting and auditing, engineering, management consulting, and management of companies and enterprises expenses. As

was done in the FY 2006-based IPPS market basket rebasing, we are proposing to determine the proportion of legal, accounting and auditing, engineering, and management consulting services that meet our definition of labor-related services based on a survey of hospitals conducted by CMS in 2008. We notified the public of our intent to conduct this survey on December 9, 2005 (70 FR 73250) and received no comments (71 FR 8588).

With approval from the OMB, we contacted the industry and received responses to our survey from 108 hospitals. Using data on FTEs to allocate responding hospitals across strata (region of the country and urban/rural status), we calculated poststratification weights. A more thorough discussion of the composition of the survey and poststratification can be found in the FY 2010 IPPS/RV 2010 LTCH PPS final rule (74 FR 43850 through 43856). Based on the weighted results of the survey, we determined that hospitals purchase, on average, the following portions of contracted professional services outside of their local labor market:

- 34 percent of accounting and auditing services;
- 30 percent of engineering services;
- 33 percent of legal services; and
- 42 percent of management consulting services.

We are proposing to apply each of these percentages to its respective Benchmark I-O cost category underlying the professional fees cost category. This is the methodology that we used to separate the FY 2006-based IPPS market basket professional fees category into professional fees: labor-related and professional fees: nonlabor-related cost categories. We are proposing to use the same methodology and survey results to

separate the FY 2010-based IPPS market basket professional fees category into professional fees: labor-related and professional fees: nonlabor-related cost categories. We believe these survey results are appropriate to use for the FY 2010-based IPPS market basket rebasing as they empirically determine the proportion of contracted professional services purchased by the industry that is attributable to local firms and the proportion that is purchased from national firms.

In the proposed FY 2010-based IPPS market basket, nonmedical professional fees that were subject to allocation based on the survey results represent 2.059 percent of total costs (and are limited to those fees related to Accounting & Auditing, Legal, Engineering, and Management Consulting services). Based on our survey results, we are apportioning 1.301 percentage points of the 2.059 percentage point figure into the labor-related share and designating the remaining 0.758 percentage point as nonlabor-related.

In addition to the professional services listed above, we also classify a proportion of the expenses under NAICS 55, Management of Companies and Enterprises, into the professional fees: labor-related cost category as was done in the previous rebasing. The NAICS 55 data are mostly comprised of corporate, subsidiary, and regional managing offices, or otherwise referred to as home offices. As was done for the FY 2006-based IPPS market basket we are proposing to include only a portion of the home office costs in the labor related share as not all hospitals are located in the same geographic area as their home office.

Our proposed methodology is based on data from the Medicare cost reports, as well as a CMS database of Home Office Medicare Records (HOMER) (a database that

provides city and State information (addresses) for home offices). The Medicare cost report requires hospitals to report their home office provider numbers and locations. Using the data reported on the Medicare Cost Report as well as the HOMER database to determine the home office location for each home office provider number, we compared the location of the hospital with the location of the hospital's home office. We determined the proportion of costs that should be allocated to the labor-related share based on the percent of total hospital home office compensation costs for those hospitals that had home offices located in their respective local labor markets--defined as being in the same Metropolitan Statistical Area (MSA). We primarily determined a hospital's and home office's MSAs using their zip code information from the Medicare cost report. For any home offices for which we could not identify a MSA from the Medicare cost report, we used the Medicare HOMER database to identify the home office's city and State.

We are proposing to determine the proportion of costs that should be allocated to the labor-related share based on the percent of hospital home office compensation as reported in Worksheet S-3, part II. Using this proposed methodology, we determined that 62 percent of hospitals' home office compensation costs were for home offices located in their respective local labor markets, and therefore, we are proposing to allocate 62 percent of NAICS 55 expenses to the labor-related share.

In the proposed FY 2010-based IPPS market basket, NAICS 55 expenses that were subject to allocation based on the home office allocation methodology represent 5.650 percent of the total operating costs. Based on the home office results, we are apportioning 3.503 percentage points of the 5.650 percentage points figure into the labor-

related share and designating the remaining 2.147 percentage points as nonlabor-related. In sum, based on the two proposed allocations mentioned above, we are proposing to apportion 4.804 percentage points into the labor-related share. This amount is added to the 0.696 percentage point of professional fees that we already identified as labor-related, resulting in a proposed professional fees: labor-related cost weight of 5.500 percent.

Below is a table comparing the proposed FY 2010-based labor-related share and the FY 2006-based labor-related share. As discussed in section IV.B.3. of the preamble of this proposed rule, the wages and salaries and employee benefits cost weight reflect contract labor costs.

Table IV05.--Comparison of the Proposed FY 2010-Based Labor-Related Share and the FY 2006-Based Labor-Related Share

	FY 2006-Based Market Basket Cost Weights	Proposed FY 2010-Based Market Basket Cost Weights
Wages and Salaries	47.213	47.233
Employee Benefits	12.414	13.105
Professional Fees: Labor-Related	5.356	5.500
Administrative and Facilities Support Services	0.626	0.619
All Other: Labor-Related Services	3.193	3.130
Total Labor-Related Share	68.802	69.587

Using the cost category weights from the proposed FY 2010-based IPPS market basket, we calculated a labor-related share of 69.587 percent, approximately 0.8 percentage point higher than the current labor-related share of 68.802.

We continue to believe, as we have stated in the past, that these operating cost categories are related to, influenced by, or vary with the local markets. Therefore, our

definition of the labor-related share continues to be consistent with section 1886(d)(3) of the Act.

Using the proposed cost category weights that we determined in section IV.B.1. of the preamble of this proposed rule, we calculated a proposed labor-related share of 69.587 percent, using the proposed FY 2010-based IPPS market basket. Accordingly, we are proposing to implement a labor-related share of 69.6 percent for discharges occurring on or after October 1, 2013. We note that section 403 of Pub. L. 108-173 amended sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless 62 percent “would result in lower payments to a hospital than would otherwise be made.”

We also are proposing to update the labor-related share for Puerto Rico. Consistent with our methodology for determining the national labor-related share, we calculate the Puerto Rico-specific relative weights for wages and salaries, employee benefits, and contract labor using FY 2010 Medicare cost report data for IPPS hospitals located in Puerto-Rico. Because there are no Puerto Rico-specific relative weights for professional fees and labor intensive services, we use the national weights as shown in Table IV05. This is the same methodology we used to determine the FY 2006-based Puerto Rico-specific labor-related share derived during the FY 2006-based IPPS market basket rebasing (74 FR 43856).

Below is a table comparing the proposed FY 2010-based Puerto Rico-specific labor-related share and the FY 2006-based Puerto Rico-specific labor-related share.

Table IV06.--Comparison of the Proposed FY 2010-Based Puerto Rico-Specific Labor-Related Share and FY 2006-Based Puerto Rico-Specific Labor-Related Share

	FY 2006-Based Market Basket Cost Weights	Proposed FY 2010- Based Market Basket Cost Weights
Wages and Salaries	44.221	44.918
Benefits	8.691	8.990
Professional Fees: Labor-Related	5.356	5.500
Administrative and Facilities Support Services	0.626	0.619
All Other: Labor-Related Services	3.193	3.130
Total Labor-Related Share	62.087	63.157

Using the proposed FY 2010-based Puerto Rico cost category weights, we calculated a labor-related share of 63.157 percent, approximately 1.1 percentage points higher than the current Puerto-Rico specific labor-related share of 62.087. Accordingly, we are proposing to adopt an updated Puerto Rico labor-related share of 63.2 percent.

C. Market Basket for Certain Hospitals Presently Excluded from the IPPS

In the FY 2010 IPPS/RV 2010 LTCH PPS final rule (74 FR 43857), we adopted the use of the FY 2006-based IPPS operating market basket percentage increase to update the target amounts for children's hospitals, PPS-excluded cancer hospitals and religious nonmedical health care institutions (RNHCIs). Children's hospitals and PPS-excluded cancer hospitals and RNHCIs are still reimbursed solely under the reasonable cost-based system, subject to the rate-of-increase limits. Under these limits, an annual target amount (expressed in terms of the inpatient operating cost per discharge) is set for each hospital based on the hospital's own historical cost experience trended forward by the applicable rate-of-increase percentages.

Under the broad authority in sections 1886(b)(3)(A) and (B), 1886(b)(3)(E), and 1871 of the Act and section 4454 of the BBA, consistent with our use of the IPPS operating market basket percentage increase to update target amounts, we are proposing to use the FY 2010-based IPPS operating market basket percentage increase to update the target amounts for children's hospitals, 11 PPS-excluded cancer hospitals, and RNHCIs that are paid on the basis of reasonable cost subject to the rate-of-increase limits under § 413.40.

Due to the small number of children's and cancer hospitals and RNHCIs that receive, in total, less than 1 percent of all Medicare payments to hospitals and because these hospitals provide limited Medicare cost report data, we are unable to create a separate market basket specifically for these hospitals. Due to the limited cost report data available, we believe that the proposed FY 2010-based IPPS operating market basket most closely represents the cost structure of children's hospitals, PPS-excluded cancer hospitals, and RNHCIs. We believe this is appropriate as the IPPS operating market basket would reflect the input price growth for providing inpatient hospital services (similar to the services provided by the above excluded hospitals) based on the specific mix of goods and services required. Therefore, we believe that the percentage change in the proposed FY 2010-based IPPS operating market basket is the best available measure of the average increase in the prices of the goods and services purchased by the 11 cancer hospitals, children's hospitals, and RNHCIs in order to provide care.

D. Rebasing and Revising the Capital Input Price Index (CIPI)

The CIPI was originally described in the FY 1993 IPPS final rule (57 FR 40016). There have been subsequent discussions of the CIPI presented in the IPPS proposed and final payment rules. The FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43857) discussed the most recent rebasing and revision of the CIPI to a FY 2006 base year, which reflected the capital cost structure of the hospital industry in that year.

For the FY 2014 IPPS update, we are proposing to rebase and revise the CIPI to a FY 2010 base year to reflect the more current structure of capital costs in hospitals. As with the FY 2006-based index, we developed two sets of weights in order to calculate the proposed FY 2010-based CIPI. The first set of weights identifies the proportion of hospital capital expenditures attributable to each expenditure category, while the second set of weights is a set of relative vintage weights for depreciation and interest. The set of vintage weights is used to identify the proportion of capital expenditures within a cost category that is attributable to each year over the useful life of the capital assets in that category. A more thorough discussion of vintage weights is provided later in this section.

Both sets of weights are developed using the best data sources available. In reviewing source data, we determined that the Medicare cost reports provided accurate data for all capital expenditure cost categories. We used the FY 2010 Medicare cost reports for IPPS hospitals to determine weights for all three cost categories: depreciation, interest, and other capital expenses.

Lease expenses are unique in that they are not broken out as a separate cost category in the CIPI, but rather are proportionally distributed among the cost categories

of Depreciation, Interest, and Other, reflecting the assumption that the underlying cost structure and price movement of leases is similar to that of capital costs in general. As was done in previous rebasings of the CIPI, we first assumed 10 percent of lease expenses represents overhead and assigned those costs to the Other category accordingly. The remaining lease expenses were distributed across the three cost categories based on the respective weights of Depreciation, Interest, and Other not including lease expenses.

Depreciation contains two subcategories: (1) Building and Fixed equipment; and (2) Movable Equipment. The proposed apportionment between building and fixed equipment and movable equipment was determined using the Medicare cost reports. This methodology was also used to compute the apportionment used in the FY 2006-based index.

The total Interest cost category is split between government/nonprofit interest and for-profit interest. The FY 2006-based CIPI allocated 85 percent of the total interest cost weight to government/nonprofit interest and proxied that category by the average yield on domestic municipal bonds. The remaining 15 percent of the interest cost weight was allocated to for-profit interest and was proxied by the average yield on Moody's Aaa bonds (74 FR 43857).

For the FY 2010-based CIPI, we are proposing to derive the split using the relative FY 2010 Medicare cost report data on interest expenses for government/nonprofit and for-profit hospitals. Based on these data, we calculated an 89/11 split between government/nonprofit and for-profit interest. We believe it is important that this split reflects the latest relative cost structure of interest expenses.

Table IV07 presents a comparison of the proposed FY 2010-based CIPI cost weights and the FY 2006-based CIPI cost weights.

Table IV07.—Proposed FY 2010-Based CIPI Cost Categories, Weights, and Price Proxies with FY 2006-Based CIPI Included for Comparison

Cost Categories	FY 2006 Weights	Proposed FY 2010 Weights	Price Proxy
Total	100.00	100.00	
Total depreciation	75.154	74.011	
Building and fixed equipment depreciation	35.789	36.153	BEA chained price index for nonresidential construction for hospitals and special care facilities--vintage-weighted (26 years)
Movable equipment depreciation	39.365	37.858	PPI for machinery and equipment--vintage-weighted (12 years)
Total interest	17.651	19.157	
Government/nonprofit interest	15.076	17.051	Average yield on domestic municipal bonds (Bond Buyer 20 bonds)—vintage-weighted (26 years)
For-profit interest	2.575	2.106	Average yield on Moody's Aaa bonds—vintage-weighted (26 years)
Other	7.195	6.832	CPI-U for residential rent

Because capital is acquired and paid for over time, capital expenses in any given year are determined by both past and present purchases of physical and financial capital. The vintage-weighted CIPI is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest. We used the vintage weights to compute vintage-weighted price changes associated with depreciation and interest expense. Following publication of the FY 2010 IPPS/RY 2010

LTCH PPS proposed rule, and in order to provide greater transparency, we posted on the CMS market basket Web page at: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html> an illustrative spreadsheet that contains an example of how the vintage-weighted price indexes are calculated.

Vintage weights are an integral part of the CIPI. Capital costs are inherently complicated and are determined by complex capital purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. The CIPI accurately reflects the annual price changes associated with capital costs, and is a useful simplification of the actual capital investment process. By accounting for the vintage nature of capital, we are able to provide an accurate, stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes and, therefore, do not reflect the actual annual price changes for Medicare capital-related costs. The CIPI reflects the underlying stability of the capital acquisition process and provides hospitals with the ability to plan for changes in capital payments.

To calculate the vintage weights for depreciation and interest expenses, we needed a time series of capital purchases for building and fixed equipment and movable equipment. We found no single source that provides a uniquely best time series of capital purchases by hospitals for all of the above components of capital purchases. The early Medicare cost reports did not have sufficient capital data to meet this need. Data we obtained from the American Hospital Association (AHA) do not include annual capital

purchases. However, AHA does provide a consistent database back to 1963. We used data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We then used data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2010.

In order to estimate capital purchases using data on depreciation expenses, the expected life for each cost category (building and fixed equipment, movable equipment, and interest) is needed to calculate vintage weights. We used FY 2010 Medicare cost reports to determine the expected life of building and fixed equipment and of movable equipment. The expected life of any piece of equipment can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated useful life of an asset if depreciation were to continue at current year levels, assuming straight-line depreciation. From the FY 2010 Medicare cost reports, the proposed expected life of building and fixed equipment was determined to be 26 years, and the proposed expected life of movable equipment was determined to be 12 years. The FY 2006-based CIPI was based on an expected life of building and fixed equipment of 25 years and 12 years as the expected life for movable equipment.

We are proposing to use the building and fixed equipment and movable equipment weights derived from FY 2010 Medicare cost reports to separate the depreciation expenses into annual amounts of building and fixed equipment depreciation

and movable equipment depreciation. Year-end asset costs for building and fixed equipment and movable equipment were determined by multiplying the annual depreciation amounts by the expected life calculations from the FY 2010 Medicare cost reports. We then calculated a time series back to 1963 of annual capital purchases by subtracting the previous year asset costs from the current year asset costs. From this capital purchase time series, we were able to calculate the vintage weights for building and fixed equipment and for movable equipment. Each of these sets of vintage weights is explained in more detail below.

For building and fixed equipment vintage weights, we used the real annual capital purchase amounts for building and fixed equipment to capture the actual amount of the physical acquisition, net of the effect of price inflation. This real annual purchase amount for building and fixed equipment was produced by deflating the nominal annual purchase amount by the building and fixed equipment price proxy, BEA's chained price index for nonresidential construction for hospitals and special care facilities. Because building and fixed equipment have an expected life of 26 years, the vintage weights for building and fixed equipment are deemed to represent the average purchase pattern of building and fixed equipment over 26-year periods. With real building and fixed equipment purchase estimates available back to 1963, we averaged twenty-two 26-year periods to determine the average vintage weights for building and fixed equipment that are representative of average building and fixed equipment purchase patterns over time. Vintage weights for each 26-year period are calculated by dividing the real building and fixed capital purchase amount in any given year by the total amount of purchases in the 26-year

period. This calculation is done for each year in the 26-year period, and for each of the twenty-two 26-year periods. We used the average of each year across the twenty-two 26-year periods to determine the average building and fixed equipment vintage weights for the proposed FY 2010-based CIPI.

For movable equipment vintage weights, the real annual capital purchase amounts for movable equipment were used to capture the actual amount of the physical acquisition, net of price inflation. This real annual purchase amount for movable equipment was calculated by deflating the nominal annual purchase amounts by the movable equipment price proxy, the PPI for machinery and equipment. Based on our determination that movable equipment has an expected life of 12 years, the vintage weights for movable equipment represent the average expenditure for movable equipment over a 12-year period. With real movable equipment purchase estimates available back to 1963, thirty-six 12-year periods were averaged to determine the average vintage weights for movable equipment that are representative of average movable equipment purchase patterns over time. Vintage weights for each 12-year period are calculated by dividing the real movable capital purchase amount for any given year by the total amount of purchases in the 12-year period. This calculation was done for each year in the 12-year period and for each of the thirty-six 12-year periods. We used the average of each year across the thirty-six 12-year periods to determine the average movable equipment vintage weights for the proposed FY 2010-based CIPI.

For interest vintage weights, the nominal annual capital purchase amounts for total equipment (building and fixed, and movable) were used to capture the value of the

debt instrument. Because we have determined that hospital debt instruments have an expected life of 26 years, the vintage weights for interest are deemed to represent the average purchase pattern of total equipment over 26-year periods. With nominal total equipment purchase estimates available back to 1963, twenty-two 26-year periods were averaged to determine the average vintage weights for interest that are representative of average capital purchase patterns over time. Vintage weights for each 26-year period are calculated by dividing the nominal total capital purchase amount for any given year by the total amount of purchases in the 26-year period. This calculation is done for each year in the 26-year period and for each of the twenty-two 26-year periods. We used the average of each year across the twenty-two 26-year periods to determine the average interest vintage weights for the proposed FY 2010-based CIPI.

The vintage weights for the FY 2006-based CIPI and the proposed FY 2010-based CIPI are presented in Table IV08.

Table IV08.--FY 2006 Vintage Weights and Proposed FY 2010 Vintage Weights for Capital-Related Price Proxies

Year ¹	Building and Fixed Equipment		Movable Equipment		Interest	
	FY 2006 25 years	FY 2010 26 years	FY 2006 12 years	FY 2010 12 years	FY 2006 25 years	FY 2010 26 years
1	0.021	0.023	0.063	0.064	0.010	0.012
2	0.023	0.024	0.067	0.068	0.012	0.013
3	0.025	0.026	0.071	0.071	0.014	0.015
4	0.027	0.028	0.075	0.073	0.016	0.017
5	0.029	0.029	0.079	0.076	0.018	0.018
6	0.031	0.031	0.082	0.078	0.020	0.021
7	0.032	0.032	0.085	0.084	0.023	0.023
8	0.033	0.034	0.086	0.088	0.025	0.025
9	0.036	0.036	0.090	0.092	0.028	0.028
10	0.038	0.038	0.093	0.098	0.031	0.030
11	0.040	0.040	0.102	0.103	0.034	0.033

Year ¹	Building and Fixed Equipment		Movable Equipment		Interest	
	FY 2006 25 years	FY 2010 26 years	FY 2006 12 years	FY 2010 12 years	FY 2006 25 years	FY 2010 26 years
12	0.042	0.041	0.106	0.106	0.038	0.036
13	0.044	0.042	--	--	0.041	0.038
14	0.045	0.042	--	--	0.044	0.040
15	0.046	0.043	--	--	0.047	0.043
16	0.047	0.044	--	--	0.050	0.045
17	0.048	0.044	--	--	0.053	0.047
18	0.050	0.044	--	--	0.057	0.048
19	0.050	0.044	--	--	0.059	0.051
20	0.050	0.044	--	--	0.060	0.052
21	0.048	0.045	--	--	0.060	0.056
22	0.048	0.045	--	--	0.062	0.057
23	0.047	0.045	--	--	0.063	0.060
24	0.049	0.046			0.068	0.062
25	0.048	0.045			0.069	0.064
26		0.045				0.066
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: Detail may not add to total due to rounding.

¹ Year 1 represents the vintage weight applied to the farthest year while the vintage weight for year 26, for example, would apply to the most recent year.

After the capital cost category weights were computed, it was necessary to select appropriate price proxies to reflect the rate-of-increase for each expenditure category.

We are proposing to use the same price proxies for the FY 2010-based CIPI that were used in the FY 2006-based CIPI. The rationale for selecting the price proxies was explained more fully in the FY 1997 IPPS final rule (61 FR 46196) and the FY 2010 IPPS/RV 2010 LTCH PPS final rule (74 FR 43857). These proposed price proxies are presented in Table IV07.

Table IV09 below compares both the historical and forecasted percent changes in the FY 2006-based CIPI and the proposed FY 2010-based CIPI.

Table IV09.--Comparison of FY 2006-Based and Proposed FY 2010-Based Capital Input Price Index, Percent Change, FY 2008 through FY 2016

Fiscal Year	CIPI, FY 2006-Based	Proposed CIPI, FY 2010-Based
FY 2008	1.5	1.1
FY 2009	1.5	1.2
FY 2010	1.0	0.7
FY 2011	1.2	0.9
FY 2012	1.2	1.0
Forecast:		
FY 2013	1.2	1.0
FY 2014	1.4	1.2
FY 2015	1.5	1.3
FY 2016	1.7	1.5
Average:		
FYs 2008-2012	1.3	1.0
FYs 2013-2016	1.5	1.3

Source: IHS Global Insight, Inc., 1st Quarter 2013 forecast.

IHS Global Insight, Inc. forecasts a 1.2 percent increase in the FY 2010-based CIPI for FY 2014, as shown in Table IV09. The underlying vintage-weighted price increases for depreciation (including building and fixed equipment and movable equipment) and interest (including government/nonprofit and for-profit) are included in Table IV10.

**Table IV10.--CMS Capital Input Price Index Percent Changes, Total and Depreciation and Interest Components--
FYs 2008 through 2016**

Fiscal Year	Total	Depreciation	Interest
FY 2008	1.1	2.0	-3.1
FY 2009	1.2	2.0	-2.0
FY 2010	0.7	1.7	-2.8
FY 2011	0.9	1.7	-2.3
FY 2012	1.0	1.7	-2.7

Fiscal Year	Total	Depreciation	Interest
Forecast:			
FY 2013	1.0	1.7	-2.8
FY 2014	1.2	1.8	-2.3
FY 2015	1.3	1.9	-1.7
FY 2016	1.5	1.9	-0.7

Source: IHS Global Insight, Inc., 1st Quarter 2013 forecast

Rebasing the CPII from FY 2006 to FY 2010 decreased the percent change in the forecasted update for FY 2014 by 0.2 percentage point, from 1.4 percent to 1.2 percent, as shown in Table IV09. The difference in the forecasted market basket update for FY 2014 is primarily due to the rebasing of the index to FY 2010 and revising the base year cost weights to incorporate the FY 2010 Medicare cost report data.

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

A. Proposed Changes in the Inpatient Hospital Update for FY 2014 (§§ 412.64(d) and 412.211(c))

1. Proposed FY 2014 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.” Section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, sets the applicable percentage increase under the IPPS for FY 2014 as 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. 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.

We note, in compliance with section 404 of the MMA, in this proposed rule, we are proposing to replace 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 also are proposing to rebase the labor-related share to reflect the more recent base year. The current labor-related share, which is based on the FY 2006-based IPPS market basket, is 68.8 percent. We are proposing a labor-related share of 69.6 percent, which is based on the proposed rebased and revised FY 2010-based IPPS market basket. For a complete discussion on the rebasing of the market basket and labor-related share, we refer readers to section IV. of the preamble of this proposed rule.

Based on the most recent data available for this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to base the proposed FY 2014 market basket update used to determine the applicable percentage increase for the IPPS on the IHS Global Insight, Inc. (IGI's) first quarter 2013 forecast of the FY 2010-based IPPS market basket rate-of-increase, which is estimated to be 2.5 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 2014, we are not proposing any change in our methodology for calculating and applying the MFP adjustment. However, for this proposed rule, we are using the most recent data available to compute the MFP adjustment. Using the methodology that we finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51690), the proposed FY 2014 market basket update, subject to the hospital submitting quality data under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act, is then reduced by the most recent estimate of the MFP adjustment (the 10-year moving average of MFP for the period

ending FY 2014) of 0.4 percent. Following application of the MFP adjustment, the applicable percentage increase is then reduced by 0.3 percentage point, as required by section 1886(b)(3)(B)(xii) of the Act (as discussed in section I. of the Addendum to this proposed rule).

Consistent with current law, and based on IGI's first quarter 2013 forecast of the FY 2014 market basket increase, we are proposing an applicable percentage increase to the FY 2014 operating standardized amount of 1.8 percent (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less an adjustment of 0.4 percentage point for economy-wide productivity (that is, the MFP adjustment) and less 0.3 percentage point) for hospitals in all areas, provided the hospital submits quality data under rules established in accordance with section 1886(b)(3)(B)(viii) of the Act. For hospitals that do not submit these quality data, we are proposing an applicable percentage increase to the operating standardized amount of -0.2 percent (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent, less 2.0 percentage points for failure to submit quality data, less an adjustment of 0.4 percentage point for the MFP adjustment, and less an additional adjustment of 0.3 percentage point). Lastly, we also are proposing that if more recent data become subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data, if appropriate, to determine the FY 2014 market basket update and MFP adjustment in the final rule.

We are proposing to revise the existing regulations at 42 CFR 412.64(d) to reflect the current law for the FY 2014 update. Specifically, in accordance with section

1886(b)(3)(B) of the Act, we are proposing to add a new paragraph (v) to § 412.64(d)(1) to reflect the applicable percentage increase to the FY 2014 operating standardized amount as the percentage increase in the market basket index less an MFP adjustment and less an additional reduction of 0.3 percentage point.

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs is also subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, we are proposing an update to the hospital-specific rates applicable to SCHs of 1.8 percent for hospitals that submit quality data or -0.2 percent for hospitals that fail to submit quality data. For FY 2014, the existing regulations in §§ 412.73(c)(16), 412.75(d), 412.77(e) and 412.78(e) contain provisions that set the update factor for SCHs equal to the update factor applied to the national standardized amount for all IPPS hospitals. Therefore, we are not proposing to make any further changes to these four regulatory provisions to reflect the FY 2014 update factor for the hospital-specific rates of SCHs.

We note that, as discussed in section V.F. of this preamble, section 606 of the American Taxpayer Relief Act of 2012 extended the MDH program from the end of FY 2012 (that is, for discharges occurring before October 1, 2012) to the end of FY 2013 (that is, for discharges occurring before October 1, 2013). Under prior law, the MDH program was to be in effect through the end of FY 2012 only. Absent additional

legislation further extending the MDH program, the MDH program will expire for discharges beginning in FY 2014. Accordingly, we are not including MDHs in our proposal to update the hospital-specific rates for FY 2014.

2. Proposed FY 2014 Puerto Rico Hospital Update

Puerto Rico hospitals are paid a blended rate for their inpatient operating costs based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 1886(d)(9)(C)(i) of the Act is the basis for determining the applicable percentage increase applied to the Puerto Rico-specific standardized amount. Section 401(c) of Pub. L. 108-173 amended section 1886(d)(9)(C)(i) of the Act, which states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for fiscal year 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are proposing an applicable percentage increase to the Puerto Rico-specific operating standardized amount of 1.8 percent for FY 2014. The regulations at § 412.211(c) currently set the update factor for the Puerto Rico-specific operating standardized amount

equal to the update factor applied to the national standardized amount for all IPPS hospitals. Therefore, it is not necessary to propose any changes to the existing regulatory text.

B. Rural Referral Centers (RRCs): Proposed Annual Update 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 Pub. L. 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 Pub. L. 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 2014 includes data from all urban hospitals nationwide, and the proposed regional values for FY 2014 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 2012 (October 1, 2011 through September 30, 2012), and include bills posted to CMS' records through December 2012.

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, 2013, they must have a CMI value for FY 2012 that is at least--

- 1.5526; 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	Case-Mix Index Value
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Region	Case-Mix Index Value
1. New England (CT, ME, MA, NH, RI, VT)	1.3319
2. Middle Atlantic (PA, NJ, NY)	1.4025
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.4799
4. East North Central (IL, IN, MI, OH, WI)	1.4542
5. East South Central (AL, KY, MS, TN)	1.4266
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.5311
7. West South Central (AR, LA, OK, TX)	1.5811
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.6393
9. Pacific (AK, CA, HI, OR, WA)	1.5568

We intend to update the preceding numbers in the FY 2014 final rule to reflect the updated FY 2012 MedPAR file, which would contain data from additional bills received through March 2013.

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its fiscal intermediary or MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS-DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. We would normally propose to update the regional standards based on discharges for urban hospitals' cost reporting periods that

began during FY 2011 (that is, October 1, 2010 through September 30, 2011), which would normally be the latest cost report data available at the time of the development of this proposed rule. However, due to a transition in our data system, in lieu of a full year of FY 2011 cost report data, we are proposing to use a combination of FY 2010 and FY 2011 cost report data in order to create a full fiscal year of cost report data for this analysis. Due to CMS' transition to a new cost reporting form effective for cost reporting periods beginning on or after May 1, 2010, some FY 2011 cost reports were not yet in our system for analysis at the time of the development of this proposed rule. Therefore, in order to have a complete fiscal year of cost report data, we utilized FY 2011 cost report data if available, and for those providers whose FY 2011 cost report data was not yet in our system, we utilized their FY 2010 cost report data. This is similar to the process we used to establish the median number of discharges for urban hospitals in the census region for FY 2013, where we utilized FY 2009 and 2010 cost report data (77 FR 53406).

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, 2013, must have, as the number of discharges for its cost reporting period that began during FY 2011 (based on a combination of FY 2010 and FY 2011 cost report data as explained in the preceding paragraph), at least-

- 5,000 (3,000 for an osteopathic hospital); or
- The median number of discharges for urban hospitals in the census region in

which the hospital is located, as indicated in the following table:

Region	Number of Discharges
1. New England (CT, ME, MA, NH, RI, VT)	7,825
2. Middle Atlantic (PA, NJ, NY)	10,891
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	11,566
4. East North Central (IL, IN, MI, OH, WI)	8,360
5. East South Central (AL, KY, MS, TN)	7,378
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,747
7. West South Central (AR, LA, OK, TX)	5,147
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	9,125
9. Pacific (AK, CA, HI, OR, WA)	8,525

We intend to update these numbers in the FY 2014 final rule based on the latest available cost report data.

We note that the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges. Therefore, 5,000 discharges would be the minimum criterion for all hospitals under this proposed rule.

We reiterate that, if an osteopathic hospital is to qualify for RRC status for cost reporting periods beginning on or after October 1, 2013, the hospital would be required to have at least 3,000 discharges for its cost reporting period that began during FY 2011 (based on a combination of FY 2010 and FY 2011 cost report data as explained earlier in this section).

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

1. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital under the IPPS beginning in FY 2005. Section

1886(d)(12) of the Act sets forth the qualifying criteria for a qualifying low-volume hospital and the methodology for determining the low-volume hospital payment adjustment.

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 by expanding the definition of a low-volume hospital and modifying the methodology for determining the payment adjustment for hospitals meeting the definition. Therefore, prior to the enactment of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112-240) on January 2, 2013, beginning with FY 2013, the low-volume hospital qualifying criteria and payment adjustment requirements would have reverted to the statutory requirements under section 1886(d)(12) of the Act that were in effect prior to FY 2011. Section 605 of the ATRA extended for an additional year, through FY 2013, the temporary changes in the low-volume hospital definition and methodology for determining the payment adjustment made by the Affordable Care Act for FYs 2011 and 2012. Beginning with FY 2014, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act and the ATRA. In section V.D.3. of this preamble, we discuss the proposed low-volume hospital payment adjustment policies for FY 2014.

a. Original Implementation of the Low-Volume Hospital Payment Adjustment

Section 1886(d)(12) of the Act, as added by section 406(a) of Pub. L. 108-173, provides for a payment adjustment to account for the higher costs per discharge for low-volume hospitals under the IPPS, effective beginning FY 2005. The additional

payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is “[i]n addition to any payment calculated under this section.” Therefore, the additional payment adjustment is based on the per discharge amount paid to the qualifying hospital under section 1886 of the Act. In other words, the low-volume hospital payment adjustment is based on total per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outlier payments. For SCHs and MDHs, the low-volume hospital payment adjustment is based in part on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment.

Section 1886(d)(12)(C)(i) of the Act defined a low-volume hospital as “a subsection (d) hospital (as defined in paragraph (1)(B)) that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and has less than 800 discharges during the fiscal year.” Section 1886(d)(12)(C)(ii) of the Act further stipulates that the term “discharge” means “an inpatient acute care discharge of an individual regardless of whether the individual is entitled to benefits under Part A.” Therefore, the term “discharge” refers to total discharges, regardless of payer (that is, not only Medicare discharges). Furthermore, under section 406(a) of Pub. L. 108-173, which initially added subparagraph (12) to section 1886(d) of the Act, the provision requires the Secretary to determine an applicable percentage increase for these low-volume hospitals based on the “empirical relationship” between “the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges.” The statute thus mandates that the Secretary develop an empirically justifiable adjustment based on the relationship between costs and discharges for these low-volume hospitals.

Section 1886(d)(12)(B)(iii) of the Act limits the applicable percentage increase adjustment to no more than 25 percent.

Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25-percent low-volume hospital payment adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. In the FY 2006 IPPS final rule (70 FR 47432 through 47434), we stated that multivariate analyses supported the existing low-volume hospital payment adjustment implemented in FY 2005. Therefore, the low-volume hospital payment adjustment of an additional 25 percent continued to be provided for qualifying hospitals with less than 200 discharges.

b. Affordable Care Act Provisions for FYs 2011 and 2012

For FYs 2011 and 2012, sections 3125 and 10314 of the Affordable Care Act expanded the definition of low-volume hospital and modified the methodology for determining the payment adjustment for hospitals meeting that definition. Specifically, those provisions of the Affordable Care Act amended the qualifying criteria for low-volume hospitals under section 1886(d)(12)(C)(i) of the Act to specify that, for FYs 2011 and 2012, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 1,600 discharges of individuals entitled to, or enrolled for, benefits under Part A during the fiscal year. In addition, section 1886(d)(12)(D) of the Act, as added by the Affordable Care Act, provides that the low-volume hospital payment adjustment (that is, the

percentage increase) is to be determined “using a continuous linear sliding scale ranging from 25 percent for low-volume hospitals with 200 or fewer discharges of individuals entitled to, or enrolled for, benefits under Part A in the fiscal year to zero percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal year.”

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414), we revised the regulations at 42 CFR 412.101 to reflect the changes to the qualifying criteria and the payment adjustment for low-volume hospitals made by sections 3125 and 10314 of the Affordable Care Act. In addition, we defined, at § 412.101(a), the term “road miles” to mean “miles” as defined at § 412.92(c)(1), and clarified the existing regulations to indicate that a hospital must continue to qualify as a low-volume hospital in order to receive the payment adjustment in that year (that is, it is not based on a one-time qualification). Furthermore, in that same final rule, we discussed the process for requesting and obtaining the low-volume hospital payment adjustment for FY 2011 (75 FR 50240). For the second year of the changes to the low-volume hospital payment adjustment provided for by section 3125 and 10314 of the Affordable Care Act (that is, FY 2012), consistent with the regulations at § 412.101(b)(2)(ii), in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51677 through 51680), we updated the discharge data source used to identify qualifying low-volume hospitals and calculate the payment adjustment (percentage increase). Under § 412.101(b)(2)(ii), for FYs 2011 and 2012, 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 hospital payment adjustment in the current year. In that same final rule, we established that, for FY 2012, qualifying low-volume hospitals and their payment adjustment are determined using Medicare discharge data from the March 2011 update of the FY 2010 MedPAR file, as these data were the most recent data available at that time. In addition, we noted that eligibility for the low-volume hospital payment adjustment for FY 2012 was also dependent upon meeting (if the hospital was qualifying for the low-volume hospital payment adjustment for the first time in FY 2012), or continuing to meet (if the hospital qualified in FY 2011), the mileage criterion specified at § 412.101(b)(2)(ii). Furthermore, we established a procedure for a hospital to request low-volume hospital status for FY 2012 (which was consistent with the process we employed for the low-volume hospital payment adjustment for FY 2011).

2. Provisions of the ATRA for FY 2013

a. Background

Section 605 of the ATRA amended sections 1886(d)(12)(B), (C)(i), and (D) of the Act to extend, for FY 2013, the temporary changes in the low-volume hospital payment adjustment policy provided for in FYs 2011 and 2012 by the Affordable Care Act. As we have noted previously, prior to the enactment of section 605 of the ATRA, beginning with FY 2013, the low-volume hospital definition and payment adjustment methodology would have reverted to the policy established under statutory requirements that were in effect prior to the amendments made by the Affordable Care Act.

Prior to the enactment of the ATRA, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53406 through 53409), we discussed the low-volume hospital payment

adjustment for FY 2013 and subsequent fiscal years. Specifically, we discussed that in accordance with section 1886(d)(12) of the Act, beginning with FY 2013, the low-volume hospital definition and payment adjustment methodology would revert back to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act. Therefore, we explained, as specified under the existing regulations at § 412.101, effective for FY 2013 and subsequent years, that 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 total discharges, including both Medicare and non-Medicare discharges) during the fiscal year. We also established a procedure for hospitals to request low-volume hospital status for FY 2013 (which was consistent with our previously established procedures for FYs 2011 and 2012).

In a **Federal Register** notice published on March 7, 2013 (78 FR 14689) (hereinafter referred to as the FY 2013 IPPS notice), we announced the extension of the Affordable Care Act amendments to the low-volume hospital payment adjustment requirements under section 1886(d)(12) of the Act for FY 2013 pursuant to section 605 of the ATRA. The applicable low-volume hospital percentage increase provided for by the provisions of the Affordable Care Act and the ATRA 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.

In the FY 2013 IPPS notice (78 FR 14689 through 14694), to implement the extension of the temporary change in the low-volume hospital payment adjustment policy for FY 2013 provided for by the ATRA, we updated the discharge data source used to identify qualifying low-volume hospitals and calculate the payment adjustment (percentage increase). Consistent with our implementation of the low-volume hospital payment adjustment policy for FYs 2011 and 2012 as set forth at existing § 412.101(b)(2)(ii), we established that, for FY 2013, qualifying low-volume hospitals and their payment adjustments are determined using Medicare discharge data from the March 2012 update of the FY 2011 MedPAR file, as these data were the most recent data available at the time of the development of the FY 2013 payment rates and factors established in the FY 2013 IPPS/LTCH PPS final rule. In addition, we noted that eligibility for the low-volume hospital payment adjustment for FY 2013 is also dependent upon meeting (in the case of a hospital that did not qualify for the low-volume hospital payment adjustment in FY 2012), or continuing to meet (in the case of a hospital that did qualify for the low-volume hospital payment adjustment in FY 2012), the mileage criterion specified at existing § 412.101(b)(2)(ii). We also established a procedure for a hospital to request low-volume hospital status for FY 2013 (which is consistent with the process for the low-volume hospital payment adjustment for FYs 2011 and 2012). Furthermore, we noted our intent to make conforming changes to the regulations text at § 412.101 to reflect the changes to the qualifying criteria and the payment adjustment for low-volume hospitals in accordance with the amendments made by section 605 of the ATRA in future rulemaking. (We refer readers to the FY 2013 IPPS notice (78 FR 14689

through 14694) for additional information on the extension of the Affordable Care Act amendments to the low-volume hospital payment adjustment requirements under section 1886(d)(12) of the Act through FY 2013 in accordance with section 605 of the ATRA.)

b. Proposed Conforming Regulatory Changes

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414), we amended the regulations at § 412.101 to specify that, beginning with FY 2013, the low-volume hospital definition and payment adjustment methodology reverted to the policy established under statutory requirements that were in effect prior to the amendments made by the Affordable Care Act. 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 FY 2013 in accordance with section 605 of the ATRA, as announced in the FY 2013 IPPS notice (as discussed above).

Specifically, we are proposing to revise paragraphs (b)(2)(i), (b)(2)(ii), (c)(1), (c)(2), and (d). Under these proposed changes to § 412.101, beginning with FY 2014, 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 the ATRA (that is, the low-volume hospital payment adjustment policy in effect for FYs 2005 through 2010).

3. Proposed Low-Volume Hospital Definition and Payment Adjustment for FY 2014 and Subsequent Fiscal Years

In accordance with section 1886(d)(12) of the Act, as amended, beginning with FY 2014, 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 the ATRA. 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 2014 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 2014 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.

As described above, for FYs 2005 through 2010 and FY 2014 and subsequent fiscal years, the discharge determination would be made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges. The hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume hospital payment adjustment in the current year (proposed § 412.101(b)(2)(i)). We use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. We note that, for FYs 2011, 2012, and 2013, we used the most recently available MedPAR data to determine the hospital's Medicare discharges because only Medicare discharges were used to determine

if a hospital met the discharge criterion for those years. In addition to a discharge criterion, the eligibility for the low-volume hospital payment adjustment also would be dependent upon the hospital meeting the mileage criterion specified at proposed § 412.101(b)(2)(i). Specifically, to meet the mileage criterion to qualify for the low-volume hospital payment adjustment for FY 2014 and subsequent fiscal years, a hospital must be located more than 25 road miles from the nearest subsection (d) hospital.

For FY 2014, we would continue to use the established 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 fiscal intermediary or MAC that it meets the discharge and distance requirements. The fiscal intermediary or MAC will determine, based on the most recent data available, if the hospital qualifies as a low-volume hospital, so that the hospital will know in advance whether or not it will receive a payment adjustment. The fiscal intermediary or MAC and CMS may review available data, in addition to the data the hospital submits with its request for low-volume hospital status, in order to determine whether or not the hospital meets the qualifying criteria. (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).)

Consistent with our previously established procedure, for FY 2014, a hospital must make its request for low-volume hospital status in writing to its fiscal intermediary or MAC by September 1, 2013, in order for the 25-percent low-volume hospital payment adjustment to be applied to payments for its discharges beginning on or after

October 1, 2013 (through September 30, 2014). If a hospital's request for low-volume hospital status for FY 2014 is received after September 1, 2013, and if the fiscal intermediary or MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the fiscal intermediary or MAC will apply the 25-percent low-volume hospital payment adjustment to determine the payment for the hospital's FY 2014 discharges, effective prospectively within 30 days of the date of the fiscal intermediary's or MAC's low-volume hospital status determination.

As we discussed in section V.C.2.b. of the preamble of this proposed rule, we are proposing to make conforming changes to the regulatory 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 FY 2013 made by section 605 of the ATRA. We are proposing changes to § 412.101 to conform the regulations to the statutory requirements that, beginning with FY 2014, the low-volume hospital qualifying criteria and payment adjustment methodology revert to that which was in effect prior to the amendments made by the Affordable Care Act and the ATRA (that is, the low-volume hospital payment adjustment policy in effect for FYs 2005 through 2010). Therefore, the low-volume hospital payment adjustment policy in effect prior for FYs 2005 through 2010 would apply for FY 2014 and subsequent years.

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

1. IME Adjustment Factor for FY 2014

Under the IPPS, an additional payment amount is made to hospitals that have residents in an approved graduate medical education (GME) program in order to reflect

the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B) of the Act states that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2014, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2014 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. Other Proposed Policy Changes Affecting GME

In sections IV.J. of the preamble of this proposed rule, we present other proposed policy changes relating to GME payment. We refer readers to that section of the preamble of this proposed rule where we present the proposed policies.

E. 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. Counting of Patient Days Associated with Patients Enrolled in Medicare Advantage Plans in the Medicare and Medicaid Fractions of the Disproportionate Patient Percentage (DPP) Calculation

The regulation at 42 CFR 422.2 defines Medicare Advantage (MA) plan to mean "health benefits coverage offered under a policy or contract by an MA organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the MA plan" Generally, each MA plan must at least provide coverage of all services that are covered by Medicare Part A and Part B, but also may provide for Medicare Part D benefits and/or additional supplemental benefits. However, certain items and services, such as hospice benefits, continue to be covered under Medicare fee-for-service (FFS).

We note that, under § 422.50 of the regulations, an individual is eligible to elect an MA plan if he or she is entitled to Medicare Part A and enrolled in Medicare Part B. Dual eligible beneficiaries (individuals entitled to Medicare and eligible for Medicaid) also may choose to enroll in a MA plan, and, as an additional supplemental benefit, the MA plan may pay for Medicare cost-sharing not covered by Medicaid.

In the FY 2004 IPPS proposed rule (68 FR 27208) in response to questions about whether the patient days associated with patients enrolled in a Medicare + Choice (M+C) plan [now Medicare Advantage (MA) plan under Medicare Part C] should be counted in the Medicare fraction or the Medicaid fraction of the disproportionate patient percentage (DPP) calculation, we proposed that once a beneficiary enrolls in an M+C plan, those patient days attributable to the beneficiary would not be included in the Medicare fraction of the DPP. Instead, those patient days would be included in the numerator of the Medicaid fraction, if the patient also were eligible for Medicaid. In the FY 2004 IPPS final rule (68 FR 45422), we did not respond to public comments on this proposal, due to the volume and nature of the public comments we received, and we indicated that we would address those comments later in a separate document. In the FY 2005 IPPS proposed rule (69 FR 28286), we stated that we planned to address the FY 2004 comments regarding M+C days in the IPPS final rule for FY 2005. In the FY 2005 IPPS final rule (69 FR 49099), we determined that, under § 412.106(b)(2)(i) of the regulations, MA patient days should be counted in the Medicare fraction of the DPP calculation. We explained that, even where Medicare beneficiaries elect Medicare Part C coverage, they are still entitled to benefits under Medicare Part A. Therefore, we noted that if a

Medicare M+C beneficiary is also an SSI recipient, the patient days for that beneficiary will be included in the numerator of the Medicare fraction (as well as in the denominator) and not in the numerator of the Medicaid fraction. We note that, despite our explicit statement in the final rule that the regulations also would be revised, due to a clerical error, the corresponding regulation at § 412.106(b)(2)(i) was not amended to explicitly reflect this policy until 2007 (72 FR 47384).

On November 15, 2012, in a ruling in the case of Allina Health Services, et al., v. Sebelius (Allina), the Federal District Court for the District of Columbia (the court) held that the final policy of putting MA patient days in the Medicare fraction adopted in the FY 2005 IPPS final rule was not a logical outgrowth of the FY 2004 IPPS proposed rule. The court held that interested parties had not been put on notice that the Secretary might adopt a final policy of counting the days in the Medicare fraction and were not provided an adequate further opportunity for public comment.

We continue to believe that individuals enrolled in MA plans are “entitled to benefits under part A” as the phrase is used in the DSH provisions at section 1886(d)(5)(F)(vi)(I) of the Act. Section 226(a) of the Act provides that an individual is automatically “entitled” to Medicare Part A when the person reaches age 65 or becomes disabled, provided that the individual is entitled to Social Security benefits under section 202 of the Act. Beneficiaries who are enrolled in MA plans provided under Medicare Part C continue to meet all of the statutory criteria for entitlement to Medicare Part A benefits under section 226 of the Act. First, in order to enroll in Medicare Part C, a beneficiary must be “entitled to benefits under Part A and enrolled under Part B” (section

1852(a)(1)(B)(i) of the Act). There is nothing in the Act that suggests that beneficiaries who enroll in a Medicare Part C plan forfeit their entitlement to Medicare Part A benefits. Second, once a beneficiary enrolls in Medicare Part C, the MA plan must provide the beneficiary with the benefits to which he or she is entitled under Medicare Part A, even though it may also provide for additional supplemental benefits (section 1852(a)(1)(A) of the Act). Third, under certain circumstances, Medicare Part A pays for care furnished to patients enrolled in Medicare Part C plans. For example, if, during the course of the year, the scope of benefits provided under Medicare Part A expands beyond a certain cost threshold due to Congressional action or a national coverage determination, Medicare Part A will pay the provider for the cost of those services directly (section 1852(a)(5) of the Act). Similarly, Medicare Part A also pays for federally qualified health center services and hospice care furnished to MA patients (section 1853(a)(4) and (h)(2) of the Act, respectively). Thus, we continue to believe that a patient enrolled in an MA plan remains entitled to benefits under Medicare Part A, and should be counted in the Medicare fraction of the DPP, and not the Medicaid fraction.

We also believe that our policy of counting patients enrolled in MA plans in the Medicare fraction was a logical outgrowth of the FY 2004 IPPS proposed rule, and, accordingly, have filed an appeal in the Allina case. However, in an abundance of caution and for the reasons discussed above, in this proposed rule, we are proposing to readopt the policy of counting the days of patients enrolled in MA plans in the Medicare fraction of the DPP. We are seeking public comments from interested parties that may support or oppose the proposal to include the MA patient days in the Medicare fraction of

the DPP calculation for FY 2014 and subsequent years. We will evaluate these public comments and consider whether a further change in policy is warranted, and will include our final determination in the FY 2014 IPPS final rule. We are not proposing any change to the regulation text at this time, because the current text reflects the policy being proposed.

3. New Payment Adjustment Methodology for Medicare Disproportionate Share Hospitals (DSHs) under Section 3133 of the Affordable Care Act (§ 412.106)

a. General Discussion and Legislative Change

Section 3133 of the Patient Protection and Affordable Care Act (PPACA), as amended by section 10316 of PPACA 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 will refer to these provisions collectively as Section 3133 of the Affordable Care Act.

Currently, 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 for discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) will receive 25 percent of the amount they previously would have received under the current statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(II) of the Act, the so-called Pickle

hospitals. Pursuant to new section 1886(r), Pickle hospitals would receive 25 percent of the 35 percent add-on adjustment for which they would otherwise qualify under section 1886(d)(5)(F)(i)(II). 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 become 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 will be 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.

Specifically, as provided by section 3133 of the Affordable Care Act, section 1886(r) of the Act requires that, for “fiscal year 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)” will receive 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 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 fiscal year 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 point for FY 2014, and minus 0.2 percentage point 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 then Director of the Congressional Budget Office to the Speaker of the House. A link to this letter is included in section V.E.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 “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.” Thus, for FY 2018 and subsequent years, the statute provides some greater flexibility in the choice of the data sources to be used in the estimate of the change in the percent of the uninsured.

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 states that this provision is effective for “fiscal year 2014 and each subsequent fiscal year.” In this proposed rule, we set forth our proposals for implementing the required changes to the DSH payment methodology. We note that, because section 1886 (r) 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 can be 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

As indicated above, the new payment methodology 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 this new provision. Consistent with the law, hospitals must receive empirically justified Medicare DSH payments in FY 2014 or a subsequent 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) is, therefore, limited to hospitals that receive empirically justified Medicare DSH payments pursuant to section 1886(r)(1) of the Act for FY 2014 and subsequent years.

In this proposed rule, we are proposing that hospitals that are not eligible to receive empirically justified Medicare DSH payments in FY 2014 and subsequent years would not receive uncompensated care payments for those respective years. We also are proposing to make a determination concerning eligibility for interim uncompensated care payments based on each hospital’s estimated DSH status for FY 2014 or the applicable year (using the most recent data that are available). 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. (We discuss these proposals in more detail below.)

In the course of developing these proposed policies for implementing the provision of section 1886(r) of the Act, we considered whether several specific classes of hospitals are included within the scope of the statutory provision. In particular, we considered whether the provision applies to (1) hospitals in the Commonwealth of Puerto Rico, (2) hospitals in the State of Maryland paid under a waiver as provided in section 1814(b) of the Act, (3) sole community hospitals (SCHs), (4) hospitals participating in

the Bundled Payments for Care Improvement Initiative developed by the Center for Medicare and Medicaid Innovation (Innovation Center), and (5) hospitals participating in the Rural Community Hospital demonstration. We discuss each of these specific classes of hospitals below.

(1) Puerto Rico Hospitals

Under section 1886(d)(9)(A) of the Act, Puerto Rico hospitals subject to the IPPS are not “subsection (d) hospitals,” but rather constitute a distinct class of “subsection (d) Puerto Rico hospitals.” However, section 1886(d)(9)(D)(iii) of the Act specifies that subparagraph (d)(5)(F) (the provision governing the current DSH payment methodology) “shall apply to subsection (d) Puerto Rico hospitals... in the same manner and to the extent as [it applies] to subsection (d) hospitals.” While the new section 1886(r) of the Act does not specifically address whether the methodology established there applies to “subsection (d) Puerto Rico hospitals,” section 3133 of the Affordable Care Act does make a revision to section 1886(d)(5)(F)(i) of the Act that is crucial for determining the eligibility of Puerto Rico hospitals for empirically justified Medicare DSH payments and uncompensated care payments under the new provision. Specifically, section 3133 of the Affordable Care Act amended section 1886(d)(5)(F)(i) of the Act to provide that this section is “[s]ubject to subsection (r).” One effect of this amendment is to provide that all hospitals subject to section 1886(d)(5)(F)(i) of the Act, including “subsection (d) Puerto Rico hospitals,” also are subject to the new payment methodology established in section 1886(r) of the Act.

In this proposed rule, we are proposing that subsection (d) Puerto Rico hospitals that are eligible for DSH payments also would be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology.

We are inviting public comments on this proposal.

(2) Hospitals Paid under a Waiver under Section 1814(b) of the Act

Under section 1814(b) of the Act, hospitals in the State of Maryland are subject to a waiver from the Medicare payment methodologies under which they would otherwise be paid. We have taken the position in other contexts, for example, for purposes of EHR incentive payments (75 FR 44448), that Maryland acute care hospitals remain subsection (d) hospitals. This is because these hospitals are “located in one of the fifty States or the District of Columbia” (as provided in the definition of subsection (d) hospitals) and do not meet the definitions of the hospitals that are specifically excluded from that category, such as cancer hospitals and psychiatric hospitals. However, section 1886(r) of the Act applies to hospitals that are both subsection (d) hospitals and hospitals that would otherwise receive a disproportionate share payment made under the previous DSH payment methodology. Because Maryland waiver hospitals are paid under section 1814(b)(3) of the Act and not under section 1886(d)(5)(F) of the Act, they are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology of section 1886(r) of the Act.

(3) Sole Community Hospitals (SCHs)

SCHs are paid based on their hospital-specific rate from certain 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 have no add-on payments. For each cost reporting period, the fiscal intermediary/MAC determines which of the payment options will yield the highest aggregate payment. Interim payments are automatically made on a claim-by-claim basis at the highest rate using the best data available at the time the fiscal intermediary/MAC makes the payment determination for each discharge. However, it may not be possible for the fiscal intermediary/MAC to determine in advance precisely which of the rates will yield the highest aggregate payment by year's end. In many instances, it is not possible to 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 fiscal intermediary/MAC makes a final adjustment at cost report settlement after it determines precisely which of the payment rates would yield the highest aggregate payment to the hospital for its cost reporting period. This payment methodology makes SCHs unique as they can change on a yearly basis from receiving hospital-specific rate payments to receiving Federal rate payments, or vice versa.

In order to implement the provisions of section 1886(r) of the Act, we are proposing to 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 are proposing that SCHs that receive interim empirically justified DSH payments in a fiscal year would receive interim uncompensated care payments that fiscal year, subject as well to settlement through the cost report. Final eligibility determinations would be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments would be adjusted accordingly. We are thus proposing to follow the same processes of interim and final payments for SCHs that we are proposing to follow for eligible IPPS DSH hospitals generally. (We discuss these processes in more detail below.)

As previously noted, under the SCH payment methodology, SCHs are paid the higher of the Federal rate or a hospital-specific payment rate. This payment methodology is defined under sections 1886(d)(5)(D)(i) and 1886(d)(1)(A)(iii) of the Act. Section 1886(d)(3) specifically provides that SCH payments are to be made on a per-discharge basis. Accordingly, as we also note below, we are proposing that the uncompensated care payments would not be accounted for in determining whether an SCH is paid the higher of the Federal rate or the hospital-specific rate. This is because the uncompensated care payments are not discharge-driven payments, but rather are payments made on the basis of a hospital's overall share of uncompensated care during a payment year. The amount of a hospital's uncompensated care payments for a year is not

directly affected by the number of the hospital's discharges for the year. Therefore, we do not believe that uncompensated care payments should be taken into account in a comparison based on discharge driven hospital-specific and Federal rate payments. Furthermore, as we propose later in this rule, we intend to make interim uncompensated care payments on a periodic basis rather than a per discharge basis in order to create more predictability for hospitals and to increase administrative efficiency. To the extent the payments are intended to reflect the relative amount of uncompensated care furnished by the hospital, it is both reasonable and appropriate to view this payment as an amount for the year, which in the interests of predictability and consistency is made periodically through interim payments.

We are inviting public comments on all of these proposals affecting SCHs.

(4) Hospitals Participating in the Bundled Payments for Care Improvement Initiative

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 this proposed rule, we are proposing to apply the new DSH payment methodology to the hospitals in this initiative, so that eligible hospitals would receive empirically justified DSH payments and uncompensated care payments.

We are inviting public comments on this proposal.

(5) Hospitals Participating in the Rural Community Hospital Demonstration

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, they receive payments for the reasonable cost of providing such services. For discharges occurring in subsequent cost reporting periods during the applicable 5-year demonstration period, hospitals receive the lesser of the current year's reasonable cost amount, or the previous year's amount updated by the percentage increase in the IPPS market basket (the target amount). (We refer readers to section V.K. of the preamble of this proposed rule for further information on the demonstration.) The instructions (CR 5020 (April 14, 2006) and CR 7505 (July 22, 2011)) for the demonstration require that the fiscal intermediary/MAC not pay Medicare DSH payments in addition to the amount received under the cost-based payment methodology. Although the amounts that would otherwise be paid for Medicare DSH payments (absent the demonstration) are calculated and identified on the hospital cost report for statistical and research purposes, as in the case of Maryland waiver hospitals, hospitals in this demonstration do not receive a separate or identifiable DSH payment.

Because hospitals participating in the Rural Community Hospital Demonstration do not receive DSH payments, these hospitals are also excluded from receiving empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology.

c. Empirically Justified Medicare DSH Payments

As we have discussed above, the statute requires CMS to pay 25 percent of the “amount of disproportionate share hospital payment that would otherwise be made under subsection (d)(5)(F) to a subsection (d) hospital.” Currently, we have a system for interim payment and final settlement of DSH payments made under section 1886(d)(5)(F). Specifically, interim payments are made for each claim based on the best available data concerning each hospital’s eligibility for DSH payments and the appropriate level of such payments. Final eligibility for Medicare DSH payments and the final amount of such payments for eligible hospitals are determined at the time of cost report settlement. 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 do not believe that it is necessary to develop and propose any new operational mechanisms for making such payments.

Therefore, we are proposing to implement 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 will also make 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 will provide more detailed operational instructions and cost report instructions following issuance of the final rule.

We are proposing to implement this provision by adding a new paragraph (f) under the regulations at 42 CFR 412.106. This proposed new paragraph provides for reducing Medicare DSH payments by 75 percent beginning in FY 2014.

We are inviting public comments on this proposal.

d. Uncompensated Care Payments

As we have discussed above, 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 a base of 2013, and each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals. Below we discuss the proposed data sources and methodologies for computing each of these factors.

Before we begin to discuss these data sources and methodologies, it is necessary to discuss the timing and manner for determining the eligibility of hospitals for uncompensated care payments. The statute provides that subsection (d) hospitals that receive a payment under section 1886(d)(5)(F) of the Act are eligible to receive a payment under section 1886(r)(2) of the Act. 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) hospitals an additional amount....” Therefore, because paragraph (1) refers to empirically justified Medicare DSH payments, the additional payment for FY 2014 and subsequent years is limited to hospitals that receive empirically justified Medicare DSH payments for the respective year. However, as we have discussed above, we currently have a system for interim payment and final settlement of DSH payments. Specifically, interim payments are made for each claim based on the best available data concerning each hospital’s eligibility for DSH payments and the appropriate level of such payments. Final determination of eligibility for Medicare DSH payments and the final amount of such payments for eligible hospitals are determined at the time of cost report settlement.

As we describe above, because section 1886(r)(1) of the Act does not revise the criteria governing eligibility for DSH payments or the underlying payment methodology, we do not believe that it is necessary to develop and propose any new operational mechanisms for making such payments and would thus continue using the existing system of interim eligibility and payment determination with final cost report settlement for the empirically justified Medicare DSH payments. We are proposing to adopt a similar system of interim eligibility and payment determination with final cost report settlement for purposes of uncompensated care payments. We discuss the specific operational details of this system in section V.E.3.f. of this preamble.

We are inviting public comments on these proposals.

(1) Proposed Methodology to Calculate Factor 1

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 if the reduction to the Medicare DSH payment by 75 percent under section 1886(r)(1) of the Act did not apply for such fiscal year. In other words, section 1886(r)(2)(A)(i) of the Act represents an estimate of the full Medicare DSH payment amount under section 1886(d)(5)(F) prior to the 75-percent reduction, for FY 2014 and subsequent years. This subparagraph specifies that, for each fiscal year to which the provision applies, such amount is to be “estimated by the Secretary.” 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, the statute gives CMS 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 FY 2014 and subsequent years, taking into

account the application of the 75 percent reduction to the DSH payment amounts prescribed under section 1886(r)(1) of the Act. Again, section 1886(r)(2)(A)(ii) of the Act gives CMS 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 FY 2014 and subsequent years, in the absence of the new payment provision; and (2) the amount of empirically justified Medicare DSH payments that are made for FY 2014 and subsequent years, which takes into account the requirement to reduce Medicare DSH payments by 75 percent. 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 FY 2014 and subsequent years.

In order to determine Factor 1 in the uncompensated care payment formula, we are proposing to develop final estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) and the aggregate amount of empirically justified Medicare DSH payments to hospitals under section 1886(r)(1) prior to each fiscal year to which the new provision applies. We believe this will create some level of predictability and finality for hospitals eligible for these payments, in addition to being administratively efficient. Specifically, in order to determine the two elements of Factor 1 (Medicare DSH payments prior to the application of the 75 percent reduction, and empirically justified Medicare DSH payments after application of the 75 percent reduction), we are proposing to use the most recently available projections of Medicare DSH payments for FY 2014 and each subsequent 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 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 2013 estimate, the data are based on the December 2012 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2013 IPPS/LTCH PPS final rule IPPS Impact file, published in conjunction with the publication of the FY 2013 IPPS/LTCH PPS final rule. For the July 2013 estimate, we anticipate that the data will be based on the March 2013 update of the Medicare Hospital Cost Report data and this proposed rule's IPPS Impact file, published in conjunction with this proposed rule. For purposes of this proposed rule, we are using the February 2013 Medicare DSH estimates to calculate Factor 1 and to model the proposed impact of this provision. If our proposal to use the Office of the Actuary's projections for Factor 1 is finalized, we would use the July 2013 Medicare DSH estimates to determine Factor 1 for the FY 2014 IPPS/LTCH PPS final rule.

In addition, because we are proposing to exclude sole community hospitals paid under their hospital specific payment rate from the application of section 1886(r) of the Act, we are also proposing to exclude these hospitals from our Medicare DSH estimate. Similarly, because Maryland hospitals and hospitals participating in the Rural

Community Hospital Demonstration do not receive DSH payments, we also exclude these hospitals from our Medicare DSH estimate.

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 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 2013 Office of the Actuary estimate for Medicare DSH payments for FY 2014, without regard to the application of section 1886(r)(1) of the Act, is 12.338 billion. This estimate excludes Maryland hospitals, sole community hospitals 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 2014, with the application of section 1886(r)(1) of the Act, is \$3.084 billion (25 percent of the total amount estimated). Under our proposal, Factor 1 is the difference of these two estimates of the Office of the Actuary. Therefore, for the purpose of modeling Factor 1, we calculate Factor 1 to be \$9.2535 billion.

We also are proposing to develop and use the estimates necessary for Factor 1 on a purely prospective basis. We are proposing to use the Actuary's most recent February Medicare DSH estimates each year to calculate Factor 1 and to model the impact of this provision for the IPPS/LTCH PPS proposed rule. Similarly, we are proposing to use the Actuary's most recent July Medicare DSH estimates to determine Factor 1 for the

IPPS/LTCH PPS final rule each year. In other words, we would not revise or update our estimates after we know the final Medicare DSH payments for FY 2014 and subsequent years. As we discussed earlier, we do not know the aggregate Medicare DSH payment amount that would be paid for each federal fiscal year until the time of cost report settlements, which occur several years after the end of the fiscal year. Because the statute provides that CMS use estimates in order to determine Factor 1 each year, we believe that applying our best estimates prospectively would be most conducive to administrative efficiency, finality, and predictability in payments.

We are inviting public comments on all the elements of this proposed methodology to calculate Factor 1.

We are proposing to add a new paragraph (g)(1)(i) under § 412.106 of our regulations to define the methodology for calculating Factor 1.

(2) Proposed Methodology to Calculate Factor 2

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) of the Act establishes, as Factor 2 in the uncompensated care payment formula, the percent change in uninsurance, based on a comparison of the percent of individuals under 65 without insurance in 2013 to the percent of such individuals without insurance in the most recent period for which we have data, minus 0.1 percentage points for FY 2014 and 0.2 percentage points for each of FYs 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...” appeared in a March 20, 2010 letter from the director of the CBO to the Speaker of the House. (Emphasis supplied.) 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). (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 CBO letter to the Speaker of the House, the CBO provides two estimates of the “post-policy uninsured population.” The first estimate is of the “Insured Share of the Nonelderly Population Including All Residents” (which is 82 percent) and the second estimate is of the “Insured Share of the Nonelderly Population Excluding Unauthorized Immigrants” (83 percent). We are proposing to use the first estimate that includes all residents, including unauthorized immigrants. 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 65. In addition, we believe that this estimate would more fully reflect the levels of uninsurance in the United States that influence uncompensated care for hospitals. Therefore, using this estimate would seem more consistent with the statutory requirement of establishing a payment for uncompensated care. For these reasons, we are proposing to use the estimate of the “Insured Share of the Nonelderly

Population Including All Residents” for 2013 to calculate the baseline percentage of individuals under age 65 without insurance.

We are inviting public comments on this proposal.

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 2013,” we are proposing to use the CBO insurance rate figure and subtract that amount from 100 percent (i.e., the total population, without regard to insurance status) to estimate the 2013 baseline percentage of individuals without insurance. In its March 20, 2010 letter, the CBO reported its estimate of the “Insured Share of the Nonelderly Population Including All Residents” as 82 percent. Therefore, we are proposing that, for FYs 2014-2017, our estimate of the uninsurance percentage for 2013 would be 18 percent. As provided for in the CBO March 20, 2010 letter, the CBO estimate for insurance for the nonelderly (under age of 65) population only includes residents of the 50 States and the District of Columbia, and the count of uninsured people includes unauthorized immigrants, as well as people who are eligible for, but not enrolled in, Medicaid. We note that, although we are proposing that acute care hospitals located in Puerto Rico that receive DSH payments will be eligible to receive payments under section 1886(r) of the Act, this estimate for insurance does not account for residents in Puerto Rico. We believe that the impact of the exclusion of Puerto Rico from the insurance estimate is negligible.

We are inviting public comments on this proposal.

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).” We are proposing to use the same data source, CBO estimates, to calculate this percent of individuals without insurance. Section 1886(r)(2)(B)(i)(I) of the Act refers to the percent of uninsured in 2013 “as calculated by the Secretary based on” the CBO data. Similarly, section 1886(r)(2)(B)(i)(II) of the Act immediately afterwards refers to the percent of uninsured for 2014 “as so calculated.” (Emphasis supplied.) The phrase “as so calculated” in the latter section can be reasonably interpreted to require the calculation to similarly be based on CBO estimates. In addition, we believe that it is preferable from a statistical point of view to calculate a percent change in insurance over time using a consistent data source. Furthermore, rather than using the estimates included in the March 20, 2010 CBO letter, we believe it is appropriate to use more recent CBO estimates of the percent of individuals with insurance. The more recent CBO projections take into account changes in the environment that can impact insurance rates, such as more recent economic conditions and the Supreme Court’s decision in National Federation of Independent Business. v. Sebelius, ___ U.S. ___, 132 S. Ct. 2566 (2012), regarding Medicaid expansions authorized by the Affordable Care Act. Because the statute requires that we use “the most recent period for which data is available” to calculate the comparison percentage of individuals without insurance, we are proposing to use the most recent update (that is, the most recent update available at the time of rulemaking with respect to

a particular fiscal year) to the percent of individuals with insurance provided by the CBO to calculate this comparison figure.

In addition, for FY 2014, we are proposing to use CBO's most recent estimate for the percent of individuals with insurance in 2014 for purposes of section 1886(r)(2)(B)(i)(II) because this is the year in which this provision is effective. This figure is used for Factor 2 and later applied to Factor 1, which is also based on an estimate for FY 2014. On February 5, 2013, the CBO released its annual Budget and Economic Outlook. The report included updated economic and budget projections that incorporated the effects of the legislation enacted prior to the start of the year, a revised economic forecast consistent with the budget projections, and other changes to CBO's estimates. (To view the report, we refer readers to the Web site at:

http://www.cbo.gov/sites/default/files/cbofiles/attachments/43900_ACAInsuranceCoverageEffects.pdf.)

In this proposed rule, we are using the February 5, 2013, CBO health insurance estimates in order to calculate the percentage of individuals without insurance for 2014. As we did for the uninsurance percentage estimate for 2013 (based on the March 20, 2010 CBO letter discussed above), we are proposing to use the "Insured Share of the Nonelderly Population Including All Residents" to calculate the comparison of percentage of people without insurance for 2014. Consistent with the CBO estimate used to calculate the baseline uninsurance estimate, this estimate for insurance only includes residents of the 50 States and the District of Columbia, and the count of uninsured people includes unauthorized immigrants, as well as people who are eligible for, but not enrolled

in, Medicaid. The CBO report projects that the “Insured Share of the Nonelderly Population Including All Residents” for 2014 will be 84 percent. Therefore, in the same manner that we calculated the uninsurance percentage for the baseline, we are proposing that the uninsurance percentage for 2014 would be 16 percent (i.e., 100 percent minus 84 percent) for the purpose of this proposed rule. If our proposal is finalized, and there is a more recent estimate of the percentage of individuals with insurance in 2014 by the CBO available for the FY 2014 IPPS/LTCH PPS final rule, we would use that estimate to calculate Factor 2. However, we would not adjust Factor 2 retroactively to account for estimates that become available after publication of the final rule.

Section 1886(r)(2)(B)(i) of the Act states that Factor 2 for FY 2014 is 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 without insurance in the baseline and in the most recent period for which we have data (minus 0.1 percentage points for FY 2014). Therefore, we are proposing that Factor 2 is 1 minus the percent change of the baseline percentage of individuals without insurance in 2013 (which is, for this proposed rule, 18 percent) and the most recent percentage of individuals without insurance for 2014 (which is, for this proposed rule, 16 percent) minus 0.1 percentage points.

Using the March 20, 2010 CBO projection for 2013 and the February 5, 2013 CBO projection of uninsurance for all residents for 2014, we are proposing to use the following computation for Factor 2 for FY 2014:

Percent of individuals without insurance for 2013: 18 percent

Percent of individuals without insurance for 2014: 16 percent

$$1 - |[(0.16 - 0.18)/0.18]| = 1 - 0.111 = 0.889 \text{ (88.9 percent)}$$

$$0.889 \text{ (88.9 percent)} - 0.001 \text{ (0.1 percentage points)} = 0.888 \text{ (88.8 percent)}$$

$$0.888 = \text{Factor 2}$$

Accordingly, we are proposing Factor 2 to be 88.8 percent for FY 2014. In conjunction with this proposal, we are therefore proposing that the amount available for uncompensated care payments for FY 2014 will be \$8.217 billion (0.888 times our proposed Factor 1 estimate of \$9.2535 billion). As we noted previously, our proposal for Factor 2 may be subject to change if more recent CBO estimates of the insurance rate for 2014 become available prior to the preparation of the final rule.

We are inviting public comment on our proposed methodology to calculate Factor 2.

In this proposed rule, we are proposing to add a new paragraph (g)(1)(ii) under §412.106 of our regulations to define the methodology for calculating Factor 2.

(3) Proposed Methodology to Calculate Factor 3

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed above, 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 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 years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, we must determine the following: (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 FY); (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 the uninsured

In the course of considering how to determine Factor 3, we considered proposing to define the amount uncompensated care for a hospital as the uncompensated care costs of that hospital and considered potential data sources for those costs. In doing so, we first considered which costs should be included in the definition of “uncompensated care costs.” We examined the broad literature on uncompensated care and the concepts of uncompensated care used in various public and private programs. We also considered input from stakeholders and public comments in various forums, including the national provider call that we held in January 2013. Our review of the information from these sources indicated that there is some variation in how different States, provider organizations, and Federal programs define “uncompensated care.” However, a common theme of almost all these definitions is that they include both “charity care” and “bad debt” as constituents of “uncompensated care.” After considering the various factors that are included in different definitions of “uncompensated care,” we considered proposing to adopt a definition which incorporated those factors that are most commonly included within the term. Thus we considered proposing to define “uncompensated care” as the cost of charity care plus bad debt which includes the cost of non-Medicare bad debt and non-reimbursed Medicare bad debt. In turn, we also considered proposing to define “charity care costs” as the cost of care for patients that meet hospitals’ individual criteria for charity care net of any partial payment received by the hospital from patients for that care, and to define “non-Medicare bad debt costs” as the cost of hospital care for non-

Medicare patients that have the financial capacity to pay, but are unwilling to settle the claim. In addition, we considered proposing to define “non-reimbursed Medicare bad debt costs” as the amount of allowable coinsurance and deductible for Medicare patients from whom the hospital has sought to collect payment through reasonable collection efforts as described in § 413.89(e) of the Medicare regulations and not reimbursed by Medicare.

Charity care is most commonly defined as hospital care provided to individuals that meet certain financial eligibility criteria, for which the hospital does not expect to receive payment because of the individual’s inability to pay. Definitions of charity care also regularly state that a patient must meet several guidelines for their care to qualify as charity care. These guidelines usually state that the patient must be uninsured, unqualified for a Federal program such as Medicaid, and/or fall under a certain Federal poverty line (FPL) standard. Some charity care is directed at insured individuals when insurance does not cover all the costs of their hospital care or when there are annual or lifetime limits. This definition also varies by hospital. Some hospitals may also seek payment from individuals who qualify for charity care as part of their financial assistance policies or to help offset the cost of that patient’s hospital care. To the extent that hospitals receive payment from a patient that qualifies for charity care for hospital care provided, we believe that those payments should be subtracted from the costs of that care. In this way, the cost of charity care reflects the financial burden on the hospital, or, stated another way, the cost of charity care reflects only the uncompensated portion of the charity care.

The literature suggests that bad debt has been consistently defined as unreimbursed care for persons for which the hospital did not receive payment. The regulations at 42 CFR 413.89(b)(1) define Medicare bad debt as “amounts considered to be uncollectible from accounts and notes receivable that were created or acquired in providing services.” The regulations also specify that: “‘accounts receivable’ and ‘notes receivable’ are designations for claims arising from the furnishing of services, and are collectible in money in the relatively near future.” Section 413.89(e) further specifies that under Medicare “bad debt must meet the following criteria to be allowable: (1) The debt must be related to covered services and derived from deductible and coinsurance amounts. (2) The provider must be able to establish that reasonable collection efforts were made. (3) The debt was actually uncollectible when claimed as worthless. (4) Sound business judgment established that there was no likelihood of recovery at any time in the future. We considered proposing to use the cost of non-Medicare and non-reimbursed Medicare bad debt (as reported on line 29 of the Worksheet S-10) as part of the proposed definition of “uncompensated care.”

Some definitions of uncompensated care, including that used for calculating the Medicaid DSH hospital payment limit at 42 CFR 447.299(c)(16), also include the difference between the costs incurred by a hospital for services to Medicaid individuals and applicable revenues for these services. While we recognize in some cases, a hospital may receive revenues that do not fully cover those costs, we note that this is true for any patient population treated by a hospital regardless of insurance status. Hospitals

negotiate contractual allowances with commercial payers, and it is possible that payment for some of these patients would be less than the costs of their care.

We emphasize, however, that we plan to monitor the potential effects of different definitions of uncompensated care on various measures designed to expand health insurance coverage under the Affordable Care Act, including Medicaid expansion.

Specifically, we wish to avoid creating a policy that would serve as a disincentive for States wishing to expand Medicaid. Using some of the data discussed in this proposed rule, we recognize it would be possible for hospitals in States that choose to expand Medicaid to receive lower uncompensated care payments because they are less likely to have uninsured patients than hospitals in a State that does not choose to expand Medicaid. In practice, because the available data sources (such as the Medicare cost report) for a given federal fiscal year are not available until some time after the end of that federal fiscal year, we believe that data to understand these effects will not be available until 2016 or later. However, we also note that hospitals in expansion States would receive full Medicaid reimbursement for many previously uninsured patients. So on balance, we believe both hospitals and States stand to benefit greatly from Medicaid expansion, regardless of the data used to determine Factor 3. However, if warranted, we may in the future reconsider how to define uncompensated care, such as to include differences between applicable Medicaid costs and revenues, or consider other definitions that would account for differences in State Medicaid coverage.

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 the Medicare cost report Worksheet S-10 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 can be found on the CMS Website at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html>.) However, Worksheet S-10 is a relatively new data source that has been used for specific payment purposes only in relatively restricted ways (e.g., to provide a source of charity care charges in the computation of EHR incentive payments; 75 FR 44456.). 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. We understand and appreciate the concerns of these stakeholders. At the same time, Worksheet S-10 is the only national data source that includes data for all Medicare hospitals and is designed to elicit data that are both accurate and consistent with the definition of uncompensated care costs that we considered proposing to use.

Charity care information is reported on Worksheet S-10, lines 20 through 23. On line 20, Column 3, hospitals report “Total initial obligation of patients approved for charity care (at full charges excluding non-reimbursable cost centers) for the entire facility” for both the insured and uninsured population. On Worksheet S-10, line 21, the charity care charges reported on line 20 are converted to charity care costs by multiplying

the charity care charges by the cost-to-charge ratio (CCR) reported on line 1 of Worksheet S-10. Partial payment by patients for charity care is reported on line 22 of Worksheet S-10. Charity care costs are reported on line 23 of Worksheet S-10 as the difference between line 21 and 22. We could use “Cost of Charity Care,” line 23, Column 3 of Worksheet S-10 to identify a hospital’s charity care costs, as part of a definition of “uncompensated care.”

Bad debt information is reported on Worksheet S-10, lines 26 through 29. On Worksheet S-10, line 26 and line 27, a hospital reports its total bad debt expense and its Medicare reimbursed bad debt expense, respectively. On Worksheet S-10, line 28 represents the non-Medicare bad debt expense and non-reimbursed Medicare bad debt expense, the difference between lines 27 and 26. The cost of non-Medicare bad debt and non-reimbursed Medicare is reported on line 29 of the Worksheet S-10 as the product of the CCR and the non-Medicare and non-reimbursed Medicare bad debt expense reported on line 28. We could use the cost of non-Medicare bad debt and non-reimbursed Medicare that is reported on line 29 of the Worksheet S-10 to identify a hospital’s bad debt costs, as part of a definition of “uncompensated care.”

To summarize, we could use the sum of line 23, Column 3 of Worksheet S-10 and line 29 of Worksheet S-10 to estimate a hospital’s uncompensated care cost. A hospital’s individual uncompensated care cost based on this estimate would represent that hospital’s numerator for Factor 3. The sum of the estimated uncompensated care costs for all the hospitals that we estimate would receive DSH payments (and thus the uncompensated care payment) for the fiscal year would represent the denominator of Factor 3.

In order to apply a definition of uncompensated care costs based upon information reported on the Worksheet S-10, it would be necessary to use the 2010/2011 cost reports, which were submitted on or after May 1, 2010, when the new Worksheet S-10 went into effect. These are the most recently available full year of cost reports and the first cost reports with detailed uncompensated care data on the Worksheet S-10 that would be available for use in implementing the new methodology for uncompensated care payments for FY 2014. Concerns about the standardization and completeness of the Worksheet S-10 data could be more acute for data collected in the first year of the Worksheet's use. Because of these concerns, we are not proposing to define of uncompensated care in a way that would require use of the Worksheet S-10 data.

We believe, however, that Worksheet S-10 of the Medicare Cost Report would otherwise be an appropriate data source to determine uncompensated care costs. In particular, we note 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. While we realize that hospitals may wish to have a more specific understanding of how this data will be used, we believe that the discussion in this proposed rule will help to increase their understanding and also inform our efforts to refine the cost report and cost report instructions so that hospitals may continue to gain experience in reporting accurate

information. We also 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 electronic health record incentive program, and will continue to monitor these data. Accordingly, 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 we describe above, we are concerned about stakeholder input that the variations in the data reported on Worksheet S-10 of the Medicare cost report regarding uncompensated care may be due to hospitals' relative lack of experience reporting all of the data elements on that worksheet. A large number of stakeholders noted that there is considerable variation and numerous inconsistencies in how uncompensated care is calculated and reported in Worksheet S-10 and they point out that these inconsistencies can produce divergent results. Some went as far as noting that data from Worksheet S-10 is "flawed" and many suggested more precision in reporting instructions to help hospitals report data in a more consistent manner. We note that most of the data elements reported on Worksheet S-10 have been previously unused for payment purposes, with only some data elements recently being used for determining a hospital's electronic health record incentive payments, and these data elements have not been subject to audit prior to this time. We believe it is important that data used to determine Factor 3 are data that have been historically publicly available, subject to audit, and used for payment purposes (or that the public understands will be used for payment purposes). It is our belief that hospitals expend more resources to ensure data accuracy when data are publicly available

and used for payments. For example, the National Quality Forum (NQF) first endorsed quality measures for readmissions for heart failure (HF) in May 2008 and acute myocardial infarction (AMI) and pneumonia (PN) in October 2008. HF was subsequently adopted in the Hospital Inpatient Quality Reporting Program in the FY 2009 IPPS rule and AMI and PN in the CY2009 OPSS rule. All three were adopted for the FY 2010 HIQR program and publicly reported in Hospital Compare in 2009. More recently, starting in FY 2013, all three were used to determine a payment adjustment under 1886(q). As the measures became linked with payment, CMS has received an increasing number of questions regarding and requests to refine these measures, leading us to believe that hospitals are increasingly focused on ensuring that their data are correct. Furthermore, it is also our belief that auditing plays an important role in ensuring data accuracy by identifying and remediating problem areas and/or hospitals as well as by having a sentinel effect in others. For example, each year, CMS and its intermediaries work with hospitals to review salary and wage data reported on Worksheet S-3 of the Medicare cost report for use in determining the wage index. This extensive process identifies errors and ensures that anomalous data are reviewed, corrected as needed, and documented. Due to stakeholder concerns and our belief in the importance of using data that have been historically publicly available, subject to audit, and used for payment purposes(or that the public understands will be used for payment purposes), for FY 2014, we have serious concerns about proposing using Worksheet S-10 to determine the amount of uncompensated care.

While the statute instructs the Secretary to estimate the amounts of uncompensated care for a period “based on appropriate data,” section 1886(r)(2)(C)(i) 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 the uninsured” for the numerator of Factor 3. For the denominator of that quotient, section 1886(r)(2)(C)(ii) requires the Secretary to use “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). (Emphasis added.) The phrase “as so estimated, based on such data” in the latter section can be reasonably interpreted to require the calculation to similarly be based on the same data as is used to estimate the numerator of the quotient in Factor 3, including any alternative data which is determined to be a better proxy for the costs of treating the uninsured. As a result of our concerns regarding variations in the data reported on the Worksheet S-10, we believe that it is appropriate to consider the use of alternative data, at least in FY 2014, the first year that this provision is effective, and possibly additional years until hospitals have adequate experience reporting all of the data elements on Worksheet S-10. We note that this 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 cannot be used for implementation of 1886(r) and who requested the opportunity to re-submit 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 S-10 reporting. For the reasons described above, we believe it would be appropriate to use data elements that have been historically publicly available, subject to audit, and used for payment purposes (or that the public understands will be used for payment purposes) as alternative data for the first year or years of implementation.

In order to implement the statutory requirements for Factor 3 using alternative data, we must: (1) determine whether alternative data would be a better proxy for the treatment costs of the uninsured than the information available on the Worksheet S-10; (2) identify a source for this alternative data; and (3) determine the timing and manner of computing the quotient for each hospital.

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 believe that this alternative data, which is currently reported on the Medicare cost report, would be a better proxy for the amount of uncompensated care provided by hospitals. Accordingly, we propose to use 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 describe our proposal and rationale more fully below and seek public comment.

As a preliminary matter, we note that precise data on health care costs are difficult to obtain. We note that for Medicare payment purposes, we estimate those costs using reported charges and cost-to-charge ratios. This approach to estimating costs is what is

used on Worksheet S-10 to determine costs for charity care and bad debt. Even though we do not believe it is appropriate to look beyond the Medicare cost report for alternative data because all hospitals are required to report data on that cost report, we think that it is important to point out that data on uninsured patients is difficult to find in a comprehensive manner on a hospital-specific basis. In a September 2002 report, *Analysis of the Joint Distribution of Disproportionate Share Hospital Payments*, RAND and Urban Institute researchers describe this difficulty, citing as an example how detailed inpatient utilization data on self-pay patients were available only for the sample of hospitals (20 percent sample) from the 24 states included in AHRQ's HCUP database.²⁵

While Worksheet S-10 does contain some information regarding the treatment costs of the uninsured, most notably of those uninsured patients who qualify for charity care at an individual hospital, for the reasons described above, we are concerned about the use of information reported on the Worksheet S-10 as appropriate data for FY 2014 and possibly additional years. As a result of these concerns, in identifying alternative data that could serve as a proxy for the treatment costs of the uninsured, we must consider methods other than costs to approximate the resources expended by hospitals to treat uninsured patients. One such method is utilization. A hospital's costs for treating uninsured patients are a function of its input costs and utilization of services. In accordance with the statute, in order to determine Factor 3, a hospital-level estimate of uncompensated care is required. Such an estimate can be constructed using detailed data regarding specific items or services. However, such data are not available to us. In

²⁵ Wynn, B. et al. *Analysis of the Joint Distribution of Disproportionate Share Hospital Payments*. PM-1387-ASPE. September 20, 2002
http://www.urban.org/UploadedPDF/410975_ASPEDSH_final.pdf

contrast, hospital level data measuring utilization as inpatient days or discharges are available. While we note that inpatient days or discharges would be more precise if they took into account the relative resource utilization of individual patients, such as case mix, no such data are available to us. In the September 2002 report discussed above, RAND and Urban Institute researchers asserted that without specific case mix data for low income populations, inpatient days are preferable to discharges as a way to measure utilization. Therefore, we believe that utilization based upon inpatient days is an appropriate method to approximate costs for the treatment costs of the uninsured.

We further believe that utilization by insured low-income patients, such as Medicaid patients or Medicare patients that receive SSI benefits (Medicare SSI), can be a reasonable proxy for utilization by uninsured patients. In its 2000 report on American's Health Care Safety Net, the Institute of Medicine considers uninsured individuals, low-income underinsured individuals, Medicaid beneficiaries, and patients with special health care needs all as vulnerable populations.²⁶ We note that when studying access to care, researchers may study Medicaid and/or low-income populations (e.g., health outcomes, utilization, etc.) in order to understand more broadly the impact of similar policy interventions for other vulnerable populations.²⁷ For example, recently, researchers have studied the effects of Medicaid expansions to gauge the effects of these expansions on health status and other indicators to inform policymakers as these expansion efforts

²⁶ Marion Ein Lewin and Stuart Altman, Editors; Committee on the Changing Market, Managed Care, and the Future Viability of Safety Net Providers, Institute of Medicine. *America's Health Care Safety Net: Intact but Endangered*. 2000. <http://www.nap.edu/catalog/9612.html>

²⁷ John K. Iglehart. Medicaid. *N Engl J Med* 1993; 328:896-900. March 25, 1993.

continue.²⁸ Researchers have also studied the ability of Medicaid patients to gain access to outpatient care in an effort to highlight the ramifications of various policy interventions, such as mandatory co-payments and utilization restrictions.²⁹ We believe that this type research is often used by state and other policy makers to evaluate how Medicaid and other public health insurance can expand access to care to uninsured populations.

While the report by RAND and the Urban Institute cited above found shortcomings in how well both Medicaid and Medicare DSH target funds towards safety net hospitals, another key finding of the report was that the allocation methods used by these programs target funds to safety net hospitals at least as well as the alternative allocation methods they examined. The allocation method used by Medicare for Medicare DSH is the sum of two computations. The first computation, defined at 42 CFR 412.106(b)(2), known as the SSI ratio or Medicare fraction, is the proportion of a hospital's Medicare SSI days relative to Medicare days. The second computation, defined at 42 CFR 412.106(b)(4), known as the Medicaid fraction, is the proportion of a hospital's Medicaid days relative to total days. The by RAND and the Urban Institute study also found that the choice of patient populations used to evaluate how well Medicare and Medicaid DSH funds are allocated is important. The study notes that including Medicare SSI beneficiaries along with all other low-income patients generally performed better, resulting in a better targeting of these payments towards safety net

²⁸ Benjamin D. Sommers, M.D., Ph.D., Katherine Baicker, Ph.D., and Arnold M. Epstein, M.D. Mortality and Access to Care among Adults after State Medicaid Expansions. *N Engl J Med* 2012; 367:1025-1034. September 13, 2012.

²⁹ The Medicaid Access Study Group. Access of Medicaid Recipients to Outpatient Care. *N Engl J Med* 1994; 330:1426-1430. May 19, 1994.

hospitals. Therefore, we believe the utilization of insured low income patients defined as insured low-income days, or inpatient days of Medicaid patients plus inpatient days of Medicare-SSI patients could be a proxy for the treatment costs of uninsured patients. Currently, for the Medicare DSH adjustment, hospitals report utilization for Medicaid and Medicare SSI patients in accordance with the regulations at 42 CFR 412.106(b)(4) and 412.106(b)(2)(i), respectively. Specifically, we would define inpatient days for Medicaid patients as they are defined in 42 CFR 412.106(b)(4) and inpatient days for Medicare-SSI patients as they are defined at § 412.106(b)(2)(i). A hospital's individual insured low-income insured days based on this calculation would represent that hospital's numerator for Factor 3. The sum of the low-income insured days under this calculation for all the hospitals that we estimate would receive DSH payments (and thus the uncompensated care payment) for FY 2014 would represent the denominator of Factor 3.

It is important to point out that when these insured low-income utilization data are used to determine Medicare DSH payments, they are subject to additional computations as described in 42 CFR 412.106(b) and 412.106(d). Therefore, using these data to determine Factor 3 will lead to a different set of results than using these data to determine hospitals' Medicare DSH payments.

We believe that the data in the Medicare cost report (and data that are used to update the SSI ratios in the cost report) are acceptable for use as a source for this alternative data because they include data for all Medicare hospitals. For the reasons described above, we considered data elements from the Medicare cost report that have been historically publicly available, subject to audit, and used for payment purposes, as

alternative data for the costs of subsection (d) hospitals for treating the uninsured.

Worksheet S-3, Part I of the CMS-2552-96 version of the Medicare cost report and Worksheet S-2, Part I of the CMS 2552-10 version of the Medicare cost report contain information on the utilization of Medicaid patients. Specifically, it contains information regarding Medicaid days (i.e., the numerator of the Medicaid fraction). The SSI ratios can be found in Worksheet E, Part A and hospitals' SSI ratios are reported by CMS on the Medicare DSH website, by Federal fiscal year, and include a hospital's Medicare SSI days. We point out that CMS calculates the SSI ratios using the MedPAR claims data and updates them annually in accordance with the process and timing set forth in the FY 2011 IPPS rule (75 FR 50282), generally issuing them in the Spring of each year for the federal fiscal year two years prior. For instance, we would expect that the SSI ratios for FY 2011 would be made available in the Spring of 2013. SSI ratios can be downloaded from <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html>. The SSI ratios for a Federal fiscal year are the data that would ultimately be used in Worksheet E, Part A to determine a hospital's Medicare DSH adjustment for that fiscal year. While a hospital may choose to have its DSH payments settled using an SSI ratio based on the hospital's cost reporting period, this choice will vary by hospital and the timing of this choice will vary. As a result, a hospital's decision whether to have its SSI ratio calculated on the basis of its cost reporting period may not be available at the time we determine Factor 3 for a specific federal fiscal year. Therefore, in an effort to balance consistency and administrative

efficiency with precision, we believe it is appropriate to use the SSI ratios based on the federal fiscal year.

Except for the data on Worksheet S-10, the Medicare cost report does not currently include information that would allow calculation of the treatment costs of uninsured patients. For the reasons described previously, for FY 2014 and possibly additional years, we have concerns with using these data. Accordingly, we propose to use Worksheet S-3 Part I of the CMS-2552-96 version of the Medicare cost report and Worksheet S-2, Part I of the CMS 2552-10 version of the Medicare cost report and data that are used to update the SSI ratios on that Worksheet E, Part A as the source of the alternative data to determine Factor 3 for FY 2014. We may propose to use data from Worksheet S-10 to determine uncompensated care costs in the future, once hospitals are submitting accurate and consistent data through this reporting mechanism.

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, the statute defines the numerator of the quotient as “the amount of uncompensated care for such hospital for a period selected by the Secretary...” The statute 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.) As we have discussed above, we are proposing 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 proposed process, we also are proposing

to determine the time period from which to estimate the numerator and denominator of the Factor 3 quotient in a way that will 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 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.

We are proposing to estimate 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 are proposing to use data from the most recently available 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 note that these data are publicly available, subject to audit, and used for payment purposes. While we recognize that older data also meet these criteria, we often use the most recently available data for payment determinations. Therefore, for FY 2014, we are proposing to use data from the 2010/2011 cost reports for the Medicaid days and the FY 2011 SSI ratios for the Medicare-SSI days (or, if the FY 2011 SSIs are unavailable, the FY 2010 SSI ratios) to estimate Factor 3 for FY 2014.

To summarize, for FY 2014, in response to stakeholder concerns regarding data variability and lack of reporting experience with Worksheet S-10, we propose to determine Factor 3 using insured low-income patient days from the 2010/2011 cost

reports (including the FY2011 or FY 2010 SSI ratios, whichever represents the most recently available inputs prior to October 1, 2013) as alternative data which are a better proxy for the treatment costs of uninsured patients. We further propose to define insured low-income patient days 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.

We are proposing to add a new paragraph (g)(1)(iii) under § 412.106 of our regulations to define the methodology for calculating Factor 3.

We are inviting public comments on this proposal. Notwithstanding our concerns regarding Worksheet S-10, we are interested to hear commenters' views on the quality of the data reported on the Worksheet S-10, and whether it would be sufficient for use in determining uncompensated care amounts for fiscal year 2014, either by itself or in combination with other data. We also seek comment on how fast we could transition to the use of Worksheet S-10 data based upon increased reliability over time, including whether the data could be used to determine uncompensated care in FY 2014 either alone or in combination with other data.

In addition, we are proposing to estimate which hospitals would receive an empirically justified DSH payment in a given Federal fiscal year using the most recent data available. As we described previously, only hospitals that receive Medicare DSH payments in a fiscal year may receive an uncompensated care payment. However, because whether or not a hospital will actually receive Medicare DSH payment is not known until cost report settlement and cost report settlement occurs several years after

end of the federal fiscal year, we believe it is necessary to estimate which hospitals will receive Medicare DSH for a given fiscal year. Because the uncompensated care amounts for these hospitals are used to determine the denominator of Factor 3, this allows for the calculation of Factor 3 in advance of or during the federal fiscal year so that interim payments can begin during the fiscal year. We believe that this will create some level of predictability and finality for hospitals eligible for these payments, in addition to being administratively efficient.

Thus for FY 2014, the denominator for Factor 3 would reflect the estimated Medicaid and Medicare SSI patient days based on data from the 2010/2011 Medicare cost report (including the most recently available data that may be used to update the SSI ratios) for all hospitals that we estimate would receive an empirically justified DSH payment in FY 2014. The numerator of Factor 3 would be the estimated Medicaid and Medicare SSI patient days for the individual hospital based on its most recent 2010/2011 Medicare cost report data (including the most recently available data that may be used to update the SSI ratios). We propose to calculate a numerator for all subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving a DSH payment regardless of whether we estimate that the hospital would receive DSH payments in the respective Federal fiscal year. In that way, if a hospital becomes eligible to receive the empirically justified DSH payment and also an uncompensated care payment, we will be able to finalize its uncompensated care payment efficiently and without affecting the uncompensated care payments of other hospitals.

We believe that this proposed approach strikes an appropriate balance between administrative efficiency, finality, and predictability in payments. Therefore, we also are proposing to publish a table or tables listing Factor 3 for all hospitals that we estimate would receive empirically justified DSH payments in a fiscal year (that is, hospitals that 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 DSH payment for the fiscal year as determined at cost report settlement. We are also proposing that hospitals have 60 days from the date of 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. We will notify hospitals concerning the specifics of this process in program instructions after the final rule. For FY 2014, we will allow hospitals 60 days from the date of 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, and we may allow an additional (perhaps shorter) such period after the publication of the final rule. For hospitals that were not estimated to receive an empirically justified DSH payment for a fiscal year, but ultimately qualify for such a payment at cost report settlement, we would make the full uncompensated care payment at that time. In the case of hospitals that we estimated would receive an empirically justified Medicare DSH payment for a fiscal year and that received interim empirically justified Medicare DSH payments and uncompensated care payments, but are found to be ineligible for DSH payments at cost report settlement, we

would recover the overpayment. However, we are proposing only to calculate the denominator once, at the time of the IPPS/LTCH PPS final rule each year. We are not proposing to recalculate the denominator at the time when cost reports are settled and final eligibility determinations for uncompensated care (and empirically justified Medicare DSH) payments are made. We discuss our proposals for interim payments and reconciliation processes later in this preamble.

For the purpose of this proposed rule, we are posting proposed tables listing Factor 3 for the hospitals that we have estimated would receive Medicare DSH payments for FY 2014 on the CMS Website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service->

[Payment/AcuteInpatientPPS/dsh.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html). We request that hospitals review these tables. In order to ensure that we have sufficient time to incorporate any updated information in the tables for the final rule, hospitals should notify CMS in writing within 60 days from the date of display of this proposed rule of any change in a hospital's subsection (d) hospital status. As we state above, for FY 2014, we may allow an additional (perhaps shorter) such period after the publication of the final rule.

Our estimates of eligibility to receive FY 2014 Medicare DSH payments are based on the December 2012 update of the Provider Specific File that lists the most recently available DSH patient percentage (DPP) and DSH payment adjustments for hospitals that qualify to receive DSH payments. We estimate that 2,349 hospitals, or 68 percent of all applicable hospitals, would be eligible for DSH payments in FY 2014. The proposed Factor 3 is based on the December 2012 update of the Medicare Hospital Cost

Report and FY 2010 SSI ratios. The data from these 2,349 hospitals is used to determine the denominator for Factor 3. However, we will estimate a Factor 3 numerator for each subsection (d) and subsection (d) Puerto Rico hospital that has the potential of receiving DSH payments for FY 2014 and therefore of qualifying for the uncompensated care payment in FY 2014. We intend to update in the final rule the list of hospitals that we estimate will be eligible for DSH payments for FY 2014 and our estimate of Factor 3 using more recent data and verified hospital notifications regarding hospital status (for example, closures).

e. Limitations on Review

Section 1886(r)(3) of the Act provides that there will be no administrative or judicial review under section 1869 of the Act, 1878 of the Act, or otherwise for any of the following:

- Any estimate of the Secretary for purposes of determining the factors described in paragraph (2) of section 1886(r) of the Act.
- Any period selected by the Secretary for such purposes.

We are proposing to codify this policy in new § 412.106(g)(2) of our regulations.

We invite public comment on this proposal.

f. Proposed Operational Considerations

As discussed earlier in section V.F.3.d. of the preamble of this proposed rule, and in accordance with section 1886(r)(2) of the Act, only subsection (d) hospitals that receive empirically justified Medicare DSH payments in a given Federal fiscal year will also receive the uncompensated care payment (that is, Factor 1 times Factor 2 times

Factor 3) for that given Federal fiscal year. In addition, as discussed above in this section, we are proposing that subsection (d) Puerto Rico hospitals that receive empirically justified Medicare DSH payments in a given Federal fiscal year would also receive the uncompensated care payment (that is, Factor 1 times Factor 2 times Factor 3) for that given Federal fiscal year. As we discussed above, we intend to estimate Factor 3 for each subsection (d) and subsection (d) Puerto Rico hospital with the potential to receive a DSH payment prior to the beginning of the Federal fiscal year and intend to make that information available via our Web site.

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html>.

Specifically, we are proposing to make interim uncompensated care payments on the basis of our best available estimates concerning the eligibility of each hospital for empirically justified Medicare DSH payments and our best available calculations concerning the amount of the uncompensated care payments that the hospital is eligible to receive. We intend to make these interim uncompensated care payments on a periodic basis and not on a per discharge basis. As discussed above, we believe that this approach is more consistent with the plain language of the statute describing the additional payment, which includes no information from which it would be possible to infer that the payment should be made on a per discharge basis. We believe that this is the most administratively efficient means to distribute a set dollar amount to individual hospitals and also creates an appropriate level of predictability for hospitals. If we were to make these interim uncompensated care payments on a per discharge basis, unless a hospital's

Medicare utilization is identical to the period used to determine the per discharge payment level, it is certain that Medicare would overpay or underpay. By making interim payments periodically, we can virtually eliminate the possibility that Medicare pays a higher or lower amount than intended and limit the need for reconciliation to whether a hospital is eligible for Medicare DSH and thus the entire uncompensated care payment at cost report settlement.

We also are proposing to make a final determination concerning eligibility for uncompensated care payments at the time of cost report settlement. As a result of this proposal, our operational system must be able to handle the various situations that may arise between interim and final eligibility determinations. For example, a hospital may receive empirically justified DSH payments and uncompensated care payments based on an initial determination that the hospital is eligible for such payments, but the hospital may then be determined to be ineligible for such payments at cost report settlement. In such situations, we must be prepared and able to recoup the interim empirically justified DSH payments and uncompensated care payments that the hospital received.

For each Federal fiscal year, as we proposed earlier in this section, we intend to estimate which hospitals will receive an empirically justified DSH payment (that is, eligible hospitals). We are proposing to provide periodic payments to these hospitals during the relevant Federal fiscal year so that they can receive their uncompensated care payments on an interim basis. For a fiscal year, each eligible hospital's interim uncompensated care payments will be determined by multiplying the final values for

Factor 1, Factor 2, and Factor 3 for that year and dividing the amount by the number of periods over which the interim payments will be made.

Because we are using historical data to estimate each hospital's eligibility for empirically justified DSH payments in FY 2014 and subsequent years, a reconciliation process will be necessary to account for cases in which a hospital's eligibility for such payments changes after we have published our estimates during the rulemaking process. For example, a hospital that had not been estimated to be eligible for these payments may become eligible during the course of a given payment period. In such cases, our estimates would have indicated that the hospital was ineligible for empirically justified DSH payments and therefore ineligible for uncompensated care payments. That hospital would not receive interim payments. However, if the data available at cost report settlement were to indicate that the hospital is eligible for an empirically justified DSH payment, the hospital would become eligible for an uncompensated care payment based on that hospital's Factor 3 value.

Therefore, we are proposing that at cost report settlement, the fiscal intermediary/MAC will make a final determination concerning whether each hospital is eligible for empirically justified Medicare DSH payments and, therefore, uncompensated care payments in FY 2014 and each subsequent year. In the case where a hospital received interim payments for its empirically justified Medicare DSH payments and uncompensated care payments for FY 2014 or a subsequent year on the basis of estimates prior to the payment year, but is determined to be ineligible for the empirically justified Medicare DSH payment at cost report settlement, the hospital would no longer be eligible

for either payment and CMS would recoup those monies. For a hospital that did not receive interim payments for its empirically justified DSH payments and uncompensated care payments for FY 2014 or a subsequent year, but at cost report settlement is determined to be eligible for DSH payments, the fiscal intermediary/MAC would calculate the uncompensated care payment for such a hospital based on the Factor 3 value determined prospectively for that fiscal year.

We are proposing to codify this policy regarding the manner and timing of payments in new § 412.106(h) of our regulations.

We invite public comment on this proposal.

The reconciliations at cost report settlement would be based on the values for Factor 1, Factor 2, and Factor 3 that we have finalized prospectively for a Federal fiscal year. For example, a hospital that was estimated by CMS to receive empirically justified DSH payments for FY 2014 and received interim uncompensated care payments would not receive a different uncompensated care payment amount if the fiscal intermediary/MAC determined that the hospital remained eligible for empirically justified DSH payments at cost report settlement. In other words, we are not proposing to include a reestimation of Factor 1, Factor 2, or Factor 3 in the reconciliation process we are describing. Rather, Factor 1, Factor 2, and Factor 3 are estimates determined prospectively using methodologies we establish through rulemaking. We recognize that, under this proposal, we may pay a total amount that could either be more or less than the product of Factor 1 and Factor 2. However, we believe this is inherent in the use of estimates to determine the Factors, similar to the manner in which we estimate the

amount of total outlier payments under section 1886(d)(5)(A)(iv) although, as in this case, the amount of actual total outlier payments might vary from that estimate. We do not know of any reason to believe that there will be a bias toward systematic overpayment or underpayment from year to year.

We are proposing to codify this policy at § 412.106(g)(1)(iv) of our regulations.

We are inviting public comments on this proposal, especially in regard to whether we should include Factor 3 within the reconciliation process. Depending on the comments, we may revise our proposed policy in the final rule so that at the time of cost report settlement and reconciliation a hospital's final uncompensated care payments could be based on Factor 3 numerators and denominators estimated using more recent cost report data (and associated inputs). In addition, we may revise our proposed reconciliation process, as appropriate, to account for any policy changes that we make in the final rule to the proposals in this proposed rule.

We also note that the uncompensated care payment will be reported on the Medicare Hospital Cost Report. We recognize that hospitals have their own cost reporting periods that may differ from the Federal fiscal year and that may span more than one Federal fiscal year. We are proposing that hospitals receive their uncompensated care payments with respect to the fiscal year in which their cost report begins. For example, if a hospital is estimated to be eligible for the empirically justified DSH payment and also an uncompensated care payment in FY 2014 and has a cost report period of January 1, 2014 through December 31, 2014, this hospital would begin to receive interim payments for its uncompensated care on October 1, 2013. If, at cost

report settlement, this hospital remained eligible for an empirically justified DSH payment, then the hospital would receive its FY 2014 uncompensated care payment on its cost report for the cost reporting period beginning on January 1, 2014 (that is, the hospital would neither owe nor be owed monies for its uncompensated care payment). As another example, if that same hospital is no longer eligible for an empirically justified Medicare DSH payment at the time of settlement of its cost report for the cost reporting period beginning January 1, 2014, the hospital would be required to pay back the interim payments it received for its uncompensated care payments. We note that this methodology would not delay the full payment of FY 2014 payments to hospitals with cost reporting periods that begin after October 1, 2013. While it is possible to align interim and final payments for the uncompensated care payment with individual hospital's cost reporting periods, we believe it administratively efficient and practical to pay the uncompensated care payment on the basis of the Federal fiscal year because that is how it is determined, and to reconcile that amount in the cost reporting period that begins in the respective Federal fiscal year. If this proposal is finalized, we will revise the cost report accordingly. We are inviting public comments on our proposal.

g. National Provider Call

On January 8, 2013, CMS hosted a National Provider Call regarding the implementation of section 3133 of the Affordable Care Act. During this call, CMS asked Dobson DaVanzo and Associates, LLC. with its subcontractor, KNG Health Consulting, LLC, to present information regarding alternative definitions, measures, and data sources for the various estimates required by section 1886(r) of the Act, including the rate of

uninsured individuals under the age of 65 years and hospital-specific uncompensated care. Approximately 1,304 participants participated in this call. The presentation materials from the call are available on the CMS Web site at:

<http://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2013-01-08-ACA-DSH-NPC.html>. Subsequent to the call, participants were encouraged to submit public comments to CMS for consideration through January 15, 2013, when we undertook rulemaking and other activities related to implementation of section 1886(r) of the Act. Approximately 64 organizations submitted comments either on the National Provider Call or subsequent to the National Provider Call. We appreciate this input and have considered the issues raised by the commenters in developing the proposals discussed above. The report “Improvements to Medicare Disproportionate Share (DSH) Payments” discusses the issues raised in this National Provider Call. A summary of the comments on the National Provider Call has also been prepared. The report and summary can be found on the CMS Website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html>.

F. 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 Pub. L. 109-171 (DRA 2005), the MDH program was to be in effect through the end of FY 2011 only. Section 3124(a) of the Affordable Care Act amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to extend the MDH program and payment methodology by striking out “October 1, 2011” and inserting “October 1, 2012”. Section 3124(b) of the Affordable Care Act made conforming amendments to sections 1886(b)(3)(D) and 1886(b)(3)(D)(iv) of the Act.

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50287 and 50414), we amended the regulations at § 412.108(a)(1) and (c)(2)(iii) to reflect the statutory extension of the MDH program through FY 2012. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684), we did not make any additional changes to the MDH regulatory text for FY 2012. As discussed below, the ATRA (Pub. L. 112-240) amended the Act to extend the MDH program through the end of FY 2013.

2. Provisions of the ATRA for FY 2013

a. Background

Prior to the enactment of the ATRA, under section 3124 of the Affordable Care Act, the MDH program authorized by section 1886(d)(5)(G) of the Act was set to expire at the end of FY 2012. Section 606 of the ATRA 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 October 1, 2012 to September 30, 2013 (FY 2013). Section 606 of the ATRA also made conforming amendments to sections 1886(b)(3)(D)(i) and 1886(b)(3)(D)(iv) of the Act. Prior to the enactment of the ATRA, in the FY 2013 IPPS/LTCH PPS final rule, we discussed the expiration of the MDH program at the end of FY 2012 (77 FR 53413 through 53414) and revised the SCH regulation at § 412.92(b) to change the effective date of SCH status for MDHs that apply for SCH status with the expiration of the MDH program (77 FR 53404 through 53405).

In a FY 2013 IPPS notice issued in the **Federal Register** on March 7, 2013 (78 FR 14689), we announced the extension of the MDH program for FY 2013 in accordance with the provisions of section 606 of the ATRA. In that notice, we explained that, as a result of section 606 of the ATRA, the MDH program is now extended for 1 additional year, through the end of FY 2013 (that is, effective October 1, 2012 through September 30, 2013). The FY 2013 IPPS notice explained how providers may be affected by the ATRA extension of the MDH program and described the steps to reapply for MDH status for FY 2013, as applicable. Generally, a provider that was classified as an MDH at the end of FY 2012 (that is, as of September 30, 2012) will be reinstated as an MDH effective October 1, 2012, with no need to reapply for MDH classification. However, if the MDH had classified as a sole community hospital (SCH) or cancelled its rural classification under § 412.103(g) effective on or after October 1, 2012, the effective date of MDH status may not be retroactive to October 1, 2012. In the FY 2013 IPPS notice, we also stated that we intended to make conforming changes to the regulations at

§§ 412.108(a)(1) and (c)(2)(iii) in future rulemaking to reflect the statutory changes made by section 606 of the ATRA. We refer readers to the FY 2013 IPPS notice (78 FR 14689 through 14694) for additional information on the extension of the MDH program through FY 2013 pursuant to section 606 of the ATRA and for additional information on how and when MDH status will be determined for hospitals classified as MDHs prior to the September 30, 2012 expiration of the program.

b. Proposed Conforming Regulatory Changes

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 through FY 2013 made by section 606 of the ATRA.

c. Expiration of the MDH Program

Because section 606 of the ATRA extends the MDH program through FY 2013 only, effective FY 2014, the MDH program will no longer be in effect. Because the MDH program is not authorized by statute beyond FY 2013, beginning in FY 2014, 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 at the end of FY 2013. 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 October 1, 2013, 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 August 31, 2013. 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 October 1, 2013, immediately after its MDH status expires with the expiration of the MDH program at the end of FY 2013, on September 30, 2013.

We note that an MDH that applies for SCH status in anticipation of the expiration of the MDH program would not qualify for the October 1, 2013 effective date upon approval if it does not apply by the August 31, 2013 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).

G. Hospital Readmissions Reduction Program: Proposed Changes (§§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 subsection (q) to section 1886 of the Act. Section 1886(q) of the Act establishes the “Hospital Readmissions Reduction Program,” effective for discharges from an “applicable hospital” beginning on or after October 1, 2012, under which payments to those 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. Pursuant to section 1886(q)(1) of the Act, payments for discharges from an “applicable hospital” will be an amount equal to the product of the “base operating DRG payment amount” and the adjustment factor for the hospital for the fiscal year. That is, “base operating DRG payments” are reduced by 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. Specifically, section 1886(q)(2)(B) of the Act states that “[i]n the case of a Medicare-dependent, small rural hospital (with respect to discharges occurring during fiscal years 2012 and 2013) or a sole community hospital . . . the payment amount that would otherwise be made under subsection (d) shall be determined without regard to subparagraphs (I) and (L) of subsection (b)(3) and subparagraphs (D) and (G) of subsection (d)(5).” 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”.

Section 1886(q)(3)(A) of the Act defines the “adjustment factor” for an applicable hospital for a fiscal year as equal to the greater of “(i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C).”

Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. It states that the ratio is “equal to 1 minus the ratio of – (i) the aggregate payments for excess readmissions...; and (ii) the aggregate payments for all discharges....” Section 1886(q)(3)(C) of the Act describes the floor adjustment factor, which is set at 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years.

Section 1886(q)(4) of the Act sets forth the definitions of 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 Readmission Ratio . . . for such hospital for such applicable period minus 1.” The “excess readmission ratio” is a hospital-specific ratio based on each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the excess readmission ratio as the ratio of “risk-adjusted readmissions based on actual readmissions” for an applicable hospital for each applicable condition, to the “risk-adjusted expected readmissions” for the applicable hospital for the applicable condition.

Section 1886(q)(5) of the Act provides definitions of “applicable condition,” “expansion of applicable conditions,” “applicable hospital,” “applicable period,” and “readmission.” The term “applicable condition” (which is addressed in detail in section IV.C.3.a. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51665 through 51666)) is defined as a “condition or procedure selected by the Secretary among conditions and procedures for which: (i) readmissions . . . represent conditions or procedures that are high volume or high expenditures . . . and (ii) measures of such readmissions . . . have been endorsed by the entity with a contract under section 1890(a) . . . and such endorsed

measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital).” Section 1886(q)(5)(B) of the Act also requires the Secretary, beginning in FY 2015, “to the extent practicable, [to] expand the applicable conditions beyond the 3 conditions for which measures have been endorsed . . . to the additional 4 conditions that have been identified by the Medicare Payment Advisory Commission in its report to Congress in June 2007 and to other conditions and procedures as determined appropriate by the Secretary.”

Section 1886(q)(5)(C) of the Act defines “applicable hospital,” that is, a hospital subject to the Hospital Readmissions Reduction Program, as a “subsection (d) hospital or a hospital that is paid under section 1814(b)(3) [of the Act], as the case may be.” The term “applicable period,” as defined under section 1886(q)(5)(D) of the Act, “means, with respect to a fiscal year, such period as the Secretary shall specify.” As explained in the FY 2012 IPPS/LTCH PPS final rule, the “applicable period” is the period from which data are collected in order to calculate various ratios and adjustments under the Hospital Readmissions Reduction Program.

Section 1886(q)(6) of the Act sets forth the public reporting requirements for hospital-specific readmission rates. Section 1886(q)(7) of the Act limits administrative and judicial review of certain determinations made pursuant to section 1886(q) of the Act. Finally, section 1886(q)(8) of the Act requires the Secretary to collect data on readmission rates for all hospital inpatients for “specified hospitals” in order to calculate the hospital-specific readmission rates for all hospital inpatients and to publicly report these readmission rates.

2. Overview

We have been implementing the requirements of the Hospital Readmissions Reduction Program in rulemakings, and will continue to do so. 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, we addressed the issues of the selection of readmission measures and the calculation of the excess readmission ratio, which will be used, in part, to calculate the readmission adjustment factor. Specifically, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676), we addressed the portions of section 1886(q) of the Act related to the following provisions:

- Selection of applicable conditions;
- Definition of “readmission”;
- Measures for the applicable conditions chosen for readmission;
- Methodology for calculating the excess readmission ratio; and
- Definition of “applicable period”;

With respect to the topics of “measures for readmission” for the applicable conditions, and “methodology for calculating the excess readmission ratio,” we specifically addressed the following:

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

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401), we finalized our policies that relate to the calculation of the hospital readmission payment adjustment factor and the process by which hospitals can review and correct their data. Specifically, in the final rule, we addressed the portions of section 1886(q) of the Act related to the following provisions:

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

In the FY 2013 IPPS/LTCH PPS final rule, we 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.

3. FY 2014 Proposals for the Hospital Readmissions Reduction Program

a. Overview

In this proposed rule, for FY 2014 and beyond, we are proposing to--

- Refine the readmissions measures and related methodology for the current applicable conditions (section V.G.3.b. of this preamble);

- Expand the “applicable conditions” for FY 2015 (section V.G.3.c. of this preamble);
- Specify additional policies for hospitals paid under section 1814(b)(3) of the Act (§ 412.154(d)), including the process to be exempted from the Hospital Readmissions Reduction Program and the definition of “base operating DRG payment amount” (section V.G.3.d. of this preamble);
- Specify the proposed adjustment factor floor for FY 2014 (section V.G.3.e. of this preamble);
- Specify the proposed applicable period for FY 2014 (section V.G.3.f. of this preamble);
- Refine the methodology to calculate the aggregate payments for excess readmissions (section V.G.3.g. of this preamble); and
- Clarify the process for reporting hospital-specific information, including the opportunity to review and submit corrections (section V.G.3.h. of this preamble).

b. Proposed Refinement of the Readmission Measures and Related Methodology for FY 2014 and Subsequent Years Payment Determinations

(1) Overview of the Inclusion of Planned Readmissions for the Calculation of the FY 2014 Readmissions Adjustment Factors

In the FY 2012 IPPS/LTCH PPS final rule, we adopted acute myocardial infarction (AMI), heart failure (HF), and pneumonia (PN) readmission measures for the Hospital Readmissions Reduction Program payment determinations beginning with FY 2013. During development of the three readmission measures for AMI, HF, and PN,

we consulted with medical experts to identify readmissions that are typically scheduled as followup care for each specific condition within 30 days of discharge. We categorized these readmissions as planned followup care and excluded them from being counted as a readmission. The AMI measure finalized for the Hospital Readmissions Reduction Program included two revascularization procedures (coronary artery bypass graft surgery (CABG) and percutaneous coronary intervention (PCI) (76 FR 51667)). We considered these procedures planned readmissions and excluded them from the readmission calculation as long as the readmissions were not for one of five acute conditions (HF, AMI, other acute/subacute forms of ischemic heart disease, arrhythmia, and cardiac arrest).

During development of the HF and PN readmission measures, we did not identify any readmissions that were typically planned as followup care at the time of the patient's discharge. Therefore, the readmission measures finalized for the Hospital Readmissions Reduction Program for these two conditions did not exclude any planned readmissions from the readmission calculation.

(2) Proposed Refinement of the Readmission Measures and Related Methodology for the FY 2014 and Subsequent Years Payment Determinations

Since the development and implementation of the initial three readmission measures adopted under the Hospital Readmissions Reduction Program, we have received comments from the medical community, other stakeholders, and the general public encouraging us to identify and not count as readmissions a broader range of planned readmissions. Stakeholders also made recommendations for expanding the

number and types of planned readmissions during the public comment period for FY 2013 IPPS/LTCH PPS proposed rule (as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53382 through 53398)).

Stakeholders commented that readmission measures are intended to capture unplanned readmissions that arise from acute clinical events requiring urgent rehospitalization within 30 days of discharge. In addition, stakeholders commented that planned readmissions do not generally signal poor quality of care. In response to stakeholders' concerns, we have worked with experts in the medical community, other stakeholders, and the public to broadly identify planned readmissions for procedures and treatments for exclusion from the readmission measures. Specifically, we developed an expanded "planned readmission algorithm" in the CMS Planned Readmission Algorithm Version 2.1 Report to identify planned readmissions across our readmission measures, and are proposing to apply the algorithm to the AMI, HF, and PN measures for FY 2014. The CMS Planned Readmission Algorithm Version 2.1 Report is available on the CMS Web site at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

We developed the algorithm based on a hospital-wide (not condition-specific) cohort of patients. We began the development by using the Agency for Healthcare Research and Quality's (AHRQ's) Clinical Classification Software (CCS) codes to group thousands of individual procedures and diagnoses codes into clinically coherent, mutually exclusive procedure and diagnosis categories (PROC-CCS categories and Diagnosis-CCS categories, respectively). A panel of independent, non-CMS clinicians then reviewed the

procedure categories and identified those that are commonly planned and require admission. Clinicians also reviewed the diagnosis categories and identified those that were acute diagnoses likely requiring hospitalization. Using these procedure and diagnosis categories and some individual ICD-9-CM procedure and diagnoses codes in the categories, we developed an initial algorithm for identifying planned readmissions for a hospital-wide cohort of patients.

The algorithm underwent several reviews by stakeholders. We initially posted the detailed algorithm for informal public comment during the measurement development process in August 2011. The National Quality Forum (NQF) reviewed and made the algorithm available for public comment during its endorsement review of the Hospital-Wide All-Cause Unplanned Readmission Measure (NQF #1789). We also recruited 27 surgical subspecialists nominated by their specialty societies to review the algorithm and suggest refinements, which resulted in Version 2.1 of the Planned Readmission Algorithm. We are proposing to use this algorithm in the readmission measures under the Hospital Readmissions Reduction Program beginning with FY 2014. A detailed description of this algorithm is included later in this section.

As required by section 1886(q)(5)(A)(ii) of the Act, the first three applicable conditions of AMI, HF and PN, must use readmission measures that have been endorsed by the entity with a contract under section 1890(a) of the Act; and such endorsed measures must have exclusions for readmissions that are unrelated to the prior discharge (such as planned readmission or transfer to another applicable hospital). Because the statute requires that the readmission measures for the three current applicable conditions

(AMI, HF and PN) be NQF-endorsed, we sought NQF's endorsement of the measures that were revised to include the CMS Planned Readmission Algorithm Version 2.1. NQF reviewed these revised measures through its ad hoc review process, which reviews previously endorsed measures that undergo material changes. Following ad hoc review, NQF endorsed the revised AMI (NQF #0505) and HF (NQF #0330) measures in January 2013 and the PN measure (NQF #0506) in (March 2013)).

(a) Description of CMS Planned Readmission Algorithm Version 2.1

This algorithm is a set of criteria for classifying readmissions as “planned” using Medicare claims. The algorithm identifies typical planned admissions that may occur within 30 days of discharge from the hospital.

We based the CMS Planned Readmission Algorithm on three principles:

- A few specific, limited types of care are always considered planned (obstetrical delivery, transplant surgery, maintenance chemotherapy, rehabilitation);
- Otherwise, a planned readmission is defined as a nonacute readmission for a scheduled procedure; and
- Admissions for acute illness or for complications of care are never planned.

The Planned Readmission Algorithm uses a flow chart and four tables of procedures and conditions to implement these principles and to classify readmissions as planned or unplanned. The flow chart and tables are available in a report, CMS Planned Readmission Algorithm Version 2.1, which is available on the CMS Web site at:

<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

We incorporated the algorithm into each condition-specific and procedure-specific readmission measure. For most readmission measures, including the AMI, HF, and PN measures, we used one standard version of the algorithm—the CMS Planned Readmission Algorithm Version 2.1. However, for a subset of readmission measures, we revised the list of potentially planned procedures or acute primary diagnosis after applying the standard algorithm version because it was clinically indicated. For example, for the Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) readmission measure that we are proposing for FY 2015, we removed diagnostic cardiac catheterization from the potentially planned procedure list because patients in the hip/knee measure are typically well enough to undergo elective surgery and would not be expected to need a catheterization within 30 days of discharge. The details of these adaptations are available in the CMS Planned Readmission Algorithm Version 2.1 report (<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>).

(b) Proposed Counting of Readmissions that Occur After a Planned Readmission

In this proposed rule, we are proposing a related change to the AMI, HF, and PN measures to address unplanned readmissions that occur after a planned readmission but within 30 days of the patient's initial index discharge. The AMI measure finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51666) counted unplanned readmissions for the index admission if they occurred within 30 days of discharge from the index admission, even if they occurred following planned readmissions (because the two other

measures did not have any planned readmissions, this method of counting only applied to the AMI measure).

For the proposed revised AMI, HF, and PN measures, all of which now account for planned readmissions by incorporating the CMS Planned Readmission Algorithm Version 2.1, we are proposing the following additional change: if the first readmission is planned, it will not count as a readmission, nor will any subsequent unplanned readmission within 30 days of the index readmission. In other words, unplanned readmissions that occur after a planned readmission and fall within the 30-day post discharge timeframe would no longer be counted as outcomes for the index admission. The rationale for this proposed change is that, in this case, either the index or the planned readmission could have contributed to the patient's unplanned readmission. Therefore, it is unclear whether the unplanned readmission should be attributed back to the index admission. This proposed change in counting practice would affect a very small percentage of readmissions (approximately 0.3 percent of index admissions nationally for AMI, 0.2 percent for HF, and less than 0.1 percent for PN). However, we intend to monitor trends in the proportion of planned readmissions for evidence of misuse or misapplication, and other unintended consequences.

(c) Anticipated Effect of the Proposed Changes of CMS Planned Readmission Algorithm Version 2.1 and Counting of Readmissions on the Readmission Measures

The proposed changes to the measures in this proposed rule would have had the following effects on the measures based on our analyses of discharges between July 2008 and June 2011, if these changes had been applied for FY 2013. We note that these

statistics are for illustrative purposes only, and we are not proposing to revise the measure calculations for the FY 2013 payment determination. Rather, we are proposing to apply these changes to the readmissions measures for the FY 2014 payment determination and subsequent years.

Among hospitals that were subject to the Hospital Readmissions Reduction Program in FY 2013 (Table V.G.1), the number of eligible discharges based on the July 2008 through June 2011 data were 501,765 discharges for AMI; 1,195,967 discharges for HF; and 957,854 discharges for PN):

- The proposed 30-day readmission rate (excluding the planned readmissions) would decrease by 1 percentage point for AMI; 1.5 percentage points for HF; and 0.7 percentage point for PN.
- The new national measure (unplanned) rate for each condition would have been 18.2 percent for AMI; 23.1 percent for HF; and 17.8 percent for PN.
- The number of readmissions considered planned (and, therefore, not counted as a readmission) would increase by 4,942 for AMI; 17,512 for HF; and 7,084 for PN.

**Table V.G.1.--Comparison of Original AMI/HF/PN Measures Finalized in FY 2013
Relative to Proposed Revised AMI/HF/PN Measures for FY 2014
(Based on July 2008 through June 2011 Discharges from 3,025 Hospitals)**

	AMI		PN		HF	
	Proposed Revised Measure	Original Measure	Proposed Revised Measure	Original Measure	Proposed Revised Measure	Original Measure
Number of Admissions	501,765	501,765	957,854	957,854	1,195,967	1,195,967
Number of Unplanned Readmissions	91,360	96,302	170,396	177,480	276,748	294,260
Readmission Rate	18.2%	19.2%	17.8%	18.5%	23.1%	24.6%
Number of Planned Readmissions	12,811	7,869	7,084	0	17,512	0
Planned Readmission Rate	2.6%	1.6%	0.7%	0.0%	1.5%	0.0%
Percent of Readmissions that are Planned	12.3%	7.6%	4.0%	0.0%	6.0%	0.0%

In summary, we are proposing to use the proposed revised versions of the AMI, HF, and PN measures to calculate the payment adjustments for the Hospital Readmissions Reduction Program in FY 2014. We believe that the proposed revised measures will address stakeholder suggestions to broaden the number of planned readmissions and will result in a more accurate readmission calculation for purposes of the payment adjustment. We are proposing to update the measures to: (1) incorporate the CMS Planned Readmission Algorithm Version 2.1 to identify planned readmissions; and (2) not count unplanned readmissions that follow planned readmissions. We are inviting public comments on this proposal.

c. Proposed Expansion of the Applicable Conditions for FY 2015

(1) Background

Under section 1886(q)(5)(B) of the Act, beginning with FY 2015, the Secretary shall, to the extent practicable, expand the applicable conditions beyond the three 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 Commission 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 conditions and procedures “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 2015, we are proposing to expand the applicable conditions and procedures to include: (1) patients admitted for an acute exacerbation of COPD; and (2) patients admitted for elective total hip arthroplasty (THA) and total knee arthroplasty (TKA). At this point, it is not feasible for CMS to add readmission measures for three of the conditions identified by MedPAC in its 2007 Report to Congress (CABG, PCI, and other vascular conditions). We note that inpatient admissions for PCI and other vascular conditions seem to be decreasing, and these

procedures are being performed more in hospital outpatient departments. This shift in setting for these procedures may make their future inclusion in the Hospital Readmission Reduction Program more difficult and impracticable.

We are also exploring how we may address CABG in this program at a future time.

We are proposing inclusion of patients admitted for an acute exacerbation of COPD based on MedPAC's recommendations and may consider other recommendations in future rulemaking. While MedPAC did not recommend inclusion of patients admitted for elective THA and TKA, we consider this category appropriate for the Hospital Readmissions Reduction Program because it is a high-volume and high-expenditure procedure.

For example, in 2003, 202,500 primary hip arthroplasties and 402,100 primary total knee arthroplasties were performed.³⁰ The number of procedures performed has increased steadily over the past decade.³¹ Although these procedures can dramatically improve patient health-related quality-of-life, they are costly. In 2005, annual hospital charges totaled \$3.95 billion and \$7.42 billion for primary THA and TKA, respectively.³² The aggregate costs for THA are projected to increase by 340 percent over a 10-year period, to \$17.4 billion per fiscal year by FY 2015, and for TKA, by 450 percent to \$40.8

³⁰ Kurtz S, Ong K, Lau E, Mowat F, Halpern M.: Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. *J Bone Joint Surg Am.* Apr 2007;89(4):780-785.

³¹ Ong KL, Mowat FS, Chan N, Lau E, Halpern MT, Kurtz SM. Economic burden of revision hip and knee arthroplasty in Medicare enrollees. *Clin Orthop Relat Res.* May 2006;446:22-28.

³² Kurtz SM, Ong KL, Schmier J, et al.: Future clinical and economic impact of revision total hip and knee arthroplasty. *J Bone Joint Surg Am.* Oct 2007;89 Suppl 3:144-151.

billion per fiscal year by 2015.³³ Medicare is the single largest payer for these procedures, covering approximately two-thirds of all THAs and TKAs performed in the United States.³⁴ THA and TKA procedures combined account for the largest procedural cost in the Medicare budget.³⁵ Therefore, as explained in detail below, we believe that it is appropriate to include THA/TKA as an applicable condition.

We developed a hospital-level, 30-day, all-cause, risk-standardized readmission measure for THA/TKA. NQF endorsed the measure (NQF #1551) in January of 2012. The measure incorporated the Planned Readmission Version 2.1 algorithm and excludes transfers. Accordingly, we believe that the THA/TKA measure met the criteria of applicable condition and are proposing it for the Hospital Readmissions Reduction Program.

The rationale for expanding the applicable conditions and the measures used to estimate the Excess Readmission Ratios are described in detail below.

(2) Proposed COPD Readmission Measure

COPD is a leading cause of readmissions to hospitals.³⁶ In 2007, the MedPAC published a report to Congress in which it identified the seven conditions associated with the most costly potentially preventable readmissions. Among these seven conditions, COPD ranked fourth.³⁷ Evidence also shows variation in readmissions for patients with

³³ Ibid.

³⁴ Ong KL, Mowat FS, Chan N, Lau E, Halpern MT, Kurtz SM. Economic burden of revision hip and knee arthroplasty in Medicare enrollees. *Clin Orthop Relat Res.* May 2006;446:22-28.

³⁵ Bozic KJ, Rubash HE, Sculco TP, Berry DJ. An analysis of medicare payment policy for total joint arthroplasty. *Journal of Arthroplasty.* 2008;23(6 Suppl 1):133-138.

³⁶ Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. *N Engl J Med.* April 2 2009;360(14):1478-1428.

³⁷ Committee MPA. Report to the Congress: Promoting Greater Efficiency in Medicare. 2007.

COPD, 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 COPD in 2008 was 22.0 percent, and ranged from 18.33 percent to 25.03 percent across 4,546 hospitals.³⁸ Clinical trials and observational studies suggest that several aspects of care provided to patients hospitalized for exacerbations of COPD can have significant effects on readmission.^{39,40,41,42} In addition, inclusion of this measure in the Hospital Readmissions Reduction Program aligns with CMS' priority objectives to promote successful transitions of care for patients from the acute care setting to the outpatient setting, and reduces short-term readmission rates. Therefore, we believe the COPD measure warrants inclusion in the Hospital Readmissions Reduction Program for FY 2015. We are inviting public comments on this proposal.

(3) Overview of COPD Measure: Hospital-Level, 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891)

The COPD readmission measure assesses hospitals' 30-day, all-cause risk-standardized rate of readmission for an acute exacerbation of COPD (AECOPD). In

³⁸Grosso L.M., Lindenauer P., Wang C., et al.: Hospital-level 30-day Readmission Following Admission for an Acute Exacerbation of Chronic Obstructive Pulmonary Disease: Report prepared for the Centers for Medicare & Medicaid Services. 2011; Available at: <http://www.qualitynet.org/>.

³⁹Global Strategy for Diagnosis M, and Prevention of COPD. 2009; Available at: <http://www.goldcopd.org/>.

⁴⁰National Institute for Health and Clinical Excellence. Chronic Obstructive Pulmonary Disease: Management of Chronic Obstructive Pulmonary Disease in Adults in Primary and Secondary Care (Partial Update):. National Collaborating Centre for Acute and Chronic Conditions. Available at: <http://www.nice.org.uk/nicemedia/live/13029/49397/49397.pdf>.

⁴¹Walters JA, PG Gibson, R Wood-Baker, M Hannay, EH Walters. Systemic corticosteroids for acute exacerbations of chronic obstructive pulmonary disease. Cochrane Database Syst Rev. 2009;CD001288(1).

⁴²Lightowler JV, Wedzicha JA, Elliott MW, Ram FS. Non-invasive positive pressure ventilation to treat respiratory Failure resulting from exacerbations of chronic obstructive pulmonary disease: Cochrane systematic review and meta-analysis. Bmj. 2003;326(7382).

general, the measure uses the same approach to risk-adjustment and hierarchical logistic modeling (HLM) methodology that is specified for CMS' AMI, HF, and PN readmission measures previously adopted for this program. Information on how the measure employs HLM can be found in the 2011 COPD 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 COPD, 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 are providing a summary of the measure methodology below. For further details on the risk-adjustment statistical model, we refer readers to the 2011 COPD Readmission Measure Methodology Report that we have posted on the CMS Web site at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment->

[Instruments/Hospital QualityInits/Measure-Methodology.html](#). NQF endorsed the measure (NQF #1891) in March 2013 (<http://www.qualityforum.org/QPS/1891>).

- **Data Sources.** The proposed COPD measure is claims-based. It uses Medicare administrative data from hospitalizations for fee-for-service Medicare beneficiaries hospitalized with an acute exacerbation of COPD (AECOPD).

- **Outcome.** The outcome for the COPD measure is 30-day, all-cause readmission, defined as an unplanned subsequent inpatient admission to any applicable acute care facility from 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.^{43,44} It is a timeframe that a readmission may reasonably be attributed to the hospital care and transitional period to a nonacute care setting.

The COPD readmissions measure assesses all-cause unplanned readmissions (excluding planned readmissions) rather than readmissions for acute exacerbations of COPD only. We are proposing this measure 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 COPD-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

⁴³Gulshan 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.

⁴⁴Nelson 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.

issues and accountability based on the documented cause of readmission. For example, a patient with COPD who 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 COPD. Finally, while the measure does not presume that each readmission is preventable, interventions generally have shown reductions in all types of readmissions.

The measure does not count planned readmissions as readmissions. Planned readmissions are identified in claims data using the CMS Planned Readmission Algorithm Version 2.1 that detects planned readmissions that may occur within 30 days of discharge from the hospital. This algorithm is described briefly in section V.G.3.b.(2)(a) of the preamble of this proposed rule and more detailed information can be found on the CMS Web site at: [http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospital QualityInits/Measure-Methodology.html](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospital%20QualityInits/Measure-Methodology.html). For the COPD measures, 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 (we refer readers to section V.G.3.b.(2)(b) of the preamble of this proposed rule on the proposed counting of readmissions that occur after a planned readmission).

- Cohort of Patients. COPD is a group of lung diseases characterized by airway obstruction. Patients hospitalized for an acute exacerbation of COPD (AECOPD) present with varying degrees of severity ranging from a worsening of baseline symptoms (dyspnea, cough, and/or sputum) to respiratory failure. To capture the full spectrum of

severity of patients hospitalized for an AECOPD, the measure includes patients with a principal diagnosis of COPD, as well as those with a principal diagnosis of respiratory failure with a secondary diagnosis of an AECOPD. Requiring AECOPD as a secondary diagnosis helps to identify respiratory failure due to COPD exacerbation versus another condition (for example, heart failure). For detailed information on the cohort definition, we refer readers to the 2013 COPD Readmission Measure Updates and Specifications Report on the CMS Web site at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospital_QualityInits/Measure-Methodology.html.

- Inclusion and Exclusion Criteria. The COPD 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 (FFS) enrollment to allow for adequate risk-adjustment. The measure excludes the following admissions from the measure cohort: (1) admissions for patients who die during the initial hospitalization (these patients are not eligible for readmission); (2) admissions for patients having a principal diagnosis of COPD during the index hospitalization and subsequently transferred to another acute care facility (these are excluded because the measure focuses on discharges to a nonacute care setting such as the home or a SNF); (3) admissions for patients that are discharged against medical advice (AMA) (excluded because providers do not have the opportunity to deliver full care and prepare the patient for discharge); (4) admissions for patients without at least a 30-day post-discharge enrollment in Medicare FFS (excluded because the 30-day readmission outcome cannot be assessed in this group); and (5) additional COPD admissions for patients within 30 days of discharge

from an index COPD admission will be considered readmissions and not additional index admissions.

- **Risk-Adjustment.** The COPD 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. 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 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.

- **Calculating the Excess Readmission Ratio.** The COPD readmission measure uses the same methodology and statistical modeling approach as the AMI, HF, and PN measures. We published a detailed description of how the readmission measures estimate the Excess Readmission Ratio used in the Hospital Readmissions Reduction Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53380 through 53381).

(4) Proposed Adoption of the COPD Measure for the Hospital Readmissions Reduction Program

We are proposing to adopt the COPD measure in the Hospital Readmissions Reduction Program beginning in FY 2015. We also are proposing the COPD measure for use in the Hospital IQR Program for FY 2014 (discussed in section IX.A. of this

preamble). 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 hospitals paid under section 1814(b)(3) of the Act (that is, Maryland hospitals), 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 COPD measure is appropriate for use in both programs. We are inviting public comments on this proposal.

(5) Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) Measure

THA and TKA are commonly performed procedures that improve quality of life. Between 2008 and 2010, over 1.4 million THA and TKA procedures were performed on Medicare FFS patients aged 65 years and older.⁴⁵ However, the costs of these procedures, especially to Medicare, are very high. Combined, THA and TKA procedures account for the largest procedural cost in the Medicare budget.⁴⁶ Evidence also shows variation in readmissions of patients with THA/TKA procedures, supporting the finding that opportunities exist for improving care. The median 30-day risk-standardized readmission rate among Medicare FFS patients aged 65 or older undergoing THA/TKA procedures between 2008 and 2010 was 5.7 percent, and ranged from 3.2 percent to 9.9

⁴⁵ Gross, L.M., Curtis, J.P., Lin, Z., et al.: Hospital-level 30-Day All-Cause Risk-Standardized Readmission Rate Following Elective Primary total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA): Report prepared for the Centers for Medicare & Medicaid Services, 2012. Available on the Web site at: <http://www.qualitynet.org/>.

⁴⁶Bozic KJ, Rubash HE, Sculco TP.: Berry DJ. An analysis of medicare payment policy for total joint arthroplasty. *J Arthroplasty*. Sep 2008;23(6 Suppl 1):133-138.

percent across 3,497 hospitals.⁴⁷ In addition, inclusion of a THA/TKA measure in the Hospital Readmissions Reduction Program aligns with CMS' priority objectives to promote successful transitions of care for patients from the acute care inpatient setting to the outpatient setting, and reduces short-term readmission rates. Therefore, we believe the THA/TKA measure warrants inclusion in the Hospital Readmissions Reduction Program for FY 2015.

(6) Overview of the THA/TKA Measure: Hospital-Level 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) (NQF #1551)

To better assess hospital care and care transitions for patients with elective THA/TKA procedures, we developed a hospital-level readmission measure for patients undergoing elective primary THA and/or TKA procedures. We finalized this measure for use in the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53519 through 53521). We are proposing to include this measure, updated with the CMS Planned Readmission Algorithm Version 2.1 adapted for THA/TKA (discussed in section V.G.3.b.(2) of this preamble) to: (1) expand the applicable conditions for the Hospital Readmissions Reduction Program; (2) derive the Excess Readmission Ratio for patients with THA/TKA procedures; and (3) calculate the readmission payment adjustments in FY 2015. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53519 through 53521) for details of the measure specifications as well as the

⁴⁷Grosso L.M., Curtis J.P., Lin Z., et al.: Hospital-level 30-Day All-Cause Risk-Standardized Readmission Rate Following Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA): Report prepared for the Centers for Medicare & Medicaid Services. 2012. Available on the Web site at: <http://www.qualitynet.org/>.

2013 Hip/Knee Readmission Measures Updates and Specifications Report which is available on the CMS Web site at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>. NQF endorsed the measure in January 2012 (<http://www.qualityforum.org/QPS/1551>).

(7) Calculating the Excess Readmission Ratio

The THA/TKA readmission measure uses the same methodology and statistical modeling approach as the AMI, HF, and PN measures. We published a detailed description of how the readmission measures estimate the Excess Readmission Rate used in the Hospital Readmissions Reduction Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53380 through 53381).

(8) THA/TKA Measure for the Hospital Readmissions Reduction Program

We are proposing to adopt the THA/TKA measure in the Hospital Readmissions Reduction Program beginning in FY 2015. We also finalized this measure for use in the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53519 through 53521). We note that the set of hospitals for which this measure is calculated for the Hospital Readmissions Reduction Program differs from the set of hospitals 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 hospitals paid under section 1814(b)(3) of the Act (that is, Maryland hospitals), while the Hospital IQR Program calculations include non-IPPS hospitals such as CAHs, cancer hospitals, and hospitals in the Territories. However, we believe that the THA/TKA

measure is appropriate for use in both programs. We are inviting public comments on this proposal.

d. Proposals for Hospitals Paid under Section 1814(b)(3) of the Act, Including the Process to be Exempt from the Hospital Readmissions Reduction Program and Definition of “Base Operating DRG Payment Amount” for Such Hospitals (§ 412.152 and § 412.154(d))

As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53397), 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 (that is, acute care Maryland hospitals that would have otherwise been paid under the IPPS, but for the waiver under section 1814(b)(3) of the Act). Section 1886(q)(2)(B)(ii) of the Act allows the Secretary to exempt such hospitals from the Hospital Readmissions Reduction Program, provided that the State submits an annual report to the Secretary describing how a similar program to reduce hospital readmissions in that State achieves or surpasses the measured results in terms of health outcomes and cost savings established by Congress for the program as applied to “subsection (d) hospitals.” Accordingly, a program established by the State of Maryland that could serve to exempt the State from the Hospital Readmissions Reduction Program would focus on those “applicable” Maryland hospitals operating under the waiver provided by section 1814(b)(3) of the Act; that is, those hospitals that would otherwise have been paid by Medicare under the IPPS absent this provision.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53384), we established criteria for evaluation of an annual report to CMS to determine whether Maryland should be

exempted from the program each year. We codified this requirement at § 412.154(d) of the regulations. In addition, we specified that we will evaluate a report submitted by the State of Maryland documenting how its program meets those criteria. However, because the Hospital Readmissions Reduction Program was in its first year and Maryland's program was completing its first year, we specified that the evaluation of Maryland's program for measurable health outcomes and cost savings would not begin until FY 2014. In that same final rule, we explained that it would be premature to evaluate Maryland's readmission program on health outcomes and cost savings at that time, as we did not have sufficient information on which to evaluate Maryland's program because FY 2013 was first year of the Hospital Readmissions Reduction Program.

We noted that our finalized criteria to evaluate Maryland's program is for FY 2013, the first year of the program, and our evaluation criteria may change through notice-and-comment rulemaking as the Hospital Readmissions Reduction Program evolves.

In this proposed rule, we are proposing to establish a deadline by which the State must submit its annual report to the Secretary under proposed revised § 412.154(d)(2) of the regulations. We also are proposing the criteria that we would use to evaluate the State in order to determine whether or not the State would be exempted from the Hospital Readmissions Reduction Program beginning with FY 2014. In addition, we are proposing to define the "base operating DRG payment amount" for Maryland hospitals under § 412.152 of the regulations in the event that the State is not exempted from the Hospital Readmissions Reduction Program.

We are proposing that the State of Maryland must submit this preliminary report to CMS no later than January 15 of each year for CMS to consider, through the IPPS/LTCH PPS proposed rule for a Federal fiscal year, its exemption from the Hospital Readmissions Reduction Program for the upcoming Federal fiscal year. For example, the State of Maryland would have to submit the report by January 15, 2014 for consideration for the FY 2015 (beginning October 1, 2014) program year. This deadline would provide CMS sufficient time to evaluate the report, have any discussions with the State regarding its program, and prepare a presentation of that report for the IPPS/LTCH PPS proposed rule. Under this proposal, we also would require that the State submit a final report, with updated information on the State's readmissions program and updated cost savings and health outcomes information, to CMS no later than June 1 of each year in order for CMS to determine, through the IPPS/LTCH PPS final rule for a Federal fiscal year, whether the State meets the requirements for exemption from the Hospital Readmissions Reduction Program in that upcoming Federal fiscal year. As such, for FY 2015, under proposed § 412.154(d)(2)(ii), the State of Maryland would submit its preliminary report to the Secretary no later than January 15, 2014, and its final report to the Secretary no later than June 1, 2014, for consideration of exemption from the Hospital Readmissions Reduction Program.

For FY 2014, we have received a preliminary report from Maryland describing its readmissions program. Similar to its report submitted for FY 2013, Maryland described its current readmissions program, the Admissions-Readmission Revenue (ARR) Program. Under the voluntary program, the State pays hospitals under a case-mix adjusted bundled

payment per episode of care, where the episode of care is defined as the initial admission and any subsequent readmissions to the same hospital or linked hospital system that occur within 30 days of the original discharge. According to the State, an initial admission with no readmissions provides the hospital with the same weight as an initial admission with multiple readmissions. Therefore, hospitals receive a financial reward for decreased readmissions (as determined through the case-mix adjusted episode of care weights). In the report, Maryland indicated that the reduction in intra-hospital readmission rates (that is, readmissions to the same hospital as the initial admission) resulted in approximately \$25 million, or 0.27 percent, in savings to the participating hospitals for 2011 and 2012. In addition, Maryland reported that its readmission rate per 1,000 Medicare beneficiaries declined from 17.14 percent (CY 2011, Quarter 2) to 15.21 percent (CY 2012, Quarter 2). The State also acknowledged in that report that it has begun to track inter-hospital readmissions, where a patient is admitted to one hospital and readmitted to another hospital, which is comparable to how readmissions are measured under the Hospital Readmissions Reduction Program. In the FY 2013 IPPS/LTCH PPS final rule, we estimated that, under the Hospital Readmissions Reduction Program, for FY 2013, Medicare IPPS operating payments would decrease by approximately \$300 million (or 0.3 percent) of total Medicare IPPS operating payments. Maryland indicated that, for FY 2013, it would achieve comparable savings because it intends to reduce the rate update factor for all hospitals by 0.3 percent, regardless of a hospital's performance on readmissions.

Furthermore, in its FY 2014 preliminary report to the Secretary, the State of Maryland indicated that, for FY 2014, subject to approval by the Commission, it is proposing a shared savings approach, which would be applied to all hospitals in the State. Under that shared savings approach, hospitals in the State would be ranked based on their performance on readmissions, under which hospitals with high readmissions above an established standard would experience a reduction in their revenue and the hospitals below the established standard would not experience a reduction in their revenue. For Maryland hospitals that are in the voluntary ARR program paid under the case-mix adjusted bundled payment per episode of care that are performing worse than the established standard for readmissions, their payment per episode of care would be reduced. In addition, the State proposes that hospitals that improve in readmissions above a certain standard would experience no reduction in their payments and those hospitals below the standard would experience a reduction. Based on this preliminary information, we believe that the State can achieve savings on readmissions that are tied to hospitals' performance on readmissions, which is comparable to the Hospital Readmissions Reduction Program applied throughout the rest of the country.

For FY 2014, we are proposing to evaluate Maryland based on whether, under the shared savings approach, it can achieve comparable health outcomes and cost savings to the Hospital Readmissions Reduction Program. We note that, for FY 2014, we project that the Hospital Readmissions Reduction Program will result in a 0.2 percent decrease, or approximately \$175 million, in payments to hospitals. We are inviting public comments on this proposal.

In this proposed rule, we also are proposing to define “base operating DRG payment amount” for hospitals paid under section 1814(b)(3) of the Act in the event that we do not exempt Maryland hospitals from the Hospital Readmissions Reduction Program in a given year. Consistent with section 1886(q)(2) of the Act, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53382), under the regulations at § 412.152, we defined the “base operating DRG payment amount” under the Hospital Readmissions Reduction Program as the wage-adjusted DRG operating payment plus any applicable new technology add-on payments. As required by the statute, the definition of “base operating DRG payment amount” does not include adjustments or add-on payments for IME, DSH, outliers, and low-volume hospitals provided for under sections 1886(d)(5)(A), (d)(5)(B), (d)(5)(F), and (d)(12) of the Act, respectively. Section 1886(q)(2) of the Act does not exclude new technology payments made under section 1886(d)(5)(K) of the Act in the definition of “base operating DRG payment amount”; therefore, any payments made under section 1886(d)(5)(K) of the Act are included in the definition of “base operating DRG payment amount.” In addition, under the regulations at § 412.152, we define “wage-adjusted DRG operating payment” as the applicable average standardized amount adjusted for resource utilization by the applicable MS-DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index (and by the applicable COLA for hospitals located in Alaska and Hawaii).

Acute care hospitals located in the State of Maryland currently are not paid under the IPPS but are, instead, paid under a special waiver as provided by section 1814(b)(3) of the Act. For these applicable hospitals, we are proposing that the term “base operating

DRG payment amount” means the base operating DRG payment amount defined at § 412.152. In other words, we are proposing to revise existing § 412.152, to specify that, for Maryland hospitals, the “base operating DRG payment amount” is an amount equal to the IPPS wage adjusted DRG payment amount or the average standardized amount adjusted for resource utilization by the applicable MS-DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index plus new technology payments that would be paid to Maryland hospitals absent section 1814(b)(3) of the Act. Although Maryland hospitals are currently paid under this waiver and not under the IPPS, if Maryland is not exempt from the Hospital Readmissions Reduction Program in a given year, we are proposing that, to determine the amount by which the hospitals’ payments under section 1814(b)(3) of the Act would be reduced under the Hospital Readmissions Reduction Program, the readmission payment adjustment under § 412.154(b) would be determined using the estimated base operating DRG payment amount that would have applied had the hospital been paid under the IPPS. To implement this policy, we are proposing that claims submitted by Maryland hospitals would be “priced” under the IPPS payment methodology, and if a Maryland hospital has a readmissions payment adjustment factor, that factor would be applied to that base operating DRG payment amount to determine the payment adjustment under § 412.154(b) (that is, the amount of the payment reduction). We are proposing that the amount of the payment reduction, if any, would be applied to (that is, subtracted from) the payments made to Maryland hospitals under the waiver. This proposed methodology

would result in Maryland hospitals having the readmissions adjustment factor applied in a manner similar to that which is applied to hospitals that are paid under the IPPS.

Furthermore, we are proposing that if Maryland is not exempt from the Hospital Readmissions Reduction Program in a given year, the proposed definition of “base operating DRG payment amount” for Maryland hospitals discussed above (that is, the base operating DRG payment amount calculated as if the hospital were paid under the IPPS), and not any payment amount made under the waiver under by section 1814(b)(3) of the Act, would be used to calculate both the “aggregate payments for excess readmissions” and “aggregate payments for all discharges” (defined at § 412.152) for purposes of determining the hospital’s readmission adjustment factor that accounts for excess readmissions under § 412.154(c). We are inviting public comments on this proposal.

e. Proposed Floor Adjustment Factor for FY 2014 (§ 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” In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53386), we codified the calculation of this ratio at § 412.154(c)(1) of the regulations. Section

1886(q)(3)(C) of the Act specifies the floor adjustment factor, which is set at 0.99 for FY 2013, 0.98 for FY 2014, and 0.97 for FY 2015 and subsequent fiscal years. We codified the floor adjustment factor at § 412.154(c)(2) of the regulations.

For FY 2013, under § 412.154(c), we specified that an applicable hospital will receive an adjustment factor that is either the greater of the ratio or a floor adjustment factor of 0.99. For FY 2014, we are proposing that the floor adjustment factor be 0.98, consistent with section 1886(q)(3) of the Act, as codified at § 412.154(c)(2). As finalized in the FY 2013 IPPS/LTCH PPS final rule, the ratio is rounded to the fourth decimal place. In other words, for FY 2014, a hospital subject to the Hospital Readmissions Reduction Program would have an adjustment factor that is between 1.0 and 0.9800. We are inviting public comments on this proposal.

f. Proposed Applicable Period for FY 2014

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 53390), 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 readmission 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.

For the Hospital Readmissions Reduction Program for FY 2013, we established an applicable period under § 412.152 as July 1, 2008, to June 30, 2011. Specifically, to calculate the excess readmission ratios and to calculate the payment adjustments for FY 2013 (including aggregate payments for excess readmissions and aggregate payments for all discharges used in the calculation of the payment adjustment), we used Medicare claims data from the 3-year time period of July 1, 2008 to June 30, 2011 (76 FR 51671 and 77 FR 53388).

In this proposed rule, consistent with the definition at § 412.152 of the existing regulations, we are proposing that the applicable period for FY 2014 under the Hospital Readmissions Reduction Program would be the 3-year period from July 1, 2009, to June 30, 2012. That is, we would determine the excess readmission 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 is the most recent available 3-year period of data upon which to base these calculations. As discussed later in this section, although we are proposing an applicable period of July 1, 2009 through June 30, 2012 for FY 2014, for purposes of determining the proposed readmissions payment adjustment factors for this FY 2014 proposed rule, we are using excess readmission ratios based on older data, that is, from the FY 2013 applicable period of July 1, 2008 to June 30, 2011 (that includes the application of the proposed planned readmission algorithm discussed earlier in this section). However, for the FY 2014 final rule, we intend to use excess

readmission ratios based on data from the applicable period of July 1, 2009 to June 30, 2012, if that period is finalized.

g. Proposed Refinements of the Methodology to Calculate the Aggregate Payments for Excess Readmissions

Section 1886(q)(3)(B) of the Act specifies the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program. It states that the ratio is “equal to 1 minus the ratio of – (i) the aggregate payments for excess readmissions . . . and (ii) the aggregate payments for all discharges” In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53387), we defined “aggregate payments for excess readmissions” and “aggregate payments for all discharges,” as well as a methodology for calculating the numerator of the ratio (aggregate payments for excess readmissions) and the denominator of the ratio (aggregate payments for all discharges).

Section 1886(q)(4) of the Act sets forth the definitions of “aggregate payments for excess readmissions” and “aggregate payments for all discharges” for an applicable hospital for the applicable period. The term “aggregate payments for excess readmissions” is defined in section 1886(q)(4)(A) of the Act as “for a hospital for an applicable period, the sum, for applicable conditions . . . of the product, for each applicable condition, of (i) the base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the ‘Excess Readmission Ratio’ . . . for such hospital for such applicable period minus 1.” In the FY 2013

IPPS/LTCH PPS final rule (77 FR 53387), we included this definition of “aggregate payments for excess readmissions” under the regulations at § 412.152.

The “Excess Readmission Ratio” is a hospital-specific ratio calculated for each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the excess readmission ratio as the ratio of “risk-adjusted readmissions based on actual readmissions” for an applicable hospital for each applicable condition, to the “risk-adjusted expected readmissions” for the applicable hospital for the applicable condition. The methodology for the calculation of the excess readmission ratio was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673). “Aggregate payments for excess readmissions” is the numerator of the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program.

The term “aggregate payments for all discharges” is defined at section 1886(q)(4)(B) of the Act as “for a hospital for an applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period.” “Aggregate payments for all discharges” is the denominator of the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53387), we included this definition of “aggregate payments for all discharges” under the regulations at § 412.152.

We note that we are taking this opportunity to propose to make a technical change to the definition of “basing operating DRG payment amount” in the existing regulations at § 412.152 to reflect our policy that the difference between the applicable

hospital-specific payment rate and the Federal payment rate for SCHs and MDHs is excluded from the base operating DRG amount for these hospitals. We note that section 1886(q)(2)(B)(i) of the Act provides “special rules” for MDHs with respect to discharges occurring during FYs 2012 and 2013, and not for subsequent years. Under current law, as discussed in section V.F. of the preamble of this proposed rule, the MDH program expires at the end of FY 2013 (that is, the MDH program is in effect through September 30, 2013); therefore, the technical change would reflect that our policy applies to MDHs for FY 2013 only.

As discussed above, when calculating the numerator (aggregate payments for excess readmissions), we determined 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 Readmission 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 that was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671) to calculate the excess readmission 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 2014, we are proposing to use MedPAR claims with discharge dates that are on or after July 1, 2009, and no later than June 30, 2012. As specified in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53387), 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 2009 through FY 2012 MedPAR data files can be purchased from CMS. Use of these files allows the public to verify the readmission adjustment factors. Interested individuals may order these files through the Web site at: <http://www.cms.hhs.gov/LimitedDataSets/> by clicking on the MedPAR Limited Data Set (LDS)-Hospital (National). This Web page describes the files and provides directions and further detailed instructions for how to order the data sets. Persons placing an order must send the following: a Letter of Request, the LDS Data Use Agreement and Research Protocol (refer to the Web site for further instructions), the LDS Form, and a check for \$3,655 to:

- 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 FY 2014 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, 2009, and no later than June 30, 2012. However, we note that, for the purposes of modeling the proposed readmissions payment adjustment factors in this proposed rule, we used excess readmission ratios based on an older performance period of July 1, 2008 to June 30, 2011 with the application of the proposed planned readmission algorithm.

Consistent with the approach taken in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27964), for the purpose of modeling the proposed FY 2014 readmissions payment adjustment factors, we are using excess readmission ratios for applicable hospitals from the FY 2013 Hospital Readmission Reduction Program applicable period. For FY 2014, applicable hospitals will have had the opportunity to review and correct data from the proposed FY 2014 applicable period of July 1, 2009 to June 30, 2012 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, we are proposing for FY 2014 to use MedPAR data from July 1, 2009 through June 30, 2012, and we are using the March 2010 update of the FY 2009 MedPAR file to identify claims within FY 2009 with discharge dates that are on or after July 1, 2009, the March 2011 update of the FY 2010 MedPAR file to identify claims within FY 2010, the March 2012 update of the FY 2011 MedPAR file to identify claims within FY 2010, and the December 2012 update of the FY 2012 MedPAR file to identify claims within FY 2012 with discharge dates no later than June 30, 2012. For the

FY 2014 IPPS/LTCH PPS final rule, we intend to use the same MedPAR files as listed above, with the exception of using the March 2013 update of the FY 2012 MedPAR file.

In order to identify the admissions for each condition for an individual hospital for calculating the aggregate payments for excess readmissions, as we did for FY 2013, we are proposing, for FY 2014, to identify each applicable condition using the same ICD-9-CM codes used to identify applicable conditions to calculate the excess readmission ratios. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51669), in our discussion of the methodology of the readmissions measures, we stated that we identify eligible hospitalizations and readmissions of Medicare patients discharged from an applicable hospital having a principal diagnosis for the measured condition in an applicable period. The discharge diagnoses for each applicable condition are based on a list of specific ICD-9-CM codes for that condition. These codes are posted on the 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, as we did for FY 2013, we are proposing, for FY 2014, to identify the claim as an applicable condition if the ICD-9-CM code for that condition is listed as the principal diagnosis on the claim, consistent with the methodology to identify conditions to calculate the excess readmission ratio. Based on public comments that we received on the FY 2013 IPPS/LTCH PPS proposed rule, which stated that the index admissions that are not considered readmissions for the purpose of the readmissions measures, and are thus excluded from the calculation of the excess readmission ratio,

should also not be considered admissions for the purposes of determining a hospital's aggregate payments for excess readmissions, we are proposing to further modify our methodology to identify the admissions included in the calculation of "aggregate payments for excess readmissions." As we did for FY 2013 in response to public comments (77 FR 53390), using our MedPAR data source, we identified admissions for the purposes of calculating aggregate payments for excess readmissions making the following exclusions: (1) hospitalizations for patients discharged with an in hospital death; (2) hospitalization for patients discharged against medical advice; (3) transfers; (4) hospitalizations for patients under 65; (5) hospitalizations for patients enrolled in Medicare Part C; and (6) same day discharges for AMI cases. These admissions were excluded based on how they were identified in the MedPAR file.

For FY 2014, we are proposing to make the same exclusions as we did in FY 2013, but, for some of the exclusions, to identify them using a different methodology which is more consistent with the manner in which exclusions are made to the admissions used to calculate the excess readmission ratio. For FY 2014, in order to have the same types of admissions to calculate aggregate payments for excess readmissions, as is used to calculate the excess readmission ratio, we are proposing to identify admissions for the purposes of calculating aggregate payments for excess readmissions as follows; we note where our proposed methodology for exclusions for FY 2014 differs from our methodology in FY 2013:

- We would exclude admissions that are identified as an applicable condition based on the ICD-9-CM code listed as the primary diagnosis if the patient died in the

hospital, as identified by the discharge status code on the MedPAR claim. This is consistent with how we identified patients who died in the hospital in the FY 2013 IPPS/LTCH PPS final rule.

- We would exclude admissions identified as an applicable condition based on the ICD-9-CM code listed as the primary diagnosis for which the patient was transferred to another acute care hospital (that is, a CAH or an IPPS hospital), as identified through examination of contiguous stays in MedPAR at other hospitals. (We note that this proposed step differs from the methodology we used in the FY 2013 IPPS/LTCH PPS final rule to identify transfers based on discharge destination codes in the MedPAR file.)

- We would exclude admissions identified as an applicable condition based on the ICD-9-CM code listed as the primary diagnosis 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. (We note that this proposed step differs from the methodology we used in the FY 2013 IPPS/LTCH PPS Rule in that we previously used claims in the MedPAR file to identify a patient's age.)

- 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. (This is consistent with how we identified patients with same day discharges for AMI in the FY 2013 IPPS/LTCH PPS final rule. In addition, it is consistent with the calculation of the excess readmission ratio for AMI where same day discharges for AMI are not included as an index admission.)

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 readmission ratios based solely on admissions and readmissions for Medicare FFS patients. For FY 2013, we had excluded admissions for Medicare Advantage patients based on whether the claim was identified as a Medicare Advantage claim in the MedPAR file or whether the FFS payment amount on the claim was for an IME payment only, also indicative of an admission for a Medicare Advantage patient. For FY 2014, we would exclude admissions for patients enrolled in Medicare Advantage as identified in the Enrollment Database, which is consistent with how admissions for Medicare Advantage patients are identified in the calculation of the excess readmission ratios.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53390), we noted that there were additional exclusions to the admissions used to calculate the excess readmission ratio that we could not apply to the calculation of aggregate payments for excess readmissions at the time of rulemaking. However, we stated our intention to modify our systems to identify the additional exclusions in order to calculate the aggregate payments for excess readmissions in a manner that would be more consistent with the calculation of the excess readmission ratio. Thus, in addition to the exclusions to the admissions we finalized in the FY 2013, we are proposing additional exclusions so that the criteria used to identify admissions for the purposes of calculating aggregate payments for excess readmissions would be the same as the criteria used to identify admissions for the purposes of calculating the excess readmission ratios. We are proposing to link our

MedPAR claims data with the Medicare Enrollment Database to make additional exclusions to the admissions used to calculate aggregate payments for excess readmissions, which is consistent with our established methodology for calculating of the excess readmission ratios. The Medicare Enrollment Database contains information on all individuals entitled to Medicare, including demographic information, enrollment dates, third party buy-in information, and Medicare managed care enrollment. For FY 2014, we are proposing to include the following additional steps to identify admissions for the purposes of calculating aggregate payments for excess readmissions:

- We are proposing to 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 are proposing to exclude admissions for patients without at least 30 days post-discharge enrollment in Medicare Parts A and B FFS, based on the information provided in the Medicare Enrollment Database.
- We are proposing to exclude all multiple admissions within 30 days of a prior index admission, 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 readmission ratio.

We are inviting public comments on these proposals.

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 2014. These ICD-9-CM codes also will be used to identify

the applicable conditions to calculate the excess readmission ratios, consistent with our policy finalized in the FY 2012 IPPS/LTCH PPS final rule. The list of ICD-9-CM codes for each condition has not changed from the list provided in the FY 2013 IPPS/LTCH PPS final rule.

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

ICD-9-CM Code	Description of Code
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

ICD-9-CM Code	Description of Code
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

For FY 2014, we are proposing to calculate aggregate payments for excess readmissions, using MedPAR claims from July 1, 2009 to June 30, 2012, 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 exclusions for the types of admissions discussed above.

Formulas to Calculate the Readmission Adjustment Factor

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

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

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

Readmissions Adjustment Factor for FY 2014 is the higher of the ratio or 0.9800.

*Based on claims data from July 1, 2009 to June 30, 2012 for FY 2014.

h. Clarification of Reporting Hospital-Specific Information, Including Opportunity to Review and Submit Corrections

In the FY 2013 IPPS/LTCH PPS final rule, we finalized our policy for the public reporting of the information for this program as well as providing hospitals with an opportunity to review and submit corrections to the information prior to public reporting. We are not proposing changes to the reporting, review, and submittal of corrections policy and the regulatory text that we finalized in the FY 2013 IPPS/LTCH final rule (77 FR 53399 through 53401). However, we wish to clarify that requests to incorporate claims previously billed under a different CMS Certification Number (CCN) by recently acquired entities into calculations for a particular CCN will not be considered. This is because the particular CCN was not responsible for the patients under the other CCN prior to the hospital merger at the time of service.

In addition to public comments on the proposed refinements to the readmissions measures, the proposed expansion of the applicable conditions for FY 2015, and the proposed changes to the readmission payment adjustment factors, we welcome public comment on the impact of the Hospital Readmissions Reduction Program on hospitals, including “safety net” hospitals.

H. 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 2013, the available funding pool was equal to 1.00 percent of the base-operating DRG payments to all participating hospitals, as estimated by the Secretary, and the size of the applicable percentage will increase to 1.25 percent for

FY 2014, 1.50 percent for FY 2015, 1.75 percent for FY 2016, and 2.0 percent for FY 2017 and successive fiscal years.

Section 1886(o)(1)(C) of the Act generally defines the term “hospital” for purposes of the Hospital VBP Program as a subsection (d) hospital (as that term is defined in section 1886(d)(1)(B) of the Act), but excludes from the definition of the term “hospital,” with respect to a fiscal year: (1) a hospital that is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) of the Act (the Hospital IQR Program) for such fiscal year; (2) a hospital for which, during the performance period for the fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients; and (3) a hospital for which there are not a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for the fiscal year involved, or for which there are not a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for such fiscal year.

2. Overview of the FY 2013 Hospital VBP Program

In April 2011, we issued the Hospital Inpatient VBP Program final rule to implement section 1886(o) of the Act (76 FR 26490 through 26547). As described more fully in that final rule, for the FY 2013 Hospital VBP Program, we adopted 13 measures, including 12 clinical process of care measures and 8 dimensions from the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS) measure that we categorized into two domains (76 FR 26495 through 26511). We grouped the 12 clinical process-of-care measures into a clinical process of care domain, and placed the

HCAHPS survey measure into a patient experience of care domain. We adopted a 3-quarter performance period from July 1, 2011 through March 31, 2012 for these measures (76 FR 26494 through 26495), and performance standards on which hospital performance will be evaluated. To determine whether a hospital meets or exceeds the performance standards for these measures, we assessed each hospital's achievement during this specified performance period, as well as its improvement during this period as compared with its performance during a 3-quarter baseline period from July 1, 2009 through March 31, 2010 (76 FR 26493 through 26495).

We then calculated a TPS for each hospital by combining the greater of the hospital's achievement or improvement points for each measure to determine a score for each domain, weighting each domain score (for the FY 2013 Hospital VBP Program, the weights were clinical process of care = 70 percent, patient experience of care = 30 percent), and adding together the weighted domain scores. We converted each hospital's TPS into a value-based incentive payment percentage using a linear exchange function and then converted the value-based incentive payment percentage into a per discharge value-based incentive payment amount. We incorporated the reduction to each hospital's base operating DRG payment amount for each discharge, as well as the value-based incentive payment amounts that the hospital earned as a result of its performance (if applicable) into our claims processing systems in January 2013, and these adjustments applied to FY 2013 discharges.

We finalized the Hospital VBP Program's payment adjustment calculation methodology, including codifying certain definitions related to the Program, in the

FY 2013 IPPS/LTCH PPS final rule (77 FR 53569 through 53571). We also finalized our methodology for estimating the total amount available for value-based incentive payments in a fiscal year under the Hospital VBP Program (77 FR 53571 through 53573), our methodology to calculate the value-based incentive payment adjustment factor (77 FR 53573 through 53576), the delayed application of the base-operating DRG payment amount reduction for FY 2013 discharges until incorporation of the value-based incentive payment adjustments into our claims processing system (77 FR 53577), and our process for reducing the base-operating DRG payment amount and applying the value-based incentive payment adjustment for FY 2013 (77 FR 53577 through 53578).

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) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53567 through 53614) for further explanation of the details of the FY 2013 Hospital VBP Program and our other finalized policies related to future fiscal years.

3. FY 2014 Payment Details

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum total of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. We finalized details on how we would implement these provisions in the FY 2013

IPPS/LTCH PPS final rule (77 FR 53571 through 53573), and refer readers to that final rule for more details.

Under section 1886(o)(7)(c)(ii) of the Act, the applicable percent for the FY 2014 Hospital VBP Program is 1.25 percent. Based on the December 2012 update of the FY 2012 MedPAR file, we estimate that the total amount available for value-based incentive payments for FY 2014 is \$1.1 billion. We intend to update this estimate for the final rule, using the March 2013 update of the FY 2012 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 Total Performance Score (TPS). We will then calculate a value-based incentive payment adjustment factor which will be applied to the base operating DRG payment amount for each discharge occurring in FY 2014, on a per-claim basis. Proxy value-based incentive payment adjustment factors may be found in Table 16 for this proposed rule (which is available on the CMS Web site). The proxy factors are based on the TPSs from the FY 2013 Hospital VBP Program. These FY 2013 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 the proxy value-based incentive payment adjustment factors is 1.8362446088. This slope, along with the estimated amount available for value-based incentive payments, may also be found in Table 16. We intend to include an update to this table, as Table 16A, in the final rule (which will be available on the CMS Web site), to reflect changes based on the

December update to the FY 2012 MedPAR file. The updated proxy value-based incentive payment adjustment factors for FY 2014 will continue to be based on historic FY 2013 Program TPSs because hospitals will not have been given the opportunity to review and correct their actual FY 2014 value-based incentive payment adjustment factors for the FY 2014 VBP program until after the final rule is published. After hospitals have been given an opportunity to review and correct their actual value-based incentive payment adjustment factors for FY 2014, we will add a new table, Table 16B (which will be available 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 2014 Hospital VBP Program. We expect that Table 16B will be posted on the CMS Web site in October 2013.

4. FY 2014 Hospital VBP Program Measures

For FY 2014, we adopted 17 measures for the Hospital VBP Program, including the 12 clinical process of care measures and the HCAHPS measure that we adopted for the FY 2013 Hospital VBP Program, 1 new clinical process of care measure (SCIP-Inf-9: Postoperative Urinary Catheter Removal on Postoperative Day 1 or 2), and 3 mortality outcome measures (Acute Myocardial Infarction (AMI) 30-Day Mortality Rate, Heart Failure (HF) 30-Day Mortality Rate, Pneumonia (PN) 30-Day Mortality Rate). The clinical process of care, HCAHPS, and mortality measures are discussed in more detail in the Hospital Inpatient VBP Program final rule (76 FR 26510 through 26511) and SCIP-Inf-9 is discussed in more detail in the CY 2012 OPPI/ASC final rule with comment period (76 FR 74530).

Although we also previously adopted 8 HAC measures, 2 AHRQ composite measures, and a Medicare Spending per Beneficiary Measure for the FY 2014 Hospital VBP Program, we have suspended the effective dates of these measures, with the result that these measures will not be included in the FY 2014 Hospital VBP Program (76 FR 74528 through 74530). However, as discussed further below, we finalized adoption of a Medicare Spending per Beneficiary Measure and an AHRQ composite measure for the FY 2015 Hospital VBP Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53582 through 53592).

Set out below is a complete list of the measures we adopted for the FY 2014 Hospital VBP Program:

Finalized Quality Measures for the FY 2014 Hospital VBP Program	
Clinical Process of Care Measures	
Measure ID	Measure Description
Acute myocardial infarction	
AMI-7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival
AMI-8a	Primary PCI Received Within 90 Minutes of Hospital Arrival
Heart Failure	
HF-1	Discharge Instructions
Pneumonia	
PN-3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital
PN-6	Initial Antibiotic Selection for CAP in Immunocompetent Patient
Healthcare-associated infections	
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose
SCIP-Inf-9	Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2
Surgeries	
SCIP-Card-2	Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period

Finalized Quality Measures for the FY 2014 Hospital VBP Program	
SCIP-VTE-1	Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery
Patient Experience of Care Measures	
Measure ID	Measure Description
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey*
Outcome Measures	
Measure ID	Measure Description
MORT-30-AMI	Acute Myocardial Infarction (AMI) 30-Day Mortality Rate
MORT-30-HF	Heart Failure (HF) 30-Day Mortality Rate
MORT-30 PN	Pneumonia (PN) 30-Day Mortality Rate

*The finalized dimensions of the HCAHPS survey for use in the FY 2014 Hospital VBP Program are: Communication with Nurses, Communication with Doctors, Responsiveness of Hospital Staff, Pain Management, Communication about Medicines, Cleanliness and Quietness of Hospital Environment, Discharge Information and Overall Rating of Hospital. These are the same dimensions that we adopted for the FY 2013 Hospital VBP Program.

5. FY 2015 Hospital VBP Program Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53582 through 53592), we adopted 12 Clinical Process of Care measures, one Patient Experience of Care measure in the form of the HCAHPS survey, 5 Outcome measures, including three 30-day mortality measures, the AHRQ PSI composite measure, and the CLABSI measure, and one Efficiency measure for the FY 2015 Hospital VBP Program.

We did not adopt two clinical process measures (SCIP-Inf-10 and AMI-10) that we determined were “topped-out” according to our criteria finalized in the Hospital Inpatient VBP Program final rule (76 FR 26496 through 26497). We also did not adopt SCIP-VTE-1 for the FY 2015 Hospital VBP Program because we believed that the measure is very similar to another measure we have adopted for the Program

(SCIP-VTE-2) and, in our view, is not as closely linked to better surgical outcomes because it assesses the ordering of VTE prophylaxis, rather than the patient's actual receipt of such prophylaxis within 24 hours of surgery. We also noted that, during a recent maintenance review of SCIP- VTE-1, the National Quality Forum (NQF) concluded that it would no longer endorse this measure.

Set out below is a complete list of the measures we adopted for the FY 2015

Hospital VBP Program:

Finalized Quality Measures for FY 2015 Hospital VBP Program	
Clinical Process of Care Measures	
Measure ID	Measure Description
AMI-7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival
AMI-8a	Primary PCI Received Within 90 Minutes of Hospital Arrival
HF-1	Discharge Instructions
PN-3b	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital
PN-6	Initial Antibiotic Selection for CAP in Immunocompetent Patient
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose
SCIP-Inf-9	Urinary Catheter Removed on Postoperative Day 1 or Postoperative Day 2
SCIP-Card-2	Surgery Patients on Beta-Blocker Therapy Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxes Within 24 Hours Prior to Surgery to 24 Hours After Surgery
Patient Experience Measures	
HCAHPS*	Hospital Consumer Assessment of Healthcare Providers and Systems Survey
Outcome Measures	
AHRQ PSI composite	Complication/patient safety for selected indicators (composite)

Finalized Quality Measures for FY 2015 Hospital VBP Program	
CLABSI	Central Line-Associated Blood Stream Infection
MORT-30-AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate
MORT-30-HF	Heart Failure (HF) 30-day mortality rate
MORT-30-PN	Pneumonia (PN) 30-day mortality rate
Efficiency Measures	
MSPB-1	Medicare Spending per Beneficiary

*Dimensions of the HCAHPS survey for use in the FY 2015 Hospital VBP Program are: Communication with Nurses, Communication with Doctors, Responsiveness of Hospital Staff, Pain Management, Communication about Medicines, Cleanliness and Quietness of Hospital Environment, Discharge Information and Overall Rating of Hospital. These are the same dimensions of the HCAHPS survey that have been finalized for prior Hospital VBP Program years.

6. FY 2016 Hospital VBP Program Measures

a. Measures Previously Adopted and Proposal to Remove AMI-8a, PN-3b, and HF-1

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592 through 53593), we adopted for the FY 2016 Hospital VBP Program the three 30-day mortality measures that we had finalized for the Hospital VBP Program for FYs 2014 and 2015. We also adopted the AHRQ patient safety composite (PSI-90) for the Hospital VBP Program for FY 2016. We adopted those measures at that time in order to adopt a longer performance period and collect more data for performance scoring than would be possible if we waited to make those proposals until this proposed rule. We also adopted those measures at that time because we recognized that under section 1886(o)(3)(C) of the Act, we must establish and announce performance standards not later than 60 days prior to the beginning of the performance period for the fiscal year involved. We also automatically readopted the remaining FY 2015 measures (with the exception of the CLABSI measure), in accordance with our policy of automatic re-adoption of measures (77 FR 53592).

In this proposed rule, we are proposing to remove three measures from the measure set previously adopted that we have discussed above. First, we analyzed the

clinical process of care measures for “topped out” status and concluded that AMI-8a: Primary PCI Received within 90 Minutes of Hospital Arrival is “topped-out.” Our methodology for evaluating whether a measure is topped-out focuses on two criteria: (1) national measure data show statistically indistinguishable performance levels at the 75th and 90th percentiles; and (2) national measure data show a truncated coefficient of variation (TCV) less than 0.10. We believe that topped-out measures should not be included in the Hospital VBP Program because measuring hospital performance on those measures has no meaningful effect on a hospital’s TPS. Therefore, we are proposing to remove AMI-8a from the FY 2016 Hospital VBP Program measure set.

We welcome public comments on our proposal to remove AMI-8a from the FY 2016 Hospital VBP Program measure set and on whether any other existing Hospital VBP Program measures are topped-out and, therefore, should be removed from the previously adopted FY 2016 measure set. We intend to update our topped-out analysis using the most recently available data and will announce in the FY 2014 IPPS/LTCH PPS final rule whether any of the other FY 2016 measures will be removed due to topped-out status.

Second, we are proposing to remove PN-3b, Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital, and HF-1, Discharge Instructions, from the FY 2016 Hospital VBP Program. Both PN-3b and HF-1 are no longer endorsed by the NQF, and we note that in its 2013 Pre-Rulemaking Report, the Measure Applications Partnership (MAP) did not recommend those measures for use in the Hospital VBP Program

As of February 28, 2012, the NQF Pneumonia Thoracic CT Work Group of the Pulmonary and Critical Care Endorsement Maintenance Project believed there was insufficient evidence that performing blood cultures prior to initiation of antibiotics led to better outcomes. The workgroup also cited significant issues with documentation of the timing of the blood cultures with respect to the initiation of the antibiotics. Documentation is often done retrospectively providing opportunities for data entry errors. The issue is compounded with EHRs as data entry is electronically time-stamped and may not accurately indicate when blood cultures were drawn or antibiotics given. Although the measure is currently “chart-abstracted,” the data might be abstracted from an EHR, instead of from a paper record.

We note further that NQF reviewed HF-1 during the summer of 2012. The NQF Steering Committee determined that there was insufficient evidence to link the HF-1 measure of discharge instructions with better outcomes. The committee noted that discharge instructions, as measured by HF-1, did not cover several important issues, including patient understanding of the instructions and their appropriateness for patients’ education and literacy levels.

Therefore, we do not believe that these measures appropriately capture relevant inpatient quality information for purposes of the Hospital VBP Program, and, as indicated above, we are proposing to remove them from the FY 2016 program.

b. Proposed New Measures for the FY 2016 Hospital VBP Program

We considered if we should adopt additional measures for the FY 2016 Hospital VBP Program. We considered what 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, as well as our priorities for quality improvement as outlined in the National Quality Strategy, which is available for download at <http://www.healthcare.gov/news/reports/nationalqualitystrategy032011.pdf>.

We believe the following measures meet the statutory requirements for inclusion in the Hospital VBP Program. We also believe that these measures represent important components of quality improvement in the acute inpatient hospital setting.

Influenza Immunization (IMM-2, NQF #1659) is a chart-abstracted prevention measure that addresses acute care hospitalized inpatients age 6 months or older that were screened for seasonal influenza immunization status and were vaccinated prior to discharge, if indicated. We believe this measure is important to quality improvement efforts because about 36,000 adults die and over 200,000 are hospitalized annually for flu-related causes. Older adults are more vulnerable to influenza, and adults over age 65 comprise about 90 percent of deaths related to flu. Vaccinations can significantly reduce the number of flu-related illnesses and deaths.

This measure was incorporated into the Hospital IQR Program for FY 2014 in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50211), and data collection began with January 1, 2012 discharges. Measure data were posted on *Hospital Compare* on December 13, 2012, and MAP supported its inclusion in the Hospital VBP Program in its February 2013 report (available at http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx), noting that it addresses a high-impact condition not adequately addressed in the program's current measure set. Therefore, we are proposing to adopt IMM-2 into the Clinical Process of Care domain for the FY 2016 Hospital VBP Program.

Catheter-Associated Urinary Tract Infection (CAUTI, NQF #0138) is an HAI measure reported via CDC's National Healthcare Safety Network (NHSN). This measure is important to quality improvement efforts because the urinary tract is the most common site of HAIs, accounting for more than 30 percent of infections reported by acute care hospitals. Complications associated with CAUTI cause discomfort to patients, prolonged hospital stays, and increased costs and mortality. More than 13,000 deaths each year are associated with UTIs.

This measure was finalized for the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51617 through 51618), and data collection began with January 1, 2012 discharges. Measure data were posted on *Hospital Compare* on December 13, 2012, and MAP supported its inclusion in the Hospital VBP Program in its February 2013 report, noting that it addresses the National Quality Strategy (NQS) priorities not adequately addressed in the program's current measure set. Therefore, we

are proposing to adopt the NHSN CAUTI measure into the Outcome domain for the FY 2016 Hospital VBP Program.

Surgical Site Infection (SSI, NQF #0753) is an HAI measure reported via CDC's NHSN. As currently specified under the Hospital IQR Program, the measure 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 done by laparoscope. The measure is reported separately on *Hospital Compare* for those two surgery sites, and does not include rectal operations.

This measure was incorporated into the Hospital IQR Program in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50211), and data collection began with January 1, 2012 discharges. Measure data were posted on *Hospital Compare* on December 13, 2012, and MAP supported its inclusion in the Hospital VBP Program in its February 2013 report, noting that it addresses NQS priorities not adequately addressed in the program's current measure set. The SSI measure was stratified by surgery site when it was adopted for the Hospital IQR Program, and is both collected and publicly reported as a stratified measure. However, because we adopted SSI as one measure under the Hospital IQR Program, we are proposing to score the measure for purposes of the Hospital VBP Program as a weighted average of the measure's strata by applicable cases per stratum. Under this proposed scoring methodology, if a hospital meets the Hospital IQR Program's threshold for public display of its SSI measure strata scores during a Hospital VBP performance period – that is, at least one predicted infection during the

applicable time period – we will calculate a weighted average of the measure’s strata to score under the Hospital VBP Program.

We believe this proposal enables us to score participating hospitals on the underlying components of the SSI measure fairly. We note further that, for purposes of calculating performance standards displayed subsequently, we will equally weight the SSI measure’s strata. We seek public comments on our proposed adoption of this measure and its proposed scoring methodology under the Hospital VBP Program.

We adopted the NHSN-based CLABSI measure in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53583), and refer readers to that regulation for further discussion of the measure. We continue to believe that the CLABSI measure is consistent with the Hospital VBP Program’s statutory requirement that we consider measures of HAIs for the FY 2013 Hospital VBP Program’s measure set. We also note that the measure was included in the HHS Action Plan to Prevent HAIs, which is referenced in section 1886(o)(2)(B)(i)(I)(ee) of the Act.

In the FY 2013 IPPS/LTCH PPS final rule, we stated that we would not automatically readopt CLABSI for the FY 2016 Program (77 FR 53592), although we stated our intent to adopt the measure in the future. We did not automatically readopt CLABSI because we understood that CDC was planning to submit a revised version of this measure to NQF for endorsement, and that there may have been substantive changes to the measure associated with reliability adjustment to the standardized infection ratio.

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.

We are aware that the CDC has submitted the reliability-adjusted version of the CLABSI measure to the NQF for endorsement. We note further that, in its February 2013 report, MAP recommended adoption of the reliability-adjusted CLABSI measure “contingent on NQF endorsement,” and noted that the “most recent NQF-endorsed version should be applied.” We believe that our proposal to adopt the current CLABSI measure is consistent with this recommendation, and we intend to consider adopting the reliability-adjusted CLABSI measure in future rulemaking.

We intend to monitor CDC’s activity on this measure, particularly as it moves toward reliability adjustment, and intend to adopt the revised measure in future program years. However, in the absence of NQF endorsement of the reliability-adjusted measure, unless and until the Hospital IQR Program adopts the reliability adjustments, we are proposing to adopt the CLABSI measure as it currently exists into the Outcome domain for the FY 2016 Hospital VBP Program.

Below is a table that describes the measures for the FY 2016 Hospital VBP Program that we previously adopted, as well as the new measures that we are proposing to adopt.

Proposed and Readopted Measures for the FY 2016 Hospital VBP Program	
Clinical Process of Care Measures	
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-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose
SCIP-Inf-9	Urinary Catheter Removed on Postoperative Day 1 or Postoperative Day 2
SCIP-Card-2	Surgery Patients on Beta-Blocker Therapy Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxes Within 24 Hours Prior to Surgery to 24 Hours After Surgery
Patient Experience Measures	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey
Outcome Measures	
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 <ul style="list-style-type: none"> • Colon • Abdominal Hysterectomy
Efficiency Measures	
MSPB-1	Medicare Spending per Beneficiary

*Measures previously finalized for the FY 2016 Hospital VBP Program.

**Proposed new measures.

***Measures finalized for FY 2015 but not subject to immediate readoption.

We are inviting public comments on this measure set.

We also seek public comment on our intent to adopt the Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia and the *Clostridium difficile* (*C. difficile*) standardized infection ratio measures for the FY 2017 Hospital VBP Program. Both of these measures are high-priority HAI measures listed in the HHS Action Plan to Prevent HAIs. We anticipate posting performance data for these measures on *Hospital Compare* later this year, and anticipate proposing to adopt these measures for the Hospital VBP Program in the FY 2015 IPPS/LTCH PPS proposed rule.

c. Future Measures for the Efficiency Domain

We are considering including additional measures in the Efficiency Domain for future years of both the Hospital IQR Program and the Hospital VBP Program. If we were to expand the Efficiency Domain in the future, we would do so through future rulemaking and in accordance with the requirements of section 1886(o) of the Act.

We are considering adding a measure of hospitals' performance on treating Medicare beneficiaries appropriately as a hospital inpatient or a hospital outpatient. Specifically, we are considering constructing a measure to assess the rate and/or dollar amount of billing hospital inpatient services to Medicare Part B, subsequent to the denial of a Part A hospital inpatient claim. We are considering such a measure in light of our recent proposal that when a Medicare Part A claim for inpatient hospital services is denied because the inpatient admission was determined not to be reasonable and

necessary, or when a hospital determines under § 482.30(d) or § 485.641 after a beneficiary is discharged that his or her inpatient admission was not reasonable and necessary, the hospital may be paid for all of the Part B services that would have been reasonable and necessary had the beneficiary been treated as a hospital outpatient rather than admitted as an inpatient, if the beneficiary is enrolled in Medicare Part B (78 FR 16632 through 16646). We are inviting public comments on this or other approaches to include a measure of appropriateness of hospital inpatient services in future years of the Hospital IQR Program and the Efficiency Domain for the Hospital VBP Program.

We also are considering the addition of Medicare spending measures specific to physician services such as Radiology, Anesthesiology, and Pathology that occur during a hospital stay. We are inviting public comment on how to best to construct measures of Medicare spending for these or other physician services provided during a hospital stay, for future inclusion in the Hospital IQR Program and the Efficiency Domain in the Hospital VBP Program.

7. Proposed Performance Periods and Baseline Periods

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.

b. Proposed Clinical Process of Care Domain Performance Period and Baseline Period for the FY 2016 Hospital VBP Program

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53594 through 53595), we finalized a 12-month performance period for FY 2015 Clinical Process of Care measures of CY 2013, or January 1, 2013 through December 31, 2013, with a corresponding baseline period of CY 2011, or January 1, 2011 through December 31, 2011, for purposes of calculating improvement points and performance standards. As we stated in that rule, a 12-month performance period provides us more data on which to score hospital performance, which is an important goal both for CMS and for stakeholders. We also noted that a 12-month performance period is consistent with the reporting periods used for these measures under the Hospital IQR Program.

We are proposing to adopt a 12-month performance period for FY 2016 Clinical Process of Care measures of CY 2014, or January 1, 2014 through December 31, 2014, for the FY 2016 Hospital VBP Program. We also are proposing to adopt a corresponding 12-month baseline period of CY 2012, or January 1, 2012 through December 31, 2012, for purposes of calculating improvement points and calculating performance standards.

We are inviting public comment on these proposals.

c. Proposed Experience of Care Domain Performance Period and Baseline Period for the FY 2016 Hospital VBP Program

Consistent with our goal of adopting a full 12-month period for this domain in order to collect a larger amount of HCAHPS survey data compared to a 9-month period, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53595), we finalized a 12-month

performance period for FY 2015 Patient Experience of Care measures of CY 2013, or January 1, 2013 through December 31, 2013, with a corresponding baseline period of CY 2011, or January 1, 2011 through December 31, 2011, for purposes of calculating improvement points and performance standards. As we stated in that rule, a 12-month performance period provides us more 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 FY 2016 Patient Experience of Care measures of CY 2014, or January 1, 2014 through December 31, 2014, for the FY 2016 Hospital VBP Program. We also are proposing to adopt a corresponding 12-month baseline period of CY 2012, or January 1, 2012 through December 31, 2012, for purposes of calculating improvement points and calculating performance standards.

We are inviting public comment on these proposals.

d. Proposed Efficiency Domain Measure Performance Period and Baseline Period for the FY 2016 Hospital VBP Program

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53595 through 53596), we finalized a performance period for the Medicare Spending per Beneficiary measure for the FY 2015 Hospital VBP Program of May 1, 2013 through December 31, 2013, with a corresponding baseline period of May 1, 2011 through December 31, 2011. We finalized that performance period based on the measure's posting date on *Hospital Compare*, our desire to ensure consistency across domains where possible, and in order to ensure that

data have been posted for at least 1 year prior to the beginning of the measure performance period.

In order to expand the dataset available for performance scoring on this measure, we are proposing to adopt a 12-month performance period for the Medicare Spending per Beneficiary measure for the FY 2016 Hospital VBP Program of CY 2014, or January 1, 2014 through December 31, 2014, with a corresponding baseline period of CY 2012, or January 1, 2012 through December 31, 2012. These proposed performance and baseline periods align with the performance and baseline periods for Clinical Process of Care Domain measures. These proposed performance and baseline periods also enable us to collect sufficient measure data, while allowing time to calculate and incorporate Medicare spending per Beneficiary measure data into the Hospital VBP Program scores in a timely manner.

We are inviting public comments on the proposed performance and baseline periods for the Medicare Spending per Beneficiary measure.

Proposed baseline and performance periods for FY 2016 (with the exception of the Outcome domain, discussed further below) are summarized in the following table.

Proposed Performance and Baseline Periods for the FY 2016 Hospital VBP Program – Clinical Process of Care, Patient Experience of Care, and Efficiency Domains		
Domain	Baseline Period	Performance Period
Clinical Process of Care	January 1, 2012 – December 31, 2012	January 1, 2014 – December 31, 2014
Patient Experience of Care	January 1, 2012 – December 31, 2012	January 1, 2014 – December 31, 2014
Efficiency	January 1, 2012 – December 31, 2012	January 1, 2014 – December 31, 2014

e. Proposed Outcome Domain Performance Periods and Baseline Periods for the FY 2017 through FY 2019 Hospital VBP Programs

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53598 through 53599) we finalized performance periods and baseline periods for the FY 2016 mortality and AHRQ PSI composite measures. These periods are summarized in the table below.

Finalized FY 2016 Performance Periods and Baseline Periods for 30-Day Mortality and AHRQ PSI Measures		
Measure	Baseline period	Performance period
Mortality	October 1, 2010 – June 30, 2011	October 1, 2012 – June 30, 2014
AHRQ PSI composite	October 15, 2010 – June 30, 2011	October 15, 2012 – June 30, 2014

In light of the time needed to process measure data for the three 30-day mortality and AHRQ PSI composite measures and our policy goal to collect enough data to generate the most reliable scores possible, we are proposing in this proposed rule to adopt performance periods for the three 30-day mortality and AHRQ PSI composite measures for the FY 2017 through FY 2019 program years. We also seek to increase transparency

about performance of the Hospital VBP Program measures through use of *Hospital Compare* as a monitoring tool for hospitals to assess their performance on the Hospital VBP Program measures. We believe 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. Further, we believe 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 these measures.

Therefore, we are proposing to adopt the following performance and baseline periods for the three 30-day mortality and AHRQ PSI composite measures for the FY 2017 through FY 2019 Hospital VBP Programs. We note that the performance periods proposed below for the AHRQ PSI composite measure reach 24 months at their maximum, compared to the 36 months proposed for the 30-day mortality measures. We are proposing those durations for the AHRQ PSI measure in order to adopt performance periods that align with AHRQ's recommended data period for public reporting.

Proposed Performance and Baseline Periods for 30-day Mortality and AHRQ PSI Composite Measures		
FY 2017 Hospital VBP Program		
Domain	Baseline Period	Performance Period
Outcome <ul style="list-style-type: none"> • Mortality • AHRQ PSI 	<ul style="list-style-type: none"> • October 1, 2010 – June 30, 2012 • October 1, 2010 – June 30, 2012 	<ul style="list-style-type: none"> • October 1, 2013 – June 30, 2015 • October 1, 2013 – June 30, 2015
FY 2018 Hospital VBP Program		
Domain	Baseline Period	Performance Period
Outcome		

<ul style="list-style-type: none"> • Mortality • AHRQ PSI 	<ul style="list-style-type: none"> • October 1, 2009 – June 30, 2012 • July 1, 2010 – June 30, 2012 	<ul style="list-style-type: none"> • October 1, 2013 – June 30, 2016 • July 1, 2014 – June 30, 2016
FY 2019 Hospital VBP Program		
Domain	Baseline Period	Performance Period
Outcome <ul style="list-style-type: none"> • Mortality • AHRQ PSI 	<ul style="list-style-type: none"> • July 1, 2009 – June 30, 2012 • July 1, 2010 – June 30, 2012 	<ul style="list-style-type: none"> • July 1, 2014 – June 30, 2017 • July 1, 2015 – June 30, 2017

We are inviting public comments on our proposal to adopt performance periods and corresponding baseline periods for these measures for the FY 2017 through FY 2019 Hospital VBP Programs.

8. 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. Achievement and improvement standards are discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513).

In addition, when establishing the performance standards, section 1886(o)(3)(D) of the Act requires the Secretary to consider appropriate factors, such as: (1) practical experience with the measures, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods; (2) historical performance standards; (3) improvement rates; and (4) the opportunity for

continued improvement. In the FY 2013 IPPS/LTCH PPS final rule, (77 FR 53599 through 53604), we codified our interpretation of the Hospital VBP statute with respect to performance standards in our regulations at § 412.165.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53599 through 53604), we adopted performance standards for FY 2015 and 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 our Web site or another publicly available Web site.

b. Performance Standards for the FY 2016 Hospital VBP Program Measures

We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for a detailed discussion of the methodology we adopted for calculating performance standards with respect to the clinical process of care, patient experience of care, and outcome measures, and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656) for a discussion of the methodology we adopted for the Medicare Spending per Beneficiary measure. We have defined the “achievement threshold” as the median, or 50th percentile, of all hospitals’ performance on a measure during a baseline period (or during the performance period in the case of the Medicare Spending per Beneficiary measure) with respect to a fiscal year (42 CFR 412.160). We are proposing to revise this definition, in order to clarify that while this is true for the majority of Hospital VBP Program measures, it does not apply to the Medicare Spending per Beneficiary measure. The performance standards for the Medicare Spending per Beneficiary measure are based on performance period data, as finalized in the FY 2012

IPPS/LTCH PPS final rule (76 FR 51655). Accordingly, we are proposing to revise the definition of “achievement threshold” at § 412.160 to read: “Achievement threshold (or achievement performance standard) means the median (50th percentile) of hospital performance on a measure during a baseline period with respect to a fiscal year, for Hospital VBP Program measures other than the Medicare Spending per Beneficiary measure, and the median (50th percentile) of hospital performance on a measure during the performance period with respect to a fiscal year, for the Medicare Spending per Beneficiary measure.” We welcome public comments on this proposed regulation text change.

We have defined the “benchmark” as the arithmetic mean of the top decile of all hospitals’ performance on a measure during the baseline period (§ 412.160). Similar to the codified definition of “achievement threshold” above, this definition of “benchmark” does not apply to the Medicare Spending per Beneficiary measure. We are proposing to revise the definition of “benchmark” at § 412.160 to read: “Benchmark means the arithmetic mean of the top decile of hospital performance on a measure during the baseline period with respect to a fiscal year, for Hospital VBP Program measures other than the Medicare Spending per Beneficiary measure, and the arithmetic mean of the top decile of hospital performance on a measure during the performance period with respect to a fiscal year, for the Medicare Spending per Beneficiary measure.” The “improvement threshold” is an individual hospital’s performance level on a measure during the baseline period with respect to a fiscal year,” and that definition applies to all measures.

We continue to believe that the finalized methodology for calculating performance standards is appropriate for the Hospital VBP Program, and we recognize that we have an obligation to calculate the numerical values for each of these standards accurately. However, we also are concerned that if we display the numerical values of the performance standards in a particular rulemaking document, but then discover that we made a data or calculation error, the result might be that hospitals are held to inaccurate performance standards. Examples of the types of errors that could occur are inaccurate variables on Medicare claims, programming errors excluding hospitals that should have been included from performance standards calculations, or other errors that result in inaccuracies. For example, if our quality measurement software incorrectly excluded a number of hospitals from a given measure's performance standards calculation, the resulting achievement thresholds and benchmarks could force participating hospitals to meet inaccurate performance standards, which could have unpredictable effects on hospitals' scores.

We also are aware that hospitals rely on the performance standards that we publicly display in order to target quality improvement efforts, and do not believe that it would be fair to participating hospitals to update repeatedly our finalized performance standards if we were to identify multiple errors.

We believe that the best method to balance our obligation to publicly display accurate performance standards with the need to correct such performance standards if we subsequently discover data errors is to make a single correction to a given measure's performance standards for a fiscal year. Under this proposed policy, if we identified data

problems, calculation issues, or other errors with a significant impact on performance standards, we would have the ability to update the measure's performance standards once for a fiscal year.

Therefore, we are proposing to interpret the finalized definitions of "achievement threshold" and "benchmark" found under § 412.160 to not include the numerical values that result when the performance standards are calculated. Further, we are proposing to 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. However, as has been our practice, and to remain fully transparent with participating hospitals, we intend to continue to display the performance standards' numerical values in rulemaking.

We finalized FY 2016 performance standards for the three 30-day mortality measures and the AHRQ PSI composite measure in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53603) and are displaying them again in the first table below. The numerical values for the proposed FY 2016 performance standards for the clinical process, outcome, and efficiency measures appear in the second table below, while numerical values for the proposed FY 2016 performance standards for the patient experience of care (HCAHPS survey) measure appear in the third table below. We note that the numerical values for the performance standards displayed below represent estimates based on the most recently-available data. We intend to update the numerical values in the FY 2014 IPPS/LTCH PPS final rule. Because the Medicare Spending per Beneficiary measure's performance standards are based on performance period data, we are unable to provide

numeric equivalents for the standards at this time. For information purposes, during the period of May 1, 2011 through December 31, 2011, the achievement threshold would have been a Medicare Spending per Beneficiary ratio of 0.99, which corresponds to a standardized, risk-adjusted Medicare Spending per Beneficiary amount of \$18,079, and the benchmark would have been 0.82, which corresponds to a Medicare Spending per Beneficiary amount of \$14,985. We also note that the performance standards for the NHSN-based CLABSI, CAUTI, and SSI measures, the AHRQ PSI composite measure, and the Medicare Spending per Beneficiary measure are calculated with lower values representing better performance, in contrast to other measures, on which higher values indicate better performance. As discussed above, the performance standards displayed below for SSI are an equally weighted average of the measure's strata.

Finalized Performance Standards for Certain FY 2016 Hospital VBP Program Outcome Domain Measures			
Measure ID	Description	Achievement Threshold	Benchmark
Outcome Measures			
MORT-30-AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate	0.847472	0.862371
MORT-30-HF	Heart Failure (HF) 30-day mortality rate	0.881510	0.900315
MORT-30-PN	Pneumonia (PN) 30-day mortality rate	0.882651	0.904181
PSI-90	Complication/patient safety for selected indicators (composite)	0.622879	0.451792

Proposed Performance Standards for the FY 2016 Hospital VBP Program Clinical Process of Care, Outcome, and Efficiency Domain Measures			
Measure ID	Description	Achievement Threshold	Benchmark
Clinical Process of Care Measures			
AMI-7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	0.88625	1.00000
IMM-2	Influenza Immunization	0.89947	0.99036
PN-6	Initial Antibiotic Selection for CAP in Immunocompetent Patient	0.96429	1.00000
SCIP-Inf-1	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	0.98942	1.00000
SCIP-Inf-2	Prophylactic Antibiotic Selection for Surgical Patients	0.98951	1.00000
SCIP-Inf-3	Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time	0.97971	1.00000
SCIP-Inf-4	Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose	0.96797	0.99977
SCIP-Inf-9	Urinary Catheter Removed on Postoperative Day 1 or Postoperative Day 2	0.96743	1.00000
SCIP-Card-2	Surgery Patients on Beta-Blocker Therapy Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period	0.97561	1.00000
SCIP-VTE-2	Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxes Within 24 Hours Prior to Surgery to 24 Hours After Surgery	0.98086	1.00000
Outcome Measures			
CAUTI	Catheter-Associated Urinary	0.826	0.000

	Tract Infection		
CLABSI	Central Line-Associated Blood Stream Infection	0.473	0.000
SSI	Surgical Site Infection	0.737	0.000
Efficiency Measures			
MSPB-1	Medicare Spending per Beneficiary	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period

Proposed Performance Standards for the FY 2016 Hospital VBP Program Patient Experience of Care Domain			
HCAHPS Survey Dimension	Floor (percent)	Achievement Threshold (percent)	Benchmark (percent)
Communication with Nurses	53.33	77.59	85.98
Communication with Doctors	61.22	80.33	88.59
Responsiveness of Hospital Staff	36.44	64.65	79.72
Pain Management	47.93	70.16	78.24
Communication about Medicines	42.23	62.28	72.67
Hospital Cleanliness & Quietness	42.16	64.93	79.12
Discharge Information	62.85	84.45	90.26
Overall Rating of Hospital	36.45	69.05	83.89

We are inviting public comments on these proposed performance standards.

c. Certain Performance Standards for the FY 2017, FY 2018, and FY 2019 Hospital VBP Programs

We are proposing to adopt the following performance standards for the three 30-day mortality and AHRQ PSI composite measures for the FY 2017, FY 2018, and FY 2019 Hospital VBP Program years:

Proposed Performance Standards for the Three 30-Day Mortality and AHRQ Composite Measures for the FY 2017 Hospital VBP Program			
Measure ID	Description	Achievement Threshold	Benchmark
Outcome 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
PSI-90	Complication/patient safety for selected indicators (composite)	0.580808	0.399880

Proposed Performance Standards for the Three 30-Day Mortality and AHRQ Composite Measures for the FY 2018 Hospital VBP Program			
Measure ID	Description	Achievement Threshold	Benchmark
Outcome Measures			
MORT-30-AMI	Acute Myocardial Infarction (AMI) 30-day mortality rate	0.850916	0.873053
MORT-30-HF	Heart Failure (HF) 30-day mortality rate	0.883421	0.907656
MORT-30-PN	Pneumonia (PN) 30-day mortality rate	0.882860	0.907900
PSI-90	Complication/patient safety for selected indicators (composite)	0.585397	0.400502

Proposed Performance Standards for the Three 30-Day Mortality and AHRQ Composite Measures for the FY 2019 Hospital VBP Program			
Measure ID	Description	Achievement Threshold	Benchmark
Outcome 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
PSI-90	Complication/patient safety for selected indicators (composite)	0.585397	0.400502

We are inviting public comments on these proposed performance standards.

9. Proposed FY 2016 Hospital VBP Program Scoring Methodology

a. Proposed General Hospital VBP Program Scoring Methodology

In the Hospital Inpatient VBP Program final rule, we adopted a methodology for scoring clinical process of care, patient experience of care, and outcome measures. As noted in that rule, this methodology outlines an approach that we believe is well understood by patient advocates, hospitals, and other stakeholders because it was developed during a lengthy process that involved extensive stakeholder input, and was based on a scoring methodology we presented in a report to Congress. We also noted in that final rule that we had conducted extensive additional research on a number of other important methodology issues to ensure a high level of confidence in the scoring methodology (76 FR 26514). In addition, we believe that, for reasons of simplicity, transparency, and consistency, it is important to score hospitals using the same general methodology each year, with appropriate modifications to accommodate new domains and measures. We finalized a scoring methodology for the Medicare Spending per Beneficiary measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656).

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 28087), for the FY 2015 Hospital VBP Program, we finalized our proposal to use these same 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.

We continue to believe that the finalized scoring methodology for the Hospital VBP Program 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. As we stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53604), 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.

Therefore, we are proposing to readopt the finalized scoring methodology adopted for the FY 2015 Hospital VBP Program for the FY 2016 Hospital VBP Program. We welcome public comments on this proposal.

b. Proposed Domain Weighting for the FY 2016 Hospital VBP Program for Hospitals That Receive a Score on All Domains

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53582 through 53592), we added the Efficiency domain to the Hospital VBP Program beginning with the FY 2015 Hospital VBP Program. We also finalized our proposal for the following domain weights for the FY 2015 Hospital VBP Program for hospitals that receive a score on all four proposed domains (77 FR 53605 through 53606):

Final Domain Weights for the FY 2015 Hospital VBP Program for Hospitals Receiving a Score on All Proposed Domains	
Domain	Weight
Clinical Process of Care	20 percent

Final Domain Weights for the FY 2015 Hospital VBP Program for Hospitals Receiving a Score on All Proposed Domains	
Domain	Weight
Patient Experience of Care	30 percent
Outcome	30 percent
Efficiency	20 percent

We stated that we believed this domain weighting appropriately reflects our priorities for quality improvement in the inpatient hospital setting and begins aligning with the National Quality Strategy's priorities. We believe that the domain weighting will continue to improve the link between Medicare payments to hospitals and patient outcomes, efficiency and cost, and the patient experience. We note that the weighting places the strongest relative emphasis on outcomes and the patient experience, which we view as two critical components of quality improvement in the inpatient hospital setting. We further note that the domain weighting, for the first time, incorporates a measure of efficiency and continues to provide substantial weight to clinical processes.

As we stated in the Hospital Inpatient VBP Program final rule (76 FR 26491), we believe that domains need not be given equal weight, and that over time, scoring methodologies should be weighted more towards outcomes, patient experience of care, and functional status measures (for example, measures assessing physical and mental capacity, capability, well-being and improvement). We took these considerations into account when developing the domain weighting proposal outlined below.

We believe that the proposed domain weighting specified below will continue to improve the link between Medicare payments to hospitals and patient outcomes, efficiency and cost, and the patient experience. We note that the proposed domain

weighting places the highest relative weight on measures of outcomes and continues to place significant weight on the patient experience and on efficiency, while maintaining clinical processes as an important component of the program's quality measurement.

Therefore, we are proposing the following domain weighting for the FY 2016 Hospital VBP Program:

Proposed Domain Weights for the FY 2016 Hospital VBP Program for Hospitals Receiving a Score on All Proposed Domains	
Domain	Weight
Clinical Process of Care	10 percent
Patient Experience of Care	25 percent
Outcome	40 percent
Efficiency	25 percent

We welcome public comments on this proposed domain weighting.

c. Proposed Domain Weighting for the FY 2016 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, since 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.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53609), we finalized our proposal for a higher minimum number of cases for the three 30-day mortality measures for the FY 2015 Hospital VBP Program than was finalized for the FY 2014 Hospital VBP Program. We made this change in our policy in order to improve these measures' reliability given the relatively short performance period for these

measures. However, we were concerned that the relatively higher minimum number of cases could result in a substantially larger number of hospitals being excluded from the Hospital VBP Program. We believe that we should make a concerted effort to include as many hospitals as possible in the program in order to offer quality incentives and encourage quality improvement.

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 domain scores (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. We are proposing to continue this approach for the FY 2016 Hospital VBP Program and subsequent fiscal years for purposes of eligibility for the program. However, as detailed further below, we are proposing to reclassify the Hospital VBP Program's quality measurement domains beginning with the FY 2017 program to align more closely with CMS' National Quality Strategy, and we are seeking public comments on how we should determine minimum numbers of cases and measures under that proposed policy.

d. Proposed Domain Reclassification and Domain Weighting for the FY 2017 Hospital VBP Program

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53593 through 53594), we outlined one possible set of measure classifications based on the National Quality Strategy. However, we did not finalize our proposal to adopt quality measurement domains based on the National Quality Strategy for the FY 2016 Hospital VBP Program, because we understood stakeholders to be concerned about our proposal to reshape the Program's scoring methodology before hospitals had actual experience with the program and its value-based incentive payments.

However, we now believe that hospitals have accumulated practical experience with all components of the Hospital VBP Program, including performance periods and payment periods. As a result of our extensive outreach efforts to hospitals and stakeholders, as well as the practical experience with the first year of the program, we also believe that hospitals and other stakeholders generally understand the program's operations and scoring methodology. Therefore, we believe that we have addressed commenters' concerns, summarized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53594), that we should wait until hospitals have experienced the program fully before fundamentally reshaping its structure.

We are attempting to align all of our quality improvement efforts with the NQS, particularly because it is a patient-centered approach that aligns public and private efforts. We are aware that NQF uses NQS-based domains, and we also use those domains in development of other agency-specific efforts. We note further that

stakeholders frequently request that HHS align its quality improvement efforts so that providers are not subjected to different measurement approaches, and we believe that adapting the Hospital VBP Program domain structure is one approach to achieving that goal. We believe that the longer we wait to adapt the Hospital VBP Program to the NQS domains, the more difficult it will be, and we believe we need a common framework as we begin alignment efforts between the Hospital IQR Program, the Hospital VBP Program, and the EHR Incentive Program. CMS's quality measurement strategic plan also centers on the NQS, and we believe that using these domains rewards hospitals for providing more efficient and more patient-centered care. The most recent Annual Progress Report to Congress addressing the NQS can be found on the Web site at: <http://www.ahrq.gov/workingforquality/nqs/nqs2012annlrpt.pdf>.

Therefore, we are proposing to align the Hospital VBP Program's quality measurement domains with the NQS' quality priorities, with certain modifications discussed further below. We are proposing to adopt this realignment beginning with the FY 2017 Hospital VBP Program.

We are proposing to combine the priorities of Care Coordination and Patient and Caregiver Centered Experience of Care into one domain for purposes of aligning the Hospital VBP Program domains with the NQS priorities. Care Coordination aligns with the NQS priority stated as promoting effective communication and coordination of care. Patient and Caregiver Centered Experience of Care aligns with the NQS priority stated as ensuring that each person and family are engaged as partners in their care. We believe that, in order to be engaged as partners, effective communication and coordination of care

must coexist. This notion is further exemplified by one of the 10 principles of the NQS, found at <http://www.ahrq.gov/workingfor quality/nqs/principles.html>, which notes that “Person-centeredness and family engagement, including understanding and valuing patient preferences, will guide all strategies, goals, and health care improvement efforts. The most successful health care experiences are often those in which clinicians, patients, and their families work together to make decisions.” We believe that care coordination includes this shared decision-making among clinicians, patients, and their families, and further believe that a component of these important concepts can be captured with the HCAHPS measure.

Therefore, we believe that placing the HCAHPS measure into the proposed combined domain below will continue to encourage hospitals to focus on improving the patient’s experience during acute care hospitalizations and will enable us to continue providing incentives that focus on patient and caregiver experience and coordination of care. However, with the exception of the HCAHPS measure described above, we do not believe that any of the other proposed measures for the FY 2016 Hospital VBP Program, which would form the basis for the FY 2017 program’s measure set, should be placed into the proposed combined Patient and Caregiver Experience of Care/Care Coordination domain. We intend to consider proposing to adopt measures of care coordination in the future as they become available.

We may propose further refinements to the Hospital VBP Program domain structure in future years to accommodate the NQS’ population health priority or other

quality improvement priorities as appropriate, but will not propose to adopt a Population Health domain at this time.

We note that the proposed NQS-based domain structure combines measures of clinical processes and outcomes under the “Clinical Care” priority. In order to ensure that outcomes remain a principal focus of hospitals’ quality improvement efforts, as well as to continue our effort to shift the program over time to include more measures of outcomes and efficiency, we are proposing to stratify the NQS-based Clinical Care domain into “Clinical Care – Outcomes” and “Clinical Care – Process,” which enables us to provide significant weight to measures of outcomes and avoid diluting hospitals’ focus on measures of outcomes.

We note further that the proposed NQS-based domains include “Efficiency and Cost Reduction,” a domain priority that we believe is analogous to the current “Efficiency” domain finalized for the Hospital VBP Program, and a “Safety” domain. We have placed measures of outcomes into both the Clinical Care – Outcome and Safety domains below and have generally distinguished between the two by focusing on the measures’ direct impact on patients. The measures we are proposing to place into the Safety domain include measures of healthcare-associated infections and the AHRQ patient safety composite. We believe that hospitals must continue to focus quality improvement efforts on these outcome safety measures, which track infection and safety events that pose direct harm to patients.

Finally, as we stated in the Hospital Inpatient VBP Program final rule (76 FR 26491), we believe that domains need not be given equal weight, and that over

time, scoring methodologies should be weighted more towards outcomes, patient experience of care, and functional status measures (for example, measures assessing physical and mental capacity, capability, well-being and improvement). We took these considerations into account when developing the domain weighting proposal outlined below. We believe that the proposed domain weighting will continue to improve the link between Medicare payments to hospitals and patient outcomes, efficiency and cost, and the patient and care giver experience.

We note further that the proposed domain weighting below places significant weight on measures of clinical outcomes, efficiency, and the patient experience, while also prioritizing safety and clinical processes. We believe that the proposed domain weighting appropriately balances the clinical quality priorities described by the NQS.

Therefore, we are proposing to adopt the following domains and domain weights for the FY 2017 Hospital VBP Program:

Proposed Domains and Domain Weights for the FY 2017 Hospital VBP Program for Hospitals Receiving a Score on All Proposed Domains	
Domain	Weight
Safety	15 percent
Clinical Care <ul style="list-style-type: none"> ● Clinical Care – Outcomes ● Clinical Care – Process 	35 percent <ul style="list-style-type: none"> ● 25 percent ● 10 percent
Efficiency and Cost Reduction	25 percent
Patient and Caregiver Centered Experience of Care/Care Coordination	25 percent

While we believe there are advantages to aligning the Hospital VBP Program domains with the NQS domains, we also recognize that there may be advantages associated with maintaining consistency with previous years' domains. Accordingly, as an alternative to realigning the Hospital VBP Program's domain structure more closely

with the NQS beginning with FY 2017, we also are inviting public comments on whether we should adopt the following domains and domain weighting, which would be consistent with the proposals outlined for FY 2016 above:

Alternative Domain Weights for the FY 2017 Hospital VBP Program for Hospitals Receiving a Score on All Proposed Domains	
Domain	Weight
Clinical Process of Care	10 percent
Patient Experience of Care	25 percent
Outcome	40 percent
Efficiency	25 percent

We also seek public comments on how we should assign proposed measures to the new NQS-aligned domains, if finalized for FY 2017, and are seeking public comments on the following domain assignments for proposed FY 2016 measures, which would form the initial basis for the FY 2017 program's measure set:

Measure ID	Current Domain	NQS-Based Domain
AMI-7a	Clinical Process of Care	Clinical Care – Process
IMM-2	Clinical Process of Care	Clinical Care – Process
PN-6	Clinical Process of Care	Clinical Care – Process
SCIP-Inf-1	Clinical Process of Care	Clinical Care – Process
SCIP-Inf-2	Clinical Process of Care	Clinical Care – Process
SCIP-Inf-3	Clinical Process of Care	Clinical Care – Process
SCIP-Inf-4	Clinical Process of Care	Clinical Care – Process
SCIP-Inf-9	Clinical Process of Care	Clinical Care – Process
SCIP-Card-2	Clinical Process of Care	Clinical Care – Process
SCIP-VTE-2	Clinical Process of Care	Clinical Care – Process
HCAHPS	Patient Experience of Care	Patient and Caregiver Centered Experience of Care / Care Coordination
CAUTI	Outcome	Safety
CLABSI	Outcome	Safety
MORT-30-AMI	Outcome	Clinical Care – Outcomes

MORT-30-HF	Outcome	Clinical Care – Outcomes
MORT-30-PN	Outcome	Clinical Care – Outcomes
PSI-90	Outcome	Safety
SSI •	Outcome	Safety
MSPB-1	Efficiency	Efficiency and Cost Reduction

We also seek comment on how we should address minimum numbers of cases and measures under sections 1886(o)(1)(C)(ii)(III) and (IV) of the Act if we finalize this domain structure for the FY 2017 program. If we adopted the NQS-based domains solely for purposes of constructing the TPS, we could retain the general case and measure minimums structure adopted for prior program years. However, given the requirement in section 1886(o)(1)(C)(iii) of the Act that the Secretary conduct an independent analysis of what numbers are appropriate, we are also considering if we should commission such an analysis for the NQS domains, as modified. We are seeking public comments on this issue.

e. Proposed Disaster/Extraordinary Circumstance Waivers under the Hospital VBP Program

We are concerned that hospital performance under the Hospital VBP Program might be adversely impacted as a direct result of a significant natural disaster or other extraordinary circumstance. We are aware, for example, that Hurricane Sandy forced some hospitals in the New York-New Jersey-Connecticut area to close during the autumn of 2012, which impacted their ability to report quality measure data that will be used for both the FY 2014 and FY 2015 Hospital VBP Programs. We also recognize that hospitals that are closed during a portion of a performance period may still be eligible to

receive a TPS and value-based incentive payments based on their measured quality performance during the remaining portion of the performance period for a fiscal year.

However, we also are aware that many hospitals that were affected by Hurricane Sandy nevertheless remained open both during and after the storm, and we are concerned more generally that these hospitals, as well as other hospitals that are able to remain open despite being impacted by a local disaster or other extraordinary circumstance, might experience a decline in performance as a direct result of remaining open. For example, a hospital might be able to demonstrate that its performance on the HCAHPS survey was adversely impacted as a direct result of remaining open during or after a natural disaster if the hospital became overcrowded due to a neighboring hospital's closure, or understaffed due to the inability of staff to get to work. We believe that these types of unforeseen extraordinary circumstances could substantially affect the ability of the hospital to perform at the same level at which it might otherwise have performed if the natural disaster or extraordinary circumstance had not occurred, and we are concerned that using cases and claims from this period to generate the TPS might negatively, and unfairly, impact the value-based incentive payment amount that the hospital would otherwise receive.

Currently, hospitals participating in the Hospital IQR Program may request that we grant an extension or waiver of one or more data submission deadlines in the event of extraordinary circumstances beyond the control of the hospital. However, we do not believe this process is entirely sufficient for the Hospital VBP Program. The Hospital IQR Program's extraordinary circumstances extensions/waiver process allows hospitals

that have been granted an extension/waiver to receive the full annual percentage increase under the IPPS for the applicable fiscal year even though they did not submit data on measures in the same time, form, and manner required of other hospitals. To the extent that a hospital, as a result of receiving an extension or waiver under the Hospital IQR Program, does not report the minimum number of cases or measures under the Hospital VBP Program (as determined appropriate by the Secretary under sections 1886(o)(1)(C)(ii)(III) and (IV) of the Act), that hospital will be excluded from the Hospital VBP Program for the applicable fiscal year.

However, the Hospital IQR Program extraordinary circumstance extension/waiver process does not address the situation we are concerned with here; namely, where a hospital is able to continue to report data on measures that are included in both the Hospital IQR Program and the Hospital VBP Program, but can demonstrate that its Hospital VBP measure rates are negatively impacted as a result of a natural disaster or other extraordinary circumstance and, as a result, the hospital receives a lower value-based incentive payment. Therefore, we are proposing to adopt a Hospital VBP Program extraordinary circumstance waiver process.

In developing our proposed approach, we considered the feasibility of adopting a waiver that would allow a hospital to not have the measure data submitted during the affected time period included in its measure scores. This type of waiver policy would enable affected hospitals to continue to participate in the Hospital VBP Program for a given fiscal year if they continued to meet applicable measure and case minimums despite the fact that their TPS would not include data that is the subject of the waiver.

Therefore, this policy could prevent the possibility that a hospital's TPS is significantly, and negatively, affected by a natural disaster or other extraordinary circumstance, which we believe would alleviate our concerns.

However, implementing this type of data waiver presents certain operational difficulties. While chart-abstracted measures generally are reported using a date of service that would enable us to correctly identify which data should be excluded, the same is not necessarily true of patient experience of care measure data because HCAHPS survey dates do not align with service dates; instead, they are dependent on the timing of the survey's completion after discharge.

A further complication arises with certain claims-based measures. For example, the risk adjustment methodology currently in use for the 30-day mortality measures requires a fixed dataset for computation of all hospitals' risk-adjusted measure rates. Adding or removing data from the national claims set used to calculate a mortality measure's rates for a given time period therefore requires recalculation of all hospitals' measure rates, as the risk profile used to adjust hospitals' measured performance for the time period would have changed. In addition, in light of our policy to generate a TPS for hospitals that receive scores on fewer than all domains, we are concerned that proposing to adopt an extraordinary circumstances "waiver" process that would apply only to the clinical process of care domain data that we may relatively easily remove from scoring would be ineffective. We do not believe that waiving only clinical process of care domain data would mitigate the effects of a disaster or other extraordinary circumstances on hospitals' TPSs under the program, particularly if hospitals' performance on all

measures is affected significantly by those circumstances. An increase in measured mortality rates, for example, would not be mitigated by a clinical process of care-centered waiver, and could penalize the hospital.

Given the operational constraints discussed above, we believe that the best way to implement an extraordinary circumstances waiver under the Hospital VBP Program is to interpret the minimum numbers of cases and measures requirement in section 1886(o)(1)(C)(ii)(III) and (IV) of the Act to enable us to “waive” all applicable quality measure data from a performance period and, thus, exclude the hospital from the Hospital VBP Program for a fiscal year during which the hospital has experienced a disaster or other extraordinary circumstance.

Under this policy, a hospital struck by a natural disaster or other extraordinary circumstance would be able to request a Hospital VBP Program disaster/extraordinary circumstance waiver at the same time that it requests an extraordinary circumstance waiver under the Hospital IQR Program. The hospital would submit the Hospital IQR Program extension/waiver request form, including any available evidence of the impact of the extraordinary circumstances on the hospital’s quality measure performance, and would note that it also seeks a waiver from the Hospital VBP Program for the program year in which the same data could be used as performance period data to generate a TPS based on the measures included in the Hospital VBP Program. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51652), we finalized a requirement that affected hospitals submit their requests within 30 days of the date that the extraordinary circumstance occurred. We believe that this timeframe is appropriate for our proposed

waiver process for the Hospital VBP Program as it aligns with the current requirements under the Hospital IQR Program and forestalls the possibility of hospitals attempting to “game” their Hospital VBP Program scores by requesting a waiver after they receive their Percentage Payment Summary Reports for a given fiscal year.

We will review waiver requests and, at our discretion based on our evaluation of the impact of the disaster/extraordinary circumstances on the hospital’s quality measure performance, provide a response to the hospital. We intend to notify hospitals about our Hospital VBP Program waiver decisions concurrent with decisions made under the Hospital IQR Program’s waiver process.

For these reasons, we are proposing that the phrases “minimum number of measures that apply to the hospital” in section 1886(o)(1)(C)(iii) of the Act and “minimum number of cases for the measures that apply to the hospital” in section 1886(o)(1)(C)(iv) of the Act do not include any measures or cases that a hospital has submitted during a performance period for which it is granted a Hospital VBP Program disaster/extraordinary circumstance waiver.

We intend to implement this policy in a limited fashion, and based on prior experience with the Hospital IQR Program, anticipate providing such waivers only to a small number of hospitals. We do not intend to allow hospitals to use this proposed process to seek exclusion from the Hospital VBP Program solely because of comparatively poor performance under the Program’s scoring methodology; rather, we intend only to provide relief to hospitals whose performance suffered as a result of a disaster or other extraordinary circumstances.

We are inviting public comments on this proposal. We are specifically interested in public comments on the structure of the proposed process, and if we should consider implementing the process differently.

10. Applicability of the Hospital VBP Program to Hospitals

a. Background

Section 1886(o)(1)(C) of the Act specifies how the Hospital VBP Program applies to hospitals. Specifically, the term “hospital” is defined under section 1886(o)(1)(C)(i) of the Act as a “subsection (d) hospital (as defined in section 1886(d)(1)(B [of the Act]).” Section 1886(o)(1)(C)(ii) of the Act sets forth a list of exclusions to the definition of the term “hospital” with respect to a fiscal year, including a hospital that is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) of the Act (the Hospital IQR Program), a hospital for which, during the performance period for the fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients, a hospital for which there are not a minimum number of measures that apply to the hospital for the applicable performance period for the fiscal year, and a hospital for which there are not a minimum number of cases for the measures that apply to the hospital for the performance period for the fiscal year.

In addition, section 1886(o)(1)(C)(iv) of the Act states that in the case of a hospital that is paid under section 1814(b)(3) of the Act, the Secretary may exempt the hospital from the Hospital VBP Program if the State submits an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes

and cost savings established under the Hospital VBP Program. We interpret the reference to section 1814(b)(3) of the Act to mean those Maryland hospitals that are paid under section 1814(b)(3) of the Act and that, absent the “waiver” specified by section 1814(b)(3) of the Act, would have been paid under the IPPS.

b. Proposed Minimum Numbers of Cases and Measures for the FY 2016 Hospital VBP Program Outcome Domain

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53609), we finalized minimum numbers of cases and measures for the FY 2015 Hospital VBP Program’s Outcome domain. For the finalized 30-day mortality measures, we finalized a 25-case minimum for FY 2015. For the AHRQ PSI composite measure, we adopted AHRQ’s methodology, which provides a score on the measure to any hospital with at least three cases on any underlying indicator. For the CLABSI measure, we adopted CDC’s minimum case criteria, which calculates a standardized infection ratio for a hospital on the CLABSI measure if the hospital has 1 predicted infection during the applicable period. We also finalized our policy to provide a TPS to hospitals with sufficient cases in at least two of the four finalized quality measure domains (77 FR 53607).

In the CY 2012 OPSS/ASC final rule with comment period (76 FR 74532 through 74534) we concluded, based on an independent analysis, that the minimum number of measures that a hospital must report in order to receive a score on the Outcome domain is two measures. We continue to believe that this minimum number is appropriate for the expanded Outcome domain because adding measure scores beyond the minimum number

of measures has the effect of enhancing the domain score's reliability. We therefore are proposing to retain the finalized minimum number of measures for the Outcome domain for the FY 2016 Hospital VBP Program.

We are inviting public comment on these proposals.

c. Hospitals Paid under Section 1814(b)(3) of the Act

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53607 through 53608), beginning with the FY 2014 Hospital VBP Program, we adopted a new procedure for submission of the report in order for a Maryland hospital to be exempt from the Hospital VBP Program for a fiscal year. Under this finalized procedure, if the State seeks an exemption with respect to a particular program year, it would need to submit a report that meets the requirements of section 1886(o)(1)(C)(iv) of the Act in a timeframe that allows it to be received by the Secretary on or before November 15 prior to the effective fiscal year (for example, the report seeking an exemption from the FY 2014 Hospital VBP Program would have to be received by the Secretary no later than November 15, 2012). We stated that we anticipate notifying the State, as well as each hospital for which the State has requested an exemption, of our decision whether to grant the request no later than 90 days following the exemption request deadline.

We received an FY 2014 exemption request from the Maryland Health Services Cost Review Commission and the State of Maryland Department of Health and Mental Hygiene in November 2012, and the Secretary approved the exemption request on December 19, 2012.

We determined that Maryland meets or exceeds the patient health outcomes and cost savings requirements for exemption from the FY 2014 Hospital VBP Program. In terms of patient health outcomes, the Maryland Quality Based Reimbursement (MQBR) program focuses rewarding high quality care on hospital performance in similar clinical areas as the Hospital VBP Program (heart attack, heart failure, pneumonia, surgical processes of care and infection control). In general, the relevant health outcomes for the State's hospitals cited in its request achieve or surpass the current national results for comparable quality process and closely related clinical outcomes. In terms of cost savings, both the Hospital VBP Program and the MQBR reward high performers in a revenue-neutral manner. In this way, Maryland has achieved cost savings under its quality programs that meet any documented savings under the Hospital VBP Program, thereby meeting the standard specified in section 1886(o)(1)(C)(iv) of the Act for hospitals paid under section 1814(b)(3) of the Act.

I. Proposed Implementation of Hospital-Acquired Condition (HAC) Reduction Program for FY 2015

1. Background

a. Overview

CMS is committed to promoting higher quality of care and improving outcomes for Medicare beneficiaries. Accordingly, as part of that effort, we have, in recent years, undertaken a number of initiatives to reduce the number of hospital-acquired conditions (HACs) among Medicare beneficiaries. HACs are conditions that patients acquire while receiving treatment for another condition in an acute care health setting. HACs include hospital-acquired infections (HAIs), such as surgical site infections, as well as conditions such as foreign objects retained after surgery. HACs constitute an adverse event for the patient and a financial burden on the health care system. Most HACs, especially those stemming from medical errors, represent a leading cause of mortality in the United States⁴⁸. Deaths from HAIs alone are twice as high as those from HIV/AIDS and breast cancer combined.⁴⁹ Many common HACs can be prevented through the proper application of evidence-based guidelines. Yet, surveys reveal that 87 percent of hospitals do not follow such guidelines⁵⁰. Further, HACs constitute a significant economic burden on the health care system. For example, in 2009, the CDC estimated that preventable

⁴⁸ Kohn L T, Corrigan J M., Donaldson MS (Institute of Medicine) To Err is Human: Building a Safer Health System. Washington, DC: National Academy Press, 2000.

⁴⁹ Binder, Leah F. The Leapfrog Group Testimony before the House of Representatives Committee of Oversight and Government Reform, April 16, 2008. Available at:

http://www.leapfroggroup.org/policy_leadership/leapfrog_news/4732651.

⁵⁰ Id.

HAIs alone added nearly \$6 billion to U.S. health care costs each year⁵¹. Accordingly, we believe that our continued efforts to reduce HACs are vital to improving patients' quality of care, and reducing complications and mortality, while simultaneously decreasing costs.

In section II.F. of the preamble of this proposed rule, we discuss prior and ongoing rulemakings to implement the provisions of section 5001(c) of the Deficit Reduction Act (DRA) of 2005. Section 5001(c) of the DRA requires the Secretary to identify conditions by October 1, 2007 that: (a) are high cost or high volume or both; (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis; and (c) could reasonably have been prevented through the application of evidence based guidelines. An adjustment to the MS-DRG payment under the IPPS is made for identified HACs. This regulatory action has supported our efforts to encourage hospitals to reduce HACs.

Our initiatives to reduce HACs continued in 2009, when we developed National Coverage Determinations (NCDs) for the Medicare Program to eliminate “never events.” These “never events” stemmed from a 2002 report conducted by the NQF that listed 27 adverse events, defined as serious reportable events, that were both serious and largely preventable.⁵² Under these NCDs, we have specified that Medicare does not cover a particular surgical or other invasive procedure to treat a particular medical condition when a practitioner erroneously performs: (1) a different procedure altogether; (2) the

⁵¹ Centers for Disease Control, *The Direct Medical Costs of Healthcare Associated Infections in US Hospitals and the Benefits of Prevention* March, 2009. Available at: http://www.cdc.gov/hai/pdfs/hai/scott_costpaper.pdf.

⁵² National Quality Forum (NQF), *Serious Reportable Events in Healthcare—2011 Update: A Consensus Report*, Washington DC: NQF (2011).

correct procedure but on the wrong body part; or (3) the correct procedure but on the wrong patient.⁵³

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50196), we adopted 8 HAC measures into the Hospital IQR Program for the FY 2012 payment determination. These quality measures comprise additional efforts to promote quality of care by reducing the number of HACs in an acute care setting. We have been publicly reporting on these eight HAC measures successfully on the [Hospital Compare](#) Web site since September 2010.

As described above, the reduction of HACs is an important marker of quality of care and has a positive impact on both patient outcomes and costs of care. In accordance with section 1886(p) of the Act, the HAC Reduction Program aligns with our national strategy to improve health care quality by promoting the prevention of HACs, such as “serious reportable events” and HAIs. Our goal for the HAC Reduction Program is to heighten the awareness of HACs and reduce the number of incidences that occur through implementing the adjustments required by section 1886(p) of the Act. We believe our efforts in using payment adjustments and our measurement authority will encourage hospitals to eliminate the incidence of HACs that could be reasonably prevented by applying evidence-based guidelines.

⁵³ Center for Medicare and Medicaid Services (CMS), National Coverage Determination (NCD) for, *Surgical or Other Invasive Procedure Performed on the Wrong Body Part* (140.7), Pub-100-3 (2009); *Surgical or Other Invasive Procedure Performed on the Wrong Patient* (140.8), Pub 100-3 (2009); *Wrong Surgery Performed on a Patient* (140.9), Pub 100-3 (2009).

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 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 program 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. Proposals to Implement the HAC Reduction Program

In this proposed rule, we are proposing the general framework for implementation of the HAC Reduction Program for the FY 2015 implementation. We are including the

following proposals 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 this proposed rule, we are proposing to establish the rules governing the payment adjustment under the HAC Reduction Program at Subpart I of 42 CFR Part 412 (proposed §§ 412.170 and 412.172). We also are proposing to amend 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 proposed §§ 412.170 and 412.172 for the HAC Reduction Program. We discuss each of the proposed regulatory provisions under the appropriate subject area below.

a. Proposed Definitions

In accordance with the provisions of section 1886(p) of the Act, we are proposing to include, under proposed § 412.170, definitions for the terms “hospital-acquired condition,” “applicable hospital,” and “applicable time period.”

- **Hospital-acquired condition.** In accordance with the definition of “hospital-acquired condition” in section 1886(p)(3) of the act, we would include a definition of the term in the regulations to read: “*Hospital-acquired condition* is 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 also refer readers to section II.F. of the preamble of this proposed rule where we discuss the HACs that have been identified and selected by the Secretary through FY 2013 in accordance with the provisions of section 1886(d)(4)(D)(iv) of the Act as established by section 5001(c) of the DRA of 2005.

- **Applicable Hospital.** Section 1886(p)(2)(A) of the Act specifies that, for the purpose of the HAC Reduction program, an “applicable hospital” is a subsection (d) hospital that meets certain criteria. A subsection (d) hospital is defined in section 1886(d)(1)(B) of the Act, in part, as a “hospital located in one of the fifty States or the District of Columbia”, subject to certain exceptions. We also note that, for purposes of determining applicable hospitals under the HAC Reduction Program, subsection (d) hospitals include hospitals paid under a waiver under section 1814(b)(3) of the Act (that is, Maryland hospitals). Section 1886(p)(2)(B) of the Act specifies that “with respect to a subsection (d) hospital, [a hospital is considered to be an applicable hospital if] ... the subsection (d) hospital is in the top quartile of all subsection (d) hospitals, relative to the national average, of hospital acquired conditions during the applicable period, as determined by the Secretary.” Therefore, we are proposing to define 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) so long as the hospital meets the criteria specified under § 412.172(e).”

We note that while all subsection (d) hospitals, including hospitals paid under section 1814(b)(3) of the Act, would be used to determine which hospitals are “applicable hospitals,” as required by section 1886(p)(2)(B) of the Act, we have identified several types of hospitals where subsection (d) status may not be clear for purposes of determining which hospitals are or are not subject to the provisions of the HAC Reduction Program. A subsection (d) hospital as defined in section 1886(d)(1)(B) of the Act does not include hospitals and hospital units excluded from the IPPS, such as LTCHs, cancer hospitals, children’s hospitals, IRFs, IPFs. Therefore, hospitals and hospital units that are excluded from the IPPS would not be considered when determining “applicable hospitals” nor would they be determined to be “applicable hospitals” subject to the payment adjustment under the HAC Reduction Program. Similarly, CAHs would not be considered when determining “applicable hospitals,” nor would they be determined to be “applicable hospitals” subject to the payment adjustment under the HAC Reduction Program, because they do not meet the definition of a “subsection (d) hospital.” CAHs are separately defined under section 1886(mm) of the Act and are paid under a reasonable cost methodology under section 1814(l) of the Act. An Indian Health Services hospital enrolled as a Medicare provider meets the definition of a subsection (d) hospital and, therefore, would be considered in determining “applicable hospitals” and would be considered to be an “applicable hospital” under the HAC Reduction Program. In addition, hospitals that are SCHs, although they may be paid under a hospital-specific

rate instead of the Federal rate under the IPPS, are subsection (d) hospitals and, therefore, would be included in determining “applicable hospitals” and would be considered to be an applicable hospital under the HAC Reduction Program. Hospitals located in the Territories, including Puerto Rico, are not subsection (d) hospitals. Section 1886(d)(9)(A) of the Act separately defines a “subsection (d) Puerto Rico hospital” as a hospital that is located in Puerto Rico and that “would be a subsection (d) hospital . . . if it were located in one of the 50 States.” However, because they are not located in “one of the fifty States,” Puerto Rico hospitals are not subsection (d) hospitals and, therefore, would not be included in determining “applicable hospitals,” nor would they be considered to be an “applicable hospital” under the HAC Reduction Program. Finally, hospitals paid under the authority of section 1814(b)(3) of the Act are located in Maryland, which is “one of the fifty States” as described under section 1886(d)(1)(B) of the Act. Therefore, these Maryland hospitals are subsection (d) hospitals and would be included in determining “applicable hospitals” and, unless the Secretary exempts them from the application of the payment adjustment under the HAC Reduction Program under the authority of section 1886(p)(2)(C) of the Act, would be considered to be “applicable hospitals” under the HAC Reduction Program.

We are inviting public comments on whether clarification is required for additional types of hospitals.

- **Applicable Time Period.** In accordance with the proposal and discussion in section V.I.3.d. of this preamble regarding the proposed performance scoring methodology for proposed measures for selected conditions and a risk-adjustment

methodology under the HAC Reduction Program, we are proposing to define the “applicable period” as, with respect to a fiscal year, the 2-year period (specified by the Secretary) from which data are collected in order to calculate the Total HAC Score for the Hospital-Acquired Reduction Program

We are inviting public comments on these proposed definitions.

b. Proposed 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 V.H. of the preamble of this proposed rule and the Hospital Readmissions Reduction Program is discussed in section V.G. 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 conditions acquired during the applicable period, as determined by the Secretary. Therefore, we are proposing to specify in proposed § 412.172(b) that, “For applicable hospitals, beginning with discharges occurring during FY 2015, the amount of payment under this section [proposed § 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 this section [proposed § 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 Value-Based Purchasing Program under § 412.162, and section 1814(l)(4) but without regard to this section 1886(p) of the Act.”

We are inviting public comments on this proposal.

(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 describe in section V.I.3. of the preamble of this proposed rule, because hospitals paid under section 1814(b)(3) of the Act are subsection (d) hospitals, they would be 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 this proposed rule, we are proposing to establish criteria for evaluation to determine whether Maryland should be exempted from the application of the payment adjustments under the HAC Reduction Program for a given fiscal year. Under proposed § 412.172(c), we would specify 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, would be paid under section 1886(d) of the Act from the application of payment adjustments under the Hospital-Acquired Condition 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 Hospital-Acquired Condition Reduction Program as applied to hospitals described in section 1886(d)(1)(B) of the Act. We would specify in the proposed 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 would also specify that “Maryland’s annual report to the Secretary and request for exemption from the Hospital-Acquired Condition Reduction Program must be resubmitted and reconsidered annually.” We are proposing that, for FY 2015, Maryland would submit a preliminary report to us by January 15, 2014 and a final report to us by June 1, 2014.

We note that our proposed 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.

We are inviting public comments on our proposals.

c. Proposed Measure Selection and Conditions, Including a Proposed Risk-Adjustment and Scoring Methodology

(1) General Selection of Proposed Measures

We are proposing measures and a scoring methodology for the HAC Reduction Program in this FY 2014 proposed rule. 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

As described more fully below, we are proposing initially to adopt eight measures for the FY 2015 determination under the HAC Reduction Program. Several of these measures are already part of the Hospital IQR Program and are reported on the [Hospital Compare](#) Web site. We note that all eight measures proposed for the HAC Reduction Program follow the criteria established by the DRA of 2005 in that they consist of high-volume or high-cost conditions that could be prevented by the use of evidence-based guidelines (we refer readers to section II.F. of the preamble of this proposed rule for further information).

In this proposed rule, we are proposing the measure selection and methodology used to determine the Total HAC Score. For measure selection under the HAC Reduction Program, we are proposing to group the measures into separate domains (Domain 1 and Domain 2) to calculate a Total HAC Score in order to determine the payment adjustment. For Domain 1, we are discussing two alternatives, and seeking to finalize a policy based upon public comment received regarding these alternatives. The first approach represents our proposal, as it is our preferred choice. However, we are including an alternative approach for public comment. Both approaches would utilize AHRQ Patient Safety Indicators (PSIs) and CDC Healthcare Associated Infection (HAI) measures collected via the National Healthcare Safety Network (NHSN), and both approaches would be grouped into two separate domains. Domain 1 would include the

AHRQ PSI measures. Domain 2 would include CDC HAI measures. As explained below, these two domains would be used as part of calculating the Total HAC Score, which is the score used to determine the top quartile of subsection (d) hospitals subject to the payment adjustment under the HAC Reduction Program. The difference between our proposal and the alternative approach, as illustrated by Table A below, lies in the AHRQ measures proposed to be used in Domain 1. Domain 2 would be the same under either approach.

We are proposing to group the AHRQ and CDC HAI measures into separate domains to calculate a Total HAC Score because of the several major differences between the AHRQ and the CDC HAI measures. First, the AHRQ and CDC HAI measures use different data sources for their respective calculations. The AHRQ measures use Medicare FFS claims data and the CDC HAI measures use chart-abstracted data. Second, the AHRQ measures capture occurrences of adverse events among Medicare FFS discharges, while the CDC HAI measures capture adverse events to Medicare and non-Medicare patients alike. Third, the AHRQ measure results⁵⁴ are risk-adjusted and reliability-adjusted based on a 24-month data period, whereas the CDC HAI measures are a Standardized Infection Ratio (SIR) based on quarterly reporting. In addition, the AHRQ measures identify adverse events occurring across units within a facility, while the CDC HAI measures identify adverse events at the unit level. The SIR adjusts for differences in levels of infection risk in patients. The CDC SIR measures are calculated by dividing the total facility number of observed HAI events by the total

⁵⁴ With the exception of PSI 5 (Volume of foreign object left in body), which is not risk-adjusted or reliability-adjusted.

facility number of predicted HAI events. The facility must have ≥ 1 predicted HAI event during the reporting time period, for example, calendar quarter, for the measure to be calculated. The number of predicted HAI events is first calculated for each patient care location by multiplying the location's denominator (that is, the number of device days, procedure days, or patient days, depending on the HAI) by the NHSN-specific HAI rates from a standard population during a baseline time period, and dividing by 1.000. Then the predicted number of specific HAIs are summed across locations and used as the total facility number of predicted HAI events to reduce the overall SIR for a facility.

Currently, CAUTI and CLABSI are inclusive of patients in the intensive care unit only. However, in this proposed rule, we are seeking public comment on the expansion of the population to include medical wards, surgical wards, and medical/surgical wards. (We refer readers to section IX.A. of the preamble of this proposed rule for a discussion of the Hospital IQR Program.) Furthermore, the AHRQ measures are risk-adjusted at the patient level,⁵⁵ while the CDC HAI measures are risk-adjusted at the hospital-level and patient-care unit level. Specifically, the calculation of the AHRQ measures takes into consideration the risk factors of the patient's age, gender, and comorbidities, while CDC HAI measures account for risk factors, including patient location within the facility, medical school affiliation, and bed size of patient care unit. Because of the important differences mentioned above in the calculation of the two sets of measures, combining measure results into a single composite measure would decrease the reliability of the

⁵⁵ The exception is PSI 5 (Volume of foreign object left in body), which is not risk-adjust or reliability-adjusted.

Total HAC Score model. As a result, we are proposing to group the AHRQ and the CDC HAI measures into two separate domains.

Both our proposal and the alternative approach under Domain 1 support the agency's efforts to identify and monitor adverse events and inform hospitals about their patient safety performance. Both approaches also will allow us to compare hospital performance and to distinguish better performing hospitals from poor performing hospitals. Thus, the measures under either Domain 1 approach would result in a consistent scoring.

However, our proposed approach for Domain 1 would provide simpler results to interpret, allow a hospital to use the results to target patient safety improvement efforts, and avoid overlap between the two measure domains. Therefore, we believe that our proposed approach for Domain 1 provides hospitals with the most comprehensive picture of patient safety performance and is the method we are proposing to use.

Under our proposed approach, we are proposing to use the following six AHRQ measures for Domain 1 (Table A):

- Pressure ulcer rate (PSI 3);
- Volume of foreign object left in the body (PSI 5);
- Iatrogenic Pneumothorax rate (PSI 6);
- Postoperative physiologic and metabolic derangement rate (PSI 10);
- Postoperative pulmonary embolism (PE) or deep vein thrombosis rate (DVT) (PSI 12); and
- Accidental puncture and laceration rate (PSI 15).

Under the alternative approach, the measures under Domain 1 would consist of a Complications/Patient Safety for Selected Conditions composite (PSI 90). This composite is made up of the following eight individual component PSIs:

- Pressure ulcer rate (PSI 3);
- Iatrogenic Pneumothorax rate (PSI 6);
- Central venous catheter-related blood stream infection rate (PSI 7);
- Postoperative hip fracture rate (PSI 8);
- Postoperative pulmonary embolism (PE) or deep vein thrombosis rate (DVT) (PSI 12);
- Postoperative sepsis rate (PSI 13);
- Wound dehiscence rate (PSI 14); and
- Accidental puncture and laceration rate (PSI 15).

For Domain 2, regardless of the approach used for Domain 1, we are proposing to use CDC HAI measures. For FY 2015, we are proposing to use the CLABSI and CAUTI measures. Both of these measures are currently part of the Hospital IQR Program, are NQF endorsed, are publicly reported on the [Hospital Compare](#) Web site and were recommended by the MAP for use in the HAC Reduction Program. For FY 2016, we are proposing to add Surgical Site Infection (SSI), which is stratified by two conditions: colon surgery and abdominal hysterectomy. For 2017, we are proposing to add Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia and *Clostridium difficile* infection. These measures are also part of the Hospital IQR Program and are being proposed for the Hospital VBP Program.

Table A.--Proposed Measures for the Hospital-Acquired Condition Reduction Program

Domain 1: AHRQ Patient Safety Indicators	
Proposed Approach: 6 individual measures (FY 2015 onward)	Alternative Approach: One composite of 8 component indicators (FY 2015 onward)
<p>PSI-3 (Pressure ulcer rate) PSI-5 (Foreign object left in body) PSI-6 (Iatrogenic pneumothorax rate) PSI-10 (Postoperative physiologic and metabolic derangement rate) PSI-12 (Postoperative PE/DVT rate) PSI-15 (Accidental puncture & laceration rate)</p>	<p>PSI-90 { 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) PSI-15 (Accidental puncture & laceration rate)</p>

**Domain 2: CDC HAI Measures Apply to Proposed Approach
and Alternative Approach
(Multiple FYs)**

- Central Line-associated Blood Stream Infection (CLABSI) (FY 2015 onward)
- Catheter-associated Urinary Tract Infection (CAUTI) (FY 2015 onward)
- Surgical Site Infection (SSI):
 - SSI Following Colon Surgery (FY 2016 onward)
 - SSI Following Abdominal Hysterectomy (FY 2016 onward)
- Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia (FY 2017 onward)
- *Clostridium difficile* (FY 2017 onward)

We are inviting public comment on whether the proposed approach or the alternative approach would better serve the HAC Reduction Program.

(3) Applicable Time Period

We are proposing a 2-year applicable period to collect data that would be used to calculate the Total HAC Score. For Domain 1 (AHRQ measures), we are proposing a 2-year data period to calculate the measures based on recommendations from AHRQ, the measure developer. In addition, an analysis by Mathematica Policy Research, a CMS contractor,⁵⁶ shows that, with a 24-month data period, 50 to 90 percent of hospitals attain a moderate or high level of reliability for the proposed AHRQ measures. We believe that the proposed 24-month data period described below would provide hospitals and the general public the most current data available. The proposed 24-month data period also would 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.

For FY 2015, we are proposing to use the 24-month period from July 1, 2011 through June 30, 2013 as the applicable time period for the AHRQ measures. The claims for all Medicare FFS beneficiaries discharged during this period would 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 national and hospital-specific rates for PSI 6, PSI 12, and PSI 15 are available on the [Hospital](#)

⁵⁶ Mathematica Policy Research (November 2011). Reporting period and reliability of AHRQ, CMS 30-day and HAC Quality Measures – Revised. Available at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability.pdf.

[Compare](#) Web site. The hospital level PSI-90 composite bucket also is available on the [Hospital Compare](#) Web site.⁵⁷

The CDC measures are currently collected and calculated on a quarterly basis. However, for purposes of the HAC Reduction Program, we are proposing to use 2 years of data to calculate the Domain 2 score so Domain 1 and Domain 2 are calculated using 24 months of data. For FY 2015, we are proposing to use calendar years 2012 and 2013 for the HAC Reduction Program.

(4) Measure Calculations

The AHRQ PSI measures are calculated using ICD-9-CM diagnosis and/or procedure codes and, for the secondary diagnoses, the present on admission (POA) value associated with each secondary diagnosis in the claim. POA data indicate whether an adverse event occurred during the hospital stay, or was already present at the time of admission. AHRQ measures also reflect the quality of inpatient care based on patient safety events that occurred during hospital stays. The FY 2008 IPPS final rule requires that all hospitals paid under the IPPS report on whether a diagnosis is present on admission (72 FR 47201). We note that in section II.F. of the preamble of this proposed rule, we also are proposing to extend this requirement to subsection (d) Maryland hospitals paid under the waiver at section 1814(b)(3) of the Act. The specifications of PSIs 3, 5, 6, 10, 12, 15, and the individual components for the composite PSI 90 can be found on the Web site at:

http://www.qualityindicators.ahrq.gov/Modules/PSI_TechSpec.aspx. For the composite PSI 90, the calculation, the individual component weighting scheme and the

⁵⁷ <http://www.medicare.gov/hospitalcompare/About/HOSInfo/RCD.aspx#ssi>.

risk-adjustment methodology can be found on the Web site at:

http://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V44/Composite_User_Technical_Specification_PSI%20V4.4.pdf. A detailed discussion of the measure

specifications and methodology of the AHRQ Patient Safety Indicators (PSIs) can be found on the Web site at:

http://www.qualityindicators.ahrq.gov/modules/psi_resources.aspx.

For the HAC Reduction Program, we are proposing that the same rules used for the Hospital IQR Program be applied to determine whether the AHRQ individual rate-based measures in our proposed approach to Domain 1, including PSI 3, PSI 5, PSI 6, PSI 10, PSI 12, and PSI 15, are calculated for a hospital. In particular, under this proposal, for each of these measures, if a hospital had fewer than three eligible discharges in the denominator in general, except as described below, we would not calculate the result for that measure for the hospital. In the most recent public reporting of the AHRQ measures, less than 6 percent of the IPPS hospitals did not have enough eligible discharges to calculate the results for these measures. However, for PSI 5 (foreign object left in body), which identifies “never events,” even if a hospital has fewer than three occurrences, these events would be included in the calculation of the hospital’s results. For the PSI 90 composite in the alternative approach for Domain 1, we also would propose that the same rules used for the Hospital IQR Program be used to determine whether this composite measure is calculated for a hospital. Specifically, if the number of eligible discharges in the denominator for a given component indicator is fewer than three, the national rate would be substituted for the hospital rate. If the number of

eligible discharges for a hospital is fewer than three for every component indicator that makes up the composite, the composite value would not be calculated.

For the HAC Reduction Program, we are proposing to use the same inclusion criteria as used under the Hospital IQR Program for the Domain 2 measures. In order to calculate a Standard Infection Ratio (SIR), a hospital's number of expected HAIs must be ≥ 1 . For hospitals that have an expected number of HAIs < 1 , we would insert zero (0) in order to calculate the Domain score. Hospitals that have no ICU and have an active IQR zero ICU beds waiver for Hospital IQR program HAI quality reporting also would receive zero (0) points. If a hospital is eligible to report HAIs, does not have an active Hospital IQR program zero ICU beds waiver, and fails to report to NHSN, it would receive the maximum penalty of 10 points for that measure to calculate the Domain 2 score. (We refer readers to the discussion of scoring under section V.I.3.d. of the preamble of this proposed rule.)

The CDC uses a SIR, which is a summary metric used to track HAIs. The SIR compares the actual number of HAIs at a facility to a national baseline. The number of observed infections is divided by the number of expected infections. The number of expected infections is calculated using event rates from a standard population during a baseline period. (http://www.cdc.gov/HAI/surveillance/OA_stateSummary.html#a6). The SIR for CLABSI and CAUTI includes ICU locations, including pediatric and neonatal units. We are proposing to expand both of the populations for these measures to care provided in areas outside of the ICU in the future. (We refer readers to section IX.A.

of the preamble of this proposed rule for a discussion of this proposal under the Hospital IQR Program.)

(5) Measure Risk-Adjustment Methodology

Section 1886(p)(2)(B)(ii) of the Act requires the Secretary to establish and apply an appropriate risk-adjustment methodology with respect to determining the top quartile of subsection (d) hospitals with respect to HACs subject to the 1 percent payment adjustment. We are proposing to use the existing measure-level risk-adjustment that is already part of the methodology for the individual measures being proposed for Domains 1 and 2 in order to fulfill this requirement. We are proposing to codify the use of this methodology under proposed § 412.172(d). First, with the exception of PSI 5, all of the proposed PSI measures are risk-adjusted and reliability-adjusted. Specifically, risk factors such as the patient's age, gender, comorbidities, and complications would be considered in the calculation of the measure rates so that hospitals serving a large proportion of sicker patients would not be unfairly penalized. We believe that such risk-adjustment is appropriate, pursuant to section 3008 of the Affordable Care Act. We note that the PSI 5 measure (foreign object left in body) is not risk-adjusted. However, a foreign object left in the body constitutes an adverse event that should never occur. Thus, such adverse events cannot be risk-adjusted because these events should not occur, regardless of patient-related or hospital-related characteristics.

We are inviting public comments on the proposed risk-adjustment methodology.

d. Criteria for Applicable Hospitals and Performance Scoring

In general, we are proposing to use a scoring methodology similar to the achievement scoring methodology that is currently used under the Hospital VBP Program. We are proposing to implement a methodology for assessing the top quartile of applicable hospitals for HACs based on performance standards, under which we would score each hospital based on whether they are in the top quartile for each applicable measure and where in the top quartile they fall. In addition, we are proposing 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 are proposing to use each hospital's Total HAC Score to determine the top quartile of subsection (d) hospitals (applicable hospitals) that would be subject to the payment adjustment beginning with discharges on or after October 1, 2014.

With respect to a subsection (d) hospital, we are proposing that CMS will identify the top quartile of all hospitals that are subsection (d) hospitals with respect to their rate of HACs during the applicable period (proposed § 412.172(e)(1)). We are proposing that CMS will use Total HAC scores to identify applicable hospitals and will identify the 25 percent of hospitals with the highest Total HAC scores as applicable hospitals (proposed § 412.172(e)(2)). In addition, we are proposing that CMS will calculate the Total HAC

score by weighing Domain 1 score plus Domain 2 equally at 50 percent (proposed § 412.172(e)(3)).

We are proposing that hospital performance under section 1886(p) of the Act would be based on a Total HAC Score, which combines a hospital's results for Domains 1 and 2. As discussed earlier, we are proposing that the Domain 1 score be a combination of each hospital's result for all of the six individual AHRQ measures (Domain 1/Proposed Approach). We presented an alternative, the hospital's result for PSI 90 (Domain 1/Alternative Approach), which also could be used. For Domain 1/Proposed Approach, because hospitals may not have complete data for every AHRQ measure in the domain, we are proposing to use the same methodology as used for the Hospital VBP Program to determine the minimum number of measures with complete data to be included in the calculation of the Outcome Domain. We are proposing to use the following rules to determine the number of AHRQ measures to be included in the calculation for a hospital's Domain 1 score (Table B). In this discussion, "complete data" refers to whether a hospital has enough eligible discharges to calculate a rate for a measure. Specifically--

If a hospital did not have complete data for all six of the AHRQ measures, or if a hospital had complete data for fewer than three AHRQ measures, we would not calculate a Domain 1 score for that hospital.

If a hospital had complete data for at least three but fewer than six AHRQ measures, we would calculate a Domain 1 score for that hospital based on the rates of the available measures. The rate of each of these three to five available measures would be

equally weighted to contribute to the Domain 1 score. We would exclude the AHRQ measure(s) for which the hospital did not have complete data. Thus, if a hospital had complete data for three AHRQ measures, each measure would contribute to one-third of the hospital's Domain 1 score; if a hospital had complete data for four AHRQ measures, each measure would contribute to one-fourth of the hospital's Domain 1 score; if a hospital had complete data for five AHRQ measures, each measure would contribute to one-fifth of the hospital's Domain 1 score.

If a hospital had complete data for all six AHRQ measures, we would calculate a Domain 1 score for that hospital based on the rates of all six measures. The rate of each of these six measures would be equally weighted to contribute to the Domain 1 score. Thus, each measure would contribute to one-sixth of the hospital's Domain 1 score.

Table B.--Overall Description of How Measures in Domain 1/Proposed Approach Would Be Handled in Total HAC Score

Domain 1 – Proposed Approach: Six individual AHRQ Patient Safety Indicators (PSIs)	
Number of PSIs with complete data*	Rules for calculating Domain 1-Option 1 score
< 3	<ul style="list-style-type: none"> ● Do not calculate Domain 1 score or Total HAC Score for hospital
3 to 5	<ul style="list-style-type: none"> ● Include PSIs with complete data in calculation of Domain 1 score. ● Exclude PSIs without complete data ● Weight each PSI equally
6	<ul style="list-style-type: none"> ● Include all 6 PSIs in calculation of Domain 1 score and Total HAC score ● Weight each PSI equally

*Complete data = A hospital having enough cases to calculate the risk-adjusted and reliability-adjusted rate for an AHRQ PSI.

The calculation of the SIR for the CDC measures requires the facility have >1 predicted HAI event. The predicted number of events is calculated using the national HAI rate and the observed number of the specific HAIs. 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 would 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 proposed for the HAC Reduction Program and the distribution of measure results, simply adding up the measure results to calculate the domain or Total HAC Scores would make the scores less meaningful to hospitals and the general public. As a result, we are proposing that points 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 result of 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 correspond with a poorer score. For the HAC Reduction Program, we are proposing a slightly different methodology for scoring points, depending on the specific measure (Table C). Specifically--

- For PSI 5 (Volume of foreign object left in body) in Domain 1 - Proposed Approach, the measure results are frequency counts.

- Because this measure captures the number of never events, which should never happen, regardless of patient or hospital characteristics, we are proposing to assign 10 points, the maximum number of points, if the hospital had at least one occurrence.
- If a hospital had no occurrence for this measure, we would assign zero points.
 - For PSI 3, 6, 10, 12, and 15 in Domain 1 – Proposed Approach, point assignment for each measure would be based on the rate of occurrence for that measure.
- If a hospital's rate is within the worse performing quartile for a measure, we would assign 1 to 10 points to the hospital for that measure. The proposed rules for determining the number of points to be assigned are discussed later.
- If a hospital's rate is not within the worse performing quartile for a measure, we would assign zero points to the hospital for that measure.
 - For the AHRQ Patient Safety for Selected Condition (PSI 90) composite in Domain 1 – Alternative Approach, point assignment would be based on a hospital's score for the composite measure.
- If a hospital's result is within the worse performing quartile for a measure, we would assign 1 to 10 points to the hospital for this composite measure. The proposed rules for determining the number of points to be assigned are discussed later.
- If a hospital's result is not within the worse performing quartile, we would assign zero points to the hospital for this composite measure.
 - For the CDC NHSN measures in Domain 2, point assignment for each measure would be based on the SIR for that measure.

- If a hospital's SIR is within the worse performing quartile for a measure, we would assign 1 to 10 points to the hospital for that measure. The proposed rules for determining the number of points to be assigned are discussed later.
- If a hospital's SIR is not within the worse performing quartile for a measure, we would assign zero points to the hospital for that measure.

Table C.--Calculation of Domain 1 and 2 Measures

Measure Name	Measure Result	Scenario	Individual Measure Score (Points)
PSI-5*	Frequency count	Occurrence = 0	0
		Occurrence \geq 1	10
PSIs 3, 6, 10, 12, 15**	Rates***	Rate \geq 75%	1 – 10
		Rate < 75%	0
PSI 90	Weighted average of rates of component indicators	Composite value \geq 75%	1 – 10
		Composite value < 75%	0
CDC NHSN measure	Standard Infection Ratio (SIR)	SIR \geq 75%	1 – 10 (see Figure A)
		SIR < 75%	0

*PSI-5 is the Volume of foreign object left in the body measure, developed by AHRQ.

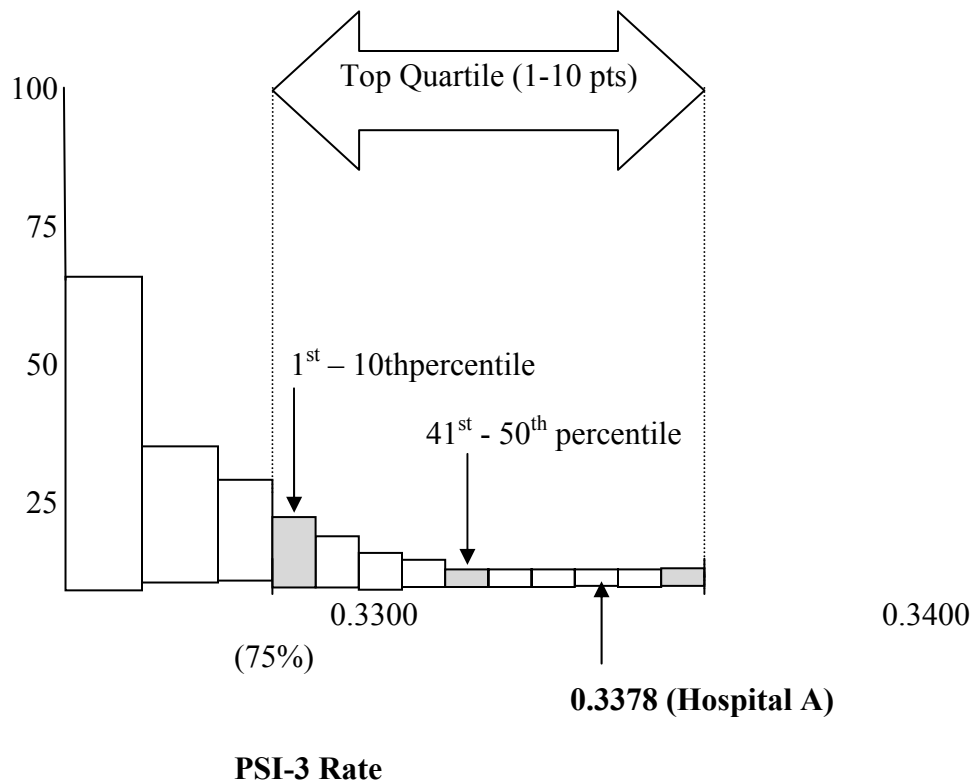
**PSI-3 is Pressure ulcer rate; PSI-6 is Iatrogenic Pneumothorax; PSI-10 is Postoperative physiological and metabolic derangement rate; PSI-12 is Postoperative pulmonary embolism or deep vein thrombosis rate; PSI-15 is Accidental puncture and laceration rate.

***These measure rates are risk-adjusted and reliability-adjusted.

For all the proposed measures for the HAC Reduction Program, with the exception of PSI 5, we are proposing the following rules to determine the number of points assigned to a measure that is within the top (or worse performing) quartile: Based on the distribution of measure results within the top (or worse performing) quartile of a measure, we would divide the measure results into percentiles. Figure A shows an example for point assignment for PSI 3 (Pressure ulcer rate). In this example, if a hospital's rate for PSI 3 is between 0.3000 and 0.3400, it is within the top (or worse performing) quartile. For Hospital A, the rate for PSI 3 is 0.3378. As a result, Hospital

A is subject to 1 to 10 points for PSI 3. Based on the distribution for PSI 3 rates for all the hospitals in the top quartile, we would divide the results into percentiles in increments of 10 with the lowest percentile ranges meaning better performance within the top quartile. Hospitals with PSI 3 rates within the lowest tenth percentile of the top quartile would be given one point; those with PSI 3 rates within the second lowest percentile range (between the 10th and 20th percentile) of the top quartile would be given 2 points, etc. Because Hospital A's rate for PSI 3 is within the eighth percentile range (between the 70th and 80th percentile), we would assign 8 points to this PSI 3 measure for Hospital A.

Figure A.--Example of Point Assignment for Hospital A with PSI-3 (Pressure ulcer rate) Rate = 0.3378



Point assignment for Hospital A's PSI-3 score:

If Hospital A's PSI-3 rate falls into this percentile above 75%	Then assign this number of points
1 st - 10 th	1
11 th - 20 th	2
21 st - 30 th	3
31 st - 40 th	4
41 st - 50 th	5
51 st - 60 th	6
61 st - 70 th	7
71 st - 80 th	8
81 - 90 th	9
91 st - 100 th	10

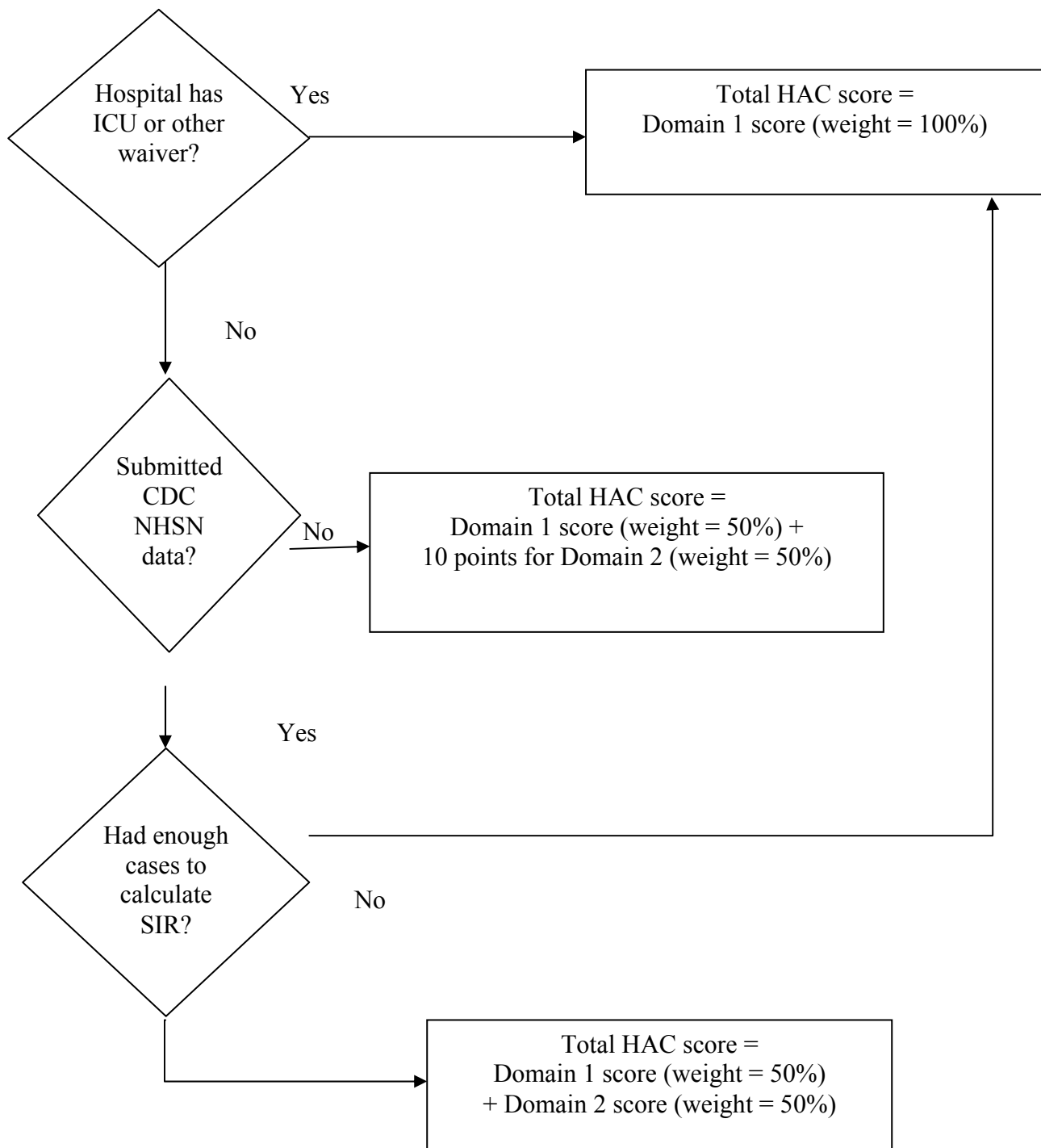
For Domain 2, we would obtain measure results that hospitals submitted to the CDC NHSN for the Hospital IQR Program. The CDC HAI measures capture adverse events that occurred within intensive care units (ICUs), including pediatric and neonatal units. For the Hospital IQR Program, hospitals that elected 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 would not be subject to the 2-percent payment reduction for nonsubmission of quality reporting data.

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 proposed CDC HAI measures impact the score for Domain 2 and eventually the Total HAC Score, CMS aims 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 are proposing the following rules (Figure B):

- If a hospital had an ICU waiver for the CDC HAI measures, we would use only the Domain 1 score to calculate its Total HAC Score.

- If a hospital did not have an ICU waiver for a CDC HAI measure:
 - If the hospital did not submit data for the CDC HAI measures, we would assign 10 points to that measure for that hospital.
 - If the hospital did 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 would 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 would use only the hospital's Domain 1 score to calculate its Total HAC Score.

Figure B. Calculation of Total HAC Score for Domain 2 CDC NHSN Measures



Key:
 Domain 1 = AHRQ Patient Safety Indicators
 Domain 2 = CDC NHSN measures

As discussed earlier, if a hospital has complete data for the measures in both Domain 1 and Domain 2, the scores of the two domains would contribute equally to the Total HAC Score. In the case of Domain 1 – Proposed Approach, if a hospital has complete data for at least three measures in Domain 1 and at least one measure in Domain 2, its Domain 1 score and Domain 2 score would contribute equally to its Total HAC Score. However, if a hospital has complete data for fewer than three measures in Domain 1 and at least one measure in Domain 2, its Total HAC Score would depend entirely on its Domain 2 score. Similarly, if a hospital has complete data for at least three of the measures in Domain 1 but none of the measures in Domain 2, its Total HAC Score would be based entirely on its Domain 1 score. If a hospital does not have complete data for at least three measures in Domain 1 and at least one measure in Domain 2, we would not calculate a Total HAC Score for this hospital.

In the case of Domain 1 – Alternative Approach, if a hospital has enough data to calculate PSI 90 for Domain 1 and complete data for at least one measure in Domain 2, the scores of the two domains would contribute equally to the Total HAC Score. However, if a hospital does not have enough data to calculate PSI 90 for Domain 1 but it has complete data for at least one measure in Domain 2, its Total HAC Score would depend entirely on its Domain 2 score. Similarly, if a hospital has complete data to calculate PSI 90 in Domain 1 but none of the measures in Domain 2, its Total HAC Score would be based entirely on its Domain 1 score. If the hospital does not have complete data to calculate PSI 90 for Domain 1 or any of the measures in Domain 2, we would not calculate a Total HAC Score for this hospital.

We are inviting public comments on this proposed scoring methodology. In addition, we are inviting public comments on alternate methodologies for scoring hospitals and determining most accurately those hospitals that are in the top quartile for the selected HACs. For example, instead of awarding points for each measure only to those hospitals that fall in the top quartile for that specific measure, an alternative option would be to award points to each hospital for each measure in deciles from the best performing hospital to the worst performing hospital. Another example would be to award points in deciles for each measure between the median rate for a particular measure and the rate of the worst performing hospital. We are seeking to identify hospitals that are in the top quartile for all of the HACs combined and are soliciting public comments on approaches to best identify this group of hospitals.

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, we are proposing that confidential reports for the HAC Reduction Program contain information related to claims-based measure data for the PSI measures, the domain score for each domain, and the Total HAC Score. We note that, although we are proposing to use chart-abstracted measures in the HAC Reduction Program, 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 believe that this method would reduce the burden on hospitals, by alleviating the need to correct data present in two different programs. However, we welcome any public comments and suggestions on this proposal.

(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, we are proposing that the following information would 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. However, because this is a new program, we are inviting public comments and suggestions on other information to be posted on the [Hospital Compare](#) Web site.

(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. We are proposing that hospitals be allowed to review and correct the following information as part of the HAC Reduction Program prior to it being made available to the public: the claims-based measures in Domain 1; the point allocations for the measures in each domain; the domain scores; and the Total HAC Score.

For the FY 2015 HAC Reduction Program, we are proposing to use individual HAC measures consisting of CDC HAI measures as well as claims-based measures. Further, we are proposing for the HAC Reduction Program that hospitals have an opportunity to review and correct chart abstracted data and claims based data for each measure through the processes discussed below. These individual measures will be used to calculate the domain and Total HAC Score, which would determine those applicable hospitals within the top quartile, or those hospitals with the highest number of HACs. We also are proposing that hospitals have the opportunity to review and submit corrections on its Domain and Total HAC Score for the HAC Reduction Program, which is also described below.

(a) Chart-Abstracted Measures (Domain 2 - CDC HAI Measures)

We are proposing to use the same process that hospitals currently have to review and correct data submitted on the Hospital IQR Program chart-abstracted measures to

review and correct chart-abstracted measures in Domain 2 under the HAC Reduction Program. Under this proposed process, hospitals would continue to have the opportunity to review and correct data they submit on all Hospital IQR Program chart abstracted measures, whether or not the measure was adopted as a measure for the HAC Reduction Program. We are proposing to use the Hospital IQR Program's data submission, review, and correction processes, which would allow for review and correction of data on a continuous basis as data are being submitted for the Hospital IQR Program, which in turn would allow hospitals to correct data used to calculate the Total HAC Score for those hospitals that participate in both the Hospital IQR Program and the HAC Reduction Program. We believe this process would satisfy the requirement in section 1886(p)(6) of the Act to allow hospitals to review and submit corrections for information that will be made public with respect to each hospital. Under the Hospital IQR Program, hospitals currently have an opportunity to submit, review, and correct any of the chart-abstracted information for the full 4 1/2 months following the last discharge date in a calendar quarter. Hospitals can begin submitting data on the first discharge day of any reporting quarter. Hospitals are encouraged to submit data early in the submission schedule to identify errors and resubmit data before the quarterly submission deadline. Users may view and make corrections to the data that they submit starting immediately following submission. The data are populated into reports that are updated immediately with all data that have been submitted successfully. Hospitals are able to view a report each quarter which shows the numerator, denominator, and percentage of total for each Clinical Measure Set and Stratum. That report contains the hospital's performance on

each measure set/stratum submitted quarterly by CDC on behalf of hospitals to CMS'QIO Clinical Warehouse. We believe that 4 1/2 months is sufficient time for hospitals to be able to submit, review data, make corrections to the data, and view their percentage of total, or measure rate, on each Clinical Measure Set/Strata for use in both the Hospital IQR Program and the HAC Reduction Program. In addition, because this process is familiar to most hospitals, use of this existing framework reduces the burden that could have been placed on hospitals that participate in the Hospital IQR Program if they had to learn a new process for submitting chart-abstracted data for the HAC Reduction Program. Subsequent to the period during which hospitals could review and correct data and measure rates for chart-abstracted measures as specified, they would have no further opportunity to correct such data or measure rates. We are proposing that once the hospital had an opportunity to review and correct quarterly data related to chart abstracted measures submitted in the Hospital IQR Program, we would consider that the hospital had been given the opportunity to review and correct the data for the HAC Reduction Program. We are proposing to use these data to calculate the measure scores for purposes of the HAC Reduction Program, and these measure scores would be used to calculate domain and Total HAC Scores for the HAC Reduction Program without further review and correction. We invite public comment on this proposal.

(b) Claims Based Measures (Domain 1 AHRQ PSI Measures)

For purposes of the HAC Reduction Program for FY 2015, we are proposing to calculate Domain 1 measure rates using the 2-year applicable period for the FY 2015 payment determination that spans from July 1, 2011 through June 30, 2013, data sources,

and apply the minimum number of discharges criteria shown in Table B for each hospital as proposed. We intend to make this information available to the public, consistent with the requirements of section 1886(p)(6)(B) of the Act, as part of the FY 2015 rulemaking process, in addition to posting this information on the [Hospital Compare](#) Web site in a subsequent release.

We are proposing to provide hospitals an opportunity to review and submit corrections for claim-based measures using a process similar to the process currently used for posting results on the [Hospital Compare](#) Web site, which is also the process currently used in the Hospital Readmissions Reduction Program. Below, we are proposing the details regarding the process for hospitals to review and submit corrections to their data score prior to making this information available to the public in rulemaking and on the [Hospital Compare](#) Web site.

For FY 2015, for the HAC Reduction Program, we are proposing to deliver confidential reports and accompanying confidential discharge level information to hospitals as defined in section V.I.3.d. of the preamble of this proposed rule. These reports would be delivered in hospitals' secure QualityNet accounts. The information in the confidential reports and accompanying confidential discharge-level information would be calculated using the claims information we had available approximately 90 days after the last discharge date in the applicable period, which is when we would create the data extract for the calculations. The discharge-level information accompanying the Domain 1 PSI measure rates would include the risk factors for the discharges that factor into the calculation of the Total HAC Score used to determine the top quartile of

applicable hospitals, dates of admission and discharge, discharge characteristics, and other information relevant to the measure calculations, that is, exclusions. Our intent in providing this information is twofold: (1) to facilitate hospitals' verification of the Domain 1 PSI measure calculations we provide during the review and correction period based upon the information we had available at the time our data extract was created; and (2) to facilitate hospitals' quality improvement efforts with respect to the PSI measures.

The review and correction process we are proposing for claims based measures in Domain 1 would not include submitting additional corrections related to the underlying claims data we used to calculate the measures for Domain 1, or adding new claims to the data extract we used to calculate the measures used in Domain 1. This is because it is necessary to take a static "snapshot" of the claims in order to perform the calculations. For purposes of this program, we would calculate the measures in Domain 1 using a static snapshot (data extract) taken at the conclusion of the 90-day period following the last date of discharge used in the applicable period. We recognize that under our current timely claims filing policy, hospitals have up to 1 year from the date of discharge to submit a claim to us. However, in using claims data to calculate measures for this program, we are proposing to create data extracts using claims in CMS' Common Working File (CWF) 90 days after the last discharge date in the applicable period which we will use for the calculations. For example, if the last discharge date in the applicable period for a measure is June 30, 2013, we would create the data extract on September 30, 2013, and use that data to calculate the claims based measures for that applicable period. Hospitals would then receive the Domain 1 Score in their confidential

reports and accompanying discharge-level information, and they would have an opportunity to review and submit corrections for the calculations of the measures in Domain 1. As we stated above, hospitals would not be able to submit corrections to the underlying claims snapshot used for the Domain 1 measure calculations after the extract date, and also would not be able to add claims to this data set. Therefore, we would consider hospitals' claims data to be complete for purposes of calculating the Domain 1 for the HAC Reduction Program at the conclusion of the 90-day period following the last date of discharge used in the applicable period. We considered a number of factors in determining that a 90-day "run-out" period is appropriate for purposes of calculating claims based measures. First, we seek to provide timely quality data to hospitals for the purpose of quality improvement and to the public for the purpose of transparency. Next, we seek to make payment adjustments to hospitals based on their performance on measures as close in time to the performance period as possible. Finally, with respect to claims-based measures, we seek to have as complete a data set as possible, recognizing that hospitals have up to 1 year from the date of discharge to submit a claim under CMS' timely claims filing policy. After the data extract is created, it takes several months to incorporate other data needed for the calculations (particularly in the case of risk-adjusted, and/or episode-based measures). We then need to generate and check the calculations, as well as program, populate, and deliver the confidential reports and accompanying data to be delivered to hospitals. We also are aware that hospitals would prefer to receive the calculations to be used for the HAC Reduction Program as soon as possible. Because several months lead time is necessary after acquiring the data to

generate these claims-based calculations, if we were to delay our data extraction point to 12 months after the last date of the last discharge in the applicable period, we would not be able to deliver the calculations to hospitals sooner than 18 to 24 months after the last discharge. We believe this would create an unacceptably long delay both for hospitals and for us to deliver timely calculations to hospitals for quality improvement and transparency, and ultimately timely readmission adjustment factors for purposes of this program. Therefore, we are proposing to extract the data needed to calculate the Domain 1 for this program 90 days after the last date of discharge for the applicable period so that we can balance the need to provide timely program information to hospitals with the need to calculate the claims based measures using as complete a data set as possible. We note that, under the proposed process, hospitals would retain the ability to submit new claims and corrections to submitted claims for payment purposes in line with CMS' timely claims filing policies. However, we emphasize that the administrative claims data used to calculate the Domain 1 measures and the resulting Domain Score reflect the state of the claims at the time of extraction from CMS' Common Working File. Under the proposed process, a hospital's opportunity to submit corrections to the calculation of the Total HAC Score ends at the conclusion of the review and correction period.

(c) Total HAC Score

We are proposing to provide hospitals with a period of 30 days to review and submit corrections for their Total HAC Scores for the HAC Reduction Program. This 30-day period would begin when the hospitals' confidential reports and accompanying discharge-level information are posted to their QualityNet accounts. This proposed

requirement will enable us to evaluate correction requests and provide decisions on those requests in a timely manner.

We believe that this proposed review and corrections process will ensure that hospitals are able to fully and fairly review their domain and Total HAC Score. We view the review and corrections process as a means to ensure that the information posted on the [Hospital Compare](#) Web site is accurate. We are inviting public comments on the proposed review and corrections process for the HAC Reduction Program. Based on previous experience with public reporting of measures under the Hospital IQR Program, and review and correction processes currently in place for the Hospital Readmission Reduction Program and the Hospital VBP Program, we believe this 30-day period allows enough time for hospitals to review their data and notify us of calculation errors, and for us to incorporate appropriate corrections to the HAC calculations prior to making the data available to the public. We are proposing that the Total HAC Score would be made available to the public via [Hospital Compare](#) Web site after the review and correction period. During the review and correction period, hospitals should notify us of suspected errors in their Total HAC Score using the technical assistance contact information provided in their confidential reports.

During the 30-day review and correction process for the Total HAC Score, if a subsection (d) hospital suspects that discrepancies exist in our application of the HAC scoring methodology (assignment of points to measures, domain scoring, domain weighting), it should notify us during the review and correction period using the technical support contacts provided in the hospital's confidential report. We would investigate the

validity of each submitted correction and notify hospitals of the results. If we confirm that we made an error in creating the data extract or in calculating the Total HAC Score, we would correct the calculations, issue new confidential reports to affected subsection (d) hospitals, and then publicly report the corrected Total HAC Score. However, if the errors take more time than anticipated to correct, we would notify hospitals that corrected HAC Scores will be made available through delivery of confidential reports followed by a second 30-day review and correction period, subsequent publication, and posting on [Hospital Compare](#) Web site. In addition, we are proposing that any corrections to a hospital's Total HAC Score would then be used to recalculate a hospital's quartile under section 1886(p)(2)(B)(i) of the Act in order to determine the hospital's adjustment factor in accordance with section 1886(p)(2)(B)(ii) of the Act.

We believe that this proposed process would fulfill the statutory requirements at section 1886(p)(2)(B), section 1886(p)(6)(B), and section 1886(p)(6)(C) of the Act. We further believe that the proposed process would allow hospitals to review and correct their Total HAC Score.

We are proposing to codify this review and correction process at proposed § 412.172(f). In summary, we are specifying that 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 (proposed paragraph (f)). To ensure that a hospital has the opportunity to review and submit corrections for its HAC rates for the applicable conditions for a fiscal year that are used to determine its total hospital acquired conditions

score, we are specifying that CMS will provide each hospital with confidential hospital-specific reports and discharge level information used in the calculation of its total hospital acquired conditions score (proposed paragraph (f)(2)). Hospitals will have a period of 30 days after receipt of the information provided to review and submit corrections for the hospital acquired conditions domain score for each condition that are used to calculate the Total HAC score for the fiscal year (proposed paragraph (f)(2)). The administrative claims data used to calculate a hospital's total hospital acquired conditions score for the conditions for a fiscal year will not subject to review and correction (proposed paragraph (f)(3)). CMS will post the total hospital acquired condition score for the applicable conditions for a fiscal year for each applicable hospital on the Hospital Compare Web site (proposed paragraph (f)(4)).

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.

We are proposing to include these statutory provisions under proposed § 412.172(g). 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 will provide hospitals with the opportunity to correct data prior to its release on the [Hospital Compare](#) Web site.

J. Payments for Direct Graduate Medical Education (GME) Costs (§§ 412.106 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. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress, through the Balanced Budget Act of 1997 (Pub. L. 105-33), established a limit on the number of allopathic and osteopathic residents that a hospital may include in its FTE resident count for direct GME

and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

The Affordable Care Act made a number of statutory changes relating to the determination of a hospital's FTE resident count for direct GME and IME payment purposes and the manner in which FTE resident limits are calculated and applied to hospitals under certain circumstances. 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 Inclusion of Labor and Delivery Days in the Calculation of Medicare Utilization for Direct GME Purposes and for Other Medicare Inpatient Days Policy

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53411), we discussed Medicare's policies with respect to the treatment of labor and delivery services in the calculation of the Medicare DSH payment adjustment. We noted that, in the FY 2010 IPPS/LTCH PPS final rule, we made a change to include, in the DPP of the Medicare DSH payment adjustment, all patient days associated with patients occupying labor and delivery beds once the patient has been admitted to the hospital as an inpatient, regardless

of whether the patient days are associated with patients who occupied a routine bed prior to occupying an ancillary labor and delivery bed. We stated that we made the change because the costs associated with labor and delivery patient days are generally payable under the IPPS.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53413), we finalized a policy extending our current approach of including labor and delivery patient days in the DPP of the Medicare DSH payment adjustment to our rules for bed counting for purposes of both the IME payment adjustment and the Medicare DSH payment adjustment. We stated that if a patient day is counted for DSH payment purposes because the services furnished are generally payable under the IPPS, the bed in which the services are furnished also should be considered to be available for IPPS-level care. To implement this policy, we amended the regulations at 42 CFR 412.105(b)(4) to remove from the list of excluded beds those beds associated with “ancillary labor/delivery services.” This change was effective for cost reporting periods beginning on or after October 1, 2012.

In response to our proposal in the FY 2013 IPPS/LTCH proposed rule to include labor and delivery bed days as available bed days for DSH and IME payment adjustment purposes, commenters noted that if these days are considered inpatient days, they also should be considered patient days for purposes of allocating direct GME payments. However, the Medicare cost report currently does not allow for labor and delivery patient days to be counted in the direct GME patient load. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53413), we stated that we would undertake further review to determine whether it was necessary to make any changes in the manner in which patient days are

reported on the Medicare cost report and whether these labor and delivery patient days should be excluded or included from the calculation of the Medicare patient load.

For this FY 2014 IPPS/LTCH PPS proposed rule, we have analyzed the calculation of the Medicare patient load and the cost reporting implications. Direct GME payments are calculated using three variables: the hospital's per resident amount; the number of FTE residents a hospital is training subject to its FTE cap and the rolling average; and the hospital's Medicare patient load. "Medicare patient load" is defined at 42 CFR 413.75(b) as "with respect to a hospital's cost reporting period, the total number of hospital inpatient days during the cost reporting period that are attributable to patients for whom payment is made under Medicare Part A divided by total hospital inpatient days. In calculating inpatient days, inpatient days in any distinct part of the hospital furnishing a hospital level of care are included and nursery days are excluded." We agree with the commenters who stated that because labor and delivery days are considered inpatient days for DSH purposes, they also should be considered inpatient days for purposes of determining the Medicare share for direct GME payments. We believe that the best way to calculate a hospital's Medicare patient load or the "Medicare utilization" (the term we will use for the remainder of this section) is to include all of the hospital's inpatient days. Consistent with the inpatient day counting rules for DSH as clarified in the FY 2010 IPPS/RV 2010 LTCH PPS final rule, we are proposing that patient days associated with maternity patients who were admitted as inpatients and were receiving ancillary labor and delivery services at the time the inpatient routine census is taken, regardless of whether the patient actually occupied a routine bed prior to occupying an

ancillary labor and delivery bed and regardless of whether the patient occupies a “maternity suite” in which labor, delivery recovery, and postpartum care all take place in the same room, will be included in the Medicare utilization calculation. We understand that including labor and delivery inpatient days in the Medicare utilization ratio invariably would reduce direct GME payments because the denominator of the ratio, which includes the hospital’s total inpatient days, would usually increase at a higher rate than the numerator of the ratio. However, because the Medicare utilization ratio is a comparison of a hospital’s total Medicare inpatient days to its total inpatient days, we believe that revising the ratio to include labor and delivery days is appropriate because they are inpatient days and, therefore, should be counted as such. Therefore, we are proposing that, effective for cost reporting periods beginning on or after October 1, 2013, for purposes of applying the Medicare utilization ratio, we would include labor and delivery inpatient days in the numerator (to the extent that there are any labor and delivery inpatient days associated with Medicare beneficiaries), and all labor and delivery inpatient days (associated with all inpatients of the hospital) in the denominator. In order to implement this proposed change, we note that we would need to amend the applicable cost report worksheets and instructions (in particular, Worksheet S-3, Part 1) to allow for the inclusion of labor and delivery inpatient days in the Medicare utilization ratio.

In addition to direct GME, which uses the ratio of Medicare inpatient days to total inpatient days to determine payment, this proposal also impacts other Medicare policies where either the number of inpatient days or a ratio of Medicare inpatient days to total inpatient days is used to determine eligibility or payment. Regarding eligibility, for

example, including labor and delivery days as inpatient days could affect a hospital's eligibility for SCH status. A hospital can be classified as an SCH if it is located more than 35 miles from other like hospitals or is located in a rural area (as defined at § 412.64 of the regulations) and meets one of the conditions listed in the regulations at § 412.92(a). In determining whether a nearby hospital is a like hospital, CMS compares the total inpatient days of the SCH applicant hospital with the total inpatient days of the nearby hospital. If the total inpatient days of the nearby hospital are greater than 8 percent of the total inpatient days reported by the SCH applicant hospital, the nearby hospital is considered a like hospital for purposes of evaluating the applicant hospital's eligibility for SCH status. Therefore, including labor and delivery days as inpatient days may impact the count of inpatient days for both the SCH applicant hospital and the nearby hospital and may affect the applicant hospital's eligibility for SCH status. However, this proposal would not impact Medicare payments calculated on a reasonable cost basis for routine inpatient services, which are apportioned in accordance with 42 CFR 413.53(a)(1).

In summary, we are proposing to include labor and delivery days as inpatient days in the Medicare utilization calculation, effective for cost reporting periods beginning on or after October 1, 2013.

3. Notice of Closure of Teaching Hospital and Opportunity to Apply for Available Slots

a. Background

Section 5506 of the Affordable Care Act authorizes the Secretary to redistribute residency cap slots after a hospital that trained residents in an approved medical residency program(s) closes. Specifically, section 5506 amended the Act by adding a

subsection (vi) to section 1886(h)(4)(H) and modifying the language at section 1886(d)(5)(B)(v) to instruct the Secretary to establish a process to increase the FTE resident caps for other hospitals based upon the FTE resident caps in teaching hospitals that closed “on or after a date that is 2 years before the date of enactment” (that is March 23, 2008). In the CY 2011 OPPI/ASC final rule with comment period issued in the **Federal Register** on November 24, 2010 (75 FR 72212), we established regulations and an application process for qualifying hospitals to apply to CMS to receive direct GME and IME FTE resident cap slots from a hospital that closed. The procedures we established apply both to teaching hospitals that closed after March 23, 2008, and on or before August 3, 2010, and to teaching hospitals that closed after August 3, 2010. We made clarifications and revisions to the policy regarding applications under section 5506 in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434 through 53477).

b. Notice of Closure of a Teaching Hospital

This notice serves to notify the public of the closure of a teaching hospital, and to initiate another round of the section 5506 application and selection process. This round would be the fourth round of the section 5506 (“Round 4”) application and selection process. The following closed teaching hospital is part of the Round 4 application process under section 5506:

Provider Number	Provider Name	City and State	CBSA Code	Terminating Date	IME Cap (including +/- MMA Sec. 422¹ Adjustment)	Direct GME Cap (including +/- MMA Sec. 422¹ Adjustment)

Provider Number	Provider Name	City and State	CBSA Code	Terminating Date	IME Cap (including +/- MMA Sec. 422¹ Adjustment)	Direct GME Cap (including +/- MMA Sec. 422¹ Adjustment)
330002	Peninsula Hospital Center	Far Rockaway, NY	35644	April 9, 2012	28.31 + 0.01 section 422 increase = 28.32 ²	28.31 + 8.03 section 422 increase = 36.34 ³

¹Section 422 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108-173, redistributed unused residency slots effective July 1, 2005.

²Peninsula Hospital Center's 1996 IME FTE cap is 28.31. Under section 422 of the MMA, the hospital received an increase of 0.01 to its IME FTE cap: $28.31 + 0.01 = 28.32$. We note that, under 42 CFR 412.105(d)(4), IME FTE cap slots associated with an increase received under section 422 of the MMA are to be paid using a special multiplier of 0.66.

³Peninsula Hospital Center's 1996 direct GME FTE cap is 28.31. Under section 422 of the MMA, the hospital received an increase of 8.03 to its direct GME FTE cap: $28.31 + 8.03 = 36.34$. We note that under 42 CFR 413.77(g), direct GME FTE cap slots associated with an increase received under section 422 of the MMA are to be paid using the appropriate locality-adjusted national average per resident amount (PRA).

c. Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 is 90 days following notification to the public of a hospital closure. Therefore, hospitals wishing to apply for and receive slots from the above hospital's FTE resident caps must submit applications directly to the CMS Central Office no later than **[insert date that is 90 days after proposed rule goes on public display]**. Unlike in the first 2 rounds of section 5506, under this round, hospitals need not submit applications to their respective CMS Regional Office. The mailing address for the CMS Central Office is included on the application form. Applications must be received, not postmarked, by **[insert date that is 90 days after proposed rule goes on public display]**. After an applying hospital sends a hard copy of a section 5506 application to the CMS Central Office mailing address, we strongly encourage it to send an email to: ACA5506application@cms.hhs.gov. In the

email, the hospital should state: “I am sending this email to notify CMS that I have mailed a hard copy of a section 5506 application to CMS.” An applying hospital should not attach an electronic copy of the application to the email. The email will only serve to notify CMS Central Office that a hard copy application has been mailed to CMS Central Office.

In the CY 2011 OPPTS/ASC final rule with comment period, we did not establish a deadline by when CMS would issue the final determinations to hospitals that receive slots under section 5506 of the Affordable Care Act. However, we will review all applications received by the deadline, and will notify applicants of our determinations as soon as possible.

We refer readers to the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dgme.html> to download a copy of the application form (Section 5506 CMS Application Form) that hospitals are to use to apply for slots under section 5506. We also refer readers to this same Web site to access a copy of the CY 2011 OPPTS/ASC final rule with comment period, a copy of the FY 2013 IPPS/LTCH PPS final rule (CMS-1488-F, 77 FR 53434 through 53447), and a list of additional section 5506 guidelines for an explanation of the policy and procedures for applying for slots, and the redistribution of the slots under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Act.

4. Payments for Residents Training in Approved Residency Programs at CAHs

a. Background

Recently, we have received questions regarding how CMS would make payment for residency training occurring in a CAH. In the past, we have advised that (1) CAHs may be paid directly under the CAH payment methodology (that is, 101 percent of the reasonable costs of the CAH in accordance with sections 1814(l) and 1834(g) of the Act), or (2) CAHs could function as nonhospital settings and therefore, as such, a hospital may be paid if it incurred the costs of training occurring in the CAH as provided under section 1886(d)(5)(B)(iv) of the Act for IME and section 1886(h)(4)(E) of the Act for direct GME.

Section 5504 of the Affordable Care Act, titled “Counting Resident Time in Non-Provider Settings,” amended the Act in connection with “cost reporting periods beginning on or after July 1, 2010,” for direct GME, and for discharges on or after July 1, 2010 for IME, 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. In connection with those periods and discharges, if more than one hospital incurs the residency training costs in a nonprovider setting, under certain circumstances, section 5504 allows 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.” Congress made that 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).

Section 5504 also changed the manner in which the Act refers to sites outside the hospital in which residents train. Specifically, section 5504(a)(4), amended the Act by adding at the end of section 1886(h)(4)(E) a sentence that specifically identified such “outpatient settings” as “nonprovider setting[s].” That is, prior to the enactment of the Affordable Care Act, section 1886(h) of the Act did not include a specific term, but rather used the phrase, “without regard to the setting” in which the residents train, and now, with amendments from the Affordable Care Act, the Act specifically refers *both* to the phrase, “without regard to the setting” and to the phrase “time spent in a nonprovider setting.” (We invite readers to compare section 1886(h)(4)(E)(i) of the Act) as of 2010 with sections 1886(h)(4)(E)(i) and 1886(h)(4)(E)(ii) of the Act as of 2011.)

We also note that prior to the amendment in section 5504(b) of the Affordable Care Act, section 1886(d)(5)(B)(iv) of the Act relating to IME referenced training in a “nonhospital” setting. This remains true in the wake of the Affordable Care Act for “discharges occurring on or after October 1, 1997 and before July 1, 2010.” (We refer readers to section 1886(d)(5)(B)(iv)(I) of the Act.) However, effective for “discharges

occurring on or after July 1, 2010,” the IME statutory language refers to training in a “nonprovider” setting. (We refer readers to section 5504(b) of the Affordable Care Act and section 1886(d)(5)(B)(iv)(II) of the Act.)

We acknowledge that, prior to the effective date of section 5504 of the Affordable Care Act (July 1, 2010), in the preamble of rules and in other policy discussions, we have used both the term “nonhospital” and “nonprovider” interchangeably in the context of allowing a hospital to count residents training at locations outside the hospital. We amended 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. Section 413.78(g) is explicitly made applicable only to “cost reporting periods beginning on or after July 1, 2010,” whereas earlier cost reporting periods are governed by other preceding paragraphs of § 413.78.

b. Residents in Approved Medical Residency Training Programs That Train at CAHs

Section 4201 of the BBA of 1997 (Pub. L. 105-33) amended section 1820 to the Act to create facilities called “Critical Access Hospitals” (CAHs). Following the enactment of the BBA, but before the enactment of the Affordable Care Act, we were asked if and how CMS would pay for residents that rotate to a CAH for some portion of the residency training program when another hospital pays for the costs of the training at the CAH. To answer this question, we considered that a CAH is a unique facility that, by definition, is not always a hospital. That is, section 1861(e) of the Act states that “the term ‘hospital’ does not include, unless the context otherwise requires, a critical access hospital (as defined in section 1861(mm)(1)).” Because a CAH is generally not

considered a “hospital” under section 1861(e) of the Act, we concluded that a CAH could be treated as a nonhospital site for GME purposes. If a CAH could be treated as a nonhospital site for GME purposes, we also concluded that if another hospital (such as an IPPS hospital that is subject to payment under section 1886(h) of the Act or an IPPS-excluded hospital), incurred the costs of training the FTE residents for the portion of the time that they train at the CAH, and met the requirements of the regulations at §§ 413.78(d) through (f), the hospital could claim the FTE residents training at the CAH for IME and/or direct GME purposes.

We recently determined that, as a result of the amendments made by section 5504 of the Affordable Care Act, we should reevaluate our policy regarding whether payment can be made to a hospital that incurs the costs of the FTE residents training at a CAH.

Section 1861(u) of the Act states that a “provider of services” is “a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or . . . a fund.” Therefore, while section 1861(e) of the Act states that a CAH is excluded from the definition of “hospital” unless the context requires otherwise, a CAH is a “provider.”

Because section 5504(a) of the Affordable Care Act amended sections 1886(d)(5)(B)(iv)(II) and 1886(h)(4)(E) of the Act on a prospective basis to specifically identify the setting in which time spent by residents training outside of the hospital setting may be counted for both direct GME and IME purposes, a hospital’s ability to count residents not training in the hospital is now limited to only those settings that are “nonproviders.” Although the term “nonprovider” is not defined in the statute, we

believe it is reasonable to define the term as meaning those settings that do not meet the definition of “provider” at section 1861(u) of the Act.

Accordingly, because a CAH is defined as a provider in the statute, we are proposing that, effective for portions of cost reporting periods occurring on or after October 1, 2013, a hospital may not claim the time FTE residents are training at a CAH for IME and/or direct GME purposes. However, under policies that were applicable prior to October 1, 2013, and that continue to apply on and after October 1, 2013, a CAH may incur the costs of training the FTE residents for the time that the FTE residents rotate to the CAH, and receive payment based on 101 percent of its Medicare reasonable costs under § 413.70 of the regulations. We also note that, consistent with the regulations at § 413.24(d)(7), a CAH may not include as an allowable cost the portion of any training costs associated with the time that a resident is *not* training at the CAH and its provider-based facilities.

5. Expiration of Inflation Update Freeze for High Per Resident Amounts (PRAs)

The Balanced Budgeted Refinement Act (BBRA) of 1999 (Pub. L. 106-113) amended section 1886(h)(2) of the Act to establish a methodology for the use of a national average per resident amount (PRA) in computing direct GME payments for cost reporting periods beginning on or after October 1, 2000, and on or before September 30, 2005. The BBRA established a “floor” for hospital-specific PRAs at 70 percent of the locality-adjusted national average PRA. In addition, the BBRA established a “ceiling” that limited the annual adjustment to a hospital-specific PRA if the PRA exceeded 140 percent of the locality-adjusted national average PRA. Section 511 of the

Benefits Improvement and Protection Act (BIPA) of 2000 (Pub. L. 106-554) further amended section 1886(h)(2) of the Act by increasing the floor established by the BBRA to 85 percent of the locality-adjusted national average PRA, for cost reporting periods beginning in FY 2002. For purposes of calculating direct GME payments, each hospital-specific PRA is compared to the floor and ceiling to determine whether the hospital-specific PRA should be revised. Section 711 of the Medicare Modernization Act of 2003 (Pub. L. 108-173) amended section 1886(h)(2)(D)(iv)(I) of the Act by freezing the annual CPI-U updates to hospital-specific PRAs for those PRAs that exceed the ceiling for FYs 2004 through 2013. The implementing regulations for these statutory provisions are located at 42 CFR 413.77(d).

We are providing notice here that the “freeze” for PRAs that exceed the ceiling expires beginning in FY 2014. That is, for cost reporting periods beginning on or after October 1, 2013, the usual full CPI-U update, as determined under 42 CFR 413.77(c)(1), would apply to all PRAs for direct GME payment purposes.

K. Rural Community Hospital Demonstration Program

1. Background

Section 410A(a) of Pub. L. 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 Pub. L. 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 7 of the originally participating hospitals (that is, hospitals that were selected to participate in either 2004 or 2008), participating in the demonstration program as of June 1, 2011.

Sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111-148) amended section 410A of Pub. L. 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 Pub. L. 108-173 for purposes of the initial 5-year period. The Affordable Care Act also allows not more than 30 rural community hospitals in such States to participate in the demonstration program during the 5-year extension period (section 410A(g)(3) of Pub. L. 108-173, as added by section 3123(a) of the Affordable Care Act and as further amended by section 10313 of such Act).

We published a solicitation for applications for additional participants in the rural community hospital demonstration program in the **Federal Register** on August 30, 2010 (75 FR 52960). Applications were due on October 14, 2010. The 20 States with the lowest population density that are eligible for the demonstration program are: Alaska, Arizona, Arkansas, Colorado, Idaho, Iowa, Kansas, Maine, Minnesota, Mississippi,

Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, and Wyoming (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003). We approved 19 new hospitals for participation in the demonstration program. We determined that each of these new hospitals would begin participating in the demonstration with its first cost reporting period beginning on or after April 1, 2011.

Three of these 19 hospitals declined participation prior to the start of the cost reporting periods for which they would have begun the demonstration. In addition to the 7 hospitals that were selected in either 2004 or 2008 and that are still participating, the new selection led to a total of 23 hospitals in the demonstration.

In addition, section 410A(c)(2) of Pub. L. 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 nine 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 2013 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, and 77 FR 53449, 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 2014 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 2014 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 and 2013, 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 Pub. L. 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 Pub. L. 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 note 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 have been unable to finalize this component of the budget neutrality offset amount accounting for the amount by which the actual demonstration costs in a given year exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule for cost reports of demonstration hospitals dating to those beginning in FY 2007. (For only a fraction of the hospitals that have participated in the demonstration from FY 2007 to FY 2010 have cost reports been finalized in any year, making the overall calculation of this component of the budget neutrality impossible at this time for any given year.)

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.

2. Proposed FY 2014 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 to continue to use the methodology finalized in that final rule to calculate a budget neutrality adjustment factor to be applied to the FY 2014 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 2014 demonstration cost for the 23 currently participating hospitals is as follows:

Step 1: For each of the 23 participating hospitals, we are proposing to identify the general reasonable cost amount calculated under the reasonable cost methodology for covered inpatient hospital services (as indicated on the “as submitted” cost report for the hospital’s cost reporting period ending in CY 2011). 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 2011 are the most recent available cost reports,

we believe they would be an accurate predictor of the costs of the demonstration in FY 2014 because they give us a recent picture of the participating hospitals' costs.

Because section 410A of Pub. L. 108-173 stipulates swing-bed services are to be included among the covered inpatient hospital services for which the demonstration payment methodology applies, we also are proposing to include the cost of these services, as reported on the cost reports for the hospitals that provide swing-bed services, within the general total estimated FY 2011 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 2011 for this calculation.

We are proposing to sum the two above-referenced amounts to calculate the general total estimated FY 2011 reasonable cost amount for covered inpatient hospital services for all 23 hospitals.

We are proposing to multiply this sum (that is, the general total estimated FY 2011 reasonable cost amount for covered inpatient hospital services for all 23 hospitals) by the FYs 2012, 2013, and FY 2014 IPPS market basket percentage increases, which are formulated by the CMS Office of the Actuary. In this proposed rule, we have used the current estimate of the FY 2014 IPPS market basket percentage increase provided by the CMS Office of the Actuary. We are proposing to use the final IPPS market basket increase in the final rule. We also are proposing to then multiply the product of the general total estimated FY 2011 reasonable cost amount for all 23 hospitals and the market basket percentage increases applicable to the years involved by a

3-percent annual volume adjustment for the years 2012 through 2014—the result would be the general total estimated FY 2014 reasonable cost amount for covered inpatient hospital services for all 23 hospitals.

We are proposing to apply the IPPS market basket percentage increases applicable for FYs 2012 through 2014 to the FY 2011 reasonable cost amount described above to model the estimated FY 2014 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 proposed because it is intended to accurately reflect the tendency of hospitals' inpatient caseloads to increase. We acknowledge the possibility that inpatient caseloads for small hospitals may fluctuate, and are proposing to incorporate into the estimate of demonstration costs a factor to allow for a potential increase in inpatient hospital services.

Step 2: For each of the 23 hospitals, we are proposing to identify the general estimated amount that would otherwise be paid in FY 2011 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 2011) 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 2011) and include it in the total FY 2011 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 2011 total payments that generally would otherwise be paid for covered inpatient hospital services for all 23 hospitals without the demonstration.

We are proposing to multiply the above amount (that is, the estimated FY 2011 total payments that generally would otherwise be paid for covered inpatient hospital services for all 23 hospitals without the demonstration) by the FYs 2012 through 2014 IPPS applicable percentage increases. In this proposed rule, the current estimate of the applicable percentage increase is specified in section V.A.1. 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 2011 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. Then we are proposing to multiply the product of the estimated FY 2011 total payments that generally would otherwise be made without the demonstration and the IPPS applicable percentage increases applicable to the years

involved by a 3-percent annual volume adjustment for FYs 2012 through 2014. The result would be the general total estimated FY 2014 costs that would otherwise be paid without the demonstration for covered inpatient hospital services to the 23 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 23 hospitals for covered inpatient hospital services for FY 2014 if the demonstration was not implemented) from the amount derived in Step 1 (representing the sum of the estimated reasonable cost amount that generally would be paid under the demonstration to all 23 hospitals for covered inpatient hospital services for FY 2014). We are proposing that the resulting difference would be the amount for which an adjustment to the national IPPS rates would be calculated.

For this proposed rule, the resulting difference is \$46,515,865. For this FY 2014 IPPS/LTCH PPS proposed rule, this amount is the estimated amount for which an adjustment to the national IPPS rates is being calculated. This estimated amount is based on the specific assumptions identified regarding the data sources that are used, that is, “as submitted” recently available cost reports. We note that if updated data become available prior to the FY 2014 final rule, we are proposing to use them to the extent appropriate to estimate the costs of the demonstration program in FY 2014. Therefore, this estimated budget neutrality offset amount may change in the final rule, depending on the availability of updated data.

Similar to previous years, we are proposing 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. Because of delays affecting the settlement process for cost reports for IPPS hospitals occurring on a larger scale than merely for the demonstration, we are unable to determine at this time the specific component of the budget neutrality offset amount accounting for the amount by which the actual demonstration costs in a given year exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule for cost reports of demonstration hospitals dating to those beginning in FY 2007. (For only a fraction of the hospitals that have participated in the demonstration from FY 2007 to FY 2010 have cost reports been finalized in any year, making the overall calculation of this component of the budget neutrality offset impossible at this time for any given year.) Similar to previous years, we are proposing that if settled cost reports for all of the demonstration hospitals that participated in the applicable fiscal year (FY 2007, 2008, 2009, or 2010) are available prior to the FY 2014 IPPS/LTCH PPS final rule, we will include in the budget neutrality offset amount any additional amounts by which the final settled costs of the demonstration for the year (FY 2007, 2008, 2009, or 2010) exceeded the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule. (The final settled costs of the demonstration for a year would be calculated by subtracting the total amount that would otherwise be paid under the applicable Medicare payment systems without the demonstration for the year

from the amount paid to those hospitals under the reasonable cost methodology for such year.)

L. Hospital Emergency Services under EMTALA: Technical Change (§ 489.24(f))

In a final rule issued in the **Federal Register** on May 16, 2012 (77 FR 29002 through 29031), we made changes to a number of regulations under 42 CFR Chapter IV governing the Medicare and Medicaid programs to achieve regulatory reforms under Executive Order 13563 on Improving Regulation and Regulatory Review and the Department's Plan for Retrospective Review of Existing rules. In the May 16, 2012 final rule (77 FR 29021), we stated that, in response to comments from the public recommending that we discontinue our use of the term "recipient" under Medicaid, we made a nomenclature change to replace "recipient" with "beneficiary" throughout 42 CFR Chapter IV in order to conform our regulations to our current use of the term "beneficiary." Our current use of the term "beneficiary" means all individuals who are entitled to, or eligible for, Medicare or Medicaid services. However, we inadvertently replaced "recipient" with "beneficiary" in the title of the regulations at 42 CFR 489.24(f), which now reads "Beneficiary hospital responsibilities." The regulations at 42 CFR 489.24(f) specifically discuss the responsibilities of a hospital with specialized capabilities to accept the appropriate transfer of an individual as required by the Emergency Medical Treatment and Labor Act. The use of the word "recipient" in the title of 42 CFR 489.24(f) is appropriate because the regulations are discussing the requirements of the "receiving" hospital. The term "recipient" in this context is not referring to a Medicare or Medicaid patient, but rather to the hospital. Therefore, in this

proposed rule, we are proposing to replace the word “beneficiary” with the word “recipient” so that the section heading of paragraph (f) of 42 CFR 489.24 is corrected to read as it did prior to the nomenclature change. The corrected regulation text at 42 CFR 489.24(f) would read “Recipient hospital responsibilities.”

M. Hospital Services Furnished under Arrangements

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51711 through 51714), we included a provision that limits the circumstances under which a hospital may furnish services to Medicare beneficiaries “under arrangement.” Under the revised policy, therapeutic and diagnostic services are the only services that may be furnished under arrangements outside of the hospital to Medicare beneficiaries. “Routine services” (that is, bed, board, and nursing and other related services) must be furnished in the hospital. Under this revised policy, routine services furnished to Medicare beneficiaries as inpatients in the hospital are considered services furnished by the hospital. If these services are furnished outside of the hospital, the services are considered to be furnished “under arrangement.” As we stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53453 through 53454), we have become aware that a number of hospitals affected by this policy need additional time to restructure existing arrangements and establish necessary operational protocols to comply with the requirement that therapeutic and diagnostic services are the only services that may be furnished outside of the hospital to Medicare beneficiaries “under arrangement,” and that “routine services” must be furnished in the hospital.

In the FY 2013 IPPS/LTCH PPS final rule, we stated that while we believe the policy to be correct and consistent with the statutory language, because a number of hospitals were actively pursuing compliance that involved building construction or restructuring, we postponed the effective date of the requirement to give hospitals additional time to comply with the provision. In the FY 2013 IPPS/LTCH PPS final rule, we changed the implementation date of the requirement to be effective for cost reporting periods beginning on or after October 1, 2013. We stated that we expected that, during FY 2013, hospitals would have completed the work needed to ensure compliance with the requirement.

While we still believe that our policy is correct and consistent with the statutory language, we are aware that a number of hospitals are still actively pursuing compliance with the requirement through major building construction to be completed in 2014. Therefore, we believe it is appropriate to further postpone the effective date of this requirement to give those hospitals additional time to comply. In this proposed rule, we are proposing to change the implementation date of the requirement to be effective for services provided on or after January 1, 2015 (instead of effective with cost reporting periods beginning on or after October 1, 2013). Because there are hospitals in the midst of significant building projects that, when completed, will enable the hospital to provide routine services in compliance with the requirements of this revised policy, we believe it is appropriate to further delay the effective date. We expect that, with the additional time before the revised “under arrangement” policy becomes effective, hospitals will complete the work needed to ensure compliance with the new requirement. Effective for services

provided on or after January 1, 2015, all hospitals would need to be in full compliance with the revised policy for services furnished under arrangement. We will continue to work with affected hospitals to communicate the requirement established by this provision, and to provide continued guidance regarding compliance with the provision.

N. Policy Proposal on Admission and Medical Review Criteria for Hospital Inpatient Services under Medicare Part A

In this section of the proposed rule, we are clarifying what is required for Medicare Part A payment of hospital inpatient services. In addition, we are proposing a time-based presumption of medical necessity for hospital inpatient services based on the beneficiary's length of stay, as part of our medical review criteria for payment of hospital inpatient services under Part A.

1. Background

In the CY 2013 OPPS/ASC proposed rule (77 FR 45155 through 45157) and final rule with comment period (77 FR 68426 through 68433), we expressed concern about recent increases in the length of time that Medicare beneficiaries spend as hospital outpatients receiving observation services. We also solicited and summarized public comments on potential policy changes we could make to improve clarity and consensus among providers, Medicare, and other stakeholders regarding the relationship between admissions decisions and appropriate Medicare payment, such as when a Medicare beneficiary is appropriately admitted to a hospital as an inpatient. (In this section, "hospital" means hospital as defined at section 1861(e) of the Act, but includes critical access hospitals (CAHs) unless otherwise specified. Although the term "hospital" does

not generally include CAHs, section 1861(e) of the Act provides that the term “hospital” includes CAHs if the context otherwise requires. We believe it is appropriate to propose to apply our proposed policies to CAHs as well as other hospitals.) Observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short-term treatment, assessment, and reassessment before a decision can be made regarding whether a patient will require further treatment as a hospital inpatient or if he or she is able to be discharged from the hospital (Section 20.6, Chapter 6 of the Medicare Benefit Policy Manual (MBPM) (Pub. 100-02)).

In recent years, the number of cases of Medicare beneficiaries receiving observation services for more than 48 hours, while still small, has increased from approximately 3 percent in 2006 to approximately 8 percent in 2011. This trend concerns us because of the potential financial impact on Medicare beneficiaries, and we have published educational materials for beneficiaries to inform them of their respective liabilities as a hospital outpatient or inpatient.⁵⁸ Beneficiaries who are treated for extended periods of time as hospital outpatients receiving observation services may incur greater financial liability than they would if they were admitted as hospital inpatients. They may incur financial liability for Medicare Part B copayments; the cost of self-administered drugs that are not covered under Part B, and the cost of post-hospital SNF care because section 1861(i) of the Act requires a prior 3-day hospital inpatient stay for coverage of post-hospital SNF care under Medicare Part A. In contrast, as a hospital inpatient under Medicare Part A, a beneficiary pays a one-time deductible for all hospital

⁵⁸ CMS Pamphlets: "Are You a Hospital Inpatient or Outpatient? If You Have Medicare Ask!", CMS Product No. 11435, Revised, February 2011; "How Medicare Covers Self Administered Drugs Given in Hospital Outpatient Settings," CMS Product No. 11333, Revised, February 2011.

inpatient services provided during the first 60 days in the hospital of the benefit period. Therefore, an inpatient deductible does not necessarily apply to all hospitalizations. Medicare Part A coinsurance applies after the 60th day in the hospital.

In the CY 2013 OPPS/ASC proposed rule and final rule with comment period (77 FR 45155 and 77 FR 68426, respectively) and in a proposed rule entitled, “Medicare Program; Part B Inpatient Billing in Hospitals” that went on display at the Office of the Federal Register on March 13, 2013, and was issued in the **Federal Register** on March 18, 2013 (78 FR 16632) (“Part B Inpatient Billing proposed rule”), we discussed how the trend towards the provision of extended observation services may be attributable in part to hospitals’ concerns about Medicare’s payment policy for billing under Part B when a Part A hospital inpatient claim is denied because a Medicare review contractor determines that the inpatient admission was not reasonable and necessary under section 1862(a)(1)(A) of the Act. Under longstanding Medicare policy, in these situations, hospitals could only receive payment for a limited set of largely ancillary inpatient services under Part B. We stated that we have heard from various stakeholders that hospitals appear to be responding to the financial risk of admitting Medicare beneficiaries for inpatient stays that may later be denied upon contractor review by electing to treat beneficiaries as outpatients receiving observation services, often for long periods of time, rather than admitting them as inpatients.

As a step to address this issue, in the Part B Inpatient Billing proposed rule (78 FR 16632), we proposed to revise our Part B inpatient billing policy to allow payment for all hospital services that were furnished and would have been reasonable and

necessary if the beneficiary had been treated as an outpatient, rather than admitted to the hospital as an inpatient. Specifically, we proposed that when a Medicare Part A claim for inpatient hospital services is denied because the inpatient admission was deemed not to be reasonable and necessary, or when a hospital determines under § 482.30(d) or § 485.641 of the regulations after a beneficiary is discharged that his or her inpatient admission was not reasonable and necessary, a hospital may be paid for all Medicare Part B services (except for services that specifically require an outpatient status) that would have been reasonable and necessary had the beneficiary been treated as a hospital outpatient rather than admitted as an inpatient, if the beneficiary is enrolled in Medicare Part B. This policy would apply when CMS or a Medicare review contractor determines that the hospital admission was not reasonable and necessary or when a hospital determines after a beneficiary has been discharged that the beneficiary should have received hospital outpatient services rather than hospital inpatient services. We also proposed to continue applying the timely filing restriction to the billing of all Part B inpatient services, under which claims for Part B services must be filed within 1 year from the date of service.

In addition to evaluating our policy related to Medicare Part B inpatient billing following denials of Medicare Part A inpatient claims on the basis that the inpatient admission was not reasonable and necessary or following a hospital self-audit, we also believe it is important to consider whether we can provide more clarity regarding the relationship between inpatient admission decisions and Medicare payment. In the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68426 through 68433), we

discussed revising hospital inpatient status criteria as one of several policy clarifications or changes suggested by stakeholders to improve our policies governing when a Medicare beneficiary should be admitted as an inpatient, and how hospitals should be paid by Medicare for the associated costs they incur.

Specifically, stakeholders suggested that we redefine “inpatient” using parameters other than the current requirements of medical necessity and a physician order, such as using the beneficiary’s length of stay at the hospital. Currently, a beneficiary’s length of stay may be a factor in determining whether he or she should be admitted as an inpatient to the hospital, but it is not the only factor for this determination. Our current manual instructions state that, typically, the decision to admit a beneficiary as an inpatient should be made within 24 to 48 hours of observation care, and that expectation of an overnight stay may be a factor in the admission decision (Section 20.6, Chapter 6 and Section 10, Chapter 1 of the Medicare Benefit Policy Manual (MBPM)). We state that physicians should use a 24-hour period as a benchmark, that is, they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis. We state that, generally, a beneficiary is considered an inpatient if formally admitted as an inpatient with the expectation that he or she will remain at least overnight, whether or not the beneficiary is later discharged or transferred and is not present overnight. Nevertheless, our longstanding policy consistently has been that we do not define or pay under Medicare Part A for inpatient admissions solely on the basis of the length of time the beneficiary actually spends in the hospital. Rather, we rely on the physician to use his or her clinical judgment and evaluation of the patient’s needs

to make the determination. We have stated in our manual guidance that the inpatient admission decision is a complex medical judgment that should take into consideration many factors, such as the patient's medical history and medical needs, the types of facilities available to inpatients and outpatients, the hospital's bylaws and admission policies, the relative appropriateness of treatment in each setting, patient risk of an adverse event, and other factors described in the MBPM provisions. The physician or other practitioner responsible for a patient's care at the hospital also is responsible for deciding whether the patient should be admitted as an inpatient.

We believe that our current inpatient admission criteria are valid and appropriately reflect that the decision to admit a patient as a hospital inpatient is a complex medical judgment that can be made only after the physician has considered a number of factors. However, upon evaluating the suggestions of stakeholders who requested that we provide more clarity in the definition of "inpatient" using parameters other than those that we currently use, we recognize that it would be helpful to address what the requirements are for Medicare Part A payment and when a beneficiary should be admitted as a hospital inpatient. Toward that end, in this proposed rule, we are clarifying that a beneficiary becomes a hospital inpatient if formally admitted following a physician order for hospital inpatient admission, and also are clarifying when we believe hospital inpatient admissions are reasonable and necessary based on how long beneficiaries have spent, or are reasonably expected to spend, in the hospital.

Specifically, in sections V.N.2.a. and b. of the preamble of this proposed rule, we are clarifying that a beneficiary becomes a hospital inpatient if a physician (or other

qualified practitioner as provided in the regulations) orders inpatient admission in accordance with the hospital conditions of participation (CoPs), and that Medicare pays under Part A for such an admission if the order is documented in the medical record. However, as we discuss in section V.N.3.d.(1) of the preamble of this proposed rule and as we specify under proposed 42 CFR 412.46(b), the order must be supported by objective medical information for purposes of the Part A payment determinations. During Medicare contractor review of an inpatient admission, documentation in the medical record is evaluated in conjunction with the physician order and the physician certification that is also required for payment of hospital inpatient services under section 1814(a) of the Act and 42 CFR 424.13. In section V.N.2. of the preamble of this proposed rule, we describe the requirements for the physician order. In section V.N.3. of the preamble of this proposed rule, we discuss the role of the physician certification in medical review where applicable.

In addition, in section V.N.3. of the preamble of this proposed rule, we are proposing a new benchmark for purposes of medical review of hospital inpatient admissions, based on how long the beneficiary is in the hospital. Under our proposal, Medicare's external review contractors would presume that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined by encounters crossing 2 "midnights") in the hospital receiving medically necessary services. If a hospital is found to be abusing this 2-midnight presumption for nonmedically necessary inpatient hospital admissions and payment (in other words, the hospital is systematically delaying the provision of care to surpass the 2-

midnight timeframe), CMS review contractors would disregard the 2-midnight presumption when conducting review of that hospital. Similarly, we would presume that hospital services spanning less than 2 midnights should have been provided on an outpatient basis, unless there is clear documentation in the medical record supporting the physician's order and expectation that the beneficiary would require care spanning more than 2 midnights or the beneficiary is receiving a service or procedure designated by CMS as inpatient-only. We note that our current manual instructions referenced above, indicating that physicians should use a 24-hour period and the expectation of a beneficiary's need for an overnight stay in the hospital as inpatient admission benchmarks, remain in effect until we have finalized a new policy, at which time we will consider whether and how the existing instructions should be updated.

2. Requirements for Physician Orders

The requirements for physician and other qualified practitioner orders are contained under the hospital and CAH CoPs (42 CFR Parts 482 and 485), which are the patient health and safety standards with which all Medicare and Medicaid hospitals and CAHs must comply in order to participate in the Medicare and Medicaid programs. The CoPs apply to facilities and services provided to all hospital patients, not just Medicare or Medicaid patients. The hospital medical record services CoP at § 482.24(c) specifies that a patient's medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services. The hospital medical record services CoP also requires specific elements that must be included in the patient record; among these elements are

an “admitting diagnosis” and “all practitioners’ orders.” The CAH CoP at § 485.638 contains similar, although not identical, language. In addition, under the hospital CoP at § 482.12(c)(2), patients are admitted to the hospital as inpatients only on the recommendation of a physician or licensed practitioner permitted by the State to admit patients to a hospital. Under the hospital CoP at § 482.12(c)(1), every Medicare patient must be under the care of a physician or other type of practitioner listed in the regulations (“the practitioner responsible for the care of the patient”). Although the CoPs do not distinguish the term “inpatient admission order” from the required physician or practitioner orders in the regulatory text, it is an accepted standard of practice in hospitals and CAHs that such an order must be given before a patient can be admitted to a hospital or CAH. Similarly, the requirement that a patient is admitted as an inpatient “only on the recommendation of a physician or licensed practitioner permitted by the State to admit patients to a hospital” is understood to mean that a patient is admitted by way of an inpatient admission order given by the practitioner responsible for the care of the patient, provided that the practitioner, either a physician or other licensed practitioner, has been authorized by the State and granted such privileges by the hospital to do so.

We note that, under these requirements of the CoPs, patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by his or her State to admit patients to a hospital. In addition, § 482.12(c)(2) of the regulations requires that a Medicare patient who is admitted by a practitioner not specified in paragraph (c)(1) of this same section of the CoPs must then be under the care of a doctor of medicine or osteopathy; however, this “...is not to be construed to limit the authority

of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism.” Therefore, the CoPs do not specifically prohibit the delegation of an inpatient admission to a nonphysician practitioner; however, neither do they specifically authorize it. We have stated that for payment purposes, as provided in the COPs at § 482.12(c), the physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient (Section 1, Chapter 10 of the MBPM). In specifying that the practitioner responsible for the patient's care is responsible for making the admission decision, we precluded that practitioner from delegating the decision to another individual. Therefore, while the COPs do not preclude a doctor of medicine or osteopathy from delegating authority to other individuals, we are specifically clarifying in regulation that, for payment purposes, the authority to admit cannot be delegated to an individual who lacks that authority in his or her own right.

The CoPs also allow for inpatient admission orders to be given verbally in person or over the telephone as well as through the use of preprinted and electronic standing orders, order sets, and protocols. Such inpatient admission orders must be in accordance with the requirements for orders found at § 482.23(c)(3)(i) and (ii), and at § 482.24(c)(2) and (3) of the regulations. Included in these provisions is the requirement that if verbal orders are used, they must be used infrequently. In addition, *all* orders must be authenticated promptly by the ordering practitioner or another practitioner responsible for the care of the patient. While the CoPs do allow for inpatient admission orders through

these mechanisms, it must be stressed that the CoPs also require that the patient medical record contains documentation that supports the decision reflected in the physician order to admit the patient to the hospital.

For all patients (not just Medicare beneficiaries), the physician admission order is the most basic means by which the hospital inpatient stay begins and by which the course of treatment and care is initially guided. The order details not only who is responsible for the patient's care while in the hospital, but also directs that care through the various diagnostic, dietary, medication, and other treatment orders. Before a Medicare beneficiary or any patient can be treated, there must be physician orders (including, and perhaps most importantly, the initiating admission order) to guide that treatment. Therefore, under the CoPs, the practitioner responsible for the care of the patient must determine that inpatient admission is medically necessary and order both the admission and reasonable and necessary inpatient services.

While the requirement for the physician admission order has long been clear in the CoPs, we are proposing to state explicitly in our payment regulations that admission pursuant to this order is the means whereby a beneficiary becomes a hospital inpatient and, therefore, is required for payment of hospital inpatient services under Medicare Part A. Accordingly, we are proposing to add a new § 412.3 titled "Admissions," that would define a hospital inpatient admission as follows: "(a) For purposes of payment under Medicare Part A, an individual is considered an inpatient of a hospital, including a critical access hospital, if formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner in accordance with paragraph (b)

of this section [discussed below] and §§ 482.24(c), 482.12(c), and 485.638(a)(4)(iii) of this chapter for a critical access hospital.” This physician order must be present in the medical record and be supported by the physician admission and progress notes, in order for the hospital to be paid for hospital inpatient services under Medicare Part A.

In proposed new § 412.3(b), we would clarify that, in contrast to the CoPs, for payment under Part A, the hospital inpatient admission order must be furnished by a physician or other specified practitioner as follows: “(b) The order must be furnished by a qualified and licensed practitioner who has admitting privileges at the hospital as permitted by State law, and who is responsible for the inpatient care of the patient at the hospital. The practitioner may not delegate the decision (order) to another individual who is not responsible for the care of that patient, is not authorized by the State to admit patients, or has not been granted admitting privileges applicable to that patient by the hospital’s medical staff.”

3. Proposed Inpatient Admission Guidelines

a. Background

CMS is authorized under section 1893 of the Act to implement the Medicare Integrity Program to conduct medical review of claims and ensure appropriateness of Medicare payment. Medicare review contractors, such as Medicare Administrative Contractors (MACs), Recovery Auditors (formerly known as the Recovery Audit Contractors, or RACs), the Comprehensive Error Rate Testing (CERT) Contractor, and other review contractors are hired by CMS to review claims on a pre-payment or post-payment basis to determine whether a claim should be paid or denied or whether a

payment was properly made under Medicare payment rules. Following documentation reviews, many claim denials are made or improper payments identified because either—

- The claim was incorrectly coded (for example, the provider did not appropriately assign the individual or grouper inpatient and/or outpatient coding for the care documented); or
- The services were not medically necessary (that is, the review indicates that the services billed were not reasonable and necessary based upon Medicare payment policies or that the documentation was insufficient to support the medical necessity of the services billed).

Hospital claim errors are identified more frequently for shorter lengths of stay. The majority of improper payments under Medicare Part A for short-stay inpatient hospital claims have been due to inappropriate patient status (that is, the services furnished were reasonable and necessary, but should have been furnished on a hospital outpatient, rather than hospital inpatient, basis).

CMS developed the CERT program to calculate the Medicare FFS program improper payment rate. The CERT program considers any claim that was paid when it should have been denied or paid at another amount (including both overpayments and underpayments) to be an improper payment. In 2012, the CERT contractor found that Medicare Part A inpatient hospital admissions for 1-day stays or less had an improper payment rate of 36.1 percent. The improper payment rate decreased significantly for 2-day or 3-day stays, which had improper payment rates of 13.2 percent and 13.1 percent, respectively. The improper payment rate further decreased to 8 percent for those

beneficiaries who were treated as hospital inpatients for 4 days.

Inpatient hospital short-stay claim errors are frequently related to minor surgical procedures or diagnostic tests. In such situations, the beneficiary is typically admitted as a hospital inpatient after the procedure is completed on an outpatient basis, monitored overnight as an inpatient, and discharged from the hospital in the morning. Medicare review contractors typically find that while the underlying services provided were reasonable and necessary, the inpatient hospitalization following the procedure was not (that is, the services following the procedure should have been provided on an outpatient basis).

Through this proposed rule, we are seeking to clarify our longstanding policy on how Medicare review contractors review inpatient hospital admissions for payment under Medicare Part A. We also will issue revised guidance to physicians and hospitals regarding when a hospital inpatient admission should be ordered for Medicare beneficiaries once this proposed rule is finalized.

b. Correct Coding Reviews

We are not proposing any changes to coding review strategies for hospital claims. Reviewers will continue to ensure that the correct codes were applied and are supported by the medical record documentation.

c. Complete and Accurate Documentation

When conducting complex medical review, Medicare review contractors will continue to employ clinicians to review practitioner documented procedures and ensure that they are supported by the submitted medical record documentation. Such is the case

when complex medical review is performed currently and will continue to be the case when the proposed review criteria are implemented.

d. Medical Necessity Reviews

(1) Physician Order and Certification

In statute and regulation, Medicare has certain requirements for physician orders and certifications, discussed above, that must be satisfied before payment may be made under Part A. We are proposing to codify in 42 CFR 412.46(b) the longstanding requirement that medical documentation must support the physician's order and certification, as prescribed by CMS Ruling 93-1. The proposed new paragraph (b) titled "Physician's order and certification regarding medical necessity" would read, "No presumptive weight shall be assigned to the physician's order under § 412.3 or the physician's certification under Subpart B of Part 424 of this chapter in determining the medical necessity of inpatient hospital services under section 1862(a)(1) of the Act. A physician's order and certification will be evaluated in the context of the evidence in the medical record." We are not proposing any changes to our current requirements for practitioner documentation of services ordered and furnished. While the physician order and the physician certification are required for all inpatient hospital admissions in order for payment to be made under Part A, the physician order and the physician certification are not considered by CMS to be conclusive evidence that an inpatient hospital admission or service was medically necessary. Rather, the physician order and physician certification are considered along with other documentation in the medical record. CMS and its medical review contractors base their payment determinations on objective

medical information documented in the medical record about the patient's condition and the services received. This documentation will be reviewed from the claims form and, when necessary, the medical record containing the physician order, the physician certification, and other supporting documentation that are required for payment under Medicare Part A.

(2) Medical Review Criteria for All Hospital Services

We will continue to review individual claims to ensure the hospital services furnished to beneficiaries are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member," as required by section 1862(a)(1) of the Act. Any hospital service determined to be not reasonable or necessary may not be paid under Medicare Part A or Part B.

(3) Inpatient Hospital Admission Guidelines

In this proposed rule, we are proposing inpatient hospital admission guidance under which a physician or other practitioner should order admission if he or she expects that the beneficiary's length of stay will exceed a 2-midnight threshold or if the beneficiary requires a procedure specified as inpatient-only under 42 CFR 419.22. We are proposing that the starting point for this time-based instruction would be when the beneficiary is moved from any outpatient area to a bed in the hospital in which the additional hospital services will be provided. However, we are soliciting public comments on this proposed method of calculating the length of stay for purposes of this 2-midnight threshold proposal.

There are certain types of cases for which a hospital inpatient admission is rarely

appropriate. We have stated in our existing Medicare manual that when a beneficiary receives a minor surgical procedure or other treatment in the hospital that is expected to keep him or her in the hospital for only a few hours (less than 24), the services should be provided as outpatient hospital services, regardless of the hour the beneficiary comes to the hospital, whether he or she uses a bed, and whether he or she remains in the hospital past midnight (Section 10, Chapter 1 of the MBPM). We note that there has been considerable variation in the interpretation of this instruction. Therefore, we are proposing to clarify this policy and codify our general rule at § 412.3(c)(1), that in addition to services designated by CMS as inpatient only, surgical procedures, diagnostic tests, and other treatments would be generally appropriate for inpatient hospital payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation. Conversely, when a patient enters a hospital for a surgical procedure not specified by Medicare as inpatient only under § 419.22(n), a diagnostic test, or any other treatment, and the physician expects to keep the patient in the hospital for only a limited period of time that does not cross 2 midnights, the services would be generally inappropriate for payment under Medicare Part A. This would be the case regardless of the hour that the patient came to the hospital or whether the patient used a bed.

Under our proposed policy, the judgment of the physician and the physician's order for inpatient admission should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. In accordance with current policy, factors that may

result in an inconvenience to a beneficiary or family would not, by themselves, justify inpatient hospital admission. When such convenience factors affect the beneficiary's health, CMS and/or its contractor would consider these factors in determining whether inpatient hospital admission was appropriate. The factors that lead a physician to admit a particular patient based on the physician's clinical expectation are significant clinical considerations.

In accordance with current policy and as discussed above, the physician would be required to clearly and completely document the clinical facts supporting the inpatient hospital admission. It is the documentation of the reasonable basis for the expectation of a stay crossing 2 midnights that would justify the medical necessity of the inpatient admission, regardless of the actual duration of the hospital stay and whether it ultimately crosses 2 midnights. As a result of the relationship that develops between a physician and his or her patient, the physician is in a unique position to incorporate complete medical evidence in beneficiary's medical records, including his or her opinions and the pertinent medical history of the patient. In creating the medical assessment, medical history, and discharge notes that become part of the medical record, we believe the physician has ample opportunity to explain in detail why the course of treatment was appropriate in the context of that patient's acute condition. In addition, the physician has the opportunity to describe and explain aspects of the beneficiary's medical history that may not otherwise be apparent. Therefore, the physician would be responsible for ensuring that the beneficiary's medical record includes complete medical information, and this information would be the basis for determining the medical necessity of the

prescribed treatment. The final determination by the Medicare review contractor for payment purposes would not be based solely on the physician's order and certification, and would reflect equal weight and evaluation of all documentation contained in the medical record.

We acknowledge that there may be an unforeseen circumstance that results in a shorter beneficiary stay than the physician's expectation of 2 midnights. We expect that the majority of such inpatient hospital admissions would occur when an inpatient hospital admission is appropriately ordered, but a beneficiary's transfer or death interrupts the beneficiary's hospital stay that would have otherwise spanned 2 midnights. Therefore, we provide an exception to the general rule in proposed § 412.3(c)(2), that "If an unforeseen circumstance, such as beneficiary 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 the hospital inpatient payment may be made under Medicare Part A." Documentation of such a circumstance constitutes supporting medical documentation in determining whether the inpatient hospital admission is reasonable and necessary for Medicare Part A payment. In addition, the physician must certify that inpatient hospital services were medically necessary in accordance with section 1814(a) of the Act and 42 CFR Part 424, Subpart B.

(4) Medical Review Criteria for Payment of Inpatient Hospital Admissions under Part A

Until such time as this proposed rule is finalized, Medicare review contractors will continue to follow the current CMS policy and instruction regarding medical review criteria for payment of inpatient admissions under Medicare Part A.

Under our proposed medical review policy, Medicare's external review contractors would presume that hospital inpatient status is reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined as encounters crossing 2 midnights) after admission. Medical review efforts for inpatient hospital admissions greater than 2 midnights would focus on undue delays in the provision of care in an attempt to meet the 2-midnight threshold (that is, inpatient hospital admissions where medically necessary treatment was not provided on a continuous basis throughout the hospital stay and the services could have been furnished in a shorter timeframe). Beneficiaries should not be held in the hospital absent medically necessary care for the purpose of meeting the 2-midnight presumption.

Patient status reviews for those admissions with lengths of stay greater than 2 midnights would typically be conducted if CMS suspects that a provider is using the time-based presumption to effectuate systematic abuse or gaming. Review contractors would continue to assess claims in which the beneficiary span of care crossed the 2-midnight threshold:

- To ensure the services provided were medically necessary;
- To validate provider coding and documentation as reflective of the medical evidence;
- If the CERT Contractor is directed to do so under the Improper Payments Elimination and Recovery Improvement Act of 2012 (Pub. L. 112-248); or
- If directed by CMS or other authoritative governmental entity (including but not limited to the HHS Office of Inspector General and Government Accountability

Office).

As a result of the proposed admission guidelines above, we are proposing that medical review efforts will focus on those inpatient hospital admissions with lengths of stay crossing only only 1midnight or less (that is, only 1 Medicare utilization day, as defined in 42 CFR 409.61 and implemented in the Medicare Benefit Policy Manual, Chapter 3, Section 20.1). As we noted earlier, such claims have traditionally demonstrated the largest proportion of inpatient hospital improper payments under Medicare Part A. If the physician admits the beneficiary as an inpatient but the beneficiary is in the hospital for less than 2 midnights after admission, we are proposing that CMS and its medical review contractors would review the inpatient admission in accordance with current policy for Part A payment, as clarified below, and would not presume that the inpatient hospital admission was reasonable and necessary for payment purposes. Medicare review contractors would evaluate the physician order for inpatient admission to the hospital, the medical documentation supporting that order, and the physician certification in order to determine whether payment under Part A is appropriate.

The Medicare review contractors would consider, in their review of the medical record, complex medical factors that support a reasonable expectation of the needed duration of the stay relative to the 2-midnight threshold. These factors include such things as beneficiary medical history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. In other words, if it was reasonable for the physician to expect the beneficiary to require a stay lasting 2

midnights, even though that did not transpire, payment would be made under Medicare Part A if the documentation in the medical record reflected such complex medical factors (and the physician's order and certification requirements also are met). As discussed above, payment may be made in the case of services on Medicare's inpatient only list and in exceptional cases such as beneficiary death or transfer.

4. Proposed Payment Adjustment

The accurate determination of a beneficiary's patient status is an issue of concern across hospitals. As we discuss in section V.N.1. of the preamble of this proposed rule, in the CY 2013 OPPS/ASC proposed rule, we sought comment on actions that we could potentially undertake to address stakeholders' concerns. We received approximately 350 public comments on this issue in response to our solicitation from hospitals and hospital associations, physician associations, rehabilitative and long-term care facilities, beneficiaries, beneficiary advocacy organizations, Quality Improvement Organizations (QIOs), organizations specializing in medical necessity review, and other interested parties. In particular, as stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68429) and discussed further in section V.N.1. of the preamble of this proposed rule, we heard from some stakeholders who specifically suggested a need for us to clarify our current instructions regarding the circumstances under which Medicare will pay for a hospital inpatient admission in order to improve hospitals' ability to make appropriate admission decisions.

The issue also has a substantial impact on improper payments under Medicare Part A for short-stay inpatient hospital claims. As discussed earlier, the majority of

improper payments under Medicare Part A for short-stay inpatient hospital claims have been due to inappropriate patient status (that is, the services furnished were reasonable and necessary, but should have been furnished on a hospital outpatient, rather than hospital inpatient, basis.) In 2012, the CERT contractor found that inpatient hospital admissions for 1-day stays or less had a Part A improper payment rate of 36.1 percent. The improper payment rate decreases significantly for 2-day or 3-day stays, which had improper payment rates of 13.2 percent and 13.1 percent, respectively. We believe the magnitude of these national figures demonstrates that the appropriate determination of a beneficiary's patient status is a systemic and widespread issue and is not isolated to a few hospitals. We also note that the RAs have recovered more than \$1.6 billion in improper payments because of inappropriate beneficiary patient status.

Our actuaries have estimated that our proposed policy that medical review of inpatient admissions will include a presumption that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined by encounters crossing 2 "midnights") in the hospital receiving medically necessary services, as discussed in section V.N.3. of the preamble of this proposed rule, would increase IPPS expenditures by approximately \$220 million. These additional expenditures result from an expected net increase in hospital inpatient encounters due to some encounters spanning more than 2 midnights moving to the IPPS from the OPSS, and some encounters of less than 2 midnights moving from the IPPS to the OPSS. Specifically, our actuaries examined FY 2009 through FY 2011 Medicare claims data for extended hospital outpatient encounters and shorter stay hospital inpatient encounters and

estimated that approximately 400,000 encounters would shift from outpatient to inpatient and approximately 360,000 encounters would shift from inpatient to outpatient, causing a net shift of 40,000 encounters. These estimated shifts of 400,000 encounters from outpatient to inpatient and 360,000 encounters from inpatient to outpatient represent a significant portion of the approximately 11 million encounters paid under the IPPS. The net shift of 40,000 encounters represents an increase of approximately 1.2 percent in the number of shorter stay hospital inpatient encounters paid under the IPPS. Since shorter stay hospital inpatient encounters currently represent approximately 17 percent of the IPPS expenditures, our actuaries estimated that 17 percent of IPPS expenditures would increase by 1.2 percent under our proposed policy. These additional expenditures are partially offset by reduced expenditures from the shift of shorter stay hospital inpatient encounters to hospital outpatient encounters. Our actuaries estimated that on average the per encounter payments for these hospital outpatient encounters would be approximately 30 percent of the per encounter payments for the hospital inpatient encounters.

In light of the widespread impact of the proposed policy discussed in section V.N.3. of the preamble of this proposed rule on the IPPS and the systemic nature of the issue as demonstrated above, we believe it is appropriate to propose to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to offset the estimated \$220 million in additional IPPS expenditures associated with this proposed policy. This special exceptions and adjustment authority authorizes us to provide “for such other exceptions and adjustments to [IPPS] payment amounts . . . as the Secretary deems appropriate.” We are proposing to reduce the standardized amount, the hospital-specific

rates, and the Puerto Rico-specific standardized amount by 0.2 percent.

VI. 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) x (DRG Weight) x (Geographic Adjustment Factor (GAF)) x (COLA for hospitals located in Alaska and Hawaii) x (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. Other Proposed Changes for FY 2014 - Proposed Adjustment to Offset the Cost of the Policy Proposal on Admission and Medical Review Criteria for Hospital Inpatient Services under Medicare Part A

In the Medicare Part B Inpatient Billing in Hospitals proposed rule that went on display at the Office of the Federal Register on March 13, 2013, and that appeared in the **Federal Register** on March 18, 2013 (78 FR 16632), we proposed to revise our Part B inpatient billing policy to allow payment of all hospital services that were furnished and would have been reasonable and necessary if the beneficiary had been treated as an outpatient, rather than admitted to the hospital as an inpatient, except for those services specifically requiring an outpatient status. This policy would apply when CMS or a Medicare review contractor determines that the hospital admission was not reasonable and necessary or when a hospital determines after a beneficiary has been discharged that the beneficiary should have received hospital outpatient services rather than hospital inpatient services. We also proposed to continue applying the timely filing restriction to the billing of all Part B inpatient services, under which claims for Part B services must be filed within 1 year from the date of service. As we discuss in section V.N. of the preamble of this proposed rule, in addition to evaluating our policy related to Medicare Part B inpatient billing following denials of Medicare Part A inpatient claims on the basis that the inpatient admission was not reasonable and necessary or following a hospital self-audit, we also believe it is important to consider whether we can provide more clarity regarding the relationship between inpatient admission decisions and Medicare payment. Toward that end, we are presenting a proposal that would clarify that a beneficiary

becomes a hospital inpatient when formally admitted following the physician order for hospital inpatient admission, and would also clarify when we believe hospital inpatient admissions are reasonable and necessary based on how long beneficiaries have spent, or are reasonably expected to spend, in the hospital as inpatients. Under this proposal, Medicare's external review contractors would presume that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than one Medicare utilization day (defined by encounters crossing 2 "midnights") in the hospital receiving medically necessary services. Similarly, we would presume that generally services spanning less than 2 midnights should have been provided on an outpatient basis, unless there is clear physician documentation in the medical record supporting the physician's order and expectation that the beneficiary required inpatient care. (For a complete discussion on our proposed inpatient admission guidelines, including our proposed time-based presumption of medical necessity for hospital inpatient services based on the beneficiary's length of stay as part of our medical review criteria for payment of hospital inpatient services under Medicare Part A, we refer readers to section V.N.3 of the preamble of this proposed rule.)

Our actuaries project an increase in IPPS expenditures as a result of our proposed policy that medical review of inpatient admissions will include a presumption that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined by encounters crossing 2 "midnights") in the hospital receiving medically necessary services as discussed in section V.N.3. of the preamble of this proposed rule (and as briefly summarized above). These additional

expenditures result from an expected net increase in hospital inpatient encounters due to some encounters spanning more than 2 midnights moving to the IPPS from the OPSS, and some encounters of less than 2 midnights moving from the IPPS to the OPSS. In making this projection, the actuaries analyzed Medicare claims data for extended hospital outpatient encounters and shorter stay hospital inpatient encounters, and estimated the number of encounters that are expected to shift from outpatient to inpatient and vice versa (that is, the number that are expected to shift from inpatient to outpatient). These estimated shifts of encounters represent a significant portion of the total encounters paid under the IPPS. Our actuaries estimate that this projected net increase in inpatient encounters would increase IPPS expenditures by approximately \$220 million. In light of the widespread impact on the IPPS of our proposed policy and the systemic nature of the issue, we believe it is appropriate to propose to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to offset the estimated \$220 million in additional IPPS expenditures associated with this proposed policy by proposing to apply a -0.2 percent adjustment to the operating IPPS standardized amount, the hospital-specific rates, and the Puerto Rico-specific standardized amount. (For additional information on our actuarial estimate, we refer readers to section V.N.5. of the preamble of this proposed rule.)

Consistent with the proposal that we are making for the operating national and Puerto Rico-specific standardized amounts and the hospital specific-rates, we believe that it is also appropriate, under the Secretary's broad authority under section 1886(g) of the Act, to propose to reduce the national capital Federal rate and Puerto Rico-specific

capital rate by 0.2 percent (an adjustment factor of 0.998) to offset the estimated increase in capital IPPS expenditures associated with the projected increase in inpatient encounters that is expected to result from our proposed inpatient admission guidelines. Because hospitals receive an operating IPPS payment and also a capital IPPS payment for each discharge, we believe it would be appropriate to reduce payments under both the operating and capital IPPS to fully offset the projected increase in expenditures associated with these inpatient discharges. (We refer readers to section V.N. of the preamble of this proposed rule for a complete discussion of our policy proposal on inpatient admission guidelines, including our proposed time-based presumption of medical necessity for hospital inpatient services based on the beneficiary's length of stay as part of our medical review criteria for hospital inpatient services under Medicare Part A.)

D. Proposed Annual Update for FY 2014

The proposed annual update to the capital PPS Federal and Puerto Rico-specific rates, as provided for at § 412.308(c), for FY 2014 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 our proposed recoupment adjustment to the standardized amounts under section 1886(d) of the Act for FY 2014 pursuant to the amendments made to section 7(b)(1)(B) of Pub. L. 110-90 by section 631 of the ATRA.

Additional prospective adjustments for the MS-DRG documentation and coding effect through FY 2010 authorized under section 1886(d)(3)(A)(vi) of the Act are discussed in section II.D.7. of this preamble. Based on an analysis of FY 2010 data on claims paid through December 2011 using our historical claims-based methodology, we determined an additional prospective documentation and coding effect of +0.8 through FY 2010. Consistent with our proposal for the operating IPPS standardized amounts, in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27997), we proposed to reduce the national capital Federal rate in FY 2013 by an additional 0.8 percent to account for the remainder of the cumulative effect of the estimated changes in documentation and coding under the MS-DRG system that did not reflect an increase in case-mix severity through FY 2010. Numerous commenters objected to that proposal, and many commenters continued to assert that our estimates of documentation and coding were overstated, and could be explained by other factors. These commenters also focused on part of the analysis provided by MedPAC in its FY 2012 comment letter indicating that a slightly smaller additional prospective adjustment of -0.55 percent rather than -0.8 percent might be required to offset the cumulative MS-DRG documentation and coding effect through FY 2010. (77 FR 53278 through 53280) Many commenters requested that if CMS were to apply an additional prospective adjustment for the MS-DRG documentation and coding effect through FY 2010, it should subtract 0.25 percentage points from its estimate, for an adjustment of -0.55 percent, given the MedPAC analysis. After consideration of the public comments, we recognized

that the issue of the estimate used for the cumulative MS-DRG documentation and coding effect through FY 2010 may merit further consideration. Therefore, consistent with the policy we adopted for the operating IPPS standardized amounts and hospital-specific rates for FY 2013, we did not finalize our proposal to apply a -0.8 percent adjustment to the national capital Federal rate until more analysis could be completed (77 FR 53456).

We continue to consider whether MedPAC's recommendation that an adjustment to offset the cumulative documentation and coding effects through FY 2010 under section 1886(d)(3)(A)(iv) of the Act is appropriate and supported by a review of the claims data. As discussed in section II.D.7. of the preamble of this proposed rule, after further consideration of the MedPAC analysis and the requests by public commenters, if we were to apply an additional adjustment for the cumulative MS-DRG documentation and coding effect through FY 2010, we believe the most appropriate additional adjustment is -0.55 percent. While we are not proposing an additional prospective adjustment in FY 2014 for the cumulative MS-DRG documentation and coding effects through FY 2010 at this time, we are soliciting comments on the issue of applying a prospective adjustment to the operating IPPS standardized amount (and hospital-specific rates) for the cumulative MS-DRG documentation and coding effect through FY 2010.

Section 631 of the ATRA, discussed in section II.D.6. of the preamble of this proposed rule, amended section 7(b)(1)(B) of Pub. L. 110-90 to require the Secretary to make a recoupment adjustment to the operating IPPS standardized

amounts 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 to the operating IPPS standardized amounts authorized under section 7(b)(1)(A) of Pub. L. 110-90 until FY 2013. Delaying the implementation of that prospective adjustment to the operating IPPS standardized amounts resulted in overstated payment rates in FYs 2010, 2011, and 2012, and those resulting overpayments could not be recovered under Pub. L. 110-90. Therefore, under the provisions of section 631 of ATRA, we are proposing a -0.8 percent recoupment adjustment to the operating IPPS standardized amount in FY 2014. 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 Pub. L. 110-90. In section II.D.7. of the preamble of this proposed rule, we are soliciting public comments as to whether any portion of the aforementioned -0.8 percent recoupment adjustment to the operating IPPS standardized amount should be reduced and instead applied as a prospective adjustment to the operating IPPS standardized amount (and hospital-specific rates) for the cumulative MS-DRG documentation and coding effect through FY 2010.

We have consistently stated since the initial implementation of the MS-DRG system that we do not believe it is appropriate for Medicare expenditures under the capital IPPS to increase due to MS-DRG related changes in documentation and coding. We continue to believe that it is appropriate to make adjustments to the capital IPPS rates to eliminate increased Medicare expenditures that result from the effect of any documentation and coding changes due to the implementation of the MS-DRGs, since that portion of the increase in aggregate payments is not due to an increase in patient severity of illness (and costs). As a result, aggregate capital IPPS payments would be inappropriately high because annual aggregate capital IPPS payments are higher than payments that otherwise would have been made through FY 2010 absent the change to the MS-DRGs (77 FR 53456). Because the cumulative documentation and coding effect through FY 2010 results in inappropriately high capital IPPS payments, if we were to apply a prospective adjustment to the operating IPPS standardized amount and the hospital-specific rates to remove this effect, we would also do so for the national capital IPPS Federal rate. This approach would be consistent with our past practice regarding the application of prospective documentation and coding adjustments. In order to make this adjustment to the national capital IPPS Federal rate, as we have done in the past, we would use the Secretary's broad authority under section 1886(g) of the Act to establish and implement the capital IPPS (discussed previously in this preamble), in conjunction with section 1886(d)(3)(A)(vi) of the Act. Therefore, if we attribute a portion of the proposed -0.8 percent recoupment adjustment to the

operating IPPS standardized amount for FY 2014 to the prospective adjustment, under the Secretary's broad authority under section 1886(g) of the Act, we would also make an appropriate adjustment to the national capital IPPS Federal rate. The capital IPPS Puerto Rico rate (and operating IPPS Puerto Rico-specific standardized amount) would not be affected as we previously found no significant additional MS-DRG documentation and coding effect through FY 2010 for Puerto Rico that would warrant any additional adjustment (77 FR 53279 and 53457).

VII. Proposed Changes for Hospitals Excluded from the IPPS

A. Proposed Rate of Increase in Payments to Excluded Hospitals for FY 2014

Historically, certain hospitals and hospital units excluded from the prospective payment system received payment for inpatient hospital services they furnished on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount as defined in § 413.40(a) of the regulations) was set for each hospital or hospital unit based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. The updated target amount was multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) on total inpatient operating costs for a hospital's cost reporting period. Prior to October 1, 1997, these payment provisions applied consistently to certain categories of excluded providers, which included rehabilitation hospitals and units (now referred to as IRFs), psychiatric hospitals and units (now referred to as IPFs), LTCHs, children's hospitals, and IPPS-excluded cancer hospitals. IRFs, IPFs, and LTCHs, which were paid previously under the reasonable cost methodology, now receive payment under their own prospective payment systems, in accordance with changes made to the statute. In general, the prospective payment systems for IRFs, IPFs, and LTCHs provided transition periods of varying lengths during which time a portion of the prospective payment was based on cost-based reimbursement rules under 42 CFR Part 413. (However, certain providers do not receive a transition period or may elect to bypass the transition period as applicable under 42 CFR Part 412, Subparts N, O, and P.)

We note that the various transition periods provided for under the IRF PPS, the IPF PPS, and the LTCH PPS have ended.

Certain hospitals excluded from a prospective payment system, including children's hospitals and 11 cancer hospitals, continue to be subject to the rate-of-increase ceiling based on the hospital's own historical cost experience. In accordance with § 403.752(a) of the regulations, RNHCIs are also subject to the rate-of-increase limits established under § 413.40 of the regulations.

Beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's and cancer hospitals and RNHCIs. As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), with IRFs, IPFs, and LTCHs being paid under their own PPS, the number of providers being paid based on reasonable cost subject to a ceiling, including children's hospitals, 11 cancer hospitals, and RNHCIs, is too small and the cost report data are too limited to be able to create a market basket solely for these hospitals. Therefore, for FY 2014 and subsequent fiscal years, we would continue to use the percentage increase in the IPPS operating market basket to update the target amounts for these cancer hospitals, children's hospitals, and RNHCIs for the reasons discussed in the FY 2006 IPPS final rule.

However, as described in section IV. of the preamble of this proposed rule, we are proposing to revise and rebase 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 children's hospitals, the 11

cancer hospitals, and RNHCIs for FY 2014 and subsequent fiscal years. Accordingly, the FY 2014 rate-of-increase percentage to be applied to the target amount for these cancer hospitals, children's hospitals, and RNHCIs would be the FY 2014 percentage increase in the FY 2010-based IPPS operating market basket. Based on IHS Global Insight, Inc.'s 2013 first quarter forecast, we estimate that the FY 2010-based IPPS operating market basket update for FY 2014 is 2.5 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 2014.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section IV. of the Addendum to this proposed rule for the specific proposed update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2014. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

B. Critical Access Hospitals (CAHs): Proposed Changes to the Conditions of Participation Relating to Payment for Inpatient Services

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.

Among the statutory requirements under section 1820(c) of the Act, a CAH must be located in a rural area (or in an area treated as rural); be located more than a 35-mile drive (or in the case of mountainous terrain or in areas with only secondary roads available, more than a 15-mile drive) from a hospital or another CAH, unless otherwise designated as a “necessary provider” prior to January 1, 2006; have not more than 25 acute care inpatient beds for furnishing inpatient care for a period that does not exceed 96 hours per patient on an annual, average basis; and make available 24-hour emergency care services. The conditions of participation (CoPs) located at 42 CFR Part 485, Subpart F, incorporate these statutory requirements as well as other criteria specified in section 1820(e)(3) of the Act.

2. Proposed Policy Changes

We have received a number of questions from stakeholders in the CAH provider community relating to whether CAHs are required to furnish acute care inpatient services under the CAH CoPs. Our interpretation is that CAHs must provide acute care inpatient services, and we are proposing revisions to clarify and restate this requirement. Using the July 2010 through June 2011 cost reports, we were able to review data for 1,230 of the existing 1,328 CAHs.⁵⁹ These data suggest that 99 percent of CAHs are regularly providing acute care inpatient services and are in compliance with such requirements.

⁵⁹ Produced by the Cecil G. Sheps Center for Health Services Research at the University of North Carolina under a Cooperative Agreement with the Federal ORHP.

However, the data regarding the remaining 1 percent, along with the questions we have received, suggest that there may be some service gaps. We further believe that a few CAHs would benefit from clarification of our interpretation that CAHs must furnish acute care inpatient services.

The CAH program was established to improve access for rural residents to essential health care services and particularly hospital services which include acute care inpatient services. We are proposing certain clarifications to ensure continued access to these critical services. Indeed, once a facility has been designated and certified as a CAH, that facility is expected to provide services as a CAH, and it is entrusted with the reliance of the general public and of the local community. When a CAH is not routinely furnishing inpatient services, service gaps arise. For example, we are aware of one instance in the past where a CAH was functioning, in essence, as a nursing home/skilled nursing facility. However, because it was classified as a CAH, it prevented a nearby rural hospital from converting to CAH status in order to continue providing acute care inpatient services to the community. In this case, the CAH in question, instead of assuring critically needed access to acute care inpatient services, not only was not offering such services, but also putting at risk the continued availability of such services in the rural community. We believe the proposed change in regulation in this proposed rule would address these gaps in service by clearly stating that CAHs are required to provide acute care inpatient services.

As set forth in section 1820 of the Act, the CAH program was established to improve access to hospital and other health services for rural residents of a State. We

believe that the statutory requirements related to the provision of emergency care and acute care inpatient services, including those at section 1820(c)(2)(B) of the Act, suggest that a CAH must furnish these acute care inpatient services, albeit, in a more limited fashion than would be expected of a hospital. Hospitals are subject to a different set of CoPs, found in 42 CFR Part 482.

We recognize that, given its resources and the needs of the community it serves, a CAH may not be actively treating inpatients at all times. Indeed, the Act fully recognizes the variable nature of a CAH's inpatient census, as it provides specific contingency language for the staffing requirements under section 1820(c)(2)(B)(iv) of the Act. For example, section 1820(c)(2)(B)(iv)(I) requires a CAH to meet the rural hospital staffing requirements under section 1861(e) of the Act, with the exception that the CAH does not need to meet the hospital standards relating to the number of hours per day or days per week when the CAH must be open and fully staffed, except as needed to make available 24-hour emergency care and nursing services, and to staff the CAH whenever an inpatient is present.

We note that a CAH is not specifically required to maintain a minimum average daily census (ADC) of inpatients receiving inpatient acute care services or a minimum number of certified inpatient beds. We are aware that there are significant seasonal variations in the inpatient occupancy rates as well as variations that are a function of the size of the community in which a CAH is located. We also recognize the need for inpatient acute care services to be furnished in the best setting for the patient. However, while it is true that CAHs generally are not able to handle patients requiring complex,

specialized inpatient services, such as those services provided by trauma centers, or cardiac surgery centers, it is also true that CAHs should be able to handle a range of patient needs requiring admission. We believe it is not in the best interest of patients for them to routinely be transferred to a more distant hospital if instead their care can be provided locally without compromising quality. The blue “H” hospital signs posted along the roadways for CAHs serve as public reminders of the services for which CAHs were created to provide.

We also wish to clarify the relationship between a CAH’s written policies and the services it offers. The regulations at 42 CFR 485.635(a) require a CAH to furnish health care services in accordance with appropriate written policies. Among other items, the CAH must describe its procedures for emergency medical services and its procedures for inpatient services. Therefore, we expect CAHs to be appropriately prepared to provide the described services. For example, a CAH’s policies and procedures should be reflected in the number of certified beds, appropriate equipment, and available staffing (whether as employees or through arrangements or agreements). Similarly, we would expect CAHs to, in fact, be providing the same services outlined in their policies and procedures, as appropriate to the needs of individual patients. To further clarify the interrelated standards at § 485.635(a) and (b) of the regulations, we are proposing to amend the regulatory language at § 485.635(b), as noted below, and we are proposing to revise the language under the standard for “Patient care policies” under § 485.635(a)(3)(vii) to remove the conditional phrase “If a CAH furnishes inpatient services.” By removing this conditional phrase, we would eliminate regulatory language

that could be creating ambiguity where none was intended. The elimination of this language would clarify that CAHs are required to provide acute care inpatient services. Our revision also would align the standard with the structure of neighboring standards under § 485.635(a).

We are proposing to remove paragraph (c)(1)(i) under § 485.635 requiring CAHs to furnish inpatient hospital care services through agreements or arrangements; to redesignate the existing language of paragraph (b)(1) as paragraph (b)(1)(i); and to add a new paragraph (b)(1)(ii) under the standard “Patient services” that more clearly requires CAHs to furnish acute care inpatient services. (Because we are proposing to remove paragraph (c)(1)(i), we are proposing to redesignate existing paragraphs (c)(1)(ii) through (c)(1)(iv) as paragraphs (c)(1)(i) through (c)(1)(iii), respectively.)

These proposed clarifying changes are in the spirit of the policies finalized in the May 16, 2012 final rule, “Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation,” that sought to reduce outmoded and unnecessarily burdensome regulations, and to increase the ability of CAHs to devote more resources to providing high quality patient care (77 FR 29034). In that final rule, at § 485.635(b), we revised the heading of the standard to read “Patient services” instead of “Direct services” to specify that a CAH can furnish certain types of services through agreement or arrangements rather than directly. We noted our expectation that furnishing timely services would be best achieved by providing CAH services onsite at the CAH as much as possible, whether through CAH employees or through agreements or arrangements (77 FR 29059). Our proposed addition of paragraph (b)(1)(ii) to § 485.635

would clarify that a CAH must provide acute care inpatient services. We expect that these services would be provided as appropriate to a CAH's resources and as appropriate to meet the needs of its patients. We regard the services furnished in accordance with § 485.635(c) as other additional services, which a CAH may also provide through agreements or arrangements.

Notwithstanding these clarifications and proposed revisions, in accordance with section 1820(d) of the Act, each CAH member of a Rural Health Network would still be required to have an agreement with at least one full-service acute care hospital member of the network regarding patient referral and transfer.

We believe these proposed changes, as discussed above, would address the issues described in this section as well as eliminate existing provider confusion by clearly stating that CAHs are required to provide acute care inpatient services. We expect a CAH to meet all of the conditions of participation under 42 CFR Part 485, including all the standards relating to the furnishing of acute care inpatient services. In the event that a CAH decides that it is no longer able to comply, or that the circumstances no longer warrant compliance, with all of the CAH requirements, such a facility may wish to engage in a dialogue with CMS to explore its options, including avenues other than the CAH program, for continued participation in the Medicare program.

Finally, we are proposing a technical change at § 485.620(a), the section addressing the "Number of beds" standard. Specifically, we are proposing to remove the phrase "after January 1, 2004," a prospective effective date established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L.

108-173) and which was subsequently restated in regulation at § 485.620(a) (69 FR 49215). The MMA revised the bed limit upwards, to allow CAHs a maximum of 25 acute care beds for inpatient services, regardless of the swing-bed approval. Prior to the MMA, CAHs were restricted to 15 acute care beds and a total of 25 beds if the CAH had been granted swing-bed approval. Retaining this date in regulation no longer serves the purpose of providing CAHs with notice that they could expand beyond 15 acute care beds. The effective date of January 1, 2004 has passed and the revised maximum bed limit of 25 continues to apply.

VIII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2014

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 VIII. of this preamble, 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 2013 rulemaking cycle.

2. Criteria for Classification as a LTCH

a. Classification as a LTCH

Under the existing regulations at §§ 412.23(e)(1) and (e)(2)(i), which implement section 1886(d)(1)(B)(iv)(I) of the Act, to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare and must have an average Medicare inpatient length of stay of greater than 25 days. Alternatively, § 412.23(e)(2)(ii) states that, for cost reporting periods beginning on or after August 5, 1997, a hospital that was first excluded from the PPS in 1986 and can demonstrate that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in FY 1997 have a principal diagnosis that reflects a finding of neoplastic disease must have an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days.

b. Hospitals Excluded from the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR Part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90-248) (42 U.S.C. 1395b-1) or section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92-603) (42 U.S.C. 1395b-1 (note)) (Statewide all-payer systems, subject to the rate-of-increase test at section 1814(b) of the Act).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). In the RY 2005 LTCH PPS final rule (69 FR 25676), we clarified that the discussion of beneficiary liability in the August 30, 2002 final rule was not meant to establish rates or payments for, or define Medicare-eligible expenses. Under § 412.507, if the Medicare payment to the LTCH is the full LTC-DRG payment amount, as consistent with other established hospital prospective payment systems, a LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83,

and 409.87 and for items and services as specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. Therefore, if the Medicare payment was for a SSO case (§ 412.529) that was less than the full LTC-DRG payment amount because the beneficiary had insufficient remaining Medicare days, the LTCH could also charge the beneficiary for services delivered on those uncovered days (§ 412.507).

4. Administrative Simplification Compliance Act (ASCA) and Health Insurance Portability and Accountability Act (HIPAA) Compliance

Claims submitted to Medicare must comply with both the Administrative Simplification Compliance Act (ASCA) (Pub. L. 107-105), and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-191). Section 3 of the ASCA requires that the Medicare Program deny payment under Part A or Part B for any expenses incurred for items or services “for which a claim is submitted other than in an electronic form specified by the Secretary.” Section 1862(h) of the Act (as added by section 3(a) of the ASCA) provides that the Secretary shall waive such denial in two specific types of cases and may also waive such denial “in such unusual cases as the Secretary finds appropriate” (68 FR 48805). Section 3 of the ASCA operates in the context of the HIPAA regulations, which include, among other provisions, the transactions and code sets standards requirements codified as 45 CFR Parts 160 and 162, Subparts A and I through R (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including covered health care providers, to

conduct certain electronic health care transactions according to the applicable transactions and code sets standards.

B. Proposed Medicare Severity Long-Term Care Diagnosis-Related Group (MS-LTC-DRG) Classifications and Relative Weights for FY 2014

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. As described in section II.G. of this preamble, for FY 2014, we are not proposing to create or delete any MS-DRGs, and as such we would continue to have a total of 751 MS-DRG groupings for FY 2014. 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 MS-LTC-DRG relative weights.

In a departure from the IPPS, and as discussed in greater detail below in section VIII.B.3.f. of this preamble, we are proposing to continue to use low-volume MS-LTC-DRGs (that is, MS-LTC-DRGs with less than 25 LTCH cases) in determining the MS-LTC-DRG relative weights because LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. For purposes of determining the relative weights for the large number of low-volume MS-LTC-DRGs, we are proposing to group all of the low-volume MS-LTC-DRGs into five quintiles based on average charge per discharge. (A detailed discussion of the initial development and application of the quintile methodology appears in the August 30, 2002 LTCH PPS final rule (67 FR 55978).) Under our existing methodology, we are proposing to account for adjustments to payments for SSO cases (that is, cases where the covered length of stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay for the MS-LTC-DRG). Furthermore, we are proposing to 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 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 relative weights in section VIII.B.3.g. (Step 6) of this preamble.)

2. Patient Classifications into MS-LTC-DRGs

a. Background

The MS-DRGs (used under the IPPS) and the MS-LTC-DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted above in this section, we refer to the DRGs under the LTCH PPS as MS-LTC-DRGs although they are structurally identical to the MS-DRGs used under the IPPS.

The MS-DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD-9-CM procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKG), or minor surgical procedures (for example, biopsy of skin and subcutaneous tissue (procedure code 86.11)) do not affect the MS-LTC-DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge and that payment varies by the MS-LTC-DRG to which a

beneficiary's stay is assigned. Cases are classified into MS-LTC-DRGs for payment based on the following six data elements:

- Principal diagnosis;
- Additional or secondary diagnoses;
- Surgical procedures;
- Age;
- Sex; and
- Discharge status of the patient.

Through FY 2010, the number of 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.11. of this preamble for additional information on the annual revisions to the ICD-9-CM codes.)

On October 1, 2014, covered entities must begin using the ICD-10-CM and ICD-10-PCS coding systems (45 CFR 162.1102(c)). We have been discussing the conversion to the ICD-10-CM and the ICD-10-PCS coding systems for many years. In prior rules published in the **Federal Register** (for example, section II.G.10. of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50122 through 50128)), we discussed the implementation date for the conversion to the ICD-10-CM and ICD-10-PCS coding systems. We refer readers to section II.G.11. of this preamble for additional information on the implementation of the ICD-10-CM and ICD-10-PCS systems.

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 contractors (that is, fiscal intermediaries and MACs) enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS-LTC-DRG can be made. During this process, certain cases are selected for further development (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS-LTC-DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS-LTC-DRG assignment, the Medicare contractor determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS-LTC-DRG assignments made by the

Medicare contractor and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS-LTC-DRG 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 2014

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, 2013, through September 30, 2014 (FY 2014) consistent with the proposed changes to specific MS-DRG classifications presented in section II.G. of this preamble (that is, proposed GROUPER Version 31.0). Therefore, the proposed MS-LTC-DRGs for FY 2014 presented in this proposed rule are the same as the proposed MS-DRGs that are being used under the IPPS for FY 2014. In addition, because the proposed MS-LTC-DRGs for FY 2014 are the same as the proposed MS-DRGs for FY 2014, the other proposed changes that affect MS-DRG (and by extension MS-LTC-DRG) assignments under proposed Version 31.0 of the GROUPER

discussed in section II.G. of the preamble of this proposed rule, including the proposed changes to the MCE software and the ICD-9-CM coding system, are also applicable under the LTCH PPS for FY 2014.

3. Development of the Proposed FY 2014 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 proposed 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 proposed 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. Development of the Proposed MS-LTC-DRG Relative Weights for FY 2014

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53462 through 53467), we presented our policies for the development of the MS-LTC-DRG relative weights for FY 2013. The basic methodology we used to develop the FY 2013 MS-LTC-DRG relative weights was the same as the methodology we used to develop the FY 2012 MS-LTC-DRG relative weights in the FY 2012 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). We are proposing to continue to apply our established methodology for FY 2014. Our development of the proposed FY 2014 MS-LTC-DRG relative weights include 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 2014, which is consistent with the methodology presented in the FY 2013 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 2014 are based on the FY 2013 MS-LTC-DRG classifications and relative weights established in Table 11 listed in section VI. of the Addendum to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53716 through 53717). (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 this proposed rule, to calculate the proposed MS-LTC-DRG relative weights for FY 2014, we are proposing to obtain total charges from FY 2012 Medicare LTCH bill data from the December 2012 update of the FY 2012 MedPAR file, which are the best available data at this time, and to use the proposed Version 31.0 of the GROUPER to classify LTCH cases. Consistent with our existing methodology, we also are proposing that if more recent data become available, we would use those data and the finalized Version 31.0 of the GROUPER in establishing the FY 2014 MS-LTC-DRG relative weights in the final rule. Consistent with our historical methodology, we are proposing to exclude the data from LTCHs that are all-inclusive rate providers and LTCHs that are reimbursed in accordance with demonstration projects authorized under section 402(a) of Pub. L. 90-248 or section 222(a) of Pub. L. 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 (73 FR 48532). Accordingly, in the development of the proposed FY 2014 MS-LTC-DRG relative weights in this proposed rule, we excluded the data of 14 all-inclusive rate providers and the 2 LTCHs that are paid in accordance with

demonstration projects that had claims in the December 2012 update of the FY 2012 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. 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 2014. 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 adjust those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for a LTCH is its case-mix, so it is reasonable

to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the cases it treats relative to the complexity of the cases treated by all other LTCHs (the average case-mix of all LTCHs).

In accordance with our established methodology, under this proposal, we would continue to standardize charges for each case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in section VIII.B.3.g. (Step 3) of this preamble) by the average adjusted charge for all cases at the LTCH in which the case was treated. SSO cases are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the MS-LTC-DRG (§ 412.529 and § 412.503). The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio is multiplied by that LTCH's case-mix index to determine the standardized charge for the case (67 FR 55989).

Multiplying the resulting ratio by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight at a LTCH with higher average costs than they would at a LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. Because we standardize charges in this manner, we count charges for a Medicare patient at a LTCH with high average charges as less resource intensive than they would be at a LTCH with low average charges. For example, a \$10,000 charge for a case at a LTCH with an average adjusted charge of \$17,500 reflects a higher level of

relative resource use than a \$10,000 charge for a case at a LTCH with the same case-mix, but an average adjusted charge of \$35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

e. Proposed Treatment of Severity Levels in Developing the MS-LTC-DRG Relative Weights

For purposes of determining the 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. MS-LTC-DRGs with at least 25 cases are each assigned a unique relative weight; low-volume MS-LTC-DRGs (that is, MS-LTC-DRGs that contain between 1 and 24 cases based on a given year's claims data) are grouped into quintiles (as described below) and assigned the relative weight of the quintile. No-volume MS-LTC-DRGs (that is, no cases in the given year's claims data are assigned to those MS-LTC-DRGs) are cross-walked to other MS-LTC-DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS-LTC-DRG (as described in greater detail below). 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 2014. (We provide in-depth discussions of our policy regarding weight-setting for proposed low-volume MS-LTC-DRGs in section VIII.B.3.f. of the preamble of this proposed rule

and for proposed no-volume MS-LTC-DRGs, under Step 5 in section VIII.B.3.g. of this preamble.)

Furthermore, in determining the proposed FY 2014 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 VIII.B.3.g. of this preamble. We refer readers to the discussion in the FY 2010 IPPS/RV 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 2014 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, 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 2014 MS-LTC-DRG relative weights in this proposed rule, in cases where the initial assignment of a proposed low-volume MS-LTC-DRG to quintiles 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 VIII.B.3.g. (Step 6) of this preamble.

In this proposed rule, using LTCH cases from the December 2012 update of the FY 2012 MedPAR file (which is currently the best available data), we identified 280 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 56 proposed MS-LTC-DRGs ($280/5 = 56$ with no 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 was evenly divisible by 5. However, had the number of proposed MS-LTC-DRGs with less than 25 cases not been evenly divisible by 5, consistent with our historical approach we would have used the average charge of the low-volume quintile to determine which of the low-volume quintiles contain the additional low-volume MS-LTC-DRGs. (For an example of the application of this approach, we refer readers to the discussion of the treatment of the low-volume MS-LTC-DRGs for FY 2013 (77 FR 53463).) 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 56th) of proposed low-volume MS-LTC-DRGs (with the lowest average charge) into Quintile 1. The proposed MS-LTC-DRGs with the highest average charge cases were assigned into Quintile 5. Table

13A, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet, lists the composition of the proposed low-volume quintiles for proposed MS-LTC-DRGs for FY 2014.

Accordingly, in order to determine the proposed FY 2014 relative weights for the proposed MS-LTC-DRGs with low volume, we are proposing to use the five low-volume quintiles described above. We determined a proposed relative weight and (geometric) average length of stay for each of the five low-volume quintiles using the methodology that we applied to the proposed MS-LTC-DRGs (25 or more cases), as described below in section VII.B.3.g. of this preamble. We are proposing to assign the same proposed relative weight and average length of stay to each of the proposed low-volume MS-LTC-DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS-LTC-DRGs with a low volume of 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 low-volume quintiles to ensure that our quintile assignments used in determining the proposed MS-LTC-DRG relative weights result in appropriate payment for such cases and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

g. Steps for Determining the Proposed FY 2014 MS-LTC-DRG Relative Weights

In this proposed rule, we are proposing to determine the FY 2014 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/RV 2010 LTCH PPS final rule (74 FR 43951 through 43966).) In summary, to determine the proposed FY 2014 MS-LTC-DRG relative weights, we are proposing to group LTCH cases to the appropriate proposed MS-LTC-DRG, while taking into account the low-volume quintile (as described above). After grouping the cases to the appropriate MS-LTC-DRG (or low-volume quintile), we calculate the proposed FY 2014 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 adjust the number of cases in each proposed MS-LTC-DRG (or low-volume quintile) for the effect of SSO cases (Step 3 below). After removing statistical outliers (Step 1 below) and cases with a length of stay of 7 days or less (Step 2 below), the SSO adjusted discharges and corresponding charges were then used to calculate “relative adjusted weights” for each proposed MS-LTC-DRG (or low-volume quintile) using the HSRV method.

Below we discuss in detail the steps for calculating the proposed FY 2014 MS-LTC-DRG relative weights. We note that, as we discussed in section VIII.B.3.c. of this preamble, we excluded the data of all-inclusive rate LTCHs, LTCHs that are paid in accordance with demonstration projects, and any Medicare Advantage claims in the December 2012 update of the FY 2012 MedPAR file.

Step 1--Remove statistical outliers.

The first step in the calculation of the proposed FY 2014 MS-LTC-DRG relative weights is to remove statistical outlier cases. Consistent with our historical relative

weight methodology, we are proposing to continue to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS-LTC-DRG. These statistical outliers are removed prior to calculating the proposed relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the proposed relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among the 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 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 2014 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 2014 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 are left with cases that have a length of stay of greater than or equal to 8 days. As the next step in the calculation of the proposed FY 2014 MS-LTC-DRG relative weights, consistent with our historical relative weight methodology, we are proposing to adjust each LTCH's charges per discharge for those remaining cases for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503).

We are proposing to make this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the MS-LTC-DRG for non-SSO cases. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS-LTC-DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS-LTC-DRG.

Counting SSO cases as full discharges with no adjustment in determining the proposed FY 2014 MS-LTC-DRG relative weights would lower the proposed FY 2014 MS-LTC-DRG relative weight for affected MS-LTC-DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within an 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 2014 MS-LTC-DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, we are proposing to calculate the proposed FY 2014 MS-LTC-DRG relative weights using the HSRV methodology, which is an iterative process. First, for each LTCH case, we are proposing to calculate a hospital-specific relative charge value by dividing the SSO adjusted charge per discharge (see Step 3) of the LTCH case (after removing the statistical outliers (see Step 1) and LTCH cases with a length of stay of 7 days or less (see Step 2)) by the average charge per discharge for the LTCH in which the case occurred. The resulting ratio is then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. An initial case-mix index value of 1.0 is used for each LTCH.

For each proposed MS-LTC-DRG, we are proposing to calculate the proposed FY 2014 relative weight by dividing the average of the adjusted hospital-specific relative charge values (from above) for the proposed MS-LTC-DRG by the overall average hospital-specific relative charge value across all cases for all LTCHs. Using these recalculated proposed MS-LTC-DRG relative weights, each LTCH's average relative weight for all of its cases (that is, its case-mix) is calculated by dividing the sum of all the

LTCH's MS-LTC-DRG relative weights by its total number of cases. The LTCHs' hospital-specific relative charge values (from above) are then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values are then used to calculate a new set of proposed MS-LTC-DRG relative weights across all LTCHs. This iterative process is continued until there is convergence between the weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 5--Determine a proposed FY 2014 relative weight for MS-LTC-DRGs with no LTCH cases.

As we stated above, we are proposing to determine the proposed FY 2014 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 2012 update of the FY 2012 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 proposed MS-LTC-DRGs were treated in LTCHs during FY 2012 and, therefore, no charge data were available for these proposed MS-LTC-DRGs. Thus, in the process of determining the proposed MS-LTC-DRG relative weights, we are unable to calculate proposed relative weights for the proposed MS-LTC-DRGs with no LTCH cases using the methodology described in Steps 1 through 4 above. However, because patients with a number of the diagnoses under these proposed MS-LTC-DRGs may be treated at LTCHs, consistent with our historical methodology, we are proposing to assign a 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 are proposing to determine proposed FY 2014 relative weights for the proposed MS-LTC-DRGs with no LTCH cases in the December 2012 update of the FY 2012 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 is 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 751 proposed MS-LTC-DRGs for FY 2014, we identified 236 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 236 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 515 (751 - 236= 515) proposed MS-LTC-DRGs for which we are able to determine

proposed relative weights based on FY 2012 LTCH claims data using the steps described above. (For the remainder of this discussion, we refer to the proposed “cross-walked” MS-LTC-DRGs as the proposed MS-LTC-DRGs to which we crosswalk one of the 236 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 made adjustments to account for nonmonotonicity.)

For this proposed rule, we are proposing to cross-walk the proposed no-volume MS-LTC-DRG to a proposed MS-LTC-DRG for which there are LTCH cases in the December 2012 update of the FY 2012 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. We evaluated the relative costliness in determining the applicable proposed MS-LTC-DRG to which a proposed no-volume MS-LTC-DRG is cross-walked in order to assign an appropriate proposed relative weight for the proposed no-volume MS-LTC-DRGs in FY 2014. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RV 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 2014, the proposed relative weights assigned based on

the proposed cross-walked MS-LTC-DRGs would result in an appropriate LTCH PPS payment because the proposed crosswalks, which are based on similar clinical similarity and relative costliness, generally require equivalent relative resource use.

We are proposing to then assign the proposed relative weight of the proposed cross-walked MS-LTC-DRG as the proposed relative weight for the proposed no-volume MS-LTC-DRG such that both of these proposed MS-LTC-DRGs (that is, the proposed no-volume MS-LTC-DRG and the proposed cross-walked MS-LTC-DRG) have the same proposed relative weight for FY 2014. We note that if the proposed cross-walked MS-LTC-DRG had 25 cases or more, its proposed relative weight, which is calculated using the proposed methodology described in Steps 1 through 4 above, is assigned to the proposed no-volume MS-LTC-DRG as well. Similarly, if the proposed MS-LTC-DRG to which the proposed no-volume MS-LTC-DRG is cross-walked has 24 or less cases and, therefore, is 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 2014. (As we noted above, in the infrequent case where nonmonotonicity involving a proposed no-volume MS-LTC-DRG results, additional adjustments as described in Step 6 were required in order to maintain monotonically increasing relative weights.)

For this proposed rule, a list of the proposed no-volume MS-LTC-DRGs and the proposed MS-LTC-DRGs to which each is cross-walked (that is, the proposed cross-walked MS-LTC-DRGs) for FY 2014 is shown in Table 13B, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet.

To illustrate this methodology for determining the proposed relative weights for the FY 2014 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 2014 provided in Table 13B.

Example: There are no cases in the FY 2012 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 0.8222 for FY 2014 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 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 2014, consistent with our historical relative weight methodology, we are proposing to establish the proposed MS-LTC-DRG relative weight of 0.0000 for the following proposed transplant MS-LTC-DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS-LTC-DRG 1); Heart Transplant or Implant of Heart Assist System without MCC (MS-LTC-DRG 2); Liver Transplant with MCC or Intestinal Transplant (MS-LTC-DRG 5); Liver Transplant without MCC (MS-LTC-DRG 6); Lung Transplant (MS-LTC-DRG 7); Simultaneous Pancreas/Kidney Transplant (MS-LTC-DRG 8); Pancreas Transplant (MS-LTC-DRG 10); and Kidney Transplant (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 GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these proposed MS-LTC-DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS-LTC-DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).)

Step 6--Adjust the proposed FY 2014 MS-LTC-DRG relative weights to account for nonmonotonically increasing relative weights.

As discussed earlier in this section, the MS-DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one code that is referred to as an MCC

(that is, major complication or comorbidity). The next lower severity level contains cases with at least one code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as “without CC/MCC.” When data do not support the creation of three severity levels, the base 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 MS-LTC-DRG, an 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 relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS-LTC-DRG (which are generally

expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS-LTC-DRG (which are generally expected to have lower resource use and costs). Consequently, in determining the proposed FY 2014 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 is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the proposed FY 2014 MS-LTC-DRG relative weights in this proposed rule by applying this proposed 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 2014 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 2014 based on the most recent available LTCH data, and apply a budget neutrality adjustment in determining the proposed FY 2014 MS-LTC-DRG relative weights.

To ensure budget neutrality in the proposed update to the MS-LTC-DRG classifications and relative weights under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology. In this proposed rule, in the first step of our MS-LTC-DRG budget neutrality methodology, for FY 2014, we are proposing to calculate and apply a normalization factor to the recalibrated relative weights (the result of Steps 1 through 6 above) to ensure that estimated payments are not influenced by changes in the composition of case types or the changes to the classification system. That is, the 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 2014 (the first step of our budget neutrality methodology), we are proposing to use the following three steps: (1.a.) we use the most recent available LTCH claims data (FY 2012) and group them using the proposed FY 2014 GROUPER (Version 31.0) and the recalibrated proposed FY 2014 MS-LTC-DRG relative weights (determined in steps 1 through 6 of the Steps for Determining the Proposed FY 2014 MS-LTC-DRG Relative Weights above) to calculate the average CMI; (1.b.) we group the same LTCH claims data (FY 2012) using the FY 2013 GROUPER (Version 30.0) and FY 2013 MS-LTC-DRG relative weights and calculate the average CMI; and (1.c.) we compute the ratio of these average CMIs by dividing the average CMI for FY 2013 (determined in Step 1.b.) by the proposed average CMI for FY 2014 (determined in Step 1.a.). In determining the proposed MS-LTC-DRG relative weights for FY 2014, each recalibrated MS-LTC-DRG relative weight is multiplied by 1.11546 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produced proposed “normalized relative weights.”

In the second step of our proposed MS-LTC-DRG budget neutrality methodology, we are proposing to determine a budget neutrality factor to ensure that estimated aggregate LTCH PPS payments (based on the most recent available LTCH claims data) after reclassification and recalibration (that is, the proposed FY 2014 MS-LTC-DRG classifications and relative weights) are equal to estimated aggregate LTCH PPS payments before reclassification and recalibration (that is, the FY 2013 MS-LTC-DRG classifications and relative weights). Accordingly, consistent with our existing methodology, we are proposing to use FY 2012 discharge data to simulate payments and

compare estimated aggregate LTCH PPS payments using the FY 2013 MS-LTC-DRGs and relative weights to estimate aggregate LTCH PPS payments using the proposed FY 2014 MS-LTC-DRGs and relative weights. Specifically, for this proposed rule, as discussed previously in section VIII.B.3.c. of this preamble, we are using LTCH claims data from the December 2012 update of the FY 2012 MedPAR file, as these are the best available data at this time. Furthermore, consistent with our historical policy of using the best available data, we also are proposing that if more recent data become available, we would use such data to determine the budget neutrality adjustment factor for FY 2014 in the final rule.

For this proposed rule, we are proposing to determine the proposed FY 2014 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 2014 and proposed GROUPER Version 31.0 (as described above); (2.b.) we simulate estimated total LTCH PPS payments using the FY 2013 GROUPER (Version 30.0) and the FY 2013 MS-LTC-DRG relative weights in Table 11 of the Addendum to the FY 2013 IPPS/LTCH PPS final rule available on the Internet (76 FR 53716); 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 2013 GROUPER (Version 30.0) and the FY 2013 MS-LTC-DRG relative weights (determined in Step 2.b.) by the estimated total LTCH PPS payments using the proposed FY 2014 GROUPER (Version 31.0) and the proposed normalized MS-LTC-DRG relative weights for FY 2014 (determined in Step 2.a.). In determining the proposed FY 2014 MS-LTC-DRG relative weights, each

proposed normalized relative weight is multiplied by a proposed budget neutrality factor of 0.9953277 (determined in Step 2.c.) in the second step of the budget neutrality methodology to determine the proposed budget neutral FY 2014 relative weight for each MS-LTC-DRG.

Accordingly, in determining the proposed FY 2013 MS-LTC-DRG relative weights in this proposed rule, consistent with our existing methodology, we are proposing to apply a normalization factor of 1.11546 and a budget neutrality factor of 0.9953277 (computed as described above). Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet, lists the proposed MS-LTC-DRGs and their respective proposed relative weights, geometric mean length of stay, five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)), and the proposed “IPPS Comparable Thresholds” (used in determining SSO payments under § 412.529(c)(3)), for FY 2014 (and reflect both the proposed normalization factor of 1.11546 and the proposed budget neutrality factor of 0.9953277).

C. Proposed LTCH PPS Payment Rates for FY 2014

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 2014, that is, effective for LTCH discharges occurring on or after October 1, 2013 through September 30, 2014.

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); and FY 2013 IPPS/LTCH PPS final rule (77 FR 53479 through 53481).

The proposed update to the LTCH PPS standard Federal rate for FY 2014 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 2014 are discussed below, including the reduction to the annual update for LTCHs that fail to submit quality reporting data for fiscal year FY 2014 as required by the statute (as discussed below in section VIII.C.2.c. of this preamble). Furthermore, as discussed below in section VIII.C.3. of this preamble, for FY 2014, in addition to the proposed update factor, under the second 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 2014 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 proposed changes to the area wage level adjustment for FY 2014 on estimated aggregate LTCH PPS payments, in accordance with § 412.523(d)(4). (We refer readers to the discussion of the proposed reduction to the annual update for LTCHs that fail to submit quality reporting data in section VIII.C.2.c. of this preamble, the proposed application of the one-time prospective adjustment under the second year of the 3-year phase-in in section VIII.C.3. of this preamble, and the proposed budget neutrality adjustment for changes in the area wage levels in section V.A. of the Addendum of this proposed rule.)

2. Proposed FY 2014 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 VIII.C.2.b. of this preamble.) We note that because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term “fiscal year” (FY) rather than “rate year” (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 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. 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 2014, 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 2014. (For details on the development of the 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. 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 a 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.

Section 1886(m)(5)(D)(iii) of the Act requires the Secretary to publish the selected measures for the LTCHQR Program that will be applicable with respect to the FY 2014 payment determination no later than October 1, 2012. Under section 1886(m)(5)(D)(i) of the Act, the quality measures for the LTCHQR Program are measures selected by the Secretary that have been endorsed by an entity that holds a contract with the Secretary under section 1890(a) of the Act, unless section

1886(m)(5)(D)(ii) of the Act applies. This contract is currently held by the National Quality Forum (NQF). Section 1886(m)(5)(D)(ii) of the Act provides that an exception may be made in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity that holds a contract with the Secretary under section 1890(a) of the Act. In such a case, section 1886(m)(5)(D)(ii) of the Act authorizes the Secretary to specify a measure(s) that is not so endorsed, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

The LTCHQR Program was implemented in section VII.C. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756). In that same final rule as discussed in section IX.C. of the preamble of this proposed rule, we adopted the following three quality measures for the FY 2014 payment determination: Urinary Catheter-Associated Urinary Tract Infection (CAUTI) rate per 1, 000 urinary catheter days, for Intensive Care Unit Patients (NQF #013); Central Line Catheter-Associated Blood Stream Infection (CLABSI) Rate for ICU and High-Risk Nursery Patients (NQF #0139); and Percent of Residents with Pressure Ulcers That are New or Worsened (Application of NQF #0678). For additional discussion and details of the history of the LTCHQR Program, including the statutory authority and further details on the three measures previously finalized for the FY 2014 payment determination, we refer readers to section IX.C. of the preamble of this proposed rule and to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756).

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, we are proposing that 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, would be 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, would be further reduced by 2.0 percentage points for LTCHs that fail to submit quality reporting data under the LTCHQR Program. Accordingly, in this proposed rule, we are proposing to implement 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 under proposed § 412.523(c)(4). Specifically, consistent with section 1886(m)(5)(A)(i) of the Act, under proposed § 412.523(c)(4)(i), we are proposing that for a 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) would be further reduced by 2.0 percentage points. (Note, as discussed

previously this section, the annual update to the standard Federal rate implemented under § 412.523(c)(3) reflects the application of the adjustments to any annual update as required by sections 1886(m)(3) and (m)(4) of the Act.) In addition, under proposed § 412.523(c)(4)(ii), consistent with section 1886(m)(5)(A)(ii) of the Act, we are proposing that any reduction of the annual update to the standard Federal rate under proposed § 412.523(c)(4)(i) would apply only to the fiscal year involved and would 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 proposed § 412.523(c)(4)(iii), we are proposing that the application of any reduction of the annual update to the standard Federal rate under proposed § 412.523(c)(4)(i) may result in an annual update that would be 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 also discuss this proposed application of the 2.0 percentage point reduction under proposed § 412.523(c)(4)(i) in our discussion of the proposed annual market basket update to the LTCH PPS standard Federal rate for FY 2014 below in section VIII.C.2.e. of this preamble.

d. Proposed Market Basket under the LTCH PPS for FY 2014

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 2014, we are proposing to continue to use the FY 2009-based LTCH-specific market basket to update the LTCH PPS for FY 2014. 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 2014

Consistent with our historical practice, we are proposing to estimate the market basket update and the MFP adjustment based on IGI's forecast using the most recent available data. Based on IGI's first quarter 2013 forecast, the proposed FY 2014 full market basket estimate for the LTCH PPS using the FY 2009-based LTCH-specific market basket is 2.5 percent. Using our established methodology for determining the MFP adjustment, the current estimate of the MFP adjustment for FY 2014 based on IGI's first quarter 2013 forecast is 0.4 percent (for additional details, we refer readers to section V.A.1. of this preamble). Consistent with our historical practice of using the best available data, we are proposing that if more recent data become available to determine the market basket estimate or the MFP adjustment, we would use such data for the final rule, if appropriate.

For FY 2014, 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 2014 market basket update by the FY 2014 MFP adjustment. To determine the market basket update for LTCHs for FY 2014, as reduced by the proposed MFP adjustment, consistent with our established methodology, we are proposing to subtract the FY 2014 MFP adjustment from the FY 2014 market basket update. Furthermore, sections 1886(m)(3)(A)(ii) and 1886(m)(4)(D) of the Act requires that any annual update to the standard Federal rate for FY 2014 be reduced by the “other adjustment” described in paragraph (4), which is 0.3 percentage point for FY 2014. Therefore, following application of the productivity adjustment, we are proposing to reduce the proposed adjusted market basket update (that is, the full market basket increase less the MFP adjustment) by the “other adjustment” specified by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act. (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 VIII.C.2.c. of this preamble, for FY 2014, 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, will be further reduced by 2.0 percentage points. Therefore, the proposed update to the LTCH

PPS standard Federal rate for FY 2014 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, will 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 2014 full market basket estimate of 2.5 percent (based on the first quarter 2013 forecast of the FY 2009-based LTCH-specific market basket) by the proposed FY 2014 MFP adjustment (that is, the 10-year moving average of MFP for the period ending FY 2014, as described in section V.A.1. of the preamble of this proposed rule) of 0.4 percentage point (based on IGI’s first quarter 2013 forecast). Following application of the proposed productivity adjustment, the proposed adjusted market basket update of 2.1 percent (2.5 percent minus 0.4 percentage point) is then reduced by 0.3 percentage point, as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4)(D) 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 2014 of 1.8 percent (that is, the most recent estimate of the LTCH PPS market basket update at this time of 2.5 percent less the MFP adjustment of 0.4 percentage point less the 0.3 percentage point required under section 1886(m)(4)(D) of the Act), provided the LTCH submits quality reporting data in accordance with section 1886(m)(5) of the Act (as discussed above in section VIII.C.2.c.

of this preamble). Accordingly, we are proposing to revise § 412.523(c)(3) by adding a new paragraph (x), which specifies that the standard Federal rate for FY 2014 is the standard Federal rate for the previous LTCH PPS year updated by 1.8 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)(x) in conjunction with proposed § 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 (as discussed previously in section VIII.C.2.c. of this preamble). Accordingly, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of -0.2 percent (that is, 1.8 percent minus 2.0 percentage points) for FY 2014 for LTCHs that fail to submit quality reporting data under the LTCHQR Program. As stated above, consistent with our historical practice of using the most recent available data, we are proposing that, if more recent data become available when we develop the final rule, we would use such data, if appropriate, in determining the final market basket update under the LTCH PPS for FY 2014. (We note that we also are proposing to adjust the FY 2014 standard Federal rate by the proposed application of the one-time prospective adjustment under the second year of the 3-year phase-in under § 412.523(d)(3) (discussed below in section VIII.C.3. of this preamble) 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 Second 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, in accordance with the existing regulations at § 412.523(d)(3), we are proposing to apply a permanent factor of 0.98734

for FY 2014 to the standard Federal rate under the second year of the 3-year phase-in of the one-time prospective adjustment. (The proposed LTCH PPS standard Federal rate for FY 2014 is presented in section V.A. of the Addendum to this proposed rule.)

D. Expiration of Certain Payment Rules for LTCH Services - The 25-Percent Threshold Payment Adjustment

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 payment adjustment threshold policy that expired for some LTCHs and LTCH satellites for cost reporting periods beginning on or after October 1, 2012 (“October” LTCHs) and for other LTCHs and LTCH satellites for cost reporting periods beginning on or after July 1, 2012 (“July” LTCHs). 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), we provided for extensions to the expiring statutory moratoria for both “October” and “July” LTCHs and LTCH satellites.

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 threshold payment adjustment policy for “October” LTCHs, and 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 their 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. But 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 hospital 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). For more details about these moratoriums, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53483 through 53484).

Under current law, the regulatory moratorium on the full application of the 25-percent threshold payment adjustment policy will expire for all LTCHs (both “October” and “July” LTCHs) for cost reporting periods beginning on or after October 1, 2013. As discussed in greater detail below, we do not anticipate further extending the regulatory moratorium of the 25-percent threshold payment adjustment policy. Therefore, LTCHs are encouraged to familiarize themselves with the prior rulemakings that established the adjustments for the various types of LTCHs and LTCH satellites. (We refer readers to the FY 2005 IPPS final rule (69 FR 49205 through 49214) and the RY 2007 LTCH PPS final rule (72 FR 26929). We note that the 25-percent

threshold payment adjustment policy does not apply to “subclause (II)” LTCHs, that is, an LTCH described under section 1886(d)(1)(B)(iv)(II) of the Act as implemented at § 412.23(e)(2)(ii) of the regulations. Subclause (II) LTCHs meeting that definition continue to be exempted from this policy.

While we could propose further extending the regulatory moratoria, we do not believe it would be appropriate to do so. We are allowing the moratoria to expire because we continue to be concerned that LTCHs that admit more than the applicable percentage of patients from a particular referring hospital are, in effect, behaving like step-down units of the referring hospital, and that results in two separate Medicare payments--one to the referring hospital and one to the LTCH--for what we believe should be structured as one episode of care. In light of our duties to protect the fiscal integrity of the Medicare program, we believe that it would be inappropriate to continue to offer the moratoria pending the implementation of the policy outcomes of the research described below. We welcome public comments on this approach.

In section VIII.E. of the preamble of this proposed rule we present interim results of CMS’ research initiatives that have been directed towards studying the different types of patients presently treated at LTCHs, and the potential options for establishing LTCH patient-level criteria. Although we are not proposing any policy changes based on the described research at this time, we indicate that such a policy might obviate the need for the 25-percent threshold payment adjustment policy. Therefore, we are inviting public comments on that possibility.

E. Research on the Development of a Patient Criteria-Based Payment Adjustment under the LTCH PPS

1. Overview

CMS has been researching the development of patient and/or facility-level criteria for LTCHs, as originally recommended by MedPAC in its June 2004 Report to the Congress, “New Approaches in Medicare.” In that report, MedPAC recommended such criteria in the report’s fifth chapter on “Defining long-term care hospitals” (p. 121 through 135). This report is hereinafter referred to as the MedPAC 2004 Report. Section 114(a) of the Medicare, Medicaid, and SCHIP Extension Act (MMSEA) of 2007, which added section 1861(ccc) to the Act, specified certain facility-level criteria for LTCHs. Therefore, we generally focused our subsequent research initiatives on the development of potential LTCH patient-level criteria.

In the FY 2013 IPPS/LTCH PPS proposed rule, we noted that two research projects were currently underway that we believed could potentially result in “... revisions to our payment policies that could render the 25-percent payment adjustment threshold policy unnecessary” (77 FR 28022). In the FY 2013 IPPS/LTCH PPS final rule, we noted that, “. . . [w]e continue to share MedPAC’s concerns regarding the treatment of medically appropriate patients in LTCHs” (77 FR 53485). We quoted MedPAC’s March 2012 Report to Congress, “Medicare Payment Policy,” in which MedPAC noted, “. . .if medically complex cases in LTCHs are, in essence, indistinguishable from medically complex cases in acute care hospitals, then Medicare must ensure that its payments for the same set of services are equitable, regardless of

where the services are provided . . . policymakers must consider whether certain models of care will best serve the needs of medically complex patients. These steps will help ensure that Medicare beneficiaries receive appropriate, high quality care in the least costly setting consistent with their clinical conditions” (77 FR 53485).

We agreed with MedPAC’s assertions, and further noted our ongoing research that focused on determining whether there were some patient-level criteria that could be used to identify patients that are appropriately treated in a LTCH, consistent with their higher costs. At that time we shared our contractors’ preliminary findings that, “...focusing on a subset of patients who are ‘chronically critically ill,’ that is who have been in intensive or coronary care units for a significant period of time at IPPS hospitals immediately preceding the admission to the LTCH may prove to be an important step at this point.” In the final rule we ended our response to the comments received with the following assurance: “[a]s we have in the past, when this research reaches the appropriate stage, we intend to reach out to hospital industry stakeholders for reactions and feedback” (77 FR 53485).

In this proposed rule, we are describing the preliminary findings of this ongoing research that is being 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 believe that this project, in large part, establishes a framework that can potentially be used to empirically identify the population of Medicare beneficiaries who we believe should form the core of LTCH patients appropriate for higher Medicare payments under the LTCH PPS. Although this research

has not been completed, we believe that the preliminary findings suggest that certain types of patients, who are chronically critically ill and considered medically complex, as identified by specific clinical factors, are more appropriate candidates for high-cost treatment at a LTCH than other types of patients. It is worth noting that this is the same population that the LTCH industry in discussions with CMS has repeatedly defined as its target population.

The framework, described below, represents the latest research for refining the LTCH PPS. Historically CMS refinements have included the input of advocates for the LTCH industry and MedPAC, as well as CMS and its contractors. We hope that they will continue to offer their insights to the framework presented below as well, and CMS will continue to take into consideration all stakeholders' input. However, we emphasize that we are not proposing a new payment policy at this time. Rather, we are interested in receiving feedback from the public on the findings of this research study and also on the potential impact that our framework could have on hospital markets with the expectation of formulating a proposal for FY 2015.

In the discussion below, we provide a summary of the research findings, discuss issues presented by our analyses of Medicare data from LTCHs and other hospital-level providers, describe the steps that led to our contractor's findings, and present the resulting framework and our current understanding of the likely impact of this work on the Medicare payment system if we were to implement this framework.

2. MedPAC's 2004 Report to the Congress

Within a year of CMS' implementation of the LTCH PPS, MedPAC noted in its June 2003 Report to the Congress, "Variation and Innovation in Medicare," that, "... LTCH patients have higher mortality rates and Medicare pays more for their care, compared with patients who do not use LTCHs" (p. 71) and "...total payments for LTCH users were 140 to 260 percent of payments for post-acute users in market areas without LTCHs (in 42 out of 44 DRG-severity levels). Death rates were higher for LTCH users compared with post-acute users in markets without LTCHs; this phenomenon may reflect unmeasured severity of illness" (p. 85).

Although the report explicitly stated that MedPAC's findings were drawn from pre-PPS data, MedPAC noted that, "...more research is needed to determine the role that LTCHs play for Medicare patients and to understand quality outcomes in this setting" (p. 87).

The following year, in its June 2004 Report to Congress, "New Approaches in Medicare," MedPAC provided a comprehensive examination of the LTCH universe based upon "...both qualitative and quantitative approaches to answer our key questions regarding the role that LTCHs play, where patients in areas without LTCHs are treated, and the differences in Medicare payments and outcomes for patients who use LTCHs compared to those treated in other settings" (p. 123). (For a detailed description of the methodology and data used in MedPAC's analysis, we refer readers to MedPAC's June 2004 Report to the Congress, p. 121 through 135). MedPAC's analysis resulted in the following findings:

- “In the absence of LTCHs, clinically similar patients are principally treated in acute hospitals or in freestanding SNFs that are equipped to handle patients requiring a high level of care” (p. 127).

- “Medicare should use more precise criteria to ensure that LTCHs treat only appropriate patients. In general, beneficiaries treated in long-term care hospitals cost Medicare more than patients treated in alternative settings; however, if LTCH care is better targeted to those patients who appear to be most suitable for LTCH care, the costs to Medicare are more comparable” (p. 127).

- “...Criteria that limit the types of patients treated in LTCHs may help avoid some of the problems that may result from current payment incentives, growth of the LTCH industry and high payment rates” (pp. 127 and 128).

Based on these and other findings, in that same report MedPAC made the following recommendation as “Recommendation 5A”:

“The Congress and the Secretary should define long-term care hospitals by facility and patient criteria that ensure that patients admitted to these facilities are medically complex and have a good chance of improvement.

- Facility-level criteria should characterize this level of care by features such as staffing, patient evaluation and review processes, and mix of patients.

- Patient-level criteria should identify specific clinical characteristics and treatment modalities” (p. 130).

MedPAC’s 2004 recommendations for the development of patient-level criteria for LTCHs have driven discussion regarding CMS’ policy on Medicare payments to

LTCHs since that time. If LTCHs actually (and appropriately) treated a unique category of patients with specific clinical features, we could justify the larger payments (as compared to alternative care settings) being made under the LTCH PPS. At the same time, the MedPAC Report noted that there were only 350 LTCHs nationwide, and these LTCHs were not dispersed throughout the country in a manner that reflected Medicare beneficiary demographics. In areas without LTCHs, they found that clinically similar patients were treated in acute care hospitals and SNFs (pp. 124 and 125).

3. LTCHs in the Medicare Program

The concerns raised by MedPAC in 2004 have continued as the number of LTCHs has grown by more than 25 percent, from 350 in 2004 to approximately 440 in 2013. The above described geographic pattern appears to have continued with “many LTCHs that have entered the Medicare program ...located in markets where LTCHs already existed instead of in new markets with few or no LTCHs” (MedPAC March 2012 Report to the Congress, “Medicare Payment Policy,” p. 261). For example, there are 38 LTCHs in Louisiana, where there is a beneficiary population of approximately 521,000, in New York State there are 4 LTCHs (all located in the New York City metropolitan area) with a beneficiary population of approximately 2,060,000. (We refer readers to the CMS Web site at: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareMedicaidStatSupp/2011.htm>, Table 2.5). Our 2012 data indicates that less than 2 percent of all Medicare beneficiaries who were hospitalized in CY 2010 were treated in LTCHs. Our 2013 data indicates that New Hampshire, Maine, and Vermont have no LTCHs and the following States have five or fewer LTCHs:

Connecticut, Delaware, Hawaii, Iowa, Idaho, Kansas, Maryland, Minnesota, Montana, Nebraska, New Mexico, New York, Wisconsin, West Virginia, Wyoming, and the District of Columbia. Therefore, the number of LTCHs and their geographic distribution suggest to us that LTCHs are only treating a small percentage of the patients that they have identified as their target population nationwide.

4. CMS' Research: The RTI Report

We awarded a multi-year contract to RTI (from 2004 through 2007) to identify and distinguish the role of LTCHs as Medicare providers. The name of the project was “Long Term Care Hospital (LTCH) Payment System Refinement/Evaluation.”

RTI's reports generated under the LTCH Payment System Refinement/Evaluation project identified noteworthy trends that were developing in the LTCH industry since the introduction of the LTCH PPS, especially in terms of continued development of for-profit LTCHs, substantial increases in Medicare payments to LTCHs, and high LTCH profit margins for for-profit LTCHs under the LTCH PPS. (We refer readers to sections 1, 2, and 5 of the January 2007 “LTCH Payment System Monitoring and Evaluation, Phase II Report,” (hereinafter referred to as the RTI Report). In addition, RTI's findings suggested that LTCHs did not treat a “unique” type of patient (p. 129). As a result, RTI believed that it would be difficult to identify patient-level criteria that differentiated a LTCH patient from patients receiving care in other provider settings, particularly in general acute care hospitals due to the non-unique nature of the LTCH patient (p. 133).

RTI based these conclusions on an extensive and careful analysis of the Medicare populations served by LTCHs during 2004, and a comparison of these

populations with those treated in other acute care settings, including IPPS, IRFs, IPFs, as well as those treated in less intensive settings such as SNFs. This analysis was further informed through the input from site visits and interviews with health professionals and hospitals. In addition, RTI contacted different stakeholder associations, including national hospital and quality review organizations, associations representing LTCHs (including one association that primarily represents non-profit LTCHs), and representatives of several of the larger LTCH chains. Through these organizations and others, RTI also sought input from physicians, nurses, and hospital administrators representing, in addition to LTCHs, acute care hospitals, IRFs, and “high-acuity” SNFs, that treat the “type” of patient who is treated in LTCHs and as inpatients in other provider settings. These individuals formed two RTI-convened technical expert panels (TEPs) that met in early 2007. Both TEPs generally agreed that LTCHs specialize in treating many of the types of patients they admit, and noted that having a high volume of these intensively ill patients was a driver for their successful outcomes. However, it was additionally noted that these medical services are also provided in general acute care hospitals, particularly in ICU step-down units. Therefore, while LTCHs may specialize in a select group of intensively ill patients, they were not the only providers to successfully provide these treatments. For more information on the TEPs, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26947 through 26948).

The Phase I and Phase II reports on RTI's research were summarized in our RY 2009 LTCH PPS proposed rule (73 FR 5374 through 5376) and have been posted under the "RTI reports" tab on the CMS Web site at:

http://www.cms.hhs.gov/LongTermCareHospitalPPS/02a_RTIREports.asp#TopOfPage.

Of key significance in the discussion of the role of LTCHs under the Medicare program was our data-based assertion that we included in our RY 2008 LTCH PPS final rule that, "[a]cross the United States, the over 3,700 acute care hospitals that discharge approximately 13 million Medicare beneficiaries treat the full range of medical issues including those that the commenters identify as LTCH cases," as compared to the 130,000 LTCH discharges that occurred during FY 2005. This Medicare data challenged the LTCH-industry commenters who believed that acute care hospitals paid under the IPPS do not and cannot deal with the medical conditions in which LTCHs specialize, and that patients remaining in general acute care hospitals rather than being transferred to LTCHs would receive "substandard care" (72 FR 26940). Several commenters argued that general acute care hospitals were "just not capable" of delivering the level of care required by typical LTCH patients. CMS responded to a number of these commenters by stating that, while "[w]e do not question that many LTCHs have highly regarded reputations for their success in treating respiratory and ventilator cases (DRG 475) but . . . the 2004 MedPAR files indicate that [while] LTCHs treated 13,394 cases assigned to DRG 475 [which codes for respiratory system diagnosis requiring ventilator support], acute care hospitals treated 18,727 Medicare patients [assigned to DRG 475

and] an additional 7,072 [that qualified for high cost outliers (HCOs) who were assigned to]DRG 475. For DRG 88, chronic obstructive pulmonary disease (COPD), LTCHs treated 4,894 cases [and] acute care hospitals treated 37,523 cases. Data on other common DRGs treated in LTCHs as compared to the same DRG treated in acute care hospitals reflect a similar pattern, particularly among the DRGs that could fall into the broad category of “medically complex” patients” (72 FR 26940 and 26041).

5. CMS’ Report to Congress: Determining Medical Necessity and Appropriateness of Care for Medicare Long-Term Care Hospitals

In 2007, Congress imposed LTCH facility and patient-level criteria research and reporting obligations on the Secretary under section 114(b) of the Medicare and Medicaid State Children’s Expansion Act of 2007 (MMSEA) (Pub.L. 110-173). The statute specified that:

“(1) In general.--The Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall conduct a study on the establishment of national long-term care hospital facility and patient criteria for purposes of determining medical necessity, appropriateness of admission, and continued stay at, and discharge from, long-term care hospitals.

(2) Report.--Not later than 18 months after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under paragraph (1), together with recommendations for such legislation and administrative actions, including timelines for implementation of patient criteria or other actions, as the Secretary determines appropriate.

(3) Considerations.--In conducting the study and preparing the report under this subsection, the Secretary shall consider--

(A) recommendations contained in a report to Congress by the Medicare Payment Advisory Commission in June 2004 for long-term care hospital-specific facility and patient criteria to ensure that patients admitted to long-term care hospitals are medically complex and appropriate to receive long-term care hospital services; and

(B) ongoing work by the Secretary to evaluate and determine the feasibility of such recommendations.”

In fulfillment of this statutory mandate, in 2008 CMS' Office of Research, Development, and Information (ORDI), which is now part of the Center for Medicare and Medicaid Innovation (the Innovation Center), awarded a contract to Kennell and Associates and their subcontractor RTI for additional analysis of data on Medicare payments and facility costs for the treatment of similar patients in LTCHs and alternative providers, as well as an analysis of patient outcomes and the range of hospital-level care delivered in each setting. In accordance with section 114(b) of the MMSEA, Kennel/RTI was tasked with, among other things, considering MedPAC's June 2004 recommendations in their research, as well as "...ongoing work by the Secretary to evaluate and determine the feasibility of such recommendations..." as they researched and developed the 2011 Report to Congress (73 FR 26829).

In March 2011, we submitted our CMS Report to Congress, "Determining Medical Necessity and Appropriateness of Care for Medicare Long Term Care Hospitals," (hereinafter referred to as the 2011 Report to Congress) on the development

of LTCH patient and facility-level criteria as required by section 114(b) of the MMSEA. The MMSEA-mandated 2011 Report to Congress concluded that, "...the Secretary does not recommend the development of additional patient and facility-level criteria for LTCHs at this time." The research offered the following support for the Secretary's conclusion:

- "An examination of Medicare quality review contractors indicated that patients who are more appropriate for treatment at LTCHs than at other postacute care facilities have multiple comorbidities and require an intense level of care with frequent physician and nurse visits.

- The two most important factors in predicting LTCH admission are:
(1) proximity to an LTCH; that is, whether the beneficiary lived in a state where many LTCHs were available; and (2) severity of illness.

- There were no differences in average outcomes between episodes from areas that have high LTCH use and those that do not.

- For the most medically complex ventilator patients, Medicare payments were the same or lower, mortality was lower, and the chance of being discharged to home was higher than those remaining in acute care settings. However, among the least complex ventilator patients, Medicare payments were much higher, hospital stays were longer, and all other outcome measures were the same or worse for those referred to LTCHs versus those remaining in acute care settings. This finding supports previous research by MedPAC that LTCHs may provide beneficial and cost-effective services for a subset of complex patients, but not for all types of patients admitted to these hospitals.

- An LTCH admission was associated with a shorter length of stay in the general acute care hospital, on average, and controlling for a number of factors, including age, gender, number of comorbid conditions, and critical care use. ... [A]t least for some patients, ... LTCH care may be substituting for what would normally be provided in the later days of an acute care hospital stay.

- Between 40 to 45 percent of all LTCH admissions qualify for a payment reduction as a “short-stay outlier”. This means that payments for these cases are reduced if the length of stay is substantially less than the average length of stay for a given LTCH-DRG. A high percentage of short-stay cases in a payment system designed for long-stay patients highlight the complexity in discerning which patients are appropriate for admissions to LTCHs.

- The RTI Technical Expert Panel (TEP) reached a consensus that LTCHs provide a service that is comparable to general acute step-down units and is not unique to LTCHs. Discussions with LTCH physicians and acute care hospital physicians practicing in areas that lack LTCHs confirmed that there is an overlap in the patient populations treated in LTCHs and in acute care. Critical care post-ICU patients whom LTCHs describe as their targeted population are treated throughout most of the country in acute care hospital step-down units.

- The TEP acknowledged that Medicare patients with respiratory conditions requiring mechanical ventilation comprise less than 15 percent of all LTCH patients. Thus, these patients insufficiently define which critically ill patients with complex medical conditions should be treated at LTCHs. It was not clear that any criteria can be

developed which identifies patients who belong in a LTCH exclusively” (2011 Report to Congress, pp. 6 and 7).

Regarding the establishment of facility-level criteria for LTCHs, the report noted the specific LTCH facility requirements established by section 114(a) of the MMSEA and stated that “CMS believes that these facility-level standards should improve the quality of care at LTCHs and has no plans for additional facility-level standards. CMS acknowledges that while these new requirements represent new standards for care provision, facility-level standards will be of very limited value in determining the appropriateness of patients for LTCH care” (2011 Report to Congress, pp. 10 and 11). The 2011 Report to Congress, which is entitled “Determining Medical Necessity and Appropriateness of Care for Medicare Long-Term Care Hospitals,” may be found on the CMS Website at: <http://www.cms.gov/officeoflegislation/downloads/RTC-long-term-care-hospitals-final.pdf>. Our contractors’ research findings can also be found in Appendix A of the 2011 Report to Congress.

Research on the development of patient and facility-level criteria for LTCHs, as summarized above, indicated the absence of any empirical findings indicating an exclusive or unique “LTCH patient.” Rather, as noted in the 2011 Report to Congress, “[f]ollowing the direction of MedPAC and the RTI TEP panels, CMS concurs with the view that LTCHs are appropriate providers for treating severely ill, **but medically stable**, patients with complex medical conditions. However, additional analysis of Medicare data across provider types is key in helping to formulate a clinically-based description of critically ill, medically complex patients” (2011 Report to Congress, pp. 11 and 12).

The Secretary also noted that additional follow-up research that CMS was sponsoring would update and refine our understanding of Medicare LTCH patients and payments. This research effort was part of the Post-Acute Care Payment Reform Demonstration (PAC-PRD), a separate initiative and report to Congress mandated by section 5008 of the Deficit Reduction Act (DRA) of 2005 (Pub. L. 109-171), and collected standardized patient assessment information using the Continuity Assessment Record and Evaluation (CARE) tool, which had been designed to be administered to patients in all acute and post acute care settings with the goal of developing consistent measures for case-mix adjustment. The 2011 Report to Congress indicated that, “[o]ngoing research using the CARE tool should facilitate CMS’ efforts to empirically define types of chronic, complex medical conditions that currently receive treatment in both general acute care hospitals and LTCHs.” To this end, the 2011 Report to Congress noted, “CMS is currently funding contract research to use the CARE tool to collect suitable patient-level clinical data to better identify chronic, critically ill patients. CMS is also currently funding research to develop payment models that would pay for these patients’ care reasonably and appropriately in LTCHs or any other site of care” (2011 Report to Congress, pp. 12 and 13).

The data collected using the CARE tool from the PAC-PRD project represent a significant new benchmark in capturing clinical patient-level data to measure outcomes, quality of care, and performance at LTCHs and other provider settings treating similar conditions. Previously, claims data was the only clinical information available to inform RTI’s LTCH research from 2004 through 2007. The data collected using the CARE tool

has allowed Kennell/RTI's follow-up research to evaluate "types of chronically ill patients with complex medical conditions, regardless of provider setting" and "to measure outcomes, quality of care and performance at LTCHs and other providers treating similar clinical conditions" (2011 Report to Congress, p. 12).

For additional information on the PAC-PRD report to Congress and for the CARE tool, we refer readers to: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Flood_PACPRD_RTC_CMS_Report_Jan_2012.pdf and http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/GAGE_PACPRD_RTC_Supp_Materials_May_2011.pdf.

In response to the established need for additional research on the key findings of the MMSEA-mandated Report to Congress, CMS extended its research contract with Kennell/RTI to utilize the clinical data provided by the CARE tool, as described above, and to examine payment issues associated with chronically critically ill and medically complex patients with long-term hospital needs. Kennell/RTI was also tasked with developing a robust clinical definition of the subgroup of chronically critically ill and medically complex patients identified as appropriate for treatment in both LTCHs and general acute care hospitals in order to allow for the evaluation of appropriate payment policies for the various settings in which patients are treated. (We refer readers to Appendix A of the 2011 Report to Congress, p. 79 through 86, for details on this follow-up research under the "Medical Necessity and Appropriateness of Care" contract for the

“Long Term Care Hospitals and the Chronically Critically Ill Population Payment Recommendations” (CCIP-PR.)

These additional recent research initiatives were focused on evaluations of clinical data on chronically critically ill Medicare beneficiaries. The variations in provider costs and the resulting Medicare payment differentials for treating these patients in different provider settings were also evaluated.

6. Current Patterns in LTCHs

Kennel/RTI’s follow-up research to the 2011 Report to Congress studied trends in LTCH utilization based on 100 percent of the MedPAR data files for LTCH claims for 2004, 2006, 2008, and 2010 provided the context and the foundation for the framework discussed below. This work indicated the following facts about LTCHs:

- LTCHs and LTCH use has expanded significantly.
 - Between calendar year 2004 and 2010: number of LTCHs grew from 369 to 443 (+20%)
 - The number of LTCH discharges grew from 125,000 to 141,000 (+13%)
 - Medicare LTCH-PPS payments grew from \$3.7 billion to \$5.2 billion (+41%)
- LTCH patients are becoming more complex:
 - more complex LTC-DRG types being admitted to LTCHs in terms of the relative value weights of the MS-LTC-DRGs used.
 - higher mix of severity within LTC DRGs in terms of the percent of patients with an MCC level of comorbidity status.
 - higher mix of severity within referral IPPS DRGs

- increasing proportion of patients admitted with critical care in their prior IPPS stay
- taken together, the evidence suggests real change in case mix, over and above any behavioral changes in coding
- It should be noted that these trends began well before the 2008 implementation of the MS-LTC-DRG system.
 - LTCH use is associated with *substantial* increases in:
 - combined IPPS + LTCH PPS payments
 - of combined IPPS + LTCH PPS costs
 - total episode inpatient days

Furthermore, RTI found that respiratory conditions (including mechanical ventilation, respiratory infections, pulmonary edema and respiratory failure), increased as a share of LTCH admissions from less than 20 percent in 2004 to almost 30 percent in 2010. The share of admissions for septicemia more than doubled, and the percentage of admissions for osteomyelitis nearly doubled. Other less complex conditions that accounted for a relatively large share of LTCH claims in CY 2004 declined rapidly. For example, the percentage of LTCH admissions for degenerative nervous system disorders and rehabilitation fell by more than half and the percentage of admissions for musculoskeletal and other types of aftercare fell by half. The number and percentage of patients with heart failure and shock and with COPD also declined. The percentage of admissions for wound and skin conditions (including cellulitis, skin graft and debridement, and wound debridement) did not change. Over this period, Medicare data

indicated that LTCH case-mix has become more concentrated in complex respiratory care and treatment of certain types of complex infections.

Medicare data also reveals changes in levels of severity both overall and within the conditions (or base DRG families) of LTCH admissions since the start of the LTCH PPS. The percentage of admissions assigned to MS-LTC-DRGs with major complications or comorbidities (MCCs) increased from 37 percent to 61 percent over the study period, and the percentage of patients assigned to any of the single-severity ventilator DRGs increased from 12 percent to 16 percent over the study period. Complications or comorbidities (CCs) that did not rise to the level of MCCs had accounted for 39 percent of LTCH admissions in CY 2004, but only 20 percent in CY 2010. MS-LTC-DRGs with no CCs fell from 9 percent to 2 percent. Finally, Kennell/RTI found that the shift toward higher severity levels is evident not only within more complex conditions where the patient load is increasing, but also within the less complex conditions where the relative patient load has been declining. In summary, since the implementation of the LTCH PPS in FY 2003 there have been significant changes in LTCH case-mix and severity within case-mix.

A comparison of MedPAR data from CY 2006 to CY 2010 also indicated that an increasing proportion of the patients transferred to LTCHs had received critical care services at an IPPS hospital immediately prior to their LTCH admission. The number of such individuals rose from 54.9 percent to 58.5 percent of transfers. The number of individuals with at least one week of critical care in an IPPS hospital immediately prior to their LTCH admission also rose from 36.2 percent to 38.8 percent of transfers; and the

number of individuals who were discharged directly from critical care to a LTCH (having spent no time in general hospital routine units) rose from 25.2 percent to 30.3 percent of transfers.

As a result, Kennell/RTI reported that, for purposes of understanding the most efficient use of Medicare resources in LTCHs and other provider settings for high acuity patients, with a focus on LTCHs, a primary step is an analysis of the spectrum of patients in LTCHs, with the chronically critically ill at one end, who overlap with hospital critical care and account for anywhere from a third to a half of the LTCH Medicare admissions continuum, and patients who may be approaching sub-acute levels of need at the other end. Kennell/RTI found that the potentially sub-acute level of care patients could account for as much as 15 to 20 percent of LTCH Medicare admissions.

Range of Levels of Required Care and Overlap of Institutions Providing That Care

Level of Required Care	Critical	Acute	Sub-acute	Skilled nursing	Non-skilled nursing
Institution Type:					
IPPS	-----				
LTCH		-----			
SNFs				-----	
Subacute/Hospital based SNFs			-----		

The chart above is useful for visualizing the observed patient acuity levels associated with various treatment sites under Medicare. It should be noted that these ranges do not necessarily represent desired or even appropriate levels of care within a setting.

While the data generally revealed an acuity continuum, RTI also developed three “categories” of patients in order to simplify presentation of their findings. The chart below summarizes RTI’s findings for these three acuity groups for LTCH patients treated in FYs 2004, 2006, 2008, and 2010:

Three LTCH Populations

Post-ICU and Chronic Critical Care		Low-acuity / Sub-acute
<p>Growing share Anywhere from 35% -50% of admissions</p>	<p>others – Continuing complex medical issues</p> <p>---- A residual category ----</p> <p>Patients could be transfers from routine or intermediate care units</p> <p>Complex medical needs including infections, surgical aftercare, wounds, multiple co-morbidities; also routine ventilator care.</p> <p>Continued need for routine-level nursing and daily physician care, some consults</p>	<p>Declining share Recently 15-20% admissions</p>
<p>Examples: Direct ICU transfers</p> <p>Mechanical ventilation – recent history of PMV, w/trach or recently weaned but with multiple comorbidities; Stable but still on pressors or other drips; Multiple organ failure and/or multiple infections.</p> <p>Continued need for critical/ intermediate - level nursing ratios & daily physician care w/ specialty consults</p> <p>DRG mix is changing toward increasing PMV and other complex respiratory</p>		<p>Examples: Routine unit transfers</p> <p>Surgical aftercare without multiple organ failure. Combinations of multiple IV management, wound care and rehabilitation.</p> <p>Patients needing complex nursing but possibly not daily physician care.</p> <p>Low-acuity DRG mix is changing – fewer rehab and organic brain syndrome cases, more infections, cellulitis, skin ulcers, other aftercare, COPD</p>

|----- Some overlap in LTC-DRGs -----|

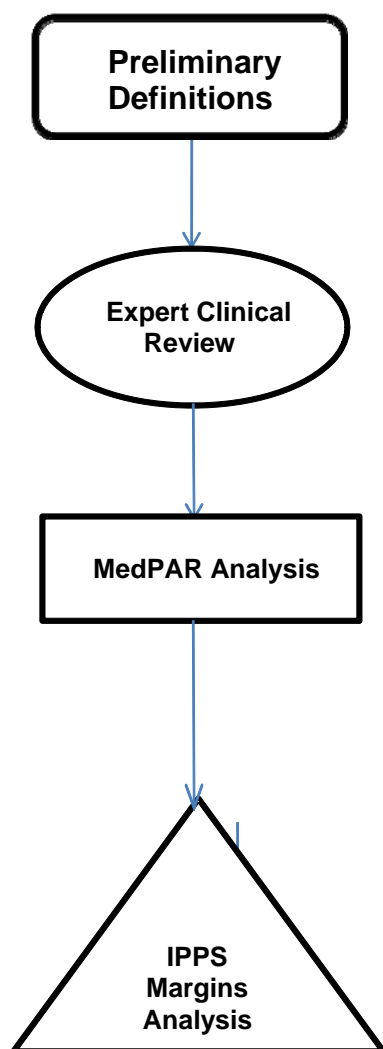
|----- Some overlap in LTC-DRGs-----|

7. Identification of Chronically Critically Ill/Medically Complex (CCI/MC) Patients

As noted above, CMS extended its research contract with Kennell/RTI following CMS’ issuance of the 2011 Report to Congress in order to develop a robust definition of the group of patients who our research confirmed could be appropriate for treatment at

LTCHs and higher payments under the LTCH PPS – that is, those who are chronically critically ill and medically complex (CCI/MC). We also tasked RTI in the CCIP-PR contract with the examination of any payment issues across provider settings that might be associated with CCI/MC patients with long-term hospital treatment needs.

The diagram below (which we discuss further below) illustrates the steps taken by Kennell/RTI to determine and refine the CCI/MC definition.



The first step illustrated in the chart above represents Kennell/RTI's further evaluation of the materials in Appendix A of the 2011 Report to Congress. Next, Kennel/RTI brought in several clinical consultants to provide feedback on those initial definitions. These experts suggested refinements to the clinical characteristics that could be used to describe CCI/MC patients in our request for RTI to examine clinical factors/conditions that are related to very long IPPS hospital or IPPS hospital plus LTCH treatment episodes, as well as factors related to long ICU stays that had not been included in the initial definitions found in Appendix A of the Phase II Report. We were particularly interested in identifying patients with certain conditions that regularly exceeded the average length of stay for MS-DRGs or that routinely became IPPS outliers.

In general, these clinical consultants agreed that the initial definitions provided in Appendix A of the Phase II Report gave an appropriate range of clinical conditions that could be used to define CCI/MC. However, they suggested some specific changes as well which, if accepted, would lead us to consider changes to some of the clinical conditions that we would want to include in our own eventual definition of CCI/MC. For example, based on feedback from the clinical consultants, we would add stroke, brain hemorrhage, and traumatic brain injury to the list of organ failure codes. We would also add leukemia and lymphoma as organ failures. Other suggestions would lead us to remove codes from the organ failure category. For example, we would remove chronic kidney disease and early stage pressure ulcers.

To confirm whether the changes in clinical characteristics recommended by the clinical consultants would identify long-staying and high-cost patients, Kennell/RTI used

a 2009 MedPAR data set to analyze the clinical consultants' recommendations related to episode lengths of stay, costs, and prevalence of the condition. This 2009 data set included index IPPS stays and additional institutional stays during the episode of care. We found that the data supported the clinical suggestions, and that patients diagnosed with lymphoma and leukemia did have long median general acute care hospital lengths of stay. Patients with Stage III and IV pressure ulcers and congestive heart failure (unspecified) were included in the data, and the MedPAR analysis confirmed the inclusion of primary and secondary diagnoses of stroke, brain hemorrhage, and traumatic brain injury.

Kennell/RTI also analyzed margins for Medicare payments to IPPS hospitals for those cases that met the preliminary definitions, including those with wounds, sepsis, multiple organ failure, and prolonged mechanical ventilation. As a result of these and additional evaluations, preliminary findings from Kennell/RTI's project "Chronically Critically Ill Population Payment Reform (CCIP-PR)" identified CCI/MC patients generally as:

- Requiring extended intensive care unit or critical care unit (ICU or CCU) stays in IPPS hospitals;
- Having high Medicare payments; and
- Having diagnoses including such factors as the presence of sepsis, prolonged mechanical ventilation (PMV), and multiple organ failure.

Specifically, Kennell/RTI's research defines CCI/MC patients as representing a population that is clinically variable in the presentation of its underlying disorders, yet definable in its final patterns of intensive service needs.

MedPAC came to similar conclusions in their March 2012 Report to Congress. In that report, they highlighted a definition of chronically critically ill patients, which was originally proposed by Nierman and Nelson in 2002, that noted "...the chronically critically ill patient exhibited metabolic, endocrine, physiologic, and immunologic abnormalities that resulted in profound debilitation and often ongoing respiratory failure, abnormalities that slowed or precluded recovery from a wide range of acute forms of medical, surgical, and neurologic critical illness" (pp. 273 and 274).

Kennell/RTI's follow-up research findings confirmed that a distinction can be drawn between chronically critically ill patients and patients who may need extended acute care, but do not require critical care. The medically complex (MC) patients are generally medically compromised (due to, for example, multiple comorbidities) and they may have prolonged care needs for surgical aftercare, wounds, or infections, but do not require long periods of mechanical ventilation and do not otherwise fit Kennell/RTI's understanding of the clinical profile of CCI/MC patients. These patients may require hospitalization over several weeks or even months due to medical complexities in their care protocol that require acute-level nursing, but they have either not needed intensive-care nursing or have progressed from intensive to less intensive nursing care needs. However, both groups have a need for continued hospital-level care that can be met either through continued treatment in the initial acute care hospital or by a transfer to

a LTCH or other provider setting. As noted, our research has indicated that the Medicare costs of delivering care to such patients in the various settings that could meet their treatment needs varies widely. Moreover, our most recent Kennell/RTI research findings indicate that, although LTCHs are admitting an increasing number of chronically critically ill patients and an increasing number of patients with prior critical care stays in the general acute care hospital, the majority of LTCH cases during the years evaluated do not fit the operational definition of CCI/MC patients or even medically complex, high acuity patients.

8. LTCH PPS Payments for CCI/MC Patients

In summary, research sponsored by CMS under the original RTI contract (awarded from 2004 through 2007), findings from the PAC-PRD Report to Congress, the 2011 Report to Congress, and Kennell/RTI's follow-up research under the CIPP-PR study, as well as findings in historic and recent MedPAC Reports to Congress, have led us to believe that there are specific factors that can be used to identify the CCI/MC patient population, which can, in turn, be used to provide a robust definition for the core group of patients that we believe are appropriate for treatment at LTCHs and payment under the LTCH PPS. Furthermore, as CMS and its contractors evaluated Medicare claims and utilized the information derived from the application of the CARE tool across treatment settings to further analyze the care needs of this unique group, we have determined that our CCI/MC definition would capture a distinct subset of patients with consistent and significant negative margins when treated by general acute care hospitals paid under the Medicare IPPS -- a phenomenon that generally does not appear to be

evident for other long-stay medically complex cases that are treated in the IPPS hospital setting.

As noted above, CMS wants to ensure that LTCHs treat the most appropriate patients given the comparatively high payments in this provider setting. While the original MedPAC recommendation that we develop LTCH-specific patient-level criteria has evolved somewhat over time, we believe we can identify CCI/MC patients as potentially appropriate for treatment in the LTCH setting. MedPAC's and CMS' data analyses have indicated that financial forces in the IPPS context may be encouraging the transfer of these and other high-cost cases to LTCHs, but the non-CCI/MC patients may not receive cost-effective care in the LTCH setting. Therefore, we are outlining potential revisions of the LTCH PPS that would be aimed at encouraging the LTCH industry to admit patients fitting the CCI/MC profile to ensure that such patients frame LTCHs' "core" patient populations. We believe that the potential revisions to the LTCH PPS, which are described below would encourage LTCHs to refocus their admissions policies on serving medically stable but high-acuity patients.

The research suggests that, for purposes of this discussion, we consider CCI/MC patients to be those with the specific characteristics described below. A system that would identify CCI/MC patients would facilitate limiting the full LTCH PPS payment to patients who meet this definition of CCI/MC while they were in an IPPS hospital inpatient setting if they are subsequently directly admitted to a LTCH. CCI/MC status would be used to identify patients as they are discharged from an IPPS hospital and then transferred to a LTCH. We could also apply an adjustment to LTCH payments for non-

CCI/MC patients, that is, patients who by definition would not be most appropriate for treatment in a LTCH. Payment for non-CCI/MC patients would be made at an “IPPS comparable amount,” that is, an amount comparable to what would have been paid under the IPPS calculated as a per diem rate with total payments capped at the full IPPS MS-DRG payment rate.

The research suggests that a patient would be identified as a CCI/MC patient in the IPPS setting based on having one or more of the five clinical factors listed in the table below, combined with a stay of 8 or more days in an ICU/CCU at an IPPS hospital. The CCI/MC patient definition would be used to identify patients as they are discharged from an IPPS hospital and then transferred to a LTCH.

Five Critically Ill/Medically Complex Status Clinical Factors
Prolonged Mechanical Ventilation (PMV)
Tracheotomy
Multiple Organ Failure/Stroke/Intercerebral Hemorrhage/TBI
Sepsis and Other Severe Infections
Severe Wounds

The CCI/MC patient population discussed above have been shown to have intensive service needs, high costs, and negative margins in IPPS hospitals. In addition, these patients typically have a predictable and consistent need for extended hospital-level care that can be met either from continued stays in the initial IPPS hospital in a step-down unit after ICU or CCU treatment, or through transfer to a LTCH.

When the LTCH PPS was implemented in FY 2003, length of patient stay was considered a proxy measure for resource use. MedPAC’s early research findings,

subsequently confirmed by our researchers, however, provided clear evidence that without knowing the mix of routine or critical care days, length of stay was not a reliable proxy for patient acuity. As noted above, Medicare data indicates that LTCHs treat many patients with very long episode stays that did not meet the CCI/MC criteria. Under section 1886(d)(1)(B)(iv)(I) of the Act, a LTCH is an acute care hospital with an average length of stay of greater than 25 days. Therefore, under current law, an LTCH may treat even short-stay, non-critically ill patients as long as it maintains an average length of stay that exceeds 25 days. However, under this framework an adjusted LTCH PPS payment equal to the “IPPS-comparable” amount could be paid to a LTCH for those patients admitted to the LTCH without meeting the CCI/MC designation -- that is, an amount comparable to what would have been paid under the IPPS calculated as a per diem rate with total payments capped at the full IPPS MS-DRG payment rate.

We anticipate that if the payment policy is revised consistent with the framework discussed above, the industry could make adjustments to their admission and referral practices, and the mix of patients admitted to LTCHs would change significantly. Furthermore, our data discussed above detailing significant changes in LTCH admission practices since the start of the LTCH PPS would appear to indicate that LTCHs are already slowly revising their practices by admitting more critically ill patients. We are inviting public comments on whether such a policy could obviate the need for the “25-percent threshold payment adjustment policy.” In the future, if LTCHs begin to focus on treating CCI/MC patients, based on our research we believe that the Medicare

program would be purchasing specialized and cost-effective services when making payment for these defined CCI/MC patients.

We believe that the potential policy changes discussed above are consistent with a significant body of research, which identifies the CCI/MC patient criteria as a useful indicator of an appropriate LTCH admission. Furthermore the CCI/MC criteria would appear to identify the patients that LTCHs have asserted in their discussions with CMS that they are best equipped to treat.

Although Kennell/RTI's research is not yet completed, we want to note that we believe that the findings from the LTCH research over the past decade, culminating in the payment policy discussion we have outlined, is consistent with MedPAC's June 2004 Report to Congress' recommendations. As discussed earlier, in that report the Commission recommended that CMS develop LTCH criteria that would result in identifying those patients whose conditions would justify Medicare's payments under the LTCH PPS and ultimately dissuade LTCHs from treating those patients who did not meet the criteria. As described above, the advent of the CARE tool significantly extended the depth and range of our prior research initiatives. By utilizing data from the CARE tool, in addition to the research methodology specified above, to identify the CCI/MC population, we believe that we have established a robust set of patient-level criteria for Medicare payment in LTCHs and have responded to MedPAC's concerns.

Finally, we note that at both its January 11, 2013 and April 5, 2013 public meetings MedPAC discussed three "policy options" to "improve payment for chronically ill beneficiaries" that are also based in part on the use of ICU services as a defining

characteristic of these CCI/MC patients. The first option offered by MedPAC would “remove the LTCH designation and pay for cases under a modified IPPS, which would include changes to the current IPPS high-cost outlier policy. The IPPS modifications would improve payment accuracy for very costly CCI patients.” A second option builds on the first by also breaking out CCI patients into separate MS-DRGs with higher payment relative weights. The third option would bundle expected post acute care costs into the new CCI MS-DRGs so that the hospital would be responsible for associated LTCH or SNF care for CCI/MC patients. MedPAC noted that more details of these options would be presented in “the coming months.” We will continue to analyze MedPAC’s work and future recommendations. (Additional information on these public meetings, including transcripts, are available on MedPAC’s Web site:

<http://www.medpac.gov/meetings.cfm>.)

We will post final reports on Kennell/RTI’s follow-up research on the CMS Web site as soon as they are completed. As previously noted, we are eager to receive public comments regarding this discussion of the research and the development of a patient criteria-based payment adjustment under the LTCH PPS as well as on the impact of such a proposal on hospital markets in advance of a policy proposal that we are expecting to include in the FY 2015 IPPS/LTCH PPS proposed rule in the spring of 2014.

IX. Proposed Quality Data Reporting Requirements for Specific Providers and Suppliers

CMS is seeking to promote higher quality and more efficient health care for Medicare beneficiaries. This effort is supported by the adoption of widely agreed-upon quality measures. CMS has worked with relevant stakeholders to define measures of quality for most settings and to measure various aspects of care for most Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, and, increasingly, outcomes.

CMS has implemented quality reporting programs for multiple settings of care, 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,

- Hospices, under the Hospice Quality Reporting Program.

CMS has also implemented an end-stage renal disease quality improvement program (76 FR 628 through 646) that links payment to performance.

In implementing the Hospital IQR Program and other quality reporting programs, we have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries. Our goal for the future is to align the clinical quality measure requirements of the Hospital IQR Program with various other Medicare and Medicaid programs, including those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act, so that the burden for reporting will be reduced. As appropriate, we will consider the adoption of measures with electronic specifications, so that the electronic collection of performance information is part of care delivery. Establishing such a system will require

interoperability between EHRs and CMS data collection systems, additional infrastructural development on the part of hospitals and CMS, and the adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. However, once these activities are accomplished, the adoption of many measures that rely on data obtained directly from EHRs will enable us to expand the Hospital IQR Program measure set with less cost and burden to hospitals. We believe that in the near future, automatic collection and reporting of data elements for many measures through EHRs will greatly simplify and streamline reporting for various CMS quality reporting programs, and that hospitals will be able to switch primarily to EHR-based reporting of data for many measures that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

We have also implemented a Hospital Value-Based Purchasing (VBP) Program under section 1886(o) of the Act. In 2011, we issued the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547). We adopted additional policies for the Hospital VBP Program in section IV.B. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51653 through 51660), in section XVI. of the CY 2012 OPPI/ASC final rule with comment period (76 FR 74527 through 74547) and in section VIII.C. of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53567 through 53614). Under the Hospital VBP Program, hospitals will receive value-based incentive payments if they meet performance standards with respect to measures for a performance period for the fiscal year involved. The measures under the Hospital VBP Program must be selected from the measures

(other than readmission measures) specified under the Hospital IQR Program as required by section 1886(o)(2)(A) of the Act.

In selecting measures for the Hospital IQR Program, we are mindful of the conceptual framework of the Hospital VBP Program. Section 1886(o)(2)(B)(i)(I) of the Act states that for FY 2013, the selected measures for the Hospital VBP Program must cover at least the following five specified conditions or procedures: Acute myocardial infarction (AMI), Heart failure (HF), Pneumonia (PN), surgical care, as measured by the Surgical Care Improvement Project (SCIP), and Healthcare-Associated Infections (HAIs), as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent HAIs (or any successor HHS plan). Section 1886(o)(2)(B)(i)(II) of the Act provides that, for FY 2013, measures selected for the Hospital VBP Program must also be related to the Hospital Consumer Assessment of Healthcare Providers and Systems survey (HCAHPS).

The Hospital IQR Program is linked with the Hospital VBP Program because the measures and reporting infrastructure for both programs overlap. We view the Hospital VBP Program as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare 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. As we stated in the Hospital Inpatient VBP Program proposed rule (76 FR 2455), we applied

the following principles for the development and use of measures and scoring methodologies:

- Public reporting and value-based payment systems should rely on a mix of standards, process, outcomes, and patient experience of care measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcome and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.
- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across public reporting and payment systems under Medicare and Medicaid. The measure sets should evolve so that they include a focused core set of measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider.
- The collection of information should minimize the burden on providers to the extent possible. As part of this effort, we will continuously seek to align our measures with the adoption of e-specified measures, and reporting of quality data via Certified Electronic Health Record Technology (CEHRT), so the electronic collection of performance information is part of care delivery.

- To the extent practicable, measures used by CMS should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

We also view the Hospital-Acquired Condition (HAC) payment adjustment program authorized by section 3008 of the Affordable Care Act and the Hospital VBP Program as 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 program established by section 3008 of the Affordable Care Act, the HAC Reduction Program, creates a payment adjustment resulting in payment reductions for the lowest performing hospitals based on their rates of HACs. Proposals for the HAC Reduction Program are included in section V.I. 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 V.H., the Hospital VBP Program.
- In section IX.A., the Hospital IQR Program.
- In section IX.B., the PCHQR Program.
- In section IX.C., the LTCHQR Program.

- In section IX.D., the IPFQR Program.

In addition, in section IX.E. of the preamble of this proposed rule, we are proposing changes to the Electronic Health Record Incentive Program and meaningful use.

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background

a. History of Measures Adopted for the Hospital IQR Program

We refer readers to the FY 2010 IPPS/RV 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 2013 IPPS/LTCH PPS final rule (77 FR 53503 through 53555) for the measures we have adopted for the Hospital IQR measure set through FY 2016.

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 <https://www.QualityNet.org>. We generally update the Specifications Manual on a semiannual basis and include in the updates detailed instructions and calculation algorithms for hospitals to use when collecting and submitting data on required measures. These semiannual updates are accompanied by notifications to users, providing sufficient

time between the change and the effective date in order to allow users to incorporate changes and updates to the specifications into data collection systems. We will provide ICD-9 to ICD-10 crosswalks for the measure specifications in the manual for preview and comment in the July 2013 manual release.

The technical specifications for the HCAHPS patient experience of care survey are contained in the current HCAHPS Quality Assurance Guidelines manual, which is available at the HCAHPS On-Line Web site, <http://www.hcahpsonline.org>. We maintain the HCAHPS technical specifications by updating the HCAHPS Quality Assurance Guidelines manual annually, and include detailed instructions on survey implementation, data collection, data submission and other relevant topics. As necessary, HCAHPS Bulletins are issued to provide notice of changes and updates to technical specifications in HCAHPS data collection systems.

Many of the quality measures used in different Medicare and Medicaid reporting programs are endorsed by the National Quality Forum (NQF). The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other healthcare stakeholder organizations. The NQF was established to standardize healthcare quality measurement and reporting through its consensus development process. As part of its regular maintenance process for endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and

will confirm existing or minor specification changes to NQF on an annual basis. NQF solicits information from measure stewards for annual reviews and in order to review measures for continued endorsement in a specific 3-year cycle.

Through NQF's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. Examples of such changes could be updated diagnosis or procedure codes, medication updates for categories of medications, changes to exclusions to the patient population, definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505), we finalized a policy under which we will use a subregulatory process to make non-substantive updates to NQF-endorsed 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 non-substantive 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 non-substantive changes may also include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based. We will revise the

Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We also will post the updates on the QualityNet Web site at <https://www.QualityNet.org>. We will provide sufficient lead time for hospitals to implement the changes where changes to the data collection systems would be necessary.

We will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed 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. The quality measure SCIP Infection 4, Controlled 6AM Glucose for Cardiac Surgery Patients (NQF #300), is an example of a measure that has undergone extensive changes as a result of the NQF maintenance process. The specifications have substantively changed and we are proposing to adopt these changes in this proposed rule. As we discuss below, the NQF Steering Committee voted to change the measure from controlled glucose at 6AM to controlled glucose 18-24 hours post-surgery for cardiac surgery patients. The specifications also require corrective action to be documented if a post-operative glucose is over 180mg/dl. The specifications for the proposed updated measure can be found at: <http://www.qualityforum.org>.

We believe that this policy adequately balances our need to incorporate non-substantive NQF updates to NQF–endorsed Hospital IQR Program measures in the most expeditious manner possible, while preserving the public’s ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process. These policies regarding what is considered substantive versus non-substantive apply to all measures in the Hospital IQR Program.

c. Proposed Public Display of Quality Measures

Section 1886(b)(3)(B)(viii)(VII) of the Act, as amended by section 3001(a)(2) of the Affordable Care Act, requires that the Secretary establish procedures for making information regarding measures submitted available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. We are proposing, for the FY 2014 Hospital IQR Program and subsequent years, to continue 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.hospitalcompare.medicare.gov>, and/or the interactive <https://data.medicare.gov> Web site, after a 30-day preview period.

The Hospital Compare Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care to those who need to select a hospital. It further serves to encourage beneficiaries to work with their doctors and hospitals to discuss the quality of care hospitals provide to patients, thereby

providing an additional incentive to hospitals to improve the quality of care that they furnish. The Hospital IQR Program currently includes process of care measures, risk-adjusted outcome measures, the HCAHPS patient experience-of-care survey, structural measures, Emergency Department Throughput timing measures, hospital acquired condition measures, immunization measures, and hospital acquired infection measures, all of which are featured on the Hospital Compare Web site.

However, information that may not be relevant to or easily understood by beneficiaries and information for which there are unresolved display issues or design considerations for inclusion on Hospital Compare may be made available on other CMS Web sites that are not intended to be used as an interactive Web tool, such as <http://www.cms.hhs.gov/HospitalQualityInits/> or <https://data.medicare.gov>. Publicly reporting the information in this manner, although not on the Hospital Compare Web site, allows CMS to meet the requirement under section 1886(b)(3)(B)(viii)(VII) of the Act for establishing procedures to make information regarding measures submitted under the Hospital IQR Program available to the public following a preview period. In such circumstances, affected parties are notified via CMS listservs, CMS e-mail blasts and memorandums, Hospital Open Door Forums, national provider calls, and QualityNet announcements regarding the release of preview reports followed by the posting of data on a Web site other than Hospital Compare.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53507 through 53508), we removed five Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicators (PSIs). We did so noting that four of these indicators were part of the AHRQ

PSI-90 measure, and that this information could be made publically available in the future in addition to the PSI-90 composite measure results that we currently make publically available. We recently received feedback from consumer advocacy groups and large purchasers that data on the individual PSI indicators that are part of the PSI-90 composite measure are highly relevant to consumers, and not publically reporting them would be a disservice to consumers of healthcare. Therefore, we are proposing to make publically available hospital level data for the PSI indicators that are part of the PSI-90 composite in addition to the composite results. We invite public comment on this proposal.

We also invite public comment on what additional quality measures and information featured on Hospital Compare may be highly relevant to patients and other consumers of healthcare, and how we may better display this information on the Hospital Compare Web site. One option we have considered is aggregating measures in a graphical display, such as star ratings.

2. Removal and Suspension of Hospital IQR Program Measures

a. Considerations in Removing Quality Measures from the Hospital IQR Program

Generally, we retain measures from the previous year's Hospital IQR Program measure set for subsequent years' measure sets except when they are removed or replaced as indicated. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53505 through 53506) for a discussion of the considerations we use in removing (formerly referred to as retiring) previously adopted Hospital IQR Program measures.

b. Hospital IQR Program Measures Removed in Previous Rulemaking

In previous rulemakings, we have removed numerous Hospital IQR Program quality measures, including:

- PN-1: Oxygenation Assessment for Pneumonia, a “topped-out” measure, because measures with very high performance among hospitals present little opportunity for improvement and do not provide meaningful distinctions in performance for consumers (73 FR 48604).

- AMI-6: Beta Blocker at Arrival measure from the Hospital IQR Program because it no longer “represent[ed] the best clinical practice,” as required under section 1886(b)(3)(B)(viii)(VI) of the Act. We stated that when there is reason to believe that the continued collection of a measure as it is currently specified raises potential patient safety concerns, it is appropriate for CMS to take immediate action to remove a measure from the Hospital IQR Program and not wait for the annual rulemaking cycle. Therefore, we adopted the policy (74 FR 43864 and 43865) that we would promptly remove such a measure, confirm the removal in the next IPPS rulemaking cycle, and notify hospitals and the public of the decision to promptly remove measures through the usual hospital and QIO communication channels used for the Hospital IQR Program. These channels include memos, email notification, and QualityNet Web site postings. To this end, we confirmed the removal of the AMI-6 measure in the FY 2010 IPPS/LTCH PPS rulemaking cycle after immediate suspension because the measure posed patient safety risks.

- Mortality for Selected Procedures Composite measure because the measure is not considered suitable for purposes of comparative reporting by the measure developer (75 FR 50186).

- Three adult smoking cessation measures: AMI-4: Adult Smoking Cessation Advice/Counseling; HF-4: Adult Smoking Cessation Advice/Counseling; and PN-4: Adult Smoking Cessation Advice/Counseling, because these measures are “topped-out” and no longer NQF-endorsed (76 FR 51611).

- PN-5c: Timing of Receipt of Initial Antibiotic Following Hospital Arrival measure out of concerns that the continued collection of this measure might lead to the unintended consequence of antibiotic overuse (76 FR 51611).

- 17 measures set out below (77 FR 53506 through 53509)

Topic	17 Measures Removed from Hospital IQR Program Measure Set for the FY 2015 Payment Determination and Subsequent Years
Surgical Care Improvement Project (SCIP) Measure	
	<ul style="list-style-type: none"> ● SCIP INF -VTE-1: Surgery patients with recommended Venous Thromboembolism (VTE) prophylaxis ordered*
AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs) and Composite Measures	
	<ul style="list-style-type: none"> ● PSI 06: Iatrogenic pneumothorax, adult**
	<ul style="list-style-type: none"> ● PSI 11: Post Operative Respiratory Failure**
	<ul style="list-style-type: none"> ● PSI 12: Post Operative PE or DVT**
	<ul style="list-style-type: none"> ● PSI 14: Postoperative wound dehiscence**
	<ul style="list-style-type: none"> ● PSI 15: Accidental puncture or laceration**
	<ul style="list-style-type: none"> ● IQI 11: Abdominal aortic aneurysm (AAA) mortality rate (with or without volume) **
	<ul style="list-style-type: none"> ● IQI 19: Hip fracture mortality rate**
	<ul style="list-style-type: none"> ● IQI 91: Mortality for selected medical conditions (composite) **
Hospital Acquired Condition Measures	
	<ul style="list-style-type: none"> ● Foreign Object Retained After Surgery**
	<ul style="list-style-type: none"> ● Air Embolism **
	<ul style="list-style-type: none"> ● Blood Incompatibility**

Topic	17 Measures Removed from Hospital IQR Program Measure Set for the FY 2015 Payment Determination and Subsequent Years
	● Pressure Ulcer Stages III & IV**
	● Falls and Trauma: (Includes: Fracture Dislocation Intracranial Injury Crushing Injury Burn Electric Shock) **
	● Vascular Catheter-Associated Infection**
	● Catheter-Associated Urinary Tract Infection (UTI)**
	● Manifestations of Poor Glycemic Control**

* Chart-abstracted measure

** Claims-based measure

c. Proposed Removal of Hospital IQR Program Measures for the FY 2016 Payment Determination and Subsequent Years

As we move toward more outcome-related measures, we have considered the removal of additional measures using our stated removal criteria. We are proposing to remove 8 measures from the Hospital IQR Program. Three measures are chart-abstracted (one pneumonia measure, one heart failure measure, and one immunization measure), and one is a structural measure (Systematic Clinical Database Registry for Stroke Care). We are also proposing to remove 4 additional chart-abstracted measures from the Hospital IQR Program because they were either recommended for removal by the MAP during the pre-rulemaking process or are considered “topped out.”

(1) Proposed Removal of PN-3b: Blood Culture Performed in the Emergency Department Prior to First Antibiotic Received in the Hospital Measure

In the FY 2007 IPPS final rule, we adopted PN-3b: Blood Culture Performed in the Emergency Department Prior to First Antibiotic Received in the Hospital. We are proposing to remove this measure based on several considerations. First, the measure is

no longer NQF-endorsed. Second, the MAP recommended removal of the measure from the Hospital IQR Program in a February 2013 pre-rulemaking report that made recommendations on measures under consideration by HHS. The MAP believed the measure was topped-out with no room for improvement. Third, the measure lacks an adequate association between processes of care and patient outcomes. Accordingly, since there is only limited data showing impact from drawing blood cultures prior to administering antibiotics and to address concerns of overuse of blood cultures, we are proposing to remove PN-3b from the Hospital IQR Program.

(2) Proposed Removal of HF-1: Discharge Instructions Measure

In the FY 2007 IPPS final rule we adopted HF-1: Discharge Instructions. We are proposing to remove this measure based on several considerations. First, the measure is no longer NQF-endorsed. Second, the MAP recommended removal of the measure from the Hospital IQR Program in a February 2013 pre-rulemaking report that made recommendations on measures under consideration by HHS. The MAP was concerned because research showed a weak correlation between this measure and patient outcomes. Third, while we consider discharge instructions an important aspect of patient care, we face a challenge in validating the efficacy of the information received with this measure. Therefore, we are proposing to remove HF-1 from the Hospital IQR Program.

(3) Proposed Removal of IMM-1: Immunization for Pneumonia Measure

We adopted IMM-1: Immunization for Pneumonia for the Hospital IQR Program for the FY 2014 payment determination with data collection beginning with January 1, 2012 discharges. We are proposing to remove this measure based on the

following consideration. In October of 2012, the Advisory Committee on Immunization Practices (ACIP) released new guidelines on the administration of pneumococcal vaccination for various populations. Because IMM-1 was already required as part of the Hospital IQR Program before the new guidelines were published, we cannot feasibly implement the measure to incorporate the potential iterations of the new guidelines. We believe that maintaining the measure in the Hospital IQR Program during this period of rapid guideline changes would detract from hospitals efforts to administer vaccines appropriately.

We emphasize that, despite the removal of IMM-1 from the Hospital IQR Program, we expect hospitals to continue to keep up-to-date with the vaccination recommendations for various populations.

(4) Proposed Removal of the Systematic Clinical Database Registry for Stroke Care Measure

We adopted the Systematic Clinical Database Registry for Stroke Care measure for the Hospital IQR Program for the FY 2013 payment determination beginning with January 1, 2011 discharges. We are proposing to remove this measure based on the following consideration. Since the adoption of this structural measure, we have adopted a Stroke measure set beginning with January 1, 2013 discharges. We believe that the Stroke measure set will provide more meaningful and detailed information regarding how well stroke care is being managed in a hospital setting than the current structural measure, which consists of a general yes/no response.

(5) Proposed Removal of Four Additional Chart-Abstracted Measures

We are also proposing to remove four chart-abstracted measures from the Hospital IQR Program because these measures were either recommended for removal by the MAP during the pre-rulemaking process or are considered “topped out.”

- AMI–2: Aspirin prescribed at discharge
- AMI–10: Statin prescribed at discharge
- HF–3: ACEI or ARB for LVSD
- SCIP-Inf–10: Surgery Patients with perioperative temperature management

We invite public comment on our proposal to remove these measures.

Topic	Proposed Removal of Hospital IQR Program Measures for the FY 2016 Payment Determination and Subsequent Years
Acute Myocardial Infarction	
	● AMI-2 Aspirin prescribed at discharge
	● AMI-10 Statin prescribed at discharge
Pneumonia	
	● PN-3b Blood culture performed in the emergency department prior to first antibiotic received in hospital
Heart Failure	
	● HF-1 Discharge instructions
	● HF-3 ACEI or ARB for LVSD
Surgical Care Improvement Project	
	● SCIP-Inf-10 Surgery patients with perioperative temperature management
Immunization	
	● IMM-1 Immunization for pneumonia
Structural Measure	
	● Participation in a systematic clinical database registry for stroke care

d. Suspension of Data Collection for the FY 2014 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51611), we suspended data collection for four measures beginning with January 1, 2012 discharges, affecting the FY 2014 payment determination and subsequent years.

Topic	Hospital IQR Program Measures Suspended for the FY 2014 Payment Determination and Subsequent Years
Acute Myocardial Infarction (AMI)	
	<ul style="list-style-type: none"> ● AMI-1 Aspirin at arrival
	<ul style="list-style-type: none"> ● AMI-3 ACEI/ARB for left ventricular systolic dysfunction
	<ul style="list-style-type: none"> ● AMI-5 Beta-blocker prescribed at discharge
Surgical Care Improvement Project (SCIP)	
	<ul style="list-style-type: none"> ● SCIP INF-6 Appropriate Hair Removal

We suspended, rather than removed, these measures, despite having evidence that these measures may be topped-out (that is, their performance is uniformly high nationwide, with little variability among hospitals) because we believe that the processes assessed by these measures are tied to better patient outcomes, and that permanent removal of the measures from the Hospital IQR Program may result in declines in performance and, therefore, worse outcomes. Therefore, we decided not to remove these measures from the Hospital IQR Program. The suspension of data collection for these four measures will be continued unless we have evidence that performance on the measures is in danger of declining. Should we determine that hospital adherence to these practices has unacceptably declined, we would resume data collection using the same form and manner and on the same quarterly schedule that we finalize for these and other

chart abstracted measures, providing at least 3 months of notice prior to resuming data collection. Hospitals would be notified of this via CMS listservs, CMS e-mail blasts, national provider calls, and QualityNet announcements. In addition, we would comply with any requirements imposed by the Paperwork Reduction Act before resuming data collection of these four measures.

3. Process for Retaining Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

For the purpose of streamlining the rulemaking process, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53513), we finalized our policy that 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.

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 and our policy, beginning with the FY 2013, to use one calendar year of data for chart-abstracted measures for payment determinations.

5. Proposed Changes to Hospital IQR Program Measures Previously Adopted for the FY 2015 and FY 2016 Payment Determinations and Subsequent Years

a. Previously Adopted Hospital IQR Program Measures for the FY 2015 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53531), we finalized 59 measures for the Hospital IQR Program measure set for the FY 2015 payment determination and subsequent years. These 59 measures are listed below.

Topic	Hospital IQR Program Measures Previously Adopted for the FY 2015 Payment Determination and Subsequent Years
Acute Myocardial Infarction (AMI) Measures	
	<ul style="list-style-type: none"> ● AMI-2 Aspirin prescribed at discharge
	<ul style="list-style-type: none"> ● AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival
	<ul style="list-style-type: none"> ● AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI)
	<ul style="list-style-type: none"> ● AMI-10 Statin Prescribed at Discharge
Heart Failure (HF) Measures	
	<ul style="list-style-type: none"> ● HF-1 Discharge instructions
	<ul style="list-style-type: none"> ● HF-2 Evaluation of left ventricular systolic function
	<ul style="list-style-type: none"> ● HF-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction
Stroke (STK) Measure Set	
	<ul style="list-style-type: none"> ● STK-1 VTE prophylaxis
	<ul style="list-style-type: none"> ● STK-2 Antithrombotic therapy for ischemic stroke†
	<ul style="list-style-type: none"> ● STK-3 Anticoagulation therapy for Afib/flutter†
	<ul style="list-style-type: none"> ● STK-4 Thrombolytic therapy for acute ischemic stroke†
	<ul style="list-style-type: none"> ● STK-5 Antithrombotic therapy by the end of hospital day 2†
	<ul style="list-style-type: none"> ● STK-6 Discharged on Statin†
	<ul style="list-style-type: none"> ● STK-8 Stroke education†
	<ul style="list-style-type: none"> ● STK-10 Assessed for rehab†
VTE Measure Set	
	<ul style="list-style-type: none"> ● VTE-1 VTE prophylaxis†
	<ul style="list-style-type: none"> ● VTE-2 ICU VTE prophylaxis†

Topic	Hospital IQR Program Measures Previously Adopted for the FY 2015 Payment Determination and Subsequent Years
	<ul style="list-style-type: none"> ● VTE-3 VTE patients with anticoagulation overlap therapy†
	<ul style="list-style-type: none"> ● VTE-4 Patients receiving un-fractionated Heparin with doses/labs monitored by protocol†
	<ul style="list-style-type: none"> ● VTE-5 VTE discharge instructions†
	<ul style="list-style-type: none"> ● VTE-6 Incidence of potentially preventable VTE†
Pneumonia (PN) Measures	
	<ul style="list-style-type: none"> ● PN-3b Blood culture performed in the emergency department prior to first antibiotic received in hospital
	<ul style="list-style-type: none"> ● PN-6 Appropriate initial antibiotic selection
Surgical Care Improvement Project (SCIP) Measures	
	<ul style="list-style-type: none"> ● SCIP INF-1 Prophylactic antibiotic received within 1 hour prior to surgical incision
	<ul style="list-style-type: none"> ● SCIP INF-2: Prophylactic antibiotic selection for surgical patients
	<ul style="list-style-type: none"> ● SCIP INF-3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery)
	<ul style="list-style-type: none"> ● SCIP INF-4: Cardiac surgery patients with controlled 6AM postoperative serum glucose
	<ul style="list-style-type: none"> ● SCIP INF-9: Postoperative urinary catheter removal on post operative day 1 or 2 with day of surgery being day zero
	<ul style="list-style-type: none"> ● SCIP INF-10: Surgery patients with perioperative temperature management
	<ul style="list-style-type: none"> ● SCIP Cardiovascular-2: Surgery Patients on a Beta Blocker prior to arrival who received a Beta Blocker during the perioperative period
	<ul style="list-style-type: none"> ● SCIP-VTE-2: Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery
Mortality Measures (Medicare Patients)	
	<ul style="list-style-type: none"> ● Acute Myocardial Infarction (AMI) 30-day mortality rate
	<ul style="list-style-type: none"> ● Heart Failure (HF) 30-day mortality rate
	<ul style="list-style-type: none"> ● Pneumonia (PN) 30-day mortality rate
Patients' Experience of Care Measures	
	<ul style="list-style-type: none"> ● HCAHPS survey (expanded to include one 3-item care transition set* and two new “About You” items)*
Readmission Measures (Medicare Patients)	
	<ul style="list-style-type: none"> ● Acute Myocardial Infarction 30-day Risk Standardized Readmission Measure
	<ul style="list-style-type: none"> ● Heart Failure 30-day Risk Standardized Readmission Measure
	<ul style="list-style-type: none"> ● Pneumonia 30-day Risk Standardized Readmission Measure
	<ul style="list-style-type: none"> ● 30-day Risk Standardized Readmission following Total Hip/Total Knee Arthroplasty*
	<ul style="list-style-type: none"> ● Hospital-Wide All-Cause Unplanned Readmission (HWR)*

Topic	Hospital IQR Program Measures Previously Adopted for the FY 2015 Payment Determination and Subsequent Years
AHRQ Patient Safety Indicators (PSIs) Composite Measures	
	<ul style="list-style-type: none"> ● Complication/patient safety for selected indicators (composite)
AHRQ PSI and Nursing Sensitive Care	
	<ul style="list-style-type: none"> ● PSI-4 Death among surgical inpatients with serious treatable complications
Structural Measures	
	<ul style="list-style-type: none"> ● Participation in a Systematic Database for Cardiac Surgery
	<ul style="list-style-type: none"> ● Participation in a Systematic Clinical Database Registry for Stroke Care
	<ul style="list-style-type: none"> ● Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care
	<ul style="list-style-type: none"> ● Participation in a Systematic Clinical Database Registry for General Surgery
Healthcare-Associated Infections Measures	
	<ul style="list-style-type: none"> ● Central Line Associated Bloodstream Infection
	<ul style="list-style-type: none"> ● Surgical Site Infection <ul style="list-style-type: none"> - SSI following Colon Surgery - SSI following Abdominal Hysterectomy
	<ul style="list-style-type: none"> ● Catheter-Associated Urinary Tract Infection
	<ul style="list-style-type: none"> ● MRSA Bacteremia
	<ul style="list-style-type: none"> ● <u>Clostridium difficile</u> (<i>C. difficile</i>)
	<ul style="list-style-type: none"> ● Healthcare Personnel Influenza Vaccination
Surgical Complications	
	<ul style="list-style-type: none"> ● Hip/Knee Complication: Hospital-level Risk-Standardized Complication Rate (RSCR) following Elective Primary Total Hip Arthroplasty*
Emergency Department (ED)Throughput Measures	
	<ul style="list-style-type: none"> ● ED-1 Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the hospital†
	<ul style="list-style-type: none"> ● ED-2 Median time from admit decision to time of departure from the emergency department for emergency department patients admitted to the inpatient status†
Prevention: Global Immunization (IMM) Measures	
	<ul style="list-style-type: none"> ● Immunization for Influenza

Topic	Hospital IQR Program Measures Previously Adopted for the FY 2015 Payment Determination and Subsequent Years
	● Immunization for Pneumonia
Cost Efficiency	
	● Medicare Spending per Beneficiary
Perinatal Care	
	● PC-01 Elective delivery prior to 39 completed weeks of gestation*/†

* New or expanded measures/items for the FY 2015 payment determination and subsequent years.

† Proposed measure for electronic reporting via CEHRT in the Hospital IQR Program (voluntary participation in CY 2014).

b. Proposed Refinements to Existing Measures in the Hospital IQR Program

We are proposing to incorporate refinements for several measures that are currently 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 measurement approaches. The measure refinements include the following:

(1) incorporation of the planned readmission algorithm in 30-day readmission measures for AMI, HF, PN, THA/TKA, and Hospital-Wide Readmission to match recent NQF endorsement maintenance decisions beginning in 2013; (2) expansion of CLABSI and CAUTI measures to select non-ICU locations in IPPS hospitals beginning with infections occurring on or after January 1, 2014 (consistent with NQF expansion of the measures beyond ICUs); (3) updates to SCIP Inf 4 to match recent NQF endorsement maintenance decisions beginning with January 1, 2014 discharges; and (4) an update to the MSPB measure to include Railroad Retirement Board (RRB) beneficiaries beginning in 2014.

These proposed refinements are described in greater detail below.

(1) Proposed Incorporation of Planned Readmission Algorithm for 30-day Readmission Measures

In response to stakeholder comments, we have developed an algorithm to identify readmissions that are likely to be planned as part of ongoing medical or surgical treatment. Planned readmissions are identified in claims data using the CMS Planned Readmission Algorithm Version 2.1 which detects readmissions that are typically planned and may occur within 30 days of discharge from the hospital. For more information on the methodology used to identify planned readmissions, and the list of planned diagnoses and procedures used in the algorithm, we refer to the Web site at: [http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospital QualityInits/Measure-Methodology.html](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospital%20QualityInits/Measure-Methodology.html), as well as the discussion of planned readmissions under section 3025 of the Affordable Care Act in section V.G. of the preamble of this proposed rule. We submitted this algorithm for NQF review during annual maintenance of the AMI, HF, PN, and Total Hip/Total Knee Replacement readmission measures as well as for the recently adopted Hospital Wide Readmission measure.

NQF has endorsed the use of the algorithm for these measures, and we are proposing to incorporate the Planned Readmission Algorithm into the AMI, HF, PN, and Total Hip/Knee Replacement readmission measures in addition to the Hospital-Wide Readmission Measure beginning in 2013. We invite public comment on this proposal.

(2) Proposed Expansion of Collection of CLABSI and CAUTI to Select Non-ICU

Locations

We are proposing to expand the collection of the CAUTI and CLABSI measures to include several non-ICU locations beginning with infections occurring on or after January 1, 2014. Those proposed locations are medical wards, surgical wards, and medical/surgical wards. This expansion is consistent with the NQF re-endorsement update to these measures allowing application of the measures beyond ICUs. We are proposing this expansion to allow hospitals that do not have ICU locations to use the tools and resources of the NHSN for quality improvement and public reporting efforts. We invite public comment on this proposal.

(3) Proposed Refinement of SCIP-INF-4 to Match Refinements Made During NQF

Reendorsement

The quality measure SCIP Infection 4, Controlled 6AM Glucose for Cardiac Surgery Patients (NQF #300), is an example of a measure that has undergone extensive changes as a result of the NQF endorsement maintenance process. The specifications have changed so substantially that we are proposing to adopt them in this proposed rule. Specifically, the NQF Steering Committee voted to change the measure from controlled glucose at 6AM to a more comprehensive measure, controlled glucose 18-24 hours post-cardiac surgery. The revised specifications also require corrective action to be documented if a post-operative glucose is over 180mg/dl. We are proposing to adopt these revised specifications for SCIP-INF-4 beginning with January 1, 2014 discharges

and invite public comment on this proposal. The revised specifications for the measure can be found at <http://www.qualityforum.org/QPS/0300>.

(4) Proposed Refinement of Medicare Spending Per Beneficiary Measure (MSPB)

(a) Inclusion of Railroad Retirement Board Beneficiaries (RRB)

We are proposing a refinement to the Medicare spending per beneficiary (MSPB) measure previously finalized for the FY 2015 and subsequent years' payment determination. We are proposing to include Railroad Retirement Board (RRB) beneficiaries in the measure for the FY 2016 and subsequent years' payment determinations. We do not consider this refinement to be a substantive change. However, we are proposing this refinement through rulemaking because we explicitly stated in previous rulemaking that these beneficiaries would be excluded from the measure (76 FR 51620). Since that time, we have learned that we have complete claims data for RRB beneficiaries, and believe that eligible MSPB episodes generated by RRB hospital discharges should be included in the MSPB measure. We finalized the details of MSPB episode construction and adjustment in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618 through 51626). The effect of including RRB beneficiaries on the MSPB ratio is minimal. For the majority of hospitals, the change in their MSPB measure rates would be small--between -0.01 and 0.01.

We welcome public comment on this proposal to refine the MSPB measure to include RRB beneficiaries.

(b) Incorporating Maryland Hospitals

We are considering how best to incorporate Maryland hospitals paid under the waiver under section 1814(b)(3) of the Act into the MSPB measure. The payments made to Maryland hospitals pose a unique challenge to the payment standardization methodology currently used for the MSPB measure. Currently, hospitalizations in Maryland hospitals that are captured in the post-discharge window of the MSPB measure are standardized by applying the hospital wage index to the labor-related share of the IPPS payment, according to the methodology found on page 10 of the “CMS Price Standardization” document

<http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350>). This approach does not account for the absence of outlier payments on Maryland claims. In order to make a comparison of Maryland hospitals to other subsection (d) hospitals paid under the IPPS, in the event that MSPB measure rates are calculated for Maryland hospitals in the future, outliers would have to be imputed. If we were to include Maryland hospitals in the MSPB measure in the future, we would do so through future rulemaking.

We welcome public comment on the best approach to including Maryland hospitals in the MSPB measure and calculating MSPB measure rates for them.

6. Proposed Additional Hospital IQR Program Measures for the FY 2016 Payment Determination and Subsequent Years

We are proposing to add five new risk-adjusted claims-based outcome measures to the Hospital IQR Program for the FY 2016 payment determination and subsequent

years: (1) 30-day risk standardized COPD Readmission; (2) 30-day risk standardized COPD Mortality; (3) 30-day risk standardized Stroke Readmission; (4) 30-day risk standardized Stroke Mortality; and (5) AMI payment per Episode of Care. In section IX.A.7. of the preamble of this proposed rule, we also are proposing that hospitals may voluntarily report certain Hospital IQR measures in an electronic format.

The proposed 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,” which has been made available on the NQF Web site at http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx. We considered the input and recommendations provided by the MAP in selecting measures to propose for the Hospital IQR Program.

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.

The proposed measures are described in greater detail below.

a. Proposed Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization Measure (NQF #1891)

We are proposing to include this NQF-endorsed measure in the Hospital IQR Program beginning with the FY 2016 payment determination. The MAP supports this measure. In 2007, MedPAC published a report to Congress in which it identified the seven conditions associated with the most costly potentially preventable readmissions; among these seven, COPD ranked fourth.⁶⁰ In 2008, 12.1 million U.S. adults were estimated to have COPD resulting in approximately 672,000 hospital discharges.⁶¹ There is also evidence of variation in outcomes at hospitals for COPD patients, supporting the finding that there are opportunities for improving care. The median 30-day risk-standardized readmission rate among Medicare fee-for-service (FFS) patients aged 65 or older hospitalized for COPD in 2008 was 22.0 percent, and ranged from 18.33 percent - 25.03 percent across 4,546 hospitals.⁶²

The AHRQ has identified COPD as an ambulatory-care-sensitive condition (ACSC). ACSCs are conditions for which good outpatient care can potentially prevent the need for hospitalization or for which early intervention can prevent complications or

⁶⁰ Committee MPA. Report to the Congress: Promoting Greater Efficiency in Medicare. 2007.

⁶¹ American Lung Association. Trends in COPD (Chronic Bronchitis and Emphysema): Morbidity and Mortality. 2010; Available at: <http://www.lungusa.org/finding-cures/our-research/trend-reports/copd-trend-report.pdf>.

⁶² Grosso L.M., Lindenauer P., Wang C., et al. Hospital-level 30-day Readmission Following Admission for an Acute Exacerbation of Chronic Obstructive Pulmonary Disease: Report prepared for the Centers for Medicare & Medicaid Services. 2011; Available at: <http://www.qualitynet.org/>.

more severe disease.⁶³ Although COPD is an ACSC, readmission rates are also influenced by inpatient care.

To better assess hospital care and care transitions for COPD patients, we developed a hospital-level readmission measure for patients hospitalized with an acute exacerbation of COPD. We are proposing this measure for use in the Hospital IQR Program as well as the Hospital Readmissions Reduction Program. We discuss the measure methodology in detail in the section of this proposed rule pertaining to the Hospital Readmissions Reduction Program. We refer readers to section IX.A.6.b. of the preamble of this proposed rule on COPD for details of the measure specifications.

Details on the technical specifications of the measure can also be found on our Web site at: (<http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>).

We invite public comment on this proposal.

b. Proposed Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization Measure (NQF #1893)

(1) Background

COPD affects as many as 24 million individuals in the United States and is the nation's fourth leading cause of death. Between 1998 and 2008, the number of patients hospitalized annually for acute exacerbations of COPD (AECOPD) increased by

⁶³ AHRQ Quality Indicators. Fact Sheet: Prevention Quality Indicators. 2006; Available at: <http://qualityindicators.ahrq.gov/downloads/pqi/2006-Feb-PreventionQualityIndicators.pdf>.

approximately 18 percent.^{64,65,66} Moreover, COPD is one of the top 20 conditions contributing to Medicare costs.⁶⁷ Finally, there is evidence of variation in outcomes at hospitals for COPD patients, supporting the finding that there are opportunities for improving care. The median 30-day risk-standardized mortality rate among Medicare FFS patients aged 65 or older hospitalized for COPD in 2008 was 8.5 percent, and ranged from 5.9 percent to 13.5 percent across 4,537 hospitals.⁶⁸

We are proposing to include a hospital 30-day, all-cause risk-standardized rate of mortality following an admission for an AECOPD in the Hospital IQR Program. The measure aims to address a prevalent and costly health problem in the nation. In addition, the measure aligns with our priority objectives to promote quality improvements leading to successful transition of care for patients from acute care to outpatient settings, and reducing short term, preventable mortality rates.

We plan to implement this measure to encourage improvement of outcomes by providing patients, physicians, and hospitals with information about hospital-level, risk-standardized mortality rates following hospitalization for an AECOPD. Clinical trials and observational studies suggest that several aspects of care provided to patients hospitalized for AECOPD can have significant effects on mortality, thus supporting the

⁶⁴ National Heart L, and Blood Institute,. The Morbidity & Mortality: Chart Book on Cardiovascular, Lung and Blood Diseases. 2009; Available at: http://www.nhlbi.nih.gov/resources/docs/2009_ChartBook.pdf.

⁶⁵ The Centers for Disease Control and Prevention. National Center for Health Statistics Chronic Lower Respiratory Disease. *FastStats* 2010; Available at: <http://www.cdc.gov/nchs/fastats/copd.htm>.

⁶⁶ Agency for Healthcare Research and Quality. Healthcare Cost and Utilization Project *Statistics on Hospitals Stays*. 2009; Available at: <http://hcupnet.ahrq.gov/>.

⁶⁷ Andrews RM. The National Hospital Bill: The Most Expensive Conditions by Payer, 2006. Rockville: Agency for Healthcare Research and Quality; 2008.

⁶⁸ Grosso L.M., Lindenauer P., Wang C., et al. Hospital-level 30-day Mortality Following Admission for an Acute Exacerbation of Chronic Obstructive Pulmonary Disease: Report prepared for the Centers for Medicare & Medicaid Services. 2011; Available at: <http://www.qualitynet.org>.

essential construct of mortality as an appropriate outcome to measure quality.^{69, 70,71,72}

Moreover, by proposing an outcome measure, we intend to broaden the view of quality of care that encompasses more than what can be captured by merely measuring individual processes-of-care. Through outcome measures, we can capture complex and critical aspects of care, such as communication between providers, prevention of, and response to, complications, patient safety and coordinated transitions to the outpatient environment, all contribute to patient outcomes but are difficult to measure by individual process measures.^{73, 74}

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>. Please see the report for further details on the risk-adjustment statistical model.

⁶⁹ Global strategy for Diagnosis M, and Prevention of COPD,. 2009; Available at: <http://www.goldcopd.org/>.

⁷⁰ National Institute for Health and Clinical Excellence. Chronic Obstructive Pulmonary Disease: Management of Chronic Obstructive Pulmonary Disease in Adults in Primary and Secondary Care (Partial Update):. National Collaborating Centre for Acute and Chronic Conditions. Available at: <http://www.nice.org.uk/nicemedia/live/13029/49397/49397.pdf>.

⁷¹ Walters JA, PG Gibson, R Wood-Baker, M Hannay, EH Walters. Systemic corticosteroids for acute exacerbations of chronic obstructive pulmonary disease. Cochrane Database Syst Rev. 2009; CD001288(1).

⁷² Lightowler JV, Wedzicha JA, Elliott MW, Ram FS. Non-invasive positive pressure ventilation to treat respiratory Failure resulting from exacerbations of chronic obstructive pulmonary disease: Cochrane systematic review and meta-analysis. Bmj. 2003;326(7382).

⁷³ Krumholz H, Normand S-L, Spertus JA, Shahian DM, Bradley EH. Measuring Performance for Treating Heart Attacks and Heart Failure: The Case for Outcomes Measurement. Health Affairs 2007;26:75-85.

⁷⁴ Bradley EH, Herrin J, Elbel B, et al. Hospital Quality for Acute Myocardial Infarction: Correlation Among Process Measures and Relationship With Short-term Mortality. The Journal of the American Medical Association 2006;296:72-8.

(2) Overview of Measure

The measure is a NQF-endorsed 30-day, all-cause risk-standardized rate of mortality after admission for an AECOPD to any non-federal acute care hospital. The MAP supports this measure for inclusion in the Hospital IQR Program.

In general, the measure uses the same approach to risk-adjustment and hierarchical logistic modeling (HLM) methodology that is specified for our inpatient outcome measures previously adopted for the Hospital IQR Program, including AMI, HF, and PN readmission and mortality measures. For a discussion of this methodology, we refer readers to our Web site at: <http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

(3) Data Sources

The proposed measure is claims-based and uses Medicare administrative data that contain hospitalizations for FFS Medicare beneficiaries hospitalized with AECOPDs.

(4) Outcome

The outcome for this measure is 30-day all-cause mortality defined as a death from any cause within 30 days of the admission date for the index hospitalization. This outcome period is consistent with other NQF-endorsed publicly reported mortality measures (AMI, HF, and PN).

The measure assesses all-cause mortality not just COPD-specific mortality for several reasons. First, limiting the measure to COPD-related mortalities may limit the focus of efforts to improve care to a narrow set of approaches (such as processes that will prevent a recurrent exacerbation) 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. For example, a COPD patient who develops a hospital-acquired infection may ultimately die from sepsis. It would be inappropriate to treat this death as unrelated to the care the patient received for COPD. Finally, from a patient perspective, death is the outcome that matters, regardless of cause.

(5) Cohort

COPD is a group of lung diseases characterized by airway obstruction. Patients hospitalized for an AECOPD present with varying degrees of severity ranging from a worsening of baseline symptoms (dyspnea, cough, and/or sputum) to respiratory failure. To capture the full spectrum of severity of patients hospitalized for an AECOPD, we included patients with a principal diagnosis of COPD, as well as those with a principal diagnosis of respiratory failure who had a secondary diagnosis of an AECOPD. Requiring AECOPD as a secondary code helps to identify respiratory failure due to COPD exacerbation versus another condition (for example, heart failure). For detailed information on the cohort definition please reference the COPD mortality technical report on our Web site at: <http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

(6) Inclusion and Exclusion Criteria

The 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 having a principal diagnosis of an AECOPD during the index hospitalization who were transferred from another acute care facility are excluded because the hospital where the patient was initially admitted made critical acute care decisions (including the decision to transfer and where to transfer); (2) 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; and (3) admissions for patients that 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.

(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. 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 COPD 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 that 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 please refer to our Web site at:

<http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

We invite public comment on this proposal.

c. Proposed Hospital 30-day, All-Cause Risk-Standardized Rate of Readmission Following Acute Ischemic Stroke (Stroke Readmission) Measure

(1) Background

Stroke is an important and common diagnosis among Medicare patients. Ischemic stroke affects hundreds of thousands of adults in the United States each year and leaves many with new disability and at increased risk for complications, recurrent stroke and clinical deterioration.⁷⁵ Hospital readmissions after stroke may result from the progression of disease, but may also be an indicator of poor care. Approximately 10 percent of stroke survivors will have a recurrent stroke within a year and one out of four stroke patients will be readmitted to the hospital.^{76, 77, 78} Moreover, stroke is one of the

⁷⁵ American Heart Association, Heart Disease and Stroke Statistics - 2012 Update. American Heart Association, *Circulation* 2012, 125:e2-e220.

⁷⁶ Sacco RL, Hauser WA, Mohr JP, Foulkes MA. One-year outcome after cerebral infarction in whites, blacks, and Hispanics. *Stroke* 1991;22:305-11.

top 20 conditions contributing to Medicare costs.⁷⁹ Finally, there is evidence of variation in outcomes at hospitals for stroke patients, supporting the finding that there are opportunities for improving care. The median 30-day risk-standardized readmission rate among Medicare FFS patients aged 65 or older hospitalized for stroke in 2007 was 14.7 percent, and ranged from 11.6 percent to 19.4 percent across 4,242 hospitals.⁸⁰

We are proposing to include this non-NQF-endorsed hospital 30-day, all-cause risk-standardized rate of readmission following acute ischemic stroke 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.6. of the preamble to this proposed rule. Although the proposed measure is not currently NQF-endorsed or MAP supported, we

⁷⁷ Andersen HE, Schultz-Larsen K, Kreiner S, Forchhammer BH, Eriksen K, Brown A. Can readmission after stroke be prevented? Results of a randomized clinical study: a postdischarge follow-up service for stroke survivors. *Stroke* 2000;31:1038-45.

⁷⁸ Gooding J, Jette AM. Hospital readmissions among the elderly. *Journal of the American Geriatric Society* 1985;33:595-601.

⁷⁹ Andrews RM. *The National Hospital Bill: The Most Expensive Conditions by Payer*, 2006. Rockville: Agency for Healthcare Research and Quality; 2008.

⁸⁰ Bernheim S.M., Wang C., Wang Y., et al. Hospital 30-Day Readmission Following Acute Ischemic

considered other available measures that have been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on this topic. We believe it is imperative to adopt this measure as it aims to address a prevalent and costly health problem in the nation. In addition, the measure aligns with our priority objectives to promote quality improvements leading to successful transition of care for patients from acute care to outpatient settings, and reduce short term, preventable readmission rates.

We plan to implement this measure to encourage improvement of outcomes by providing patients, physicians, and hospitals with information about hospital-level, risk-standardized readmission rates following hospitalization for acute ischemic stroke. Studies have shown stroke readmission to be related to quality of care, and that improvements in care can reduce readmission rates.^{81, 82, 83} Moreover, by proposing an outcome measure, we intend to broaden the view of quality of care that encompasses more than what can be captured by merely measuring individual processes-of-care.

⁸¹ Jack BW, Chetty VK, Anthony D, et al. A Reengineered Hospital Discharge Program to Decrease Rehospitalization. *Annals of Internal Medicine* 2009;150:178-88.

⁸² Naylor MD, Brooten D, Cambell R, et al. Comprehensive Discharge Planning and Home Follow-up of Hospitalized Elders: A Randomized Clinical Trial. *The Journal of the American Medical Association* 1999; 281:613-20.

⁸³ Bravata DM, Ho SY, Meehan TP, Brass LM, Concato J. Readmission and death after hospitalization for acute ischemic stroke: 5-year follow-up in the Medicare population. *Stroke* 2007; 38:1899-904.

Through outcome measures, we can capture complex and critical aspects of care, such as communication between providers, prevention of, and response to, complications, patient safety and coordinated transitions to the outpatient environment, all of which contribute to patient outcomes but are difficult to measure by individual process measures.^{84, 85}

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.

(2) Overview of Measure

The measure is a 30-day, all-cause risk-standardized rate of readmission following hospitalization for acute ischemic stroke to any non-federal acute care hospital. The measure includes Medicare FFS patients aged 65 or older admitted for an acute ischemic stroke and assesses if the patient was readmitted within 30 days of discharge.

In general, the measure uses the same approach to risk-adjustment and HLM methodology that is specified for our inpatient outcome measures previously adopted for the Hospital IQR Program, including AMI, HF, and PN readmission and mortality measures. For a discussion of this methodology, we refer readers to our Web site at:

<http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

⁸⁴ Krumholz H, Normand S-L, Spertus JA, Shahian DM, Bradley EH. Measuring Performance for Treating Heart Attacks and Heart Failure: The Case for Outcomes Measurement. *Health Affairs* 2007;26:75-85.

⁸⁵ Bradley EH, Herrin J, Elbel B, et al. Hospital Quality for Acute Myocardial Infarction: Correlation Among Process Measures and Relationship With Short-term Mortality. *The Journal of the American Medical Association* 2006;296:72-8.

Furthermore this measure, which is calculated using CMS claims or administrative data, is validated by comparing it to a medical record model in a matched cohort of admissions for which stroke medical record data and administrative claims data are available.

(3) Data Sources

The proposed measure is claims-based and uses Medicare administrative data that contain hospitalizations for fee-for-service Medicare beneficiaries hospitalized with acute

ischemic stroke.

(4) Outcome

The outcome for this measure is 30-day all-cause readmission defined as an unplanned subsequent inpatient admission to any acute care facility from any cause within 30 days of the admission date for the index hospitalization. A number of studies have demonstrated that improvements in care at the time of patient discharge can reduce

30-day readmission rates.^{86, 87,88} It is a timeframe in which a readmission may reasonably

be attributed to the hospital care and transitional period to a non-acute setting.

The measure assesses all-cause unplanned readmission (excluding planned readmissions) rather than only stroke-specific readmissions for several reasons. First, from the patient perspective, readmission for any reason is likely to be an undesirable outcome of care, even though not all readmissions are preventable. Second, limiting the

⁸⁶ Jack BW, Chetty VK, Anthony D, et al. A Reengineered Hospital Discharge Program to Decrease Rehospitalization. *Annals of Internal Medicine* 2009;150:178-88.

⁸⁷ Coleman EA, Parry C, Chalmers S, Min S-j. The Care Transitions Intervention: Results of a Randomized Controlled Trial. *Archives of Internal Medicine* 2006;166:1822-8.

⁸⁸ Anderson C, Deepak BV, Amoateng-Adjepong Y, Zarich S. Benefits of Comprehensive Inpatient Education and Discharge Planning Combined With Outpatient Support in Elderly Patients With Congestive Heart Failure. *Congestive Heart Failure* 2005;November-December:315-21.

measure to stroke-related readmissions may limit the focus of efforts to improve care to a

narrow set of approaches (such as processes that will prevent recurrent stroke) as opposed to encouraging broader initiatives aimed overall at improving the 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 instance, a patient who came back with pneumonia may have aspirated due to inadequate preventive measures and therefore we would not want to discount such a readmission.

The measure does not count readmissions that are considered planned. Planned readmissions are identified in claims data using the CMS Planned Readmission Algorithm Version 2.1 which detects readmissions that are typically planned and may occur within 30 days of discharge from the hospital. For more information on the methodology used to identify planned readmissions, and the list of planned diagnoses and procedures used in the algorithm, please refer to on our Web site at:

<http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>. The stroke readmission measure makes one modification to the planned readmissions algorithm as it does not consider readmissions as planned for patients who are readmitted for debridement of wound; infection or burn (AHRQ's Clinical Classification Software procedure category 169). Such treatments are commonly provided for decubitus ulcers that can easily be

unplanned readmissions following stroke care, because such ulcers can complicate a stroke. The algorithm includes planned readmissions for common related follow-up care for stroke patients (for example, carotid endarterectomy) as well as readmissions which are generally planned regardless of the original admission (for example, a stroke patient readmitted for cholecystectomy). Unplanned readmissions that fall within the 30-day post discharge timeframe from the index admission are not counted as outcomes for the index admission if they are preceded by a planned readmission.

(5) Cohort

The cohort of index hospital admissions included in the measure is restricted to hospitalizations for ischemic stroke. The measure is limited to ischemic stroke hospitalizations for several reasons. First, ischemic strokes are the most common type of stroke, accounting for the vast majority of stroke hospitalizations.⁸⁹ Second, the etiology and prognosis of ischemic stroke is quite different than that of hemorrhagic stroke, so a combined cohort would be more heterogeneous. This heterogeneity could make it more difficult to account for a hospital's patient mix and lead to a less fair measure. Similarly, patients with transient ischemic attacks (TIAs) are not included largely due to concerns about inconsistency in the use of administrative codes to define TIA and potential for inclusion of patients without cerebrovascular conditions. For detailed information on the

⁸⁹ Thom T, Haase N, Rosamond W, et al. Heart Disease and Stroke Statistics-2006 Update: A Report From the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Journal of the American Heart Association* 2006;85-151.

cohort definition, we refer readers to the stroke readmission technical report on our Web site at: <http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

(6) Inclusion and Exclusion Criteria

The 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 who die during the initial hospitalization because they are not eligible for readmission; (2) admissions for patients having a principal diagnosis of stroke during the index hospitalization and subsequently transferred to another acute care facility are excluded because the measure's focus is on hospitals that discharge patients to a non-acute setting (for example, to home or a skilled nursing facility); (3) admissions for patients that are discharged against medical advice are excluded because providers did not have the opportunity to deliver full care and prepare the patient for discharge; (4) admissions for patients without at least 30-days post-discharge enrollment in Medicare FFS are excluded because the 30-day readmission outcome cannot be assessed in this group; and (5) additional stroke admissions for patients within 30 days of discharge from an index stroke admission will be considered readmissions and not additional index admissions.

(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. 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 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 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. 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 ischemic stroke hospitalization, 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. In addition, the measure takes into account situations where patients initially present at one ED but are then admitted to another hospital for their index stroke hospitalization. The measure includes a risk-adjustment factor to account for ED-transfer patients.

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 readmission 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/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

We are proposing to adopt this measure in the Hospital IQR Program for the FY 2016 payment determination and subsequent years under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section IX.A.6. of the preamble of this proposed rule. Although the proposed measure is not currently NQF-endorsed or MAP supported, we considered other available measures that have

been endorsed or adopted by the NQF, and were unable to identify any other NQF-endorsed measures that assess stroke readmission with a standard period of follow-up. We also are not aware of any other 30-day stroke readmission measures that have been endorsed or adopted by a consensus organization. The development of this measure went through the same rigorous development process as the other publicly reported outcomes measures and involved extensive input by stakeholders and clinical experts. It follows the same scientific approach to evaluate hospital performance as other Hospital IQR Program outcome measures. Finally, it has been validated with medical record measures and shown to produce similar hospital-level results. Accordingly, we are proposing to adopt the 30-day stroke readmission measure under the Secretary's authority set forth at section 1886(b)(3)(B)(IX)(bb) of the Act.

We invite public comment on this proposal.

d. Proposed Hospital 30-Day, All-Cause Risk-Standardized Rate of Mortality Following an Admission for Acute Ischemic Stroke (Stroke Mortality) Measure

(1) Background

Stroke is an important and common diagnosis among Medicare patients. Stroke affects approximately 795,000 people each year in the U.S. with high rates of mortality and morbidity. Stroke is the fourth most common cause of death after heart disease, cancer, and chronic lower respiratory disease.⁹⁰ Moreover, stroke is one of the top 20 conditions contributing to Medicare costs.⁹¹ Finally, there is evidence of variation in

⁹⁰ American Heart Association, Heart Disease and Stroke Statistics - 2012 Update. American Heart Association, Circulation 2012, 125:e2-e220.

⁹¹ Andrews RM. The National Hospital Bill: The Most Expensive Conditions by Payer, 2006. Rockville: Agency for Healthcare Research and Quality; 2008.

outcomes at hospitals for stroke patients, supporting the finding that there are opportunities for improving care. The median 30-day risk-standardized mortality rate among Medicare FFS patients aged 65 or older hospitalized for stroke in 2007 was 15.3 percent, and ranged from 10.7 percent to 23.5 percent across 4,288 hospitals.⁹²

We are proposing to include a non-NQF endorsed hospital 30-day, all-cause risk-standardized rate of mortality following an admission for acute ischemic stroke 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.6. of the preamble of this proposed rule. Although the proposed measure is not currently NQF-endorsed or MAP supported, we considered other available measures that have been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on this topic. We believe it is important to adopt this measure as it aims to address a prevalent and costly health problem in the nation. In addition, the measure aligns with our priority objectives to promote quality improvements leading to successful transition of care for patients from acute care to outpatient settings, and reducing short term, preventable mortality rates.

We plan to implement this measure to encourage improvement of outcomes by providing patients, physicians, and hospitals with information about hospital-level, risk-standardized mortality rates following hospitalization for acute ischemic stroke. Studies

⁹² Bernheim S.M., Wang C., Wang Y., et al. Hospital 30-Day Mortality Following Acute Ischemic Stroke

have shown stroke mortality to be related to quality of care, and that there are effective interventions that hospitals can adopt to reduce mortality rates.^{93,94} Moreover, by proposing an outcome measure, we intend to broaden the view of quality of care that encompasses more than what can be captured by merely measuring individual processes-of-care. Through outcome measures, we can capture complex and critical aspects of care, such as communication between providers, prevention of, and response to, complications, patient safety and coordinated transitions to the outpatient environment, all of which contribute to patient outcomes, but are difficult to measure by individual process measures.^{95,96}

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.

(2) Overview of Measure

The measure is a 30-day, all-cause risk-standardized rate of mortality after admission for acute ischemic stroke to any non-federal acute care hospital. The measure

⁹³ Fonarow GC, Reeves MJ, Zhao X, et al. Age-Related Differences in Characteristics, Performance Measures, Treatment Trends, and Outcomes in Patients With Ischemic Stroke. *Journal of the American Heart Association* 2010;121:879-91.

⁹⁴ Bravata DM, Wells CK, Lo AC, et al. Processes of Care Associated With Acute Stroke Outcomes. *Archives of Internal Medicine* 2010;170:804-10.

⁹⁵ Krumholz H, Normand S-L, Spertus JA, Shahian DM, Bradley EH. Measuring Performance for Treating Heart Attacks and Heart Failure: The Case for Outcomes Measurement. *Health Affairs* 2007;26:75-85.

⁹⁶ Bradley EH, Herrin J, Elbel B, et al. Hospital Quality for Acute Myocardial Infarction: Correlation Among Process Measures and Relationship With Short-term Mortality. *The Journal of the American Medical Association* 2006;296:72-8.

includes Medicare fee-for-service patients aged 65 or older admitted for an acute ischemic stroke and assesses if the patient died within 30 days of admission.

In general, the measure uses the same approach to risk-adjustment and HLM methodology that is specified for our inpatient outcome measures previously adopted for the Hospital IQR Program, including AMI, HF, and PN readmission and mortality measures. For a discussion of this methodology, we refer readers to our Web site at: <http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

Furthermore this measure, which is calculated using CMS claims or administrative data, is validated by comparing it to a medical record model in a matched cohort of admissions for which stroke medical record data and administrative claim data are available.

(3) Data Sources

The proposed measure is claims-based and uses Medicare administrative data that contain hospitalizations for Medicare FFS beneficiaries hospitalized with acute ischemic stroke.

(4) Outcome

The outcome for this measure is 30-day all-cause mortality defined as a death from any cause within 30 days of the admission date for the index hospitalization. Thirty days is a standard time period used in other measures of stroke mortality.^{97,98} It is a

⁹⁷ Saposnik G, Hill MD, O'Donnell M, Fang J, Hachinski V, Kapral MK. Variables Associated With 7-Day, 30-Day, and 1-Year Fatality After Ischemic Stroke. *Journal of the American Heart Association* 2008;39.

timeframe in which a death may reasonably be attributed to the hospital care and transitional period to a non-acute setting.

The measure assesses all-cause mortality as opposed to stroke-specific mortality for several reasons. First of all, limiting the measure to stroke-related mortalities may limit the focus of efforts to improve care to a narrow set of approaches (such as processes that will prevent recurrent stroke) as opposed to encouraging broader initiatives aimed at improving the overall care within the hospital. Second, cause of death may be unreliably recorded and it is often impossible to exclude quality issues and accountability based on the documented cause of mortality. For example, a stroke patient who develops a hospital-acquired infection may ultimately die from sepsis. It would be inappropriate to treat this mortality as unrelated to the care the patient received for stroke. Finally, from a patient perspective, death is the outcome that matters, regardless of cause.

(5) Cohort

The cohort of index hospital admissions included in the measure is restricted to hospitalizations for ischemic stroke. The measure is limited to ischemic stroke hospitalizations for a few reasons. First, ischemic strokes are the most common type of stroke, accounting for the vast majority of stroke hospitalizations.⁹⁹ Second, the causes and prognosis of ischemic stroke are quite different than that of hemorrhagic stroke, so a combined cohort would be more heterogeneous. This heterogeneity could make it more difficult to account for a hospital's patient mix and lead to a less fair measure. Similarly,

⁹⁸ Counsell C, Dennis M, McDowall M, Warlow C. Predicting Outcome After Acute and Subacute Stroke: Development and Validation of New Prognostic Models *Journal of the American Heart Association* 2002;1041-7.

⁹⁹ American Heart Association, Heart Disease and Stroke Statistics - 2012 Update. American Heart Association, *Circulation* 2012, 125:e2-e220.

patients with TIAs are not included largely due to concerns about inconsistency in the use of administrative codes to define TIA and potential for inclusion of patients without cerebrovascular conditions. For detailed information on the cohort definition please reference the stroke mortality technical report on our Web site at:

<http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

(6) Inclusion and Exclusion Criteria

The 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 having a principal diagnosis of stroke during the index hospitalization who were transferred from another acute care facility are excluded because the hospital where the patient was initially admitted made critical acute care decisions (including the decision to transfer and where to transfer); (2) 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; and (3) admissions for patients that 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.

(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. 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 stroke hospitalization, 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. In addition, the measure takes into account situations where patients initially present at one ED, are then admitted to

another hospital for their index stroke hospitalization. The measure includes a risk-adjustment factor to account for ED-transfer patients.

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 that 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 an “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://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

We are proposing to adopt this measure in the Hospital IQR Program for the FY 2016 payment determination and subsequent years under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section IX.A.6. of the preamble of this proposed rule. Although the proposed measure is not currently

NQF-endorsed or MAP supported, we considered other available measures that have been endorsed or adopted by the NQF, and were unable to identify any other NQF-endorsed measures that assess stroke mortality with a standard period of follow-up. We also are not aware of any other 30-day stroke mortality measures that have been endorsed or adopted by a consensus organization. The development of this measure went through the same rigorous development process as the other publicly reported outcomes measures and involved extensive input by stakeholders and clinical experts. It follows the same scientific approach to evaluate hospital performance as other Hospital IQR outcome measures. Finally, it has been validated with medical record measures and shown to produce similar hospital-level results. Accordingly, we are proposing to adopt the 30-day stroke mortality measure under the Secretary's authority set forth at section 1886(b)(3)(B)(IX)(bb) of the Act.

We invite public comment on this proposal.

e. Proposed Hospital Risk-Standardized Payment Associated with a 30-day Episode-of-Care for Acute Myocardial Infarction (AMI) Measure

(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 AMI patients; mean 30-day risk-standardized payment among Medicare FFS patients aged 65 or older hospitalized

for AMI in 2008 was \$20,207, and ranged from \$15,521 to \$27,317 across 1,846 hospitals.¹⁰⁰ 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 a non-NQF-endorsed measure: hospital risk-standardized payment associated with a 30-day episode-of-care for acute myocardial infarction (AMI) 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.6. of the preamble of this proposed rule. Although the proposed measure is not currently NQF-endorsed, we considered other available 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 contingent on NQF-endorsement.

We believe it is important to adopt this measure as it is aligned with our 30-day AMI mortality measure and can also be paired with our 30-day AMI readmission measure. This would facilitate assessing hospital value, 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 AMI. The measure reflects differences in the management of care for patients with AMI both during hospitalization and immediately post-discharge. AMI is a condition with

¹⁰⁰ Kim N., Bernheim S.M., Ott L.S., et al. Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for AMI: Report prepared for the Centers for Medicare & Medicaid Services. 2013; Available at: <http://www.qualitynet.org>.

substantial variation in costs of care and, therefore, is an ideal condition for assessing relative value for an episode-of-care that begins with an acute hospitalization. By focusing on one specific condition, value assessments may provide actionable feedback to hospitals and incentivize targeted improvements in care.

(2) Rationale for Examining Payments for a 30-Day Episode-of-Care

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 AMI payment measure is intended to be paired with our 30-day AMI 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](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) Overview of the Measure

The AMI payment measure assesses hospital risk-standardized payment associated with a 30-day episode-of-care for AMI for any non-federal acute care hospital. The measure includes Medicare FFS patients aged 65 or older admitted for an AMI 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, including the AMI, HF, and PN readmission and mortality measures. We refer readers to our Web site at: <http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

(4) Data Sources

The proposed measure is claims-based and uses Medicare administrative data that contain hospitalizations and payments for Medicare FFS beneficiaries hospitalized with AMI.

(5) Outcome

The primary outcome of the AMI payment measure is the hospital-level risk-standardized payment for an AMI 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 AMI payment to other hospitals with the same

case-mix. The analytic time frame for the AMI payment measure begins with the index admission for AMI and ends 30 days post-admission.

In order to isolate payment variation that reflects practice patterns rather than CMS payment adjustments, the AMI 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 AMI.

(6) Cohort

We created the AMI payment measure cohort to be aligned with the publicly reported AMI mortality measure cohort. Consistent with these measures, the AMI payment measure includes hospitalizations with a principal hospital discharge diagnosis of AMI using the International Classification of Diseases, Ninth revision, Clinical Modification. 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://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>. An index hospitalization is the initial AMI 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).

(7) Inclusion and Exclusion Criteria

The AMI 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 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 AMI 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 AMI 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 AMI; (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.

(8) 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.

(9) Calculating the Risk Standardized Payment (RSP)

The measure is calculated using hierarchical generalized linear statistical models with a log link and an inverse Gaussian 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 AMI 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>.

We are proposing to adopt the AMI payment measure in the Hospital IQR Program for the FY 2016 payment determination and subsequent years under the exception authority in section 1886(b)(3)(B)(IX)(bb) of the Act as previously discussed in section IX.A.6. 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 acute myocardial infarction. We also are not aware of any other 30-day episode-of-care for acute myocardial infarction measures that have been endorsed or adopted by a consensus organization.

This measure is meant to be paired with our 30-day AMI 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.

Set out below is a table showing both the previously adopted and proposed new quality measures for the FY 2016 payment determination and subsequent years. This table does not include suspended measures and measures proposed for removal.

Topic	Previously Adopted and Proposed Hospital IQR Program Measures for the FY 2016 Payment Determination and Subsequent Years
Acute Myocardial Infarction (AMI) Measures	
	<ul style="list-style-type: none"> ● AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival
	<ul style="list-style-type: none"> ● AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI)
Heart Failure (HF) Measures	
	<ul style="list-style-type: none"> ● HF-2 Evaluation of left ventricular systolic function
Stroke Measure (STK) Set	
	<ul style="list-style-type: none"> ● STK-1 VTE prophylaxis
	<ul style="list-style-type: none"> ● STK-2 Antithrombotic therapy for ischemic stroke†
	<ul style="list-style-type: none"> ● STK-3 Anticoagulation therapy for Afib/flutter†
	<ul style="list-style-type: none"> ● STK-4 Thrombolytic therapy for acute ischemic stroke†
	<ul style="list-style-type: none"> ● STK-5 Antithrombotic therapy by the end of hospital day 2†
	<ul style="list-style-type: none"> ● STK-6 Discharged on Statin†
	<ul style="list-style-type: none"> ● STK-8 Stroke education†
	<ul style="list-style-type: none"> ● STK-10 Assessed for rehab†
VTE Measure Set	
	<ul style="list-style-type: none"> ● VTE-1 VTE prophylaxis†
	<ul style="list-style-type: none"> ● VTE-2 ICU VTE prophylaxis†
	<ul style="list-style-type: none"> ● VTE-3 VTE patients with anticoagulation overlap therapy†
	<ul style="list-style-type: none"> ● VTE-4 Patients receiving un-fractionated Heparin with doses/labs monitored by protocol†
	<ul style="list-style-type: none"> ● VTE-5 VTE discharge instructions†
	<ul style="list-style-type: none"> ● VTE-6 Incidence of potentially preventable VTE†
Pneumonia (PN) Measures	
	<ul style="list-style-type: none"> ● PN-6 Appropriate initial antibiotic selection
Surgical Care Improvement Project (SCIP) Measures	
	<ul style="list-style-type: none"> ● SCIP INF-1 Prophylactic antibiotic received within 1 hour prior to surgical incision
	<ul style="list-style-type: none"> ● SCIP INF-2: Prophylactic antibiotic selection for surgical patients
	<ul style="list-style-type: none"> ● SCIP INF-3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery)
	<ul style="list-style-type: none"> ● SCIP INF-4: Cardiac surgery patients with controlled 6AM postoperative serum glucose
	<ul style="list-style-type: none"> ● SCIP INF-9: Postoperative urinary catheter removal on post operative day 1 or 2 with day of surgery being day zero
	<ul style="list-style-type: none"> ● SCIP Cardiovascular-2: Surgery Patients on a Beta Blocker prior to

Topic	Previously Adopted and Proposed Hospital IQR Program Measures for the FY 2016 Payment Determination and Subsequent Years
	arrival who received a Beta Blocker during the perioperative period
	<ul style="list-style-type: none"> ● SCIP-VTE-2: Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery
Mortality Measures (Medicare Patients)	
	<ul style="list-style-type: none"> ● Acute Myocardial Infarction (AMI) 30-day mortality rate
	<ul style="list-style-type: none"> ● Heart Failure (HF) 30-day mortality rate
	<ul style="list-style-type: none"> ● Pneumonia (PN) 30-day mortality rate
	<ul style="list-style-type: none"> ● Stroke 30-day mortality rate***
	<ul style="list-style-type: none"> ● COPD 30-day mortality rate***
Patients' Experience of Care Measures	
	<ul style="list-style-type: none"> ● HCAHPS survey (expanded to include one 3-item care transition set* and two new “About You” items)*
Readmission Measures (Medicare Patients)	
	<ul style="list-style-type: none"> ● Acute Myocardial Infarction (AMI) 30-day Risk Standardized Readmission Measure
	<ul style="list-style-type: none"> ● Heart Failure (HF) 30-day Risk Standardized Readmission Measure
	<ul style="list-style-type: none"> ● Pneumonia (PN) 30-day Risk Standardized Readmission Measure
	<ul style="list-style-type: none"> ● 30-day Risk Standardized Readmission following Total Hip/Total Knee Arthroplasty*
	<ul style="list-style-type: none"> ● Hospital-Wide All-Cause Unplanned Readmission (HWR)*
	<ul style="list-style-type: none"> ● Stroke 30-day Risk Standardized Readmission***
	<ul style="list-style-type: none"> ● COPD 30-day Risk Standardized Readmission***
AHRQ Patient Safety Indicators (PSIs) Composite Measures	
	<ul style="list-style-type: none"> ● Complication/patient safety for selected indicators (composite)
AHRQ PSI and Nursing Sensitive Care	
	<ul style="list-style-type: none"> ● PSI-4 Death among surgical inpatients with serious treatable complications
Structural Measures	
	<ul style="list-style-type: none"> ● Participation in a Systematic Database for Cardiac Surgery
	<ul style="list-style-type: none"> ● Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care
	<ul style="list-style-type: none"> ● Participation in a Systematic Clinical Database Registry for General Surgery
	<ul style="list-style-type: none"> ● Safe Surgery Checklist Use**
Healthcare-Associated Infections Measures	

Topic	Previously Adopted and Proposed Hospital IQR Program Measures for the FY 2016 Payment Determination and Subsequent Years
	<ul style="list-style-type: none"> ● Central Line Associated Bloodstream Infection
	<ul style="list-style-type: none"> ● Surgical Site Infection <ul style="list-style-type: none"> - SSI following Colon Surgery - SSI following Abdominal Hysterectomy
	<ul style="list-style-type: none"> ● Catheter-Associated Urinary Tract Infection
	<ul style="list-style-type: none"> ● MRSA Bacteremia
	<ul style="list-style-type: none"> ● <u>Clostridium difficile</u> (<u>C. difficile</u>)
	<ul style="list-style-type: none"> ● Healthcare Personnel Influenza Vaccination
Surgical Complications	
	<ul style="list-style-type: none"> ● Hip/Knee Complication: Hospital-level Risk-Standardized Complication Rate (RSCR) following Elective Primary Total Hip Arthroplasty*
Emergency Department (ED) Throughput Measures	
	<ul style="list-style-type: none"> ● ED-1 Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the hospital†
	<ul style="list-style-type: none"> ● ED-2 Median time from admit decision to time of departure from the emergency department for emergency department patients admitted to the inpatient status†
Prevention: Global Immunization (IMM) Measures	
	<ul style="list-style-type: none"> ● Immunization for Influenza
Cost Efficiency	
	<ul style="list-style-type: none"> ● Medicare Spending per Beneficiary
	<ul style="list-style-type: none"> ● AMI Payment per Episode of Care***
Perinatal Care	
	<ul style="list-style-type: none"> ● Elective delivery prior to 39 completed weeks of gestation*/†

* New or expanded measures/items for FY 2015 payment determination and subsequent years.

** New measures for FY 2016 payment determination and subsequent years.

*** Proposed measures for FY 2016 payment determination and subsequent years.

† Proposed measure for electronic reporting via CEHRT in the Hospital IQR Program (voluntary participation in CY 2014).

7. Electronic Clinical Quality 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 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 hospital 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 29 clinical quality measures from which hospitals must select a total of 16 measures covering at least three domains to report beginning in FY 2014. We anticipate that, as health information technology evolves and infrastructure is 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.

Recently, we published in the **Federal Register** (78 FR 308 through 310) a Request for Information (RFI) entitled, “Medicare Program; Request for Information on Hospital and Vendor Readiness for Electronic Health Records Hospital Inpatient Quality Data Reporting” to gather stakeholder feedback to determine the optimal timing and transition strategy for adopting electronic reporting of quality measures by hospitals participating in the Hospital IQR Program. The information sent in response to the RFI was considered as the proposals set forth below were developed. We are proposing an

approach that begins to align the Hospital IQR and Medicare EHR Incentive Programs by providing hospitals currently participating in the Hospital IQR Program with the option of electronically reporting a subset of measures.

We are proposing that hospitals would be able to, on a voluntary basis, electronically report 16 measures across four measure sets, (stroke [STK], venous thromboembolism [VTE], emergency department [ED] and perinatal care [PC]) in CY 2014 for the FY 2016 Hospital IQR Program payment determination. These four measure sets are also already included in the Hospital IQR Program as chart-abstracted measures. The measures in three of these four measure sets – STK, VTE, ED – (15 measures) are already included in the Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs (76 FR 74489). With regard to the measure set perinatal care (PC), we stated in the 2013 IPPS/LTCH PPS final rule that we would consider electronic reporting when the e-specification of the PC-01 measure became available. The electronic specifications for these measures are included in the electronic clinical quality measure library at: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html. We recognize that PC-01 is a highly burdensome measure for hospitals to report via chart abstraction. Also, we do not believe that the measures, in their electronically specified form, are substantively different than they are in their chart-abstracted form, although we recognize that the EHR-based extraction methodology is different from the chart abstraction data collection methodology.

We considered proposing to require hospitals to electronically report either a greater or lesser number of Hospital IQR quality measures. Based on the RFI comments, we grew concerned that hospitals, vendors and other stakeholders might not be able to comply with a requirement to report certain quality measures electronically in CY 2014. As a result, we are proposing to make electronic reporting voluntary in CY 2014. We strongly encourage participation in voluntary electronic reporting during CY 2014 to prepare for required electronic reporting that we intend to propose for certain measures beginning in CY 2015. The proposed requirements for electronic reporting are discussed below in section IX.A.9.d.of the preamble of this proposed rule. We invite public comment on this proposal.

8. Possible New Quality Measures and Measure Topics for Future Years

We anticipate that, as EHR technology evolves, hospitals will electronically report all chart-abstracted 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 proposal will provide hospitals and CMS with the ability to test systems in CY 2014 in order to prepare for required electronic reporting that we intend to propose for CY 2015. 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 that hospitals report additional electronic measures in an effort to reduce the burden associated with reporting chart abstracted measures and to continue to promote the adoption of CEHRT.

We are inviting public comment on our intention to add 5 new measures to be collected via EHRs in the future. The five new measures listed below were reviewed by the MAP for inclusion in the Hospital IQR Program:

- Severe Sepsis and Septic Shock Management Bundle NQF #0500 (MAP supported)
- PC-02 Cesarean Section NQF #0471 (MAP supported)
- PC-05 Exclusive Breast Milk Feeding NQF #0480 (MAP supported)
- Healthy Term Newborn NQF #0716 (MAP supported the direction of this measure)
- Hearing Screening Prior to Hospital Discharge NQF #1354 (MAP supported).

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. 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 (formerly known as QualityNet Exchange) Web site (<https://www.QualityNet.org>). This Web site meets or exceeds all current Health Insurance Portability and Accountability Act requirements for security of protected health information.

In order to participate in the Hospital IQR Program, hospitals must meet specific procedural requirements. Hospitals choosing to participate in the Hospital IQR Program must also meet specific data collection, submission, and validation requirements.

b. Procedural Requirements for the FY 2016 Payment Determination and Subsequent Years

The Hospital IQR Program procedural requirements are now codified in regulation at 42 CFR § 412.140. Hospitals should generally refer to the regulation for participation requirements. We are, however, proposing to make three changes to the procedural requirements in this proposed rule.

We are proposing to align the last date to withdraw with the final submission deadline. The current withdrawal deadline is August 15 of the fiscal year preceding the fiscal year for which a Hospital IQR Program payment determination will be made. We are proposing to change that deadline to May 15 prior to the start of the payment year affected in order to align with the last submission quarter deadline. For example, if a hospital wanted to withdraw from the program for the FY 2016 payment determination, the hospital would need to complete the withdrawal by May 15, 2015. We are proposing to amend the language at 42 CFR § 412.140(b) to reflect this proposal. We are proposing this change because we are striving to provide more timely feedback to hospitals regarding their annual payment update (APU) status. We do not believe this change would add any additional burden to hospitals and it would provide CMS the ability to make earlier participation decisions. We invite public comment on this proposal.

In addition, we are proposing two technical corrections to the regulation text at 42 CFR § 412.140. The first correction is to the title of this section. The current title is “Participation, Data Submission, and Validation Requirements under the Hospital Inpatient Quality Review (IQR) Program.” This should state “Participation, Data

Submission, and Validation Requirements Under the Hospital Inpatient Quality Reporting (IQR) Program.” The second technical correction is at paragraph (a)(3) which states: “Submit a completed Notice of Participation Form to CMS if the hospital is participating in the program for the first time, has previously withdrawn from the program and would like to participate again, or has received a new CMS Certification Number (CNN).” We are proposing to correct the acronym “CNN” to “CCN”. The proposed language would state: “Submit a completed Notice of Participation Form to CMS if the hospital is participating in the program for the first time, has previously withdrawn from the program and would like to participate again, or has received a new CMS Certification Number (CCN).”

c. Proposed Data Submission Requirements for Chart-Abstracted Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536 through 53537), for the FY 2015 payment determination and subsequent years, we retained the 4½ months quarterly submission deadline for chart-abstracted quality measures. We also retained the aggregate population and sampling deadline of 4 months. Hospitals would continue to be required to submit aggregate population and sample size counts to CMS on a quarterly basis for Medicare and non-Medicare discharges for the topic areas for which chart-abstracted data must be submitted (76 FR 51640 through 51641). We adopted the same 14-day period after the aggregate population and sample size count deadline to submit the required patient-level records. For the FY 2016 payment determination and subsequent years, hospitals must submit data for four consecutive calendar year discharge quarters. For example, for the FY 2016 payment determination, the submission quarters are as

follows: 1Q CY 2014, 2Q CY 2014, 3Q CY 2014 and 4Q CY 2014. We also adopted this submission deadline for the new chart-abstracted measure for FY 2016, Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation which is collected via a Web Based Tool.

For the FY 2016 payment determination and subsequent years, we are proposing to clarify the submission deadline time. Although we have historically stated that the submission deadline is 11:59 pm, we have not clarified which time zone. For the FY 2016 payment determination and subsequent years we are proposing to clarify that submissions to QualityNet will be accepted until 11:59 pm Pacific time. We invite public comment on this proposal.

d. Proposed Data Submission Requirements for Quality Measures That May be Voluntarily Electronically Reported for the FY 2016 Payment Determination

We are proposing the following approach to begin to align quality measure reporting under the Hospital IQR and Medicare EHR Incentive Programs. (We note that this proposal does not implement any statutory provisions of the HITECH Act or change any of the existing regulatory provisions of the Medicare EHR Incentive Program, which are the subject of section IX.E of the preamble of this proposed rule, separate rulemaking and public comment.) Under the Hospital IQR Program, for the FY 2016 payment determination, hospitals may choose to either (1) electronically report at least one quarter of CY 2014 quality measure data for each measure in each of four Hospital IQR measure sets (STK, VTE, ED and PC), or (2) to continue reporting all of these measures using

chart-abstracted data for all four quarters of CY 2014. If a hospital chooses to electronically report the four measure sets, all of the quality measures in those four measure sets must be electronically reported for the same reporting quarter(s) although, as stated above, the hospital may choose which quarter(s) to report.

We strongly recommend hospitals electronically report the 16 measures in these four measure sets in CY 2014, to provide hospitals and CMS with the ability to test systems and adjust workflow in CY 2014 in order to prepare for required electronic reporting that we intend to propose for CY 2015 in the Hospital IQR Program. We believe this will simplify quality reporting and submission for the Hospital IQR Program, and will reduce the reporting burden on hospitals. To further incentivize hospitals to choose this option, we also intend to use the electronically reported data to determine whether the hospital has satisfied the Medicare EHR Incentive Program clinical quality measure reporting requirement. The hospital must also satisfy all other requirements for the Medicare EHR Incentive Program.

We are proposing different Hospital IQR Program data submission deadlines for each quarter depending on whether the hospital is submitting the data solely for the Hospital IQR Program (that is, if the hospital does not want the data to be used to determine whether the hospital has satisfied the Medicare EHR Incentive Program clinical quality measure reporting requirement) or whether the hospital wishes to satisfy the requirements of both programs.

If a hospital chooses to report the four measure sets electronically for the Hospital IQR Program, but does not want the data to be used to determine whether the hospital has

satisfied the Medicare EHR Incentive Program clinical quality measure reporting requirement, the reporting periods and deadlines are as follows,:

FY 2016 Hospital IQR Program Chart-Abstracted Measure Reporting Periods and Deadlines	
Discharge Reporting Periods	Submission Deadlines
January 1, 2014 - March 31, 2014	August 15, 2014
April 1, 2014 - June 30, 2014	November 15, 2014
July 1, 2014 - September 30, 2014	February 15, 2015
October 1, 2014 - December 31, 2014	May 15, 2015

However, if the hospital does want us to use the electronically reported data to also determine whether the hospital has satisfied the Medicare EHR Incentive Program clinical quality measure reporting requirement, we are proposing to modify this data submission schedule to align the reporting periods and deadlines for the Hospital IQR and Medicare EHR Incentive Programs. Specifically, we are proposing that if a hospital wants us to also use the electronically reported data to determine whether the hospital has satisfied the Medicare EHR Incentive Program clinical quality measure reporting requirement, the Medicare EHR Incentive Program reporting periods and deadlines could be used to satisfy the Hospital IQR Program requirements. The Medicare EHR Incentive Program clinical quality measure reporting follows the Federal fiscal year while the Hospital IQR Program follows the calendar year. The table below lists the FY 2014 Medicare EHR Incentive Program reporting periods and submission deadlines.

Medicare EHR Incentive Program Reporting Periods and Deadlines FY 2014¹⁰¹	
Reporting Periods	Submission Deadlines
For eligible hospitals in their first year of the Medicare EHR Incentive Program - Any 90 consecutive days in FY 2014 prior to July 1, 2014	July 1, 2014
For eligible hospitals that are beyond their first year of the Medicare EHR Incentive Program reporting electronically – Any FY 2014 quarter, or the entire FY 2014 (October 1, 2013 - September 30, 2014)	November 30, 2014

We note that the submission deadline is November 30, 2014 for hospitals that are beyond their first year of the Medicare EHR Incentive Program. Accordingly, if such a hospital chooses to electronically report 3Q CY 2014 data under the Hospital IQR Program, it would need to submit the data by November 30, 2014 (not February 15, 2015) for us to also use that data to determine whether the hospital has satisfied its Medicare EHR Incentive Program clinical quality measurement requirement. In addition, as noted above, the hospital must satisfy all other program requirements established for the Medicare EHR Incentive Program.

We also note that because of the difference in reporting deadlines, we will not be able to use 4Q 2014 electronically submitted Hospital IQR data for purposes of determining whether a hospital has satisfied its Medicare EHR Incentive Program clinical quality measurement requirement. Hospitals, however, can still report the data electronically to meet their Hospital IQR Program requirements.

¹⁰¹ We refer readers to Tables 5 and 6 at 77 FR 54051.

We are proposing in section IX.E. of the preamble of this proposed rule to extend the beginning of the electronic submission period to January 2. If finalized, we note that hospitals in their first year of demonstrating meaningful use could also electronically submit the four measure sets (STK, VTE, ED and PC) for one quarter by July 1, 2014 to meet the clinical quality measure reporting criteria for the Medicare EHR Incentive Program as well as the Hospital IQR Program reporting requirement for those measure sets. We are also proposing that hospitals choosing to report at least one quarter of quality measure data electronically would not need to submit chart-abstracted quality measure data for the other quarters in CY 2014 for these four measure sets (STK, VTE, ED and PC).

For hospitals choosing to report electronically in the Hospital IQR Program, we are proposing that hospitals submitting these four measure sets electronically must use the Medicare EHR Incentive Program process for electronically submitting quality measure data into QualityNet (for EHR-based reporting). We are proposing Hospital IQR Program hospitals follow the submission requirements finalized in the Medicare EHR Incentive Program Stage 2 final rule (77 FR 54080). Hospitals will utilize their existing QualityNet account to submit electronic quality measure data. Specific submission procedures will be posted on the QualityNet Web site at: <https://www.qualitynet.org/>. We are proposing to align with the case threshold exemption from the Medicare EHR Incentive Program, which means that for each quality measure for which hospitals do not have a minimum number of patients that meet the patient population denominator criteria for the relevant EHR reporting period, hospitals

will have the ability to declare a “case threshold exemption” of five or fewer discharges. . Our intent is to finalize the same process in both the Medicare EHR Incentive Program and the Hospital IQR Program as further detailed below.

In preparation for this transition to electronic quality measure reporting under the Hospital IQR Program, we are proposing that if a hospital chooses to report the four measure sets (STK, VTE, ED and PC) electronically during CY 2014, the hospital’s data will be extracted from the Certified Electronic Health Record Technology (CEHRT) and submitted to CMS using the Health Level Seven (HL7) Quality Reporting Document Architecture (QRDA) Category I Revision 2 standard. Certified EHR Technology is defined for the Medicare EHR Incentive Program at 42 CFR § 495.4 and 45 CFR § 170.102.

We recognize that a small percentage of Hospital IQR Program-participating hospitals are not currently participating in the Medicare EHR Incentive Program and that this proposal may not be applicable to those hospitals. These hospitals should continue to report the four measure sets using chart-abstraction. However, we believe greater adoption of CEHRT and reporting of quality measures electronically across Medicare hospital quality reporting will reduce the administrative burden on hospitals associated with the reporting of chart-abstracted quality measures. This will help hospitals to meet both Hospital IQR Program and Medicare EHR Incentive Program requirements with a streamlined data submission to CMS. We invite public comment on this proposal.

In the recent HHS ONC final rule regarding standards, implementation specifications, and certification criteria for health information technology (77 FR 54163

through 54292), HHS adopted “2014 Edition” EHR certification criteria that will require CEHRT to provide the capability to submit electronic clinical quality measure data in the HL7 QRDA Category I standard to support patient-level data submissions. We do not believe that our proposal to use QRDA Category I (patient-level) data under the Hospital IQR Program will create a new reporting burden for hospitals because we already require hospitals to submit “all-payer” patient-level data under the Hospital IQR Program.

The QRDA standard specifies the framework for quality reporting, standardizes measure-defined data elements for interoperability between organizations, and is used to transmit clinical quality measure data needed to meet meaningful use (MU) requirements under the Medicare EHR Incentive Program.

We are proposing that we will not publicly report data collected from hospitals choosing to report these four measure sets electronically in CY 2014. After reviewing comments we received from our Request for Information (RFI) entitled “Medicare Program; Request for Information on Hospital and Vendor Readiness for Electronic Health Records Hospital Inpatient Quality Data Reporting” (78 FR 308 through 310), it became clear that we should consider not publicly reporting clinical quality measure data submitted electronically for the four proposed measure sets due to possible abnormalities in the data and/or the submission process that may occur during the first year of electronic reporting to CMS. This proposal will provide us time to assess the data reported to determine the optimal timing and transition strategy for electronic quality measure reporting by hospitals participating in the Hospital IQR Program. However, we would like to recognize hospitals that report electronically and invite public comment on

whether hospitals choosing electronic reporting of quality measures would like to be acknowledged on the Hospital Compare Web site as “Pioneers” in Medicare EHR-based reporting. However, the data results for Medicare EHR-based measures would not be publicly reported.

We are concerned that a large number of hospitals would not be able to meet the Hospital IQR Program requirements for FY 2016 if we proposed to require hospitals to electronically report the four measure sets. Accordingly, we believe this proposal – providing hospitals the opportunity for voluntary electronic submission of data for one quarter of CY 2014 discharges – represents a balanced policy that some hospitals will be able to take advantage of while ensuring that the FY 2016 Hospital IQR Program requirements are attainable for all participating hospitals. As we move further toward alignment of quality measures reporting among our reporting initiatives, we intend to propose in the future to require hospitals to report electronically specified quality measures. We invite public comment on this approach.

We are not proposing to validate any of the data that is electronically reported for the FY 2016 Hospital IQR Program. However, we share the concern among hospitals, vendors, and other stakeholders that there is a need to develop a comprehensive validation process that applies to electronically reported data. We intend to develop and propose to adopt a data validation strategy for electronically reported quality measure data in the FY 2015 IPPS/LTCH PPS proposed rule. This strategy will be informed, in part, by comments we receive in response to this proposed rule. We invite public comment regarding potential data validation methodologies.

e. Sampling and Case Thresholds for the FY 2016 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), we continued, for the FY 2015 payment determination and subsequent years, the approach we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230) regarding hospital submission of population and sampling data. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), we did not make any changes to these requirements. For the FY 2016 payment determination and subsequent years, we are not proposing to make any changes to these requirements.

We strongly recommend that hospitals review the QIO Clinical Warehouse Feedback Reports and the Hospital IQR Program Provider Participation Reports that are available after patient-level data are submitted to the QIO Clinical Warehouse. We generally update these reports on a daily basis to provide accurate information to hospitals about their submissions. These reports enable hospitals to ensure that their data were submitted on time and accepted into the QIO Clinical Warehouse.

f. Proposed HCAHPS Requirements for the FY 2017 Payment Determination and Subsequent Years

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220), we adopted the HCAHPS requirements for the FY 2013 and FY 2014 Hospital IQR Program payment determinations.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), we made one change to these requirements. Beginning with discharges occurring in third

quarter CY 2011, we established that hospitals will have about 13 weeks after the end of a calendar quarter to submit HCAHPS data for that quarter to the QIO Clinical Warehouse.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), for the FY 2016 Hospital IQR Program payment determination, we continued these HCAHPS requirements.

For the FY 2017 payment determination and subsequent years, we are proposing to retain these requirements. Under these requirements, a hospital must continuously collect and submit HCAHPS data in accordance with the current HCAHPS Quality Assurance Guidelines and the quarterly data submission deadlines, both of which are posted at <http://www.hcahponline.org>. In order for a hospital to participate in the collection of HCAHPS data, a hospital must either: (1) contract with an approved HCAHPS survey vendor that will conduct the survey and submit data on the hospital's behalf to the QIO Clinical Warehouse; or (2) self-administer the survey without using a survey vendor provided that the hospital attends HCAHPS training and meets Minimum Survey Requirements as specified on the HCAHPS Web site at:

<http://www.hcahponline.org>. A current list of approved HCAHPS survey vendors can be found on the HCAHPS Web site. For the FY 2017 Hospital IQR Program, the HCAHPS data would be based on discharges from January 1, 2015 through December 31, 2015.

Every hospital choosing to contract with a survey vendor must provide the sample frame of HCAHPS-eligible discharges to its survey vendor with sufficient time to allow

the survey vendor to begin contacting each sampled patient within 6 weeks of discharge from the hospital. (We refer readers to the Quality Assurance Guidelines located at <http://www.hcahponline.org> for details about HCAHPS survey administration.)

Hospitals are strongly encouraged to submit their entire patient discharge list, excluding patients who had requested “no publicity” status or who are excluded because of State regulations, in a timely manner to their survey vendor to allow adequate time for sample creation, sampling, and survey administration. We emphasize that hospitals must also provide the administrative data that is required for HCAHPS in a timely manner to their survey vendor. This includes the patient MS-DRG at discharge, or alternative information that can be used to determine the patient’s service line, in accordance with the survey protocols in the most recent HCAHPS Quality Assurance Guidelines.

We note that the HCAHPS Quality Assurance Guidelines require that hospitals maintain complete discharge lists that indicate which patients were eligible for the HCAHPS survey, which patients were not eligible, and which patients were excluded, and the reason(s) for ineligibility and exclusion. (We refer readers to the Quality Assurance Guidelines located at <http://www.hcahponline.org> for details about HCAHPS eligibility and sample frame creation.) In addition, the hospital must authorize the survey vendor to submit data via My QualityNet, the secure part of the QualityNet Web site, on the hospital’s behalf.

Hospitals must obtain and submit at least 300 completed HCAHPS surveys in a rolling four-quarter period unless the hospital is too small to obtain 300 completed surveys. We wish to emphasize that the absence of a sufficient number of HCAHPS

eligible discharges is the only acceptable reason for obtaining and submitting fewer than 300 completed HCAHPS surveys in a rolling four quarter period. If a hospital obtains fewer than 100 completed surveys, the hospital's HCAHPS scores will be accompanied by an appropriate footnote on the Hospital Compare Web site alerting the Web site users that the scores should be reviewed with caution, as the number of surveys may be too low to reliably assess hospital performance.

After the survey vendor submits the data to the QIO Clinical Warehouse, we strongly recommend that hospitals employing a survey vendor promptly review the two HCAHPS Feedback Reports (the Provider Survey Status Summary Report and the Data Submission Detail Report) and the HCAHPS Review and Correction Report that are available. These reports enable a hospital to ensure that its survey vendor has submitted the data on time, the data has been accepted into the QIO Clinical Warehouse, and the data accepted into the QIO Clinical Warehouse are complete and accurate.

In order to ensure compliance with HCAHPS survey and administration protocols, survey vendors and hospitals that self-administer the HCAHPS Survey must: (1) meet HCAHPS Minimum Survey Requirements and Rules of Participation presented in the current HCAHPS Quality Assurance Guidelines; (2) adhere to the HCAHPS survey administration protocols provided in the current HCAHPS Quality Assurance Guidelines and updated through HCAHPS Bulletins and announcements on the official HCAHPS On-Line Web site, www.hcahponline.org; and (3) participate in all oversight activities. As part of the oversight process, during the onsite visits or conference calls, the HCAHPS Project Team will review the hospital's or survey vendor's survey systems and assess

protocols based upon the most recent HCAHPS Quality Assurance Guidelines. All materials relevant to survey administration will be subject to review.

The systems and program review includes, but is not limited to: (a) survey management and data systems; (b) printing and mailing materials and facilities; (c) telephone and Interactive Voice Response (IVR) materials and facilities; (d) data receipt, entry and storage facilities; and (e) written documentation of survey processes. As needed, hospitals and survey vendors will be subject to follow-up site visits or conference calls. We point out that the HCAHPS Quality Assurance Guidelines state that hospitals should refrain from activities that explicitly influence how patients respond on the HCAHPS survey. If we determine that a hospital is not compliant with HCAHPS program requirements, we may determine that the hospital is not submitting HCAHPS data that meet the requirements of the Hospital IQR Program.

We strongly recommend that hospitals approved to self-administer the HCAHPS Survey attend both HCAHPS Introductory Training and HCAHPS Update Training every year. The dates of HCAHPS training session are announced on the HCAHPS On-Line Web site, www.hcahponline.org.

The HCAHPS Survey is available in official translations in several languages other than English: Spanish (mail and telephone modes); Chinese (mail mode); Russian (mail mode); and Vietnamese (mail mode). All official translations of the HCAHPS Survey instrument are available in the current HCAHPS Quality Assurance Guidelines. We strongly encourage hospitals with a significant patient population that speaks Spanish, Chinese, Russian or Vietnamese to offer the HCAHPS Survey in those

languages. We plan to offer an official translation of the HCAHPS Survey in Portuguese (mail mode) in 2013. We encourage hospitals that serve patient populations that speak languages other than those noted to request CMS to create an official translation of the HCAHPS Survey in those languages. Only the official translations of the HCAHPS Survey instrument can be implemented.

We continue to strongly recommend that each new hospital participate in an HCAHPS dry run, if feasible, prior to beginning to collect HCAHPS data on an ongoing basis to meet Hospital IQR Program requirements. New hospitals can conduct a dry run in the last month of a calendar quarter. The dry run will give newly participating hospitals the opportunity to gain first-hand experience collecting and transmitting HCAHPS data without the public reporting of results. Using the official survey instrument and the approved modes of administration and data collection protocols, hospitals/survey vendors will collect HCAHPS dry-run data and submit the data to My QualityNet, the secure portion of QualityNet.

We wish to emphasize that, barring the exception that the hospital is too small to obtain 300 completed surveys in a four-quarter period, IPPS hospitals that do not meet the minimum 300 completed surveys requirement may not be in compliance with the Hospital IQR Program's requirement that hospitals submit quality data in the form, manner, and time specified by the Secretary in order to receive the full APU. If we become aware of specific cases in which a hospital has not met the finalized HCAHPS survey protocols, we may determine that the hospital has failed to meet the applicable APU requirement, and will reduce that hospital's APU accordingly.

We are proposing to codify the current guideline that approved HCAHPS survey vendors and self-administering hospitals must fully comply with all HCAHPS oversight activities, including allowing CMS and its HCAHPS Project Team to perform site visits at hospitals' and survey vendors' locations. We are proposing to codify this survey requirement at § 412.140(f)(1).

We are proposing to codify the current guideline that CMS approves survey vendor applicants to administer the HCAHPS survey for hospitals clients when applicants have met the Minimum Survey Requirements and Rules of Participation listed in the current HCAHPS Quality Assurance Guidelines and adhere to the survey administration protocols provided in the current HCAHPS Quality Assurance Guidelines and occasionally updated through HCAHPS Bulletins and announcements on the official HCAHPS On-Line Web site. We are proposing to include this survey requirement at § 412.140(f)(2).

The absence of a sufficient number of HCAHPS eligible discharges is the only acceptable reason for obtaining and submitting fewer than 300 completed HCAHPS surveys in a rolling quarter period. Hospitals and HCAHPS survey vendors should regularly check the official HCAHPS Web site at <http://www.hcahponline.org> for new information and program updates regarding the HCAHPS Survey, its administration, oversight and data adjustments. We invite public comment on our proposal to continue using these HCAHPS requirements for the FY 2016 payment determination and subsequent years.

g. Proposed Data Submission Requirements for Structural Measures for the FY 2015 and FY 2016 Payment Determinations

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 through 51644), beginning with FY 2013, we finalized the period of data collection for which hospitals will submit the required structural measure information once annually for the structural measures via a Web-Based Measure Tool. We finalized our proposal for FY 2014 for submission of structural measures between April 1, 2013 and May 15, 2013 with respect to the time period of January 1, 2012 through December 31, 2012. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53538 through 53539), we finalized our proposal to continue this policy for the FY 2015 payment determination and subsequent years.

However, in order to provide the more timely feedback to hospitals regarding APU participation status, for the FY 2015 payment determination, we are proposing to change the date that structural measures will be submitted from April 1 2014- May 15, 2014 to January 1, 2014- February 15 2014. For the FY 2016 payment determination, we are proposing that the period of data collection for which hospitals will submit the required registry participation information for the structural measures via a Web-Based Measure Tool be between January 1, 2015 and February 15, 2015, with respect to the time period of January 1, 2014 through December 31, 2014. These proposals will allow us to provide earlier feedback to hospitals regarding APU status. We invite public comment on our proposals.

h. Proposed Data Submission and Reporting Requirements for Healthcare-Associated Infection (HAI) Measures Reported via NHSN

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51644 through 51645), we adopted the data submission and reporting standard procedures that have been set forth by CDC for NHSN participation in general and for submission of the HAI measures to NHSN. The existing data collection and submission timeframes for the HAI measures for the FY 2015 payment determination and subsequent years align with the submission timeframes for chart-abstracted measures with the exception of Healthcare Provider Influenza Vaccination as defined below. The data submission deadlines are posted on the QualityNet Web site at: <http://www.QualityNet.org/>.

Hospitals will have until the Hospital IQR Program final submission deadline to submit their quarterly data for CLABSI, SSI, CAUTI, MRSA Bacteremia and Clostridium difficile to NHSN. After the final Hospital IQR Program submission deadline has occurred for each calendar quarter of CY 2013, we will obtain the hospital-specific calculations that have been generated by the NHSN for the Hospital IQR Program.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), we continued the data submission and reporting standard procedures we adopted in the FY 2012 IPPS/LTCH PPS final rule, with two exceptions discussed below, for the FY 2015 payment determination and subsequent years.

The HAI measures that will be included in the FY 2016 payment determination are included in the following chart:

Topic	FY 2016 Payment Determination: Hospital Associated Infection Measures (CDC/NHSN)
	Central Line Associated Blood Stream Infection
	Surgical Site Infection
	Catheter-Associated Urinary Tract Infection
	MRSA <u>Bacteremia</u>
	<u>Clostridium difficile</u>
	Healthcare Provider Influenza Vaccination

We realize that some hospitals may not have locations that meet the NHSN criteria for CLABSI or CAUTI reporting, for example, when a hospital has no ICUs. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), we provided an exception for the CLABSI and CAUTI measures for hospitals that do not have an ICU, reducing the burden associated with reporting to NHSN.

In addition, we recognize that some facilities may perform so few procedures requiring surveillance under the SSI measure that the data may not meaningfully assess the hospital's performance on the measure. Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), we provided an exception for these hospitals from the reporting requirement in any given year if the hospital performed fewer than a combined total of 10 colon and abdominal hysterectomy procedures in the calendar year prior to the reporting year. For example, a hospital that performed only 2 colon surgeries and 4 abdominal hysterectomies in CY 2013 is not required to report the SSI measure in CY 2014. We finalized our proposal to provide hospitals with a single HAI exception form, to be used for seeking an exception for any of the CLABSI, CAUTI and SSI measures, which is available on QualityNet at: <https://www.qualitynet.org/Hospitals-Inpatient>Healthcare>

Associated Infections (HAI). For the FY 2016 payment determination and subsequent years, we are not proposing to make any changes to these requirements and exceptions.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51631-51633) we finalized collection of the Healthcare Provider Influenza Vaccination measure data from October 1 through March 31st to coincide with the flu season. Because this measure is collected seasonally, we are proposing to collect this measure on May 15th of the calendar year for which the season ends. For example, for the Healthcare Provider Influenza Vaccination measure collection for vaccinations given from October 1, 2013 (or when the vaccine becomes available) – March 31, 2014, the submission deadline would be May 15, 2014. We invite public comment on this proposal.

For the FY 2016 payment determination and subsequent years we are proposing to require hospitals to report the Medicare Beneficiary ID numbers to the NHSN system for all events reported for Medicare beneficiaries. The NHSN system currently supports the voluntary submission of this information, but CMS is proposing to make it mandatory for patients with HIC numbers. We make this proposal to better support our validation efforts. CMS currently matches medical records to NHSN data as part of validation. With the information available for matching, CMS may occasionally fail to match a reported event. By requiring that hospitals report the HIC number when it is available, we increase our confidence that records reported to NHSN will appropriately be matched with the records we sample for validation. Because we cannot anticipate in advance which records may be sampled for validation, we are proposing to require that hospitals

provide this information for all reported events. We invite public comment on this proposal.

10. Proposed Modifications to the Validation Process for Chart-Abstracted Measures under the Hospital IQR Program

For the FY 2015 payment determination and subsequent years, we are proposing some modifications to the validation requirements and methods we finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553). As described below, these proposals are intended to strengthen the Hospital IQR Program by validating new HAI measures while simultaneously decreasing burden relative to previous years.

The procedures to which we are proposing to modify are organized into the following sections: (a) number and timing of quarters included in validation; (b) selection of measures and sampling of charts to be included in validation; (c) procedures for computing the validation score; (d) selection of hospitals for validation of chart-abstracted measures; and (e) procedures for submitting records for validation.

a. Proposed Timing and Number of Quarters Included in Validation

As finalized in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50219), the quarters included in the validation effort for each year's Hospital IQR Program payment determination are the 4th calendar quarter (October through December) of the year that occurs 2 years before the payment determination and the first 3 calendar quarters (January through September) of the following calendar year. For example, as illustrated below, for the FY 2015 payment determination, the quarters previously finalized for inclusion in validation are the fourth quarter of CY 2012 through the third quarter of

CY 2013. The first figure below shows the timeline and steps associated with the Hospital IQR Program and the subsequent steps in annual validation as previously finalized and as proposed.

Section 1886(o)(1)(C)(ii)(I) of the Act precludes a hospital from participating in the Hospital VBP Program for a fiscal year if the hospital is subject to the payment reduction under the Hospital IQR Program for that fiscal year. As illustrated in the figure, the process previously finalized (75 FR 50219), yields the determination of a hospital's Hospital IQR Program APU in August of every year. However, to support the hospital's payment determination under the Hospital VBP Program in a timely manner, the IQR APU determination must be made by July 1 of each year. Therefore, we are proposing the changes discussed below.

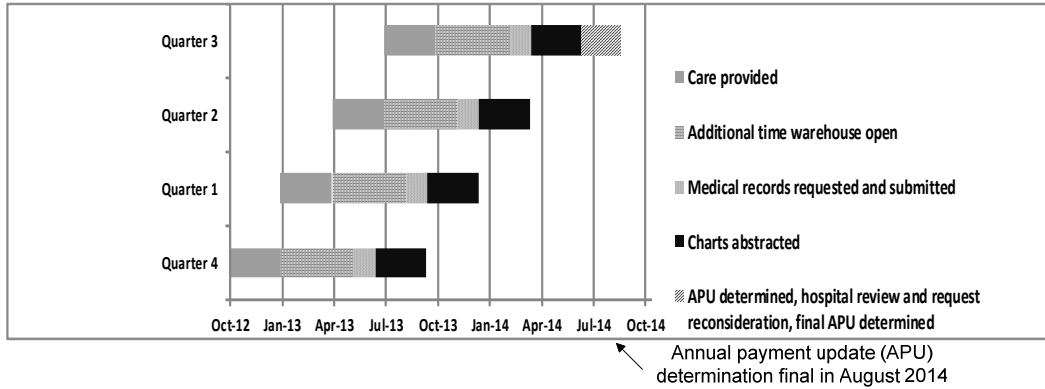
For the FY 2015 payment determination and subsequent years, we are proposing to change this requirement to include in validation only the 4th quarter of the calendar year that occurs 2 years before the payment determination and the first 2 calendar quarters (January through June) of the following calendar year. As illustrated below, for the FY 2015 payment determination, the quarters proposed for inclusion in validation are the fourth quarter of CY 2012 through the second quarter of CY 2013; and for the FY 2016 payment determination, the quarters proposed for inclusion in validation are the fourth quarter of CY 2013 through the second quarter of CY 2014.

For the FY 2016 payment determination and subsequent years, we are also proposing to change the validation requirement to include the 3rd and 4th calendar quarters of the year that occurs 2 years before the payment determination is made and the 1st and

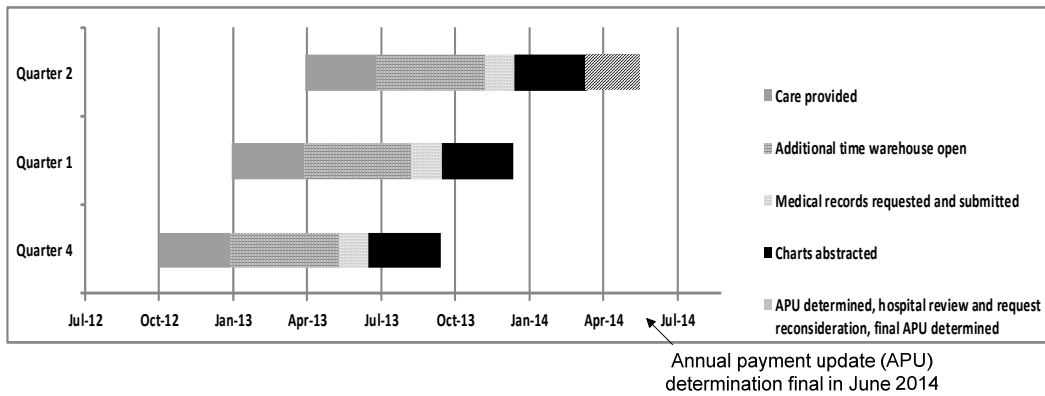
2nd quarters of the subsequent year for validation. As discussed above, this timeframe still allows an APU determination by July 1 each year. From an operational standpoint, gathering data for the entire year is preferable to gathering data for only three quarters. Also, we believe that all four quarters of data that are used for the Hospital IQR and VBP Programs should be checked for accuracy.

However, as described further below, we will not have built the infrastructure needed to support the proposed HAI validation process by the 3rd quarter of CY 2013. Therefore, for the FY 2016 payment determination, we are proposing to validate all measures except for HAIs starting with 3rd quarter of CY 2013, and to initiate validation of HAIs in the 4th quarter of CY 2013. We invite public comment on this proposal.

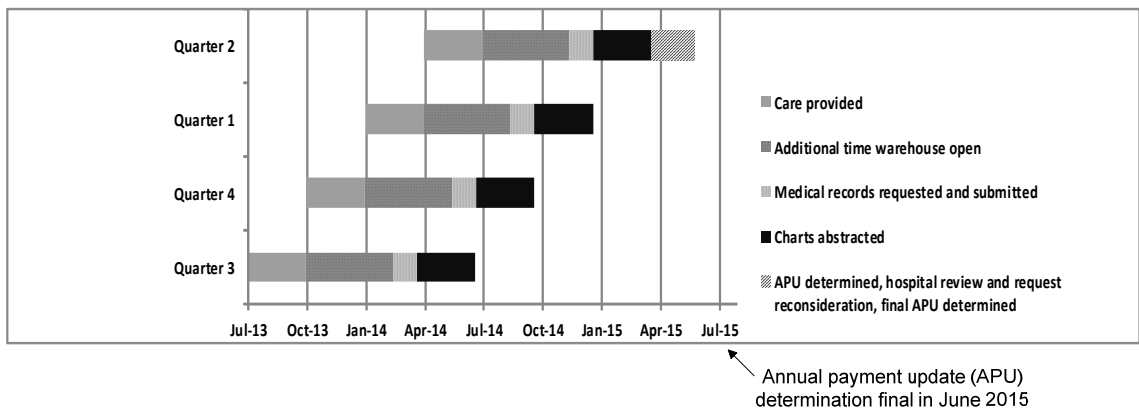
Timeline for validation of chart-abstracted measures for the FY 2015 Payment Determination, as previously finalized (75 FR 50227-50229)



Proposed timeline for validation of chart-abstracted measures for the FY 2015 Payment Determination



Proposed timeline for validation of chart-abstracted measures for the FY 2016 Payment Determination



b. Proposed Selection of Measures and Sampling of Charts to be Included in Validation

(1) Clinical Process of Care Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53540 through 53550), for the FY 2015 payment determination and subsequent years, we finalized separate processes for selecting and scoring for validation of 21 chart-abstracted clinical process of care measures and three HAI measures. The measures finalized for validation for clinical processes of care were included in 6 measure sets: acute myocardial infarction (AMI), heart failure (HF), pneumonia (PN), surgical care improvement project (SCIP), emergency department (ED) and immunization (IMM) (77 FR 53541 through 53542).

For the purposes of the FY 2016 payment determination and subsequent years, we are proposing to retain for validation 12 of the 21 chart-abstracted clinical process of care measures and to suspend validation for the remaining 9 chart-abstracted clinical process of care measures. With respect to seven of the nine measures, we are not proposing to include them in the FY 2016 measure set.

However, we are proposing to suspend validation of ED-1 and ED-2, despite their proposed inclusion in the FY 2016 measure set, because we do not operationally have the ability to validate electronically reported versions of the measures. We believe that continuing to validate the measures only when they are reported via chart-abstraction could create inequity in the validation process that favors hospitals opting to report the measures electronically. Therefore, we are proposing to delete the ED measure set from the validation process. We invite public comment on these proposals.

Hospital IQR Program Chart-Abstracted Clinical Process of Care Measures Proposed for Validation for the FY 2016 Payment Determination
Measure
AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival
AMI-8a Timing of receipt of primary percutaneous coronary intervention
HF-2 Evaluation of left ventricular systolic function
PN-6 Appropriate initial antibiotic selection
SCIP INF-1 Prophylactic antibiotic received within 1 hour prior to surgical incision
SCIP INF-2: Prophylactic antibiotic selection for surgical patients
SCIP INF-3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery)
SCIP INF-4: Cardiac surgery patients with controlled 6AM postoperative serum glucose
SCIP INF-9: Postoperative urinary catheter removal on postoperative day 1 or 2 with day of surgery being day zero
SCIP Cardiovascular-2: Surgery Patients on a Beta Blocker prior to arrival who received a Beta Blocker during the perioperative period
SCIP-VTE-2: Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery
IMM-2 Immunization for pneumonia

The process for sampling of clinical process of care cases previously finalized for the FY 2015 payment determination and subsequent years in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53540 through 53541) is as follows. A sample of 15 records per quarter is to be drawn for validation of the chart-abstracted clinical process of care measures (77 FR 53540 through 53541). As finalized in the FY 2012 IPPS/LTCH PPS final rule for the FY 2014 payment determination and subsequent years, the sample is to include 3 records each sampled from among the AMI, HF, PN, and SCIP measure sets, and 3 records to validate for both the ED and IMM measures sets from among “principal diagnoses and surgical procedures not already included in the AMI, HF, PN, and SCIP populations eligible for validation sampling in these four topic areas (76 FR 51648).” As finalized in the FY 2012 IPPS/LTCH PPS final rule, the records sampled for AMI, HF,

PN, and SCIP will also be validated for ED/IMM (76 FR 51648), but as finalized in the FY 2013 IPPS/LTCH PPS final rule these cases will not be validated from among charts sampled for HAI validation (77 FR 53540 through 53541).

We are proposing to modify this process for the FY 2016 payment determination and future years in two ways. First, we are proposing to eliminate validation of the ED measure set for the reasons described immediately above. Second, we are proposing to change the requirement to validate ED and IMM for all records included in the validation sample for AMI, HF, PN, and SCIP (77 FR 53540 through 53541). When previously finalized, this policy was intended for two purposes. When a patient chart sampled for validation for AMI, HF, PN, or SCIP also had data submitted to the warehouse for ED/IMM, we have been evaluating the accuracy of the data submitted to the warehouse for ED and IMM and including our assessment of accuracy in the validation score. In addition, when a patient chart sampled for validation for AMI, HF, PN, or SCIP did not include data submitted to the warehouse, our intention in abstracting data on ED and IMM was to assess the extent to which hospitals may have misdrawn the sample such that the ED and IMM data reported to the warehouse was inaccurate. Although it was our intention to use the data for both reasons, we have found it challenging to use the data to evaluate inaccurate sampling and have not yet done so.

Therefore, for the FY 2016 payment determination and future years, we are proposing to validate IMM for between 3 and 15 charts per hospital per quarter. These include the 3 charts sampled for IMM from among principal diagnoses and surgical procedures not already included in the AMI, HF, PN, and SCIP populations eligible for

validation sampling in these four topic areas, and as many of the 12 charts sampled for AMI, HF, PN, and SCIP populations as have IMM data submitted to the warehouse. We invite public comment on this proposal.

(2) HAI Measures Included in the Current Validation Process

The three HAIs specified for chart-abstracted validation in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53542), for FY 2015 payment determination and subsequent years are CLABSI, CAUTI, and SSI for patients undergoing abdominal hysterectomies and colon procedures. HAIs are very rare events, which makes validating that they have been reported accurately more challenging than validating the clinical process of care measures. As previously finalized in the FY 2012 and FY 2013 IPPS/LTCH PPS final rules (76 FR 51645 through 51648 and 77 FR 53542 through 53548, respectively), for each HAI, we identify a set of patient episodes of care which have a much higher probability of containing a reportable HAI than others. Each quarter, we sample up to 12 of these candidates, request patient charts from hospitals to determine whether or not an HAI occurred, and score these charts by determining whether events were appropriately reported to NHSN.

In order to identify candidate cases referenced above for CLABSI and CAUTI, we also require hospitals to submit supplemental information on certain patient episodes of care quarterly. In the FY 2012 and FY 2013 IPPS/LTCH PPS final rules (76 FR 51645 through 51648 and 77 53542 through 53548, respectively), we identified the supplemental information to be provided and the types of patient episodes of care for which this information is needed. We require hospitals to submit this supplemental

information in two separate “Validation Templates” according to formats specified on QualityNet. We require separate CLABSI and CAUTI Validation Templates because different information is required to identify candidate CLABSIs and candidate CAUTIs.

For a detailed discussion of these requirements, we refer readers to our Web site at:

<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228760487021>.

As stated in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51646), for the FY 2012 payment determination and subsequent years, hospitals are required to report positive blood cultures for intensive care unit patients and are also required to “self-identify intensive care unit patients with a CVC [central venous catheter] that are on this blood culture list.” We are proposing for the FY 2016 payment determination and subsequent years to remove the requirement to note a CVC and replace it with a requirement to note a “central line.” In other words, we are proposing to require that hospitals note on the CLABSI Validation Template whether patients had a “central line” present at any time during their hospital stay. We are making this proposal to better align with current NHSN definitions.

The FY 2012 IPPS/LTCH PPS final rule (76 FR 51646) also specified which organisms should be reported on the CLABSI Validation Template, which are also regarded as common commensals (often referred to as skin contaminants), and where hospitals could find an updated list of these commensals. This list is frequently updated, but the link containing updates is currently out of date. When we review the CLABSI Validation Templates for the FY 2016 payment determination and subsequent years, we

are proposing to apply the most up-to-date list available at the time of review. At present that list may be found at: <http://www.cdc.gov/nhsn/acute-care-hospital/clabsi/index.html>.

We also are proposing for the FY 2016 payment determination and subsequent years that hospitals must exclude from CAUTI Validation Templates urine cultures with more than 2 organisms, even if they have greater than or equal to 1,000 colony-forming units (CFUs)/ml. We are making this proposal because, when we finalized the requirement to include on the CAUTI Validation Templates all urine cultures with greater than or equal to 1,000 CFUs /ml (77 FR 53542 through 53545), our intention was to identify urine cultures that conform to NHSN definitions for CAUTI. Although these definitions vary, all require that there be no more than 2 organisms identified in the result (because multiple organisms often indicate contamination).¹⁰² We invite public comment on this proposal.

We are proposing for the FY 2016 payment determination and subsequent years to notify hospitals of future changes to the definition of candidate HAI events through HAI Validation guidance documents to be posted annually on QualityNet. As illustrated by several proposals immediately above identifying places where CMS and NHSN are slightly misaligned, we believe that these very detailed specifications may more appropriately be addressed through sub-regulatory guidance than through the rulemaking process. Therefore, we are making this proposal to simplify future proposed rules regarding validation, to ensure that we are able to remain current with NHSN guidance

¹⁰²“Catheter-Associated Urinary Tract Infection (CAUTI) Event”
<http://www.cdc.gov/nhsn/PDFs/pscManual/7pscCAUTIcurrent.pdf>, last accessed February 19, 2013.

and protocols, and to ensure that hospitals are made aware of these updates. We invite public comment on this proposal.

For the FY 2016 payment determination and subsequent years, we also are proposing to exclude from HAI validation all patient episodes of care with lengths of stay of more than 120 days. Patient episodes of care involving lengths of stay over 120 days are very rare, accounting for much less than one percent of the records submitted for Q1 2012 CLABSI validation. Because medical records for patients with very long lengths of stay may be tens of thousands of pages, the burden and costs of validation to hospitals and CMS are disproportionate to the information gained from their validation. In addition, this proposed change aligns the HAI episode of care maximum length of stay with the Hospital IQR Program's clinical process of care measures episode of care maximum length of stay of 120 days as detailed in the Specifications Manual for the National Hospital Inpatient Quality Measures (<http://www.qualitynet.org>). We invite public comment on this proposal.

For the FY 2016 payment determination and subsequent years, we also are proposing to require each hospital to submit data without modifications to the format within the Validation Template posted on QualityNet at the beginning of each validation cycle. We believe this requirement is needed based on our experience with the CLABSI Validation Template for the FY 2013 payment determination. We have observed that many hospitals enter the required data but alter the format of the downloadable Validation Template. For example, hospitals may change the length or format of a column or change its column name. Because our contractors must process hundreds of

these templates in a matter of weeks, even minor alterations to formats of the data within the Template create significant operational delays. We will continue to give hospitals feedback on their Validation Templates prior to the submission deadline. To assist hospitals in meeting this formatting requirement, we will include formatting in future feedback. We invite public comment on this proposal.

(3) HAI Measures to be Added to the Validation Process

For the FY 2016 payment determination and subsequent years, we are proposing to validate two new HAI measures: methicillin-resistant staphylococcus aureus (MRSA) bacteremia Laboratory-identified (LabID) Events and Clostridium difficile (CDI) LabID Events. MRSA and CDI were finalized for inclusion in the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51629 through 51631) starting with the FY 2015 payment determination. We are proposing to validate MRSA and CDI consistent with requirements under section 1886(b)(3)(B)(viii)(XI) of the Act which requires us to establish a process to validate measures included in the Hospital IQR Program as appropriate. We invite public comment on this proposal.

For MRSA and CDI validation, we are proposing a process similar to that for CLABSI and CAUTI for the FY 2016 payment determination and subsequent years. Specifically, we are proposing to require sampled hospitals to provide to CMS or its contractor one list of final blood cultures positive for MRSA and a second list of all final stool specimens toxin positive for CDI. We note that although CMS only publicly reports hospital-onset infections, CMS requires hospitals to report both hospital and community-onset cases. We require hospitals to report community-onset cases because

NHSN employs this information in risk-adjustment. Validation of MRSA and CDI requires confirmation that both hospital and community-onset cases are reported correctly and completely. Therefore, for the FY 2016 payment determination and subsequent years, we are proposing that both types of cases be included on the MRSA and CDI Validation Templates.

For these payment determinations, we are proposing to collect the following information on the MRSA and CDI Validation Templates needed to identify each candidate event: (1) laboratory accession number, collection date, and location; (2) necessary information to identify the patient (that is, patient identifier, Medicare Beneficiary number also known as the health insurance claim [HIC] number, sex, and date of birth); (3) the patient's admission and discharge dates; and (4) necessary information to identify the hospital (NHSN Facility ID, Provider ID/CCN, Hospital Name and State, Contact Information for the Person Completing the Template).

Draft versions of the proposed MRSA and CDI Validation Templates will be posted on the QualityNet Web site at: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228760487021> during the public comment period. We are proposing this approach for MRSA and CDI validation, because we believe that this is the best way for us to systematically identify candidates that are likely to yield a high proportion of cases that should have appropriately been reported to NHSN. Consistent with the process we have been using for the CLABSI and CAUTI Validation Templates, we are proposing that quarterly submission deadlines correspond to those for population

and sampling data as defined in section IX.A.9.e. of the preamble of this proposed rule.

We invite public comment on this proposal.

We recognize that the proposal to add two new HAI Validation Templates has the potential to increase burden to individual hospitals selected for validation. As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53551 through 53553), for the FY 2015 payment determination and subsequent years, the annual validation sample includes 400 randomly selected hospitals and up to 200 hospitals sampled based on targeting criteria. To add these new Templates without increasing burden for the FY 2016 payment determination and subsequent years, we are proposing to randomly assign half of hospitals to submit templates for CLABSI and CAUTI validation and half of hospitals to submit templates for MRSA and CDI validation. We believe this proposal will limit hospital burden to that finalized in the FY 2013 IPPS/LTCH PPS final rule, because no hospital would be required to submit more than two templates per quarter.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53547 through 53548), we established a sample size of 12 records for HAI validation per quarter for the FY 2015 payment determination and subsequent years. Each quarterly sample is to be drawn from a list of patient episodes of care for all three types of candidate HAIs (CLABSI, CAUTI, and SSI) combined in one non-stratified sampling frame. For the FY 2016 payment determination and subsequent years, we are proposing to target separate sampling strata for each type of HAI. We are making this proposal because we believe that having separate sampling targets for each infection will better accommodate the very different incidence of different types of HAI events, particularly for hospitals which are to be

validated for SSI, MRSA, and CDI. This proposal also supports the objective to evaluate how well each HAI is reported to NHSN when considered across all hospitals combined.

APU Determination	HAI	Number of Hospitals	Number of Quarters	Number of Records/Quarter /Hospital	Number of Records per Hospital
FY 2015 (previously finalized)	CLABSI, CAUTI, SSI combined	Up to 600	4	12	48
In the preamble to this proposed rule					
FY 2015	CLABSI, CAUTI, SSI combined	Up to 600	3	12	36
FY 2016	CLABSI	Up to 300	3	5	15
FY 2016	CAUTI	Up to 300	3	5	15
FY 2016	MRSA	Up to 300	3	5	15
FY 2016	CDI	Up to 300	3	5	15
FY 2016	SSI	Up to 600	3	2	6
FY 2017 and subsequent years	CLABSI	Up to 300	4	3.75	15
FY 2017 and subsequent years	CAUTI	Up to 300	4	3.75	15
FY 2017 and subsequent years	MRSA	Up to 300	4	3.75	15
FY 2017 and subsequent years	CDI	Up to 300	4	3.75	15
FY 2017 and subsequent years	SSI	Up to 600	4	1.5	6

The sample sizes for each HAI proposed for the FY 2016 payment determination are shown in the table above. For hospitals submitting CLABSI and CAUTI templates, the infection-specific sample sizes per hospital per quarter proposed are: 2 for SSI, 5 for

CLABSI, and 5 for CAUTI (12 per quarter). For hospitals submitting MRSA and CDI Validation Templates, the infection-specific sample sizes per hospital per quarter proposed are: 2 for SSI, 5 for MRSA, and 5 for CDI. For each hospital, in each quarter, these cases would be drawn randomly from each individual Validation Template (or from claims for SSI) from among episodes of care containing at least one candidate event. Across all hospitals and quarters combined, we are assuming that approximately 10 percent of patients with candidate CLABSI events had a CLABSI. This will yield approximately 450 hospital discharges with actual events. Assuming a design effect resulting from clustered data collection of no more than 2, this will allow us to estimate accurate reporting (+/- 5 percentage points with 90 percent confidence) of CLABSI if it occurs approximately 75 percent of the time. We developed sample size requirements based on a 75 percent score to align with CMS requirements for a 75 percent score to pass validation as specified in 42 CFR § 412.140(d)(2), and using a two-tailed 90 percent confidence interval as finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53551). Based on these statistics, we believe this is the smallest sample size needed to meet the objective of accurately evaluating how well hospitals report CLABSI data to NHSN.

Because we have less data on which to base sample size calculations for CAUTI, MRSA bacteremia, and CDI than we have for CLABSI, we are proposing similar sample size targets for these 4 HAIs. By proposing similar sample size requirements across these 4 HAIs for the FY 2016 payment determination and subsequent years, we assure that

hospitals will be required to submit the same number of records regardless of which set of Validation Templates they are assigned to submit.

For SSI, the proposed sample size assumes that most hospitals will not have more than 2 candidate SSIs per quarter. By sampling fewer SSI cases over twice as many hospitals, we ensure that the sample size for SSI validation is also adequate. Because SSI cases may be sampled without the added submission requirement of a Validation Template, we foresee no difficulty in requiring all hospitals sampled for validation to provide information for SSI. We invite public comment on these proposals.

Within each hospital for each type of HAI event each quarter, a random sample would be drawn from among patient episodes of care with at least one candidate event identified from the Validation Template (or claims data for SSI) to meet the targeted sample size. If there are not enough cases in any stratum, we are proposing for the FY 2016 payment determination and subsequent years to reallocate those cases to any stratum or strata that have more than enough cases to meet sample size targets. We are proposing to reallocate cases because different hospitals may have different relative frequencies of each HAI. The proposed reallocation process will give CMS the flexibility to meet sample size quotas in the event that one hospital has more than enough candidate MRSA events but not enough candidate CDI events and the next hospital has more than enough candidate CDI events and not enough candidate MRSA events. We invite public comment on this proposal.

For the FY 2017 payment determination and subsequent years, we are proposing to reduce the quarterly HAI sample from 12 to 9. Please see the chart above. This is to

reflect the fact that we are proposing to collect data for 4 quarters instead of for 3 quarters starting with the FY 2017 payment determination (section IX.A.10.a. of the preamble of this proposed rule). When we distribute over 4 quarters, the 15 annual patient charts each for CLABSI, CAUTI, MRSA, and CDI and 6 annual patient charts each for SSI, the process produces fractions. We are proposing to request 9 patient charts by establishing quarterly targets of 3, 3, and 1 respectively for CLABSI, CAUTI, and SSI and 3, 3, and 1 respectively for MRSA, CDI, and SSI, and then randomly allocating the remaining 2 records to meet the hospital target of 9 HAIs for the quarter. We invite public comment on these proposals.

c. Proposed Procedures for Scoring Records for Validation

We are not proposing any changes to the procedures for scoring records for validation for the clinical process of care measures for the FY 2016 payment determination or subsequent years. This process was described in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50226). However, we are proposing changes to the procedures for scoring records for validation of HAI measures.

(1) Scoring of CLABSI, CAUTI, and SSI

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53550 through 53551), for the FY 2015 payment determination and subsequent years), we finalized a scoring approach considering all three HAI measures simultaneously. In general, if hospitals have matched data on all three HAIs, they would receive a score of 1, and if they have a mismatch on one or more HAIs, they would receive a score of 0. For example, if a patient had a CLABSI during an episode of care and no CAUTI or SSI and the CLABSI was properly

reported, the hospital received a score of 1 for that patient. We developed this approach primarily out of an interest in maximizing the information available to us about CLABSI, CAUTI, and SSI using the same set of records reviewed for all three infections at once, and because we recognized that an individual infection event could not simultaneously be attributed to more than one cause, that is, a particular infection was either a primary CLABSI, CAUTI, or SSI, but never all three at once. In addition, the records were sampled from a single unduplicated frame. With a single sampling frame for all three events, it was not always possible to determine in advance which event to evaluate for a particular case. Moreover, it is apparent that an event that was sampled because of a MRSA bacteremia result does not need to be evaluated for CDI or vice-versa. For both of these reasons, we are proposing for the FY 2016 payment determination and subsequent years, to evaluate and score each case only for the infection for which it was sampled as having candidate events. For example, episodes of care for patients on the CLABSI Validation Template will be evaluated and scored only for CLABSI. We invite public comment on this proposal.

We also are proposing for the FY 2016 payment determination and subsequent years to score charts selected for SSI, CLABSI, and CAUTI in the manner that scoring was finalized for CLABSI in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51647). If the Clinical Data Abstraction Center (CDAC) contractor reviews a medical record and determines that patient had no CLABSI events and the hospital reported no CLABSI to NHSN, the case will receive a score of 1. If the CDAC contractor determines that the patient had a CLABSI and this was reported to NHSN, the case will also receive a score

of 1. If a mismatch occurs and the CDAC contractor determined that the patient had no CLABSI when one is reported, or that the patient had a CLABSI that was not reported, the hospital will receive a score of 0. If the CMS quarterly validation process identified that 3 out of 4 total sampled records accurately reported the presence of CLABSI or did not report a CLABSI when none was present, then the hospitals' quarterly CLABSI validation score would be $\frac{3}{4}$ or 75 percent. If two or more infections are detected for a patient episode of care, the case may receive separate scores for each event. For example, if one patient episode of care included two CLABSIs, both of which were reported correctly, and reported correctly for 2 of the remaining three records evaluated for CLABSI, then the validation score for CLABSI that quarter would be $\frac{4}{5}$ or 80 percent.

(2) Scoring of MRSA and CDI

MRSA bacteremia and CDI, have very different reporting requirements from other HAIs included in the Hospital IQR Program. The major difference between the case definitions for MRSA and CDI relative to other HAIs being reported as part of IQR is that MRSA and CDI are laboratory-identified events that do not require extensive clinical judgment on the part of the reporting hospital. If the laboratory events and date of hospital admission are reported accurately, CDC makes the determination as to whether the event was community or hospital onset.

Our proposal entails evaluating each patient episode of care on a minimum of two components, with a score of 1 for each matched component and 0 for each mismatched component. We are proposing to evaluate each laboratory identified event on the

following components: (1) whether it was reported to NHSN when it should have been reported; and (2) whether the correct dates of admission and event were reported such that NHSN correctly classified the event as hospital or community onset. Each of these components contributes to an assessment of the accuracy and completeness of the public reporting result that appears on Hospital Compare, and each is important.

Because each candidate event will be scored on two different components, scores will be reported in multiples of two. For example, if a sampled patient episode of care has only one candidate event, and 1 out of 2 elements matched for that event, the total score for that candidate event would be 1/2. If a particular patient episode of care contains multiple candidate events, that patient episode will be evaluated on each of these events, increasing the number of possible elements to be validated by 2, one for each candidate event evaluated. The maximum number of events that we would validate for any episode of care would be 4. Therefore, the maximum possible score for any one patient episode of care would be 8 (2 x 4). NHSN has an automated process to remove events that should not have been reported to NHSN if they occurred within 14 days of a previous laboratory-identified event for the same infection. Because NHSN excludes these events automatically, we are proposing for the FY 2016 payment determination and subsequent years that hospitals will not be credited or penalized for reporting or failing to report an automatically excluded event. We invite public comment on these proposals.

(3) Combined Scores

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53549), we finalized the process for combining the clinical process of care and HAI validation scores for the

FY 2015 payment determination and subsequent years scores by weighting them proportionate to the number of measures validated in each group. We are not proposing any changes to this process. Using the finalized procedure for combining the clinical process of care and HAI validation scores, the relative weights for the FY 2016 payment determination would be 12/17 for the clinical process of care measures included in validation and 5/17 for the HAI measures included in validation.

As previously finalized in the FY 2013 IPPS/LTCH PPS payment rule for the FY 2015 payment determination and subsequent years (77 FR 53551), we use the upper bound of a two-tailed 90 percent confidence interval around the combined score to determine if a hospital passes or fails validation. If this number is greater than or equal to 75 percent, then the hospital passes validation. We are not proposing changes to this methodology. We intend to post the specific formulas used to compute the confidence interval on the QualityNet Web site at least one year prior to computation as we have done in the past

(<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 are sampled and scored for the measures corresponding to the payment determination period.

d. Proposed Procedures to Select Hospitals for Validation

In the FY 2013 IPPS/LTCH PPS final rule, for the FY 2015 payment determination and subsequent years, we finalized an annual hospital validation sample size of 400 randomly selected hospitals and a supplemental sample of up to 200 hospitals

to be selected for more targeted validation (77 FR 53552 through 53553). The supplemental sample of up to 200 hospitals will include all hospitals that fail validation in the previous year and a random sample of hospitals meeting certain targeting criteria for the FY 2015 payment determination and subsequent years. The targeting criteria were finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53552 through 53553) for the FY 2016 payment determination and subsequent years. A summary of these criteria is set out below.

- Any hospital with abnormal or conflicting data patterns.
- Any hospital with rapidly changing data patterns.
- Any hospital that submits data to NHSN after the Hospital IQR Program data submission deadline has passed.
- Any hospital that joined the Hospital IQR Program within the previous 3 years, and which has not been previously validated.
- Any hospital that has not been randomly selected for validation in any of the previous 3 years.
- Any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent.

For the FY 2016 payment determination and subsequent years, we are proposing one additional criterion for targeting as follows: any hospital which failed to report to NHSN at least half of actual HAI events detected as determined during the previous year's validation effort. We are making this proposal to increase incentives for properly reporting HAI events that should have been reported to NHSN. To ensure a fair process

for validation scoring, we credit hospitals for following NHSN protocols correctly. In this regard, hospitals receive credit for not reporting to NHSN candidate HAI events that we determine were not actually events and reporting candidate HAI events to NHSN that we determine were actually HAI events. We anticipate that hospitals may receive credit for not reporting many such candidate events. We believe it is appropriate to pass hospitals for following NHSN protocols correctly by not reporting non-events. However, we recognize that the Hospital VBP Program might give hospitals an unintended incentive to underreport HAI events because the lower their HAI measure rates, the more points they will earn.

Therefore, we are proposing to use evidence of severe under-reporting (less than 50 percent) as a targeting criterion for supplemental validation. In making this proposal, we recognize that the sample size of events, which should have been reported to NHSN, may not be reliable as it is a subset of the sample of 36 candidate HAI events per hospital per year. For the 30 candidate CLABSI and CAUTI records selected each year, we expect less than half of candidate events to be actual events. We would not wish to fail hospitals based upon such a small sub-sample. Instead, in such situations we would like to gather more data, which is why we are proposing to add a targeting criterion for hospitals that appear to frequently under-report HAIs. We invite public comment on this proposal.

e. Proposed Procedures for Submitting Records for Validation

(1) Separate Submission Requirements for MRSA Bacteremia and CDI Validation

Under section 412.140(d)(1) of our regulations, a hospital must submit to CMS a sample of patient charts that the hospital used for purposes of data submission under the program. Historically, we have requested the entire medical record where the content of the medical record is defined under 42 CFR § 482.24. For validation of the MRSA bacteremia and CDI measures for the FY 2016 payment determination and subsequent years, we are proposing to require hospitals to submit only those two specific parts of the medical record that are needed to validate these measures. For each sampled charts, the two required parts are: (1) all final positive blood cultures for MRSA and toxin-positive specimens for CDI with specimen collection dates; and (2) all documentation of the dates on which a patient was admitted to, transferred to, or discharged from each location within the hospital during his/her stay. We are proposing to request only this information because it is all that CMS needs to complete validation for these measures. Therefore, this proposal will save CMS effort in completing validation, resulting in more timely feedback to hospitals. In addition, we believe that this more limited request may alleviate burden for many hospitals. Finally, this proposal should reduce the cost to CMS in both photocopying and shipping compared with submission of the entire patient chart. We invite public comment on this proposal.

(2) Proposed Secure Transmission of Electronic Versions of Medical Information

The current regulation at 42 CFR § 412.140(d)(1) states:

“(d) *Validation of Hospital IQR Program data.* CMS may validate one or more measures selected under section 1886(b)(3)(B)(viii) of the Act by reviewing patient charts submitted by selected participating hospitals. (1) Upon written request by CMS or its contractor, a hospital must submit to CMS a sample of patient charts that the hospital used for purposes of data submission under the program. The specific sample that a hospital must submit will be identified in the written request. A hospital must submit the patient charts to CMS or its contractor within 30 days of the date identified on the written request.”

We are proposing that this requirement may be met by employing either of the following options each quarter: (1) a hospital may submit paper medical records, which is the form in which CMS has historically requested them; or (2) a hospital may securely transmit electronic versions of medical information for the FY 2016 payment determination and subsequent years. The intent of this proposal is to offer an additional mode through which hospitals may meet the requirement to submit patient charts. The content of the patient charts to be submitted are defined at 42 CFR § 482.24(c). We are not proposing to change the content of these charts (except for MRSA bacteremia and CDI as proposed in section IX.A.10.e.(1) of the preamble of this proposed rule). We are proposing this change because hospitals are rapidly adopting EHR systems as their primary source of information about patient care. Our understanding is that as of December 2012, more than 4,000 hospitals, including 77 percent of hospitals participating in the Hospital IQR Program, had enrolled in the Medicare EHR Incentive Program.

Based on the instructions that we have historically provided with written requests for records under 42 CFR § 412.140(d)(1), hospitals have only been able to submit this information in paper format. For records stored electronically, hospitals expend additional resources printing records onto paper that may be more efficiently transmitted electronically. We pay hospitals at a rate of 12 cents per page, plus shipping (70 FR 23667). In addition, the length of paper charts has been increasing, and the paper used to submit these records has an environmental impact. As shown in the table below, the average patient chart based on the most recent available statistics from our CDAC contractor, is much larger than when CMS began validating quality reporting data.

IPPS/LTCH PPS Final or Proposed Rule FY	Approximate average page length	Citation
Final 2006	140	70 FR 47702
Final 2009	150	73 FR 49075
Final 2012	275	76 FR 51828
Proposed 2014	410	

In examining the most recent statistics available, which are based on records submitted for 2Q 2012, most of the increase in chart length is attributable to including HAI charts in the sample; HAI charts are on average 1,500 pages long, but other inpatient chart lengths are also larger, now averaging about 300 pages. Therefore, the proposal to allow hospitals to choose between submitting paper copy patient charts and securely transmitting electronic versions of medical information has the potential for significant reduction in administrative burden, cost, and environmental impact. Furthermore, this

potential for savings grows as the measures selected for Hospital IQR Program chart validation increasingly focus on HAIs.

We are proposing for the FY 2016 payment determination and subsequent years that those hospitals wishing to securely transmit electronic versions of medical information to download or copy the digital image of the patient chart onto CD, DVD, or flash drive and ship it following instructions similar to those for shipping paper copies of patient charts. The precise guidelines to achieve this process will be posted on QualityNet and included with CMS' written requests for patient charts. This proposal requires hospitals to use this single method for secure transmission of electronic versions of medical information, because it will enable us to efficiently process records and provide timely feedback to hospitals. We recognize that there may be many other methodologies under which transmission of electronic versions of medical information might occur. After evaluating several different potential approaches, we are proposing the only one available at this time that has been successfully tested. We will continue to develop and test additional technologies for secure transmission of electronic versions of medical information. We will notify hospitals through QualityNet as we acquire any new capabilities for accepting electronic versions of medical information, and to update available methodologies through future payment rules. We invite public comment on this proposal.

For the FY 2016 payment determination and subsequent years, we also are proposing to incentivize the electronic option by offering reimbursement for the labor and supply costs of submitting electronic versions of medical information. Because hospitals

can choose between the current paper and the proposed electronic option of submitting validation records, we believe that this proposal does not increase cost or burden to hospitals. We invite public comment on this proposal.

11. Proposed Data Accuracy and Completeness Acknowledgement Requirements for the FY 2015 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), we finalized our proposal to require hospitals to continue to electronically acknowledge their data accuracy and completeness once annually. For the FY 2015 payment determination and subsequent years, the submission deadline finalized for the Data Accuracy and Completeness Acknowledgement (DACA) was aligned with the final submission quarter for each fiscal year. For example, for the FY 2015 payment determination, the submission deadline for the Data Accuracy and Completeness Acknowledgement is currently May 15, 2014, with respect to the reporting period of January 1, 2013, through December 31, 2013.

In order to provide the timely feedback to hospitals regarding the APU status, we are proposing that for the FY 2015 payment determination and subsequent years, we would collect the DACA in alignment with the 3rd quarter submission deadline. This would mean, for example, the electronic acknowledgement of data accuracy and completeness for the FY 2015 payment determination would be submitted between January 1, 2014 and February 15, 2014, with respect to the reporting period of January 1, 2013 through December 31, 2013. We invite public comment on this proposal.

12. Public Display Requirements for the FY 2016 Payment Determination and Subsequent Years

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), we continued, for the FY 2014 payment determination and subsequent years, the approach we adopted in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230) for public display requirements for the FY 2012 payment determination and subsequent years. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), we did not make any changes to these requirements. For the FY 2016 payment determination and subsequent years, we are not proposing to make any changes to these requirements. As previously stated in section IX.A.9.d. of the preamble of this proposed rule, we are proposing that we would not publicly report data collected from hospitals choosing to report the four measure sets (VTE, STK, ED and PC) electronically in CY 2014.

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 require that hospitals sign a Notice of Participation form when they first register to participate in the Hospital IQR Program. Once a hospital has submitted a form, the hospital is considered to be an active Hospital IQR Program participant until such time as the hospital submits a withdrawal form to CMS (72 FR 47360). Hospitals signing this form agree that they will allow us to publicly report the quality measures included in the Hospital IQR Program.

We will continue to display quality information for public viewing as required by section 1886(b)(3)(B)(viii)(VII) of the Act. Before we display this information, hospitals will be permitted to review their information as recorded in the QIO Clinical Warehouse.

13. Proposed Reconsideration and Appeal Procedures for the FY 2015 Payment Determination and Subsequent Years

The Hospital IQR Program reconsideration and appeals requirements were adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651) and are found at section 412.140(e) of our regulations. The form for reconsiderations and a detailed description of the reconsideration process are available on the QualityNet Web site at: <http://www.qualitynet.org/> > Hospitals-Inpatient>Hospital Inpatient Quality Reporting Program>APU Reconsiderations. We are proposing to interpret this requirement to allow for this form to be completed online via the secure portion of the QualityNet Web site.

In the past, it has been CMS's process to allow hospitals with a quarterly Overall Validation Result of <75 percent to request a review by or appeal mismatched data element(s) to their State Quality Improvement Organization (QIO). This process requires that the CDAC contractor copy and ship all records for any hospital that receives an overall validation score of <75 percent to the State QIO. In the past two years, none of the mismatch appeals would have resulted in a change to the final APU determination. As described at § 412.140(e) of our regulations, hospitals can also request a reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital IQR Program for a particular fiscal year. This includes reconsideration on

the basis that CMS concluded it did not meet the validation requirements. We believe this process is redundant and, for the FY 2015 payment determination and subsequent years, we are proposing to remove the quarterly appeal of mismatched data elements to the State QIO. We invite public comment on this proposal.

14. Hospital IQR Program Extraordinary Circumstances Extensions or Waivers

The Hospital IQR Program extraordinary circumstances disaster extensions or waiver requirements were adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651 through 51652) and can be found at 42 CFR § 412.140(c)(2). In the FY 2012 IPPS/LTCH PPS final rule, we explained the requirements for disaster extensions or waivers. The forms and a detailed description of the extension or waiver process are available on the QualityNet Web site at: <http://www.qualitynet.org/> > Hospitals-Inpatient>Hospital Inpatient Quality Reporting Program.

We are proposing to allow for not only a CEO, but also other hospital-designated personnel contact to complete and sign waiver/extraordinary circumstances forms. This proposed change would allow hospitals to designate an appropriate, non-CEO, contact at its discretion. This individual would be responsible for the submission, and would be the one signing the form.

In addition, we are proposing to allow for this form to be completed online via the secure portion of the QualityNet Web site securely online via the QualityNet Web site.

We also are proposing that we may grant a waiver or extension to hospitals if we determine that a systemic problem with one of our data collection systems directly affected the ability of the hospitals 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 basis frequently.

If we make the determination to grant a waiver or extension, we are proposing to communicate this decision through routine communication channels to hospitals, vendors and QIOs by means of, for example, memoranda, emails, and notices on the QualityNet Web site. We invite public comment on these proposals.

B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Statutory Authority

Section 3005 of the Affordable Care Act added new subsections (a)(1)(W) and (k) to section 1866 of the Act. Section 1866(k) of the Act establishes a quality reporting program for a hospital described in section 1886(d)(1)(B)(v) of the Act (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 shall submit data to the Secretary in accordance with section 1866(k)(2) of the Act with respect to such a fiscal year.

Section 1866(k)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, each hospital described in section 1886(d)(1)(B)(v) of the Act shall submit data to the Secretary on quality measures specified under section 1866(k)(3) of the Act in a form and manner, and at a time, specified by the Secretary.

Section 1866(k)(3)(A) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act, unless an exception under section 1866(k)(3)(B) of the Act applies. The 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 PCHQR Program. Such procedures must ensure that a PCH has the opportunity to review the data that is to be made public with respect to the 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 Quality Measures for PCHs Beginning with the FY 2014 Program

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 CDC/NHSN-based HAI quality measures (outcome

measures): (1) Central Line-Associated Bloodstream Infection (CLABSI); and (2) Catheter-Associated Urinary Tract Infection (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 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.

The finalized measures are shown below.

PCHQR Program Measures Finalized in the FY 2013 IPPS/LTCH PPS Final Rule Beginning with the FY 2014 Program Year	
Safety and Healthcare-Associated Infections—HAI	
	<ul style="list-style-type: none"> ● (NQF #0139) NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure ● (NQF #0138) NHSN Catheter-Associated Urinary Tract Infections (CAUTI) Outcome Measure
Clinical Process/Cancer-Specific Treatments	
	<ul style="list-style-type: none"> ● (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 ● (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

We are not proposing to remove or replace any of the previously finalized measures from the PCHQR program for the FY 2015 program year. We discussed the

collection requirements and submission timeframes for these measures in the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563 through 53564).

4. Considerations in the Selection of the Quality Measures

Section 1866(k)(3)(A) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act, unless section 1866(k)(3)(B) of the Act applies. Section 1866(k)(3)(B) of the Act states that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556), we indicated that we have taken a number of principles into consideration when developing measures for the PCHQR Program, and that many of these principles are modeled on those we use for measure development 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 also supports the National Quality Strategy, national priorities, HHS Strategic Plans and Initiatives, and CMS Strategic Plans, as well as takes into consideration the recommendations of the MAP and strives for burden reduction whenever possible.

We invite public comment on these considerations.

5. Proposed New Quality Measures

For the PCHQR Program beginning with FY 2015, we are proposing to adopt one new measure: NHSN HAI measure of Surgical Site Infection (SSI).

For the PCHQR Program beginning with FY 2016, we are proposing to adopt 13 new measures: six measures of Surgical Care Improvement Project (SCIP), six Clinical Process/Oncology Care Measures, and one Patient Experience of Care measure (the HCAHPS Survey).

All 14 of these proposed measures are NQF-endorsed. Some address inpatient care, and others address outpatient care. All of the measures address treatment provided

to cancer patients in PCH inpatient or outpatient settings. In addition, the adoption of measures that apply to more than one healthcare setting is one of our objectives in promoting quality care consistently across all health care settings. The 14 proposed measures are a subset of 19 measures that we 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. These measures were reviewed by the MAP, a multi-stakeholder body convened by the NQF for the purpose of providing input to HHS on the selection of measures, and the MAP’s conclusions can be found in the “MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS.” The MAP Report can be accessed at:

http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx.

We considered the input and recommendations provided by the MAP in selecting the 14 measures we are proposing for the PCHQR Program. Of these 14 measures, the MAP supported the inclusion of 13 of them in the PCHQR Program, and supported the direction of the proposed HCAHPS measure, noting that additional experience with the survey is needed so that the survey questions are applicable for use in the PCH settings. Although we recognize that some stakeholders would prefer that we adopt an experience of care measure developed specifically for the cancer hospital setting, we believe that other stakeholders think HCAHPS is appropriate for the cancer hospital setting, and are aware that approximately 27 percent of PCHs are currently administering HCAHPS to their patients. For these reasons, we believe that until a new patient experience measure

is developed specifically for the PCH setting, the HCAHPS will provide valuable information to the public on the patient experience of care in PCHs.

In addition, the proposed measures address the National Quality Strategy domains of Patient Safety, Clinical Effectiveness, and Patient Experience/Engagement, and further our goal of aligning measures across programs because they are already in use in either the Hospital IQR Program or the PQRS Program. We describe these proposed measures in greater detail below.

a. Proposed New Measure Beginning with FY 2015 - NHSN Healthcare-Associated Infection (HAI) Measure: Surgical Site Infection (SSI) (NQF #0753)

This NQF-endorsed American College of Surgeons/CDC harmonized measure of surgical site infection (SSI) meets the measure selection requirements at section 1866(k)(3)(A) of the Act, and expands upon the existing Healthcare-Associated Infections (HAIs) measurement topic that is part of the PCHQR Program. The measure addresses HAIs, a topic area widely acknowledged by HHS, the Institute of Medicine, the National Priorities Partnership and others as a high priority requiring measurement and improvement. HAIs are among the leading causes of death in the United States. The CDC estimates that as many as 2 million infections are acquired each year in hospitals and that HAIs result in approximately 90,000 deaths per year. It is estimated that more Americans die each year from HAIs than from auto accidents and homicides combined. HAIs not only put the patient at risk, but also increase the days of hospitalization required for patients and add considerable health care costs.

HAIs are largely preventable through interventions such as better hygiene and advanced scientifically tested techniques for surgical patients. Therefore, many health care consumers and organizations have called for public disclosure of HAIs, arguing that public reporting of HAI rates provides the information health care consumers need to choose the safest hospitals, and give hospitals an incentive to improve infection control efforts (75 FR 50201).

Detailed specifications for this proposed measure can be found at:

http://www.cdc.gov/nhsn/TOC_manual.html. This measure assesses the incidence of surgical site infections following colon surgeries and abdominal hysterectomies performed by PCHs and includes laparoscopic procedures. The measure rate is calculated as the Standardized Infection Ratio for each procedure type. Adult patients 18 years and older with deep incisional and organ space infections during the 30-day postoperative period are included in the measure. This measure is risk-adjusted and reported at the facility level. It is not specific to a hospital ward or setting, rather it is applicable to all postoperative patients who fall into the numerator criteria. The denominator is calculated using logistic regression models, determining the expected number of SSI's by facility and procedure type. We invite public comment on this proposed SSI measure.

b. Proposed New Measures Beginning with the FY 2016 PQHQR Program

(1) Surgical Care Improvement Project (SCIP) Measures

Measures from the Surgical Care Improvement Project (SCIP) have been collected as part of the Hospital IQR Program for most subsection (d) hospitals paid

under the IPPS and reported on the Hospital Compare Web site for a number of years, because they assess effective care for patients undergoing surgery. In general, these measures are also applicable to patients undergoing surgery in PCHs. We are proposing to adopt six NQF-endorsed, SCIP measures for the PCHQR Program beginning with the FY 2016 program year. All six of the measures are NQF-endorsed and therefore meet the selection requirements at section 1866(k)(3)(A) of the Act.

In addition, all six of these measures were supported by the MAP for inclusion in the PCHQR Program in its February 2013 pre-rulemaking report to HHS located at:

http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.

Four of these measures: SCIP – Inf 1 (NQF #0527); SCIP – Inf 2 (NQF #0528), SCIP – Inf 3 (NQF #0529); and SCIP – Inf 9 (NQF #0453) assess hospital performance with regard to infection prevention practices. SCIP-Card-2 (NQF #0284) assesses the continuity of beta blocker treatment during the perioperative period for cardiac patients undergoing non-cardiac surgery. SCIP – VTE 2 (NQF #0218) assesses hospital performance regarding effective preventive care for venous thromboembolism.

These measures are described below, and detailed measure specifications for all six of these measures can be found in the Hospital IQR Program Specifications Manual located at:

<https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772433589>.

We invite public comment on these six proposed SCIP measures.

(A) SCIP – Inf 1: Prophylactic Antibiotics received within 1 Hour Prior to Surgical Incision (NQF #0527)

This measure assesses the percent of surgical patients with prophylactic antibiotics initiated within one hour prior to surgical incision. Patients who received vancomycin or a fluoroquinolone for prophylactic antibiotics should have the antibiotics initiated within 2 hours prior to surgical incision. This measure addresses the National Quality Strategy domain of Clinical Effectiveness, and complements the proposed SSI measure.

(B) SCIP – Inf 2: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528)

This measure assesses the percent of surgical patients who received prophylactic antibiotics consistent with current guidelines (specific to each type of surgical procedure). A goal of prophylaxis with antibiotics is to use an agent that is safe, cost-effective, and has a spectrum of action that covers most of the probable intraoperative contaminants for the operation. This measure addresses the National Quality Strategy domain of Clinical Effectiveness, and complements the SSI measure.

(C) SCIP – Inf 3: Prophylactic Antibiotic Discontinuation within 24 Hours after Surgery End Time (NQF #0529)

This measure assesses the percentage of surgical patients whose prophylactic antibiotics were discontinued within 24 hours after Anesthesia End Time. A goal of prophylaxis with antibiotics is to provide benefit to the patient with as little risk as possible. It is important to maintain therapeutic serum and tissue levels throughout the operation. Intraoperative re-dosing may be needed for long operations. However,

administration of antibiotics for more than 24 hours after the incision is closed offers no additional benefit to the surgical patient. Prolonged administration increases the risk of Clostridium difficile infection and the development of antimicrobial resistant pathogens. This measure addresses the National Quality Strategy domain of Clinical Effectiveness, and complements the proposed SSI measure.

(D) SCIP – Inf 9: Urinary Catheter Removed on Post-Operative Day 1 or Post-Operative Day 2 with Day Surgery being Day Zero (NQF #0453)

This measure assesses the percent of surgical patients with urinary catheter removed on Postoperative Day 1 or Postoperative Day 2 with day of surgery being day zero. The risk of catheter-associated urinary tract infection (UTI) increases with longer duration of indwelling urinary catheterization. This measure complements the CAUTI measure currently adopted for the PCHQR Program.

(E) SCIP – Card 2: Surgery Patients on Beta Blocker Therapy Prior to Admission Who Received a Beta Blocker during the Perioperative Period (NQF #0284)

This measure assesses the percent of surgery patients on beta-blocker therapy prior to arrival who received a beta-blocker during the perioperative period. The perioperative period for this measure is defined as the day prior to surgery through postoperative day two, with day of surgery being day zero. The American College of Cardiology/American Heart Association promote continuation of beta-blocker therapy in the perioperative period as a class I indication, and accumulating evidence suggests that titration to maintain tight heart rate control should be the goal. We believe that this measure targets an important process of care, beta blocker administration for non-cardiac

surgery patients. Concerns regarding the discontinuation of beta-blocker therapy in the perioperative period have existed for several decades. This measure addresses the National Quality Strategy domain of Clinical Effectiveness.

(F) SCIP – VTE 2: Surgical Patients who Received Appropriate VTE Prophylaxis within 24 Hours prior to Surgery to 24 Hours after Surgery End Time (NQF #0218)

This measure assesses the percent of surgery patients who received appropriate VTE prophylaxis within 24 hours prior to Anesthesia Start Time to 24 hours after Anesthesia End Time. The frequency of VTE, which includes deep vein thrombosis and pulmonary embolism, is related to the type and duration of surgery, patient risk factors, duration and extent of postoperative immobilization, and use or nonuse of prophylaxis. Despite the evidence that VTE is one of the most common postoperative complications and prophylaxis is the most effective strategy to reduce morbidity and mortality, it is often underused. We believe that this measure will encourage practices to reduce the risk of post-operative complications associated with VTE. This measure addresses the National Quality Strategy domain of Clinical Effectiveness.

(2) Clinical Process/Oncology Care Measures

We are proposing to add to the PCHQR Program, beginning with FY 2016, six measures specific to assessing the quality of medical treatment and staging of cancer by PPS-exempt cancer hospitals. All six measures are specified and endorsed for outpatient settings to evaluate the performance of a cancer treatment team which is an integral part of a cancer center. In addition, all six of these measures are NQF-endorsed and address

the quality of outpatient cancer treatment provided at PCHs; therefore, they meet the measure selection requirement at section 1866(k)(3)(A) of the Act.

All six measures also are recommended as priorities for program alignment in the PCHQR Program by the MAP in a June 2012 Final Report entitled “Performance Measurement Coordination Strategy for PPS-Exempt Cancer Hospitals.” In addition, all six of the measures are supported for inclusion in the PCHQR Program by the MAP in its 2013 Pre-Rulemaking Final Report issued in February 2013. Both of these MAP reports can be located at:

http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx.

Detailed specifications of these six proposed measures can be found in Appendix A of the December 2012 NQF Cancer endorsement maintenance project report at:

http://www.qualityforum.org/Publications/2012/12/Cancer_Endorsement_Maintenance_2011.aspx. We invite public comment on these six proposed clinical process/oncology care measures.

(A) Clinical Process/Oncology Care - Multiple Myeloma-Treatment with Bisphosphonates (NQF #0380)

This measure assesses the percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, for which intravenous bisphosphonate therapy was prescribed or received within the 12-month reporting period. This measure is intended to promote the appropriate use of bisphosphonates to reduce morbidity and mortality in multiple-myeloma patients. Bisphosphonates specifically decrease osteoclast

activity, thereby reducing bone pain and fractures in patients with multiple myeloma.¹⁰³

This measure addresses the National Quality Strategy domain of Clinical Effectiveness.

(B) Clinical Process/Oncology Care - Radiation Dose Limits to Normal Tissues

(NQF #0382)

This measure assesses the percentage of patients, regardless of age, with a diagnosis of pancreatic or lung cancer receiving 3D conformal radiation therapy with documentation in the medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues. This measure is intended to assess the appropriate use of 3D conformal radiation therapy in the treatment of pancreatic and lung cancers. Treatment is important due to the high rate of morbidity and mortality associated with these cancers. For example, among cancers in US adults, lung cancers are the leading cause of deaths in both men and women. It is estimated from 2006 - 2008 rates that 6.94 percent of U.S. men and women born today will be diagnosed with cancer of the lung and bronchus at some time during their lifetime.¹⁰⁴

Regarding pancreatic cancer, there has been an increased frequency of this cancer since 1998 of 0.8 percent in men and 1.0 percent in women.¹⁰⁵ Based on rates from 2006 through 2008, 1.45 percent of men and women born today will be diagnosed with cancer of the pancreas at some time during their lifetime. A major goal of radiation therapy is

¹⁰³ NQF. Cancer Endorsement Maintenance 2011.Candidate Review Consensus – Phase 1. Available at: http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C.

¹⁰⁴ NQF. Cancer Endorsement Maintenance 2011.Candidate Review Consensus – Phase 1. Available at: http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C.

¹⁰⁵ NQF. Cancer Endorsement Maintenance 2011.Candidate Review Consensus – Phase 1. Available at: http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C.

the delivery of the desired dose distribution of radiation to target tissue while limiting the radiation dose to the surrounding normal tissues to an acceptable level.

Patients treated with 3D conformal radiation therapy are often subjected to radiation dose levels that exceed normal tissue tolerance. Precise specification of maximum doses to be received by normal tissues during radiation treatment planning is considered a best practice to avoid delivering unnecessary radiation to patients.

(C) Clinical Process/Oncology Care - Plan of Care for Pain (NQF #0383)

This measure assesses the percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy, who report having pain, with a documented plan of care to address that pain. Pain is one of the most common symptoms associated with cancer, occurring in approximately one quarter of patients with newly diagnosed malignancies, one third of patients undergoing treatment, and three quarters of patients with advanced disease. Proper pain management is critical to achieving pain control. “Unrelieved pain denies [patients] comfort and greatly affects their activities, motivation, interactions with family and friends, and overall quality of life.”¹⁰⁶ This measure aims to improve attention to pain management and requires a plan of care for cancer patients who report having pain to allow for individualized treatment based on clinical circumstances and patient wishes.¹⁰⁷ This measure addresses the National Quality Strategy domain of Patient and Family Engagement. This measure is intended to be paired with NQF #0384 below.

¹⁰⁶ NQF. Cancer Endorsement Maintenance 2011.Candidate Review Consensus – Phase 1. Available at: http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C.

¹⁰⁷ NQF. Cancer Endorsement Maintenance 2011.Candidate Review Consensus – Phase 1. Available at: http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C.

(D) Clinical Process/Oncology Care - Pain Intensity Quantified (NQF #0384)

This measure assesses the percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified. As described above for Oncology: Plan of Care for Pain (NQF #0383), pain is the most common symptom in cancer patients and this measure is used in conjunction with NQF #0384 to encourage consistent assessment of pain intensity to better guide the care of pain.¹⁰⁸ This measure addresses the National Quality Strategy domain of Patient and Family Engagement. Higher rates are indicative of better performance. This measure is intended to be paired with NQF #0383 above.

(E) Clinical Process/Oncology Care - Prostate Cancer-Avoidance of Overuse

Measure-Bone Scan for Staging Low-Risk Patients (NQF #0389)

This measure assesses the percentage of patients, regardless of age, with a diagnosis of prostate cancer at low risk of recurrence receiving interstitial prostate brachytherapy, or external beam radiotherapy to the prostate, or radical prostatectomy, or cryotherapy, who did not have a bone scan performed at any time since diagnosis of prostate cancer.

Prostate cancer is the most commonly diagnosed cancer and the second leading cause of cancer death in men over the age of 40 years in the United States. Current guidelines and best practices do not recommend bone scans for patients in the low risk stratum for prostate cancer bony involvement. This goal of this measure is to reduce the use of bone scans that are clinically unnecessary and reduce economic burden to the

¹⁰⁸ NQF. Cancer Endorsement Maintenance 2011.Candidate Review Consensus – Phase 1. Available at: http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C.

patient and payer.¹⁰⁹ This measure addresses the National Quality Strategy domain of Clinical Efficiency.

(F) Clinical Process/Oncology Care - Prostate Cancer-Adjuvant Hormonal Therapy for High-Risk Patients (NQF #0390)

This measure assesses the percentage of patients, regardless of age, with a diagnosis of prostate cancer at high risk of recurrence receiving external beam radiotherapy to the prostate, who were prescribed adjuvant hormonal therapy (GnRH agonist or antagonist). Prostate cancer is the most commonly diagnosed cancer and the second leading cause of cancer death in men over the age of 40 years in the United States. If patients are receiving external beam radiotherapy as primary therapy, those patients that are designated as high risk may be prescribed hormonal therapy. Adjuvant hormonal therapy in these patients has been shown to increase the effectiveness of the radiotherapy and may also prolong survival. Further, the American Urological Association and the National Comprehensive Cancer Network guidelines recommend adjuvant hormonal therapy with radiotherapy for high risk prostate cancer patients for prolonged survival. This measure attempts to encourage compliance with this guideline for this specific patient population.¹¹⁰ This measure addresses the National Quality Strategy domain of Clinical Effectiveness.

¹⁰⁹ NQF. Cancer Endorsement Maintenance 2011.Candidate Review Consensus – Phase 1. Available at: http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C.

¹¹⁰ NQF. Cancer Endorsement Maintenance 2011.Candidate Review Consensus – Phase 1. Available at: http://www.qualityforum.org/Projects/Cancer_Endorsement_Maintenance_2011.aspx#t=2&s=&p=3%7C.

(3) Patient Experience of Care Survey: HCAHPS

To advance patient safety and quality improvement in cancer hospital settings, we are proposing that for the FY 2016 PCHQR Program and subsequent years PCHs submit data on the HCAHPS Survey of patient experience-of-care. We partnered with AHRQ to develop HCAHPS. The HCAHPS Survey is the first national, standardized, publicly reported survey of patients' experience of hospital care. HCAHPS, also known as CAHPS[®] Hospital Survey, is a survey instrument and data collection methodology for measuring patients' perceptions of their hospital experience.

The HCAHPS Survey asks recently discharged patients 32 questions about aspects of their hospital experience that they are uniquely suited to address. The core of the survey contains 21 items that ask "how often" or whether patients experienced a critical aspect of hospital care. The survey also includes four items to direct patients to relevant questions, five items to adjust for the mix of patients across hospitals, and two items that support Congressionally-mandated reports (77 FR 53513 through 53515).

Ten HCAHPS measures (six summary measures, two individual items and two global items) are currently publicly reported on the Hospital Compare Web site (<http://www.hospitalcompare.hhs.gov/>) for each hospital participating in the Hospital IQR Program. One new composite item, "Transition to post-hospital care," will be added to the Hospital Compare Web site for the Hospital IQR Program once participating hospitals have submitted four calendar quarters of data on the three Care Transition Measure items that were added to the HCAHPS Survey beginning with January 2013 discharges (77 FR 53513 through 53515).

Each of the six currently reported summary measures, or composites, is constructed from two or three survey questions. The six composites summarize how well doctors communicate with patients, how well nurses communicate with patients, how responsive hospital staff are to patients' needs, how well hospital staff helps patients manage pain, how well the staff communicates with patients about medicines, and whether key information is provided at discharge. The two individual items address the cleanliness and quietness of patients' rooms, while the two global items report patients' overall rating of the hospital, and whether they would recommend the hospital to family and friends.

The HCAHPS Survey is administered to a random sample of adult inpatients between 48 hours and 6 weeks after discharge. Patients admitted in the medical, surgical and maternity care service lines are eligible for the survey; the survey is not restricted to Medicare beneficiaries. PCHs may use an approved survey vendor, or collect their own HCAHPS data (if approved by CMS to do so). To accommodate hospitals, HCAHPS can be implemented using one of four different survey modes: mail, telephone, mail with telephone follow-up, or active interactive voice recognition (IVR). Regardless of the mode used, the PCH would be required to make multiple attempts to contact patients.

PCHs may use the HCAHPS Survey alone, or include additional questions after the 21 core items discussed above. PCHs must survey patients throughout each month of the year, and PCHs participating in the PCHQR Program must target at least 300 completed surveys over four calendar quarters in order to attain the reliability criterion CMS has set for publicly reported HCAHPS scores. The HCAHPS Survey is

available in official translations in several languages other than English: Spanish (mail and telephone modes); Chinese (mail mode); Russian (mail mode); and Vietnamese (mail mode). All official translations of the HCAHPS Survey instrument are available in the current HCAHPS Quality Assurance Guidelines. The survey itself and the protocols for sampling, data collection, coding and file submission can be found in the current HCAHPS Quality Assurance Guidelines manual, available on the HCAHPS On-Line Web site located at: <http://www.hcahpsonline.org>.

We partnered with AHRQ to develop and test the HCAHPS Survey. AHRQ carried out a rigorous and multi-faceted scientific process, including a public call for measures; literature review; cognitive interviews; consumer focus groups; stakeholder input; a three-State pilot test; extensive psychometric analyses; consumer testing; and numerous small-scale field tests. In addition, we provided three separate opportunities for the public to comment on HCAHPS, and responded to over 1,000 comments.

In May 2005, the HCAHPS Survey was NQF-endorsed and in December 2005 OMB gave its final approval for the national implementation of HCAHPS for public reporting purposes. We implemented the HCAHPS Survey for the Hospital IQR Program in October 2006 and the first public reporting of HCAHPS results under that program occurred in March 2008. The survey, its methodology and the results it produces are available on Hospital Compare.

Currently, nearly 3,900 hospitals that participate in the Hospital IQR Program publicly report their HCAHPS scores on Hospital Compare, and about 27 percent of PCHs voluntarily administer the HCAHPS Survey. We strongly encourage those PCHs

that are currently submitting the HCAHPS measure to continue their current data submission.

In summary, we invite public comment on our proposals to adopt one new measure (SSI measure) beginning with the FY 2015 PCHQR Program and 13 new measures (six SCIP measures, six Clinical Process/Oncology Care measures, and one HCAHPS measure) beginning with the FY 2016 PCHQR Program. We refer readers to section IX.B.9. of the preamble of this proposed rule for more detailed information about the form, manner, and timing of data collection for these proposed measures. The tables below list the proposed new measures for the PCHQR Program beginning with the FY 2015 and FY 2016 respectively.

Topic	Proposed New Measure for the PCHQR Program Beginning with the FY 2015 Program Year
Safety and Healthcare-Associated Infection—HAI	
	<ul style="list-style-type: none"> ● (NQF #0753) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure

Topic	Proposed New Measures for the PCHQR Program Beginning with the FY 2016 Program Year
SCIP	
	<ul style="list-style-type: none"> ● (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

Topic	Proposed New Measures for the PCHQR Program Beginning with the FY 2016 Program Year
	<ul style="list-style-type: none"> ● (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	
	<ul style="list-style-type: none"> ● (NQF #0380) Multiple Myeloma-Treatment with Bisphosphonates ● (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	
	<ul style="list-style-type: none"> ● (NQF #0166) HCAHPS

6. Possible New Quality Measure Topics for Future Years

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the PPS-exempt cancer hospital setting. Therefore, through future rulemaking, we intend to propose to adopt new or updated measures, such as measures that assess the safety and efficiency of diagnosis and treatment of cancer, measures that take into account novel diagnostic and treatment modalities, measures that assess symptoms and functional status, measures of appropriate disease management and care coordination, and measures of admissions for complications of cancer and treatment for cancer, that help us further our goal of achieving better health care and improved health for Medicare beneficiaries who obtain cancer services through the widespread dissemination and use of performance information.

We welcome public comment and suggestions for the following measure domains: 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 National Quality Strategy, and we believe that selecting measures to address these domains will promote better cancer care while bringing the PCHQR Program in line with other established quality reporting and pay for performance programs such as the Hospital IQR Program, the Hospital VBP Program, and the Hospital OQR Program, and others within our purview.

7. Maintenance of Technical Specifications for Quality Measures

Many of the quality measures used in different Medicare and Medicaid reporting programs are NQF-endorsed. As part of its regular maintenance process for endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes to NQF on an annual basis. NQF solicits information from measure stewards for annual reviews and in order to review measures for continued endorsement in a specific 3-year cycle.

Through NQF's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantively change the nature of the measure. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or

different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53562), we adopted a policy to use a subregulatory process to make nonsubstantive updates to NQF-endorsed measures used for the PCHQR Program. We also said that we expected to make the determination of what constitutes a substantive versus a nonsubstantive change on a case-by-case basis, and provided examples of the types of changes that would fall into each category. We further said that the policies regarding what is considered substantive versus nonsubstantive changes would apply to all PCHQR Program measures.

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 HCAHPS On-Line Web site, <http://www.hcahpsonline.org>. As necessary, HCAHPS Bulletins are issued to provide notice of changes and updates to technical specifications in HCAHPS data collection systems. As stated in our previous rulemaking (77 FR 53562), the specifications for the other measures are posted on the Specification Manual on the QualityNet Web site at www.qualitynet.org.

The Specifications Manual contains links to measure specifications, data abstraction information, data submission information, and other information necessary for PCHs to participate in the PCHQR Program. We maintain the technical specifications for the quality measures by updating this Manual periodically as we continue to expand and update our PCHQR Program. These updates include detailed instructions for PCHs to use when collecting and submitting data on the required measures and are

accompanied by notifications to PCHQR Program-participating users, providing sufficient time between the change and effective dates in order to allow users to incorporate changes and updates to the measure specifications into data collection systems. We also revise the Specifications Manual and provide links to reflect measure changes which are also posted on the QualityNet Web site at:

<https://www.QualityNet.org>.

8. Public Display Requirements Beginning with FY 2015 Program Year

Section 1866(k)(4) of the Act requires the Secretary to establish procedures for making the data submitted under the PCHQR Program available to the public. Such procedures shall ensure that a PCH has the opportunity to review the data that is to be made public with respect to the hospital prior to such data being made public.

Section 1866(k)(4) of the Act also provides that the Secretary shall report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospital on the CMS Web site.

In order to meet these requirements, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53562 through 56563), 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.

This year we have more information on the state of our systems' capability and readiness, therefore, we are proposing to publicly display in 2014 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).

However, at this time, we are proposing to defer the public reporting of the remaining three finalized measures for FY 2014 PCHQR Program. We are in the process of testing and assessing data quality, including the reliability and validity of the measure rates, and do not believe that the data will be ready for public posting until sometime in the future. We will provide more information in future rulemaking.

We invite public comment on these proposals.

9. Form, Manner, and Timing of Data Submission Beginning with the FY 2015 Program Year

a. Background

Section 1866(k)(2) of the Act requires that, beginning with 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.

The complete data submission requirements and submission deadlines for FY 2014 have been posted on the QualityNet Web site at: <https://www.QualityNet.org>.

We also refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563 through 535567) for more information.

b. Proposed Waivers from Program Requirements

In our experience with other quality reporting and/or performance programs, we have noted occasions when providers have been unable to submit required quality data due to extraordinary circumstances that are not within their control (for example, natural disasters). We do not wish to unduly increase their burden during these times.

Therefore, we are proposing that, beginning with FY 2014, PCHs may request and we may grant waivers with respect to the reporting of required quality data when extraordinary circumstances beyond the control of the PCH warrant. When waivers are granted, we will notify the respective PCH.

Under the proposed process, in the event of extraordinary circumstances not within the control of the PCH, such as a natural disaster, the PCH may request a reporting extension or a complete waiver of the requirement to submit quality data for one or more quarters. Such facilities would submit to CMS a request form that would be made available on the QualityNet Web site. The following information should be noted on the form:

- The PCH's CCN;
- The PCH's name;
- Contact information for the PCH's CEO and any other designated personnel, including name, email address, telephone number, and mailing address (the address must be a physical address, not a post office box);

- The PCH's reason for requesting an extension or waiver;
- Evidence of the impact of extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the PCH will again be able to submit PCHQR Program data, and a justification for the proposed date.

We are proposing that the request form must be signed by the PCH's CEO or designee, and must be submitted within 30 days of the date that the extraordinary circumstances occurred. Following receipt of the request form, we would: (1) provide a written acknowledgement, using the contact information provided in the request, to the CEO and any additional designated PCH personnel, notifying them that the PCH's request has been received; and (2) provide a formal response to the CEO and any additional designated PCH personnel, using the contact information provided in the request, notifying them of our decision.

This proposal does not preclude us from granting waivers or extensions to PCHs that have not requested them when we determine that an extraordinary circumstance, such as an act of nature (for example, a hurricane or other natural disaster that could reasonably affect a PCH's ability to compile or report data), affects an entire region or locale. If we make the determination to grant a waiver or extension to PCHs in a region or locale, we are proposing to communicate this decision through routine communication channels to PCHs and vendors, by means of memoranda, emails, and notices on the QualityNet Web site, among other means.

We invite public comment on this proposal.

c. Proposed Reporting Periods and Submission Timelines for the Proposed SSI Measure

We are proposing that PCHs report the proposed SSI measure beginning with January 1, 2014 events. We believe that this date will provide enough advance notice for PCHs to prepare to report the measure, and we base this belief on our experience gained from collecting the SSI measure for the Hospital IQR Program.

We are proposing to calculate the SSI measure rate for purposes of the FY 2015 PCHQR Program using data from the first quarter (Q1) of calendar year (CY) 2014. We recognize that using data from only one quarter may not provide a complete picture of the quality of care provided at a PCH. However, our intent is to align the PCHQR reporting timeline with the reporting timeline used by the Hospital IQR Program as well as to leverage current IT infrastructure to minimize cost and burden.

We are proposing to calculate the SSI measure rate for purposes of the FY 2016 program using data from the last three quarters (Q2, Q3, and Q4) of CY 2014, and we are proposing to calculate the SSI measure rate for purposes of the FY 2017 program using data from all four quarters (Q1, Q2, Q3, and Q4) of CY 2015. The table below outlines the proposed reporting periods and submission timeframes for FY 2015, FY 2016, and FY 2017.

Proposed SSI Measure Reporting Periods and Submission Timeframes for FYs 2015, 2016 and 2017		
Program Year (FY)	Reporting Periods (CY)	Data Submission Deadlines
2015	Q1 2014 events (January 1, 2014 – March 31, 2014)	August 15, 2014
2016	Q2 2014 events (April 1, 2014 – June 30, 2014)	November 15, 2014
	Q3 2014 events (July 1, 2014 – September 30, 2014)	February 15, 2015

Proposed SSI Measure Reporting Periods and Submission Timeframes for FYs 2015, 2016 and 2017		
Program Year (FY)	Reporting Periods (CY)	Data Submission Deadlines
	Q4 2014 events (October 1, 2014 – December 31, 2014)	May 15, 2015
2017	Q1 2015 events (January 1, 2015 – March 31, 2015)	August 15, 2015
	Q2 2015 events (April 1, 2015 – June 30, 2015)	November 15, 2015
	Q3 2015 events (July 1, 2015 – September 30, 2015)	February 15, 2016
	Q4 2015 events (October 1, 2015 – December 31, 2015)	May 15, 2016

We are proposing that PCHs submit the SSI measure data to the CDC through the NHSN database. This is the same procedural/reporting mechanism requirement used for the CLABSI and CAUTI measures we finalized in FY 2013 IPPS/LTCH PPS final rule (77 FR 53563 through 53564). The data submission and reporting procedures have been set forth by CDC for NHSN participation in general and for submission of the SSI measure to NHSN. We refer readers to the CDC's Web site (<http://www.cdc.gov/nhsn/>) for detailed data submission and reporting procedures. After the final submission deadline has passed, we will obtain the PCH-specific calculations that have been generated by the NHSN for the PCHQR Program.

As noted in the table above, we are proposing to adopt a quarterly submission process for the SSI measure that uses a reporting mechanism that is the same as the one finalized for the Hospital IQR Program (77 FR 53539). We have successfully implemented this reporting mechanism in the Hospital IQR Program, and we strongly

believe that this type of data submission is the most feasible option because PCHs are accustomed to reporting the CAUTI and CLABSI measures to the NHSN this way.

We welcome public comment on this proposal.

d. Proposed Exceptions to Reporting and Data Submission for HAI Measures (CAUTI, CLABSI, and Proposed SSI)

Last year we finalized policies for the Hospital IQR Program providing exceptions to the reporting and data submission requirements for the CLABSI, CAUTI and SSI measures (77 FR 53539). We implemented these exceptions because we realize that some hospitals may not have locations that meet the NHSN criteria for CLABSI or CAUTI reporting and that some hospitals may perform so few procedures requiring surveillance under the SSI measure that the data may not be meaningful for Hospital Compare or sufficiently reliable to be utilized for payment determination. We also finalized last year the CLABSI and CAUTI measures for PCHQR Program starting with FY 2014 (77 FR 53557) but did not propose to adopt the same exceptions for those measures. This year, we are proposing to adopt the same exceptions to the CLABSI and CAUTI measures for PCHs, which are outlined in CDC's specifications manual, because we realize that some hospitals may not have locations that meet the NHSN criteria. We refer readers to the CDC's specifications manual for more information on location exceptions for the CAUTI¹¹¹ and CLABSI.¹¹²

¹¹¹ Catheter-Associated Urinary Tract Infection (CAUTI) Event at <http://www.cdc.gov/nhsn/pdfs/pscManual/7pscCAUTIcurrent.pdf>

¹¹² Central Line-Associated Bloodstream Infection (CLABSI) Event at: http://www.cdc.gov/nhsn/pdfs/pscmanual/4psc_clabscurrent.pdf

In addition, as with the Hospital IQR Program, we recognize that some PCHs may perform so few procedures requiring surveillance under the proposed SSI measure that the data may not be meaningful for Hospital Compare or sufficiently reliable to be utilized for quality reporting purposes. We are proposing to provide an exception for these PCHs from the reporting requirement in any given year if the PCH performed less than a combined total of 10 colon and abdominal hysterectomy procedures in the calendar year prior to the reporting year.

We are proposing to provide PCHs with a single HAI exception form, to be used for seeking an exception for any of the CLABSI, CAUTI, and SSI measures. This exception form will be available on QualityNet Web site.

We invite public comment on this proposal.

e. Proposed Reporting and Data Submission Requirements for the Proposed Clinical Process/Oncology Care Measures

We are proposing that PCHs report the proposed clinical process/oncology care measures beginning with January 1, 2015 discharges. We believe that this date will provide enough advance notice for PCHs to prepare to report the measures. We believe that this timeline provides PCHs with sufficient time to prepare to report on the new measures. We are proposing to calculate the clinical process/oncology care measure rates for purposes of the FY 2016 program using data from the first quarter (Q1) of CY 2015, and that PCHs submit aggregated data for each measure for this quarter during a data submission window that will be open from July 1 through August 15, 2015. We are proposing to calculate the clinical process/oncology care measure rates for purposes of

the FY 2017 program using data from the last three quarters (Q2, Q3, and Q4) of CY 2015. We are proposing that PCHs submit aggregated data for each measure for each of these quarters during a data submission window that will be open from July 1 through August 15, 2016. We are proposing to calculate the clinical process/oncology care measure rates for purposes of the FY 2018 program using data from the four quarters (Q1, Q2, Q3, and Q4) of CY 2016. We are proposing that PCHs submit aggregated data for each measure for each of these quarters during a data submission window that will be open from July 1 through August 15, 2017. The table below outlines the proposed reporting periods and submission timeframes for FY 2016, FY 2017, and FY 2018 for the proposed clinical process/oncology care measures.

Proposed Clinical Process/Oncology Care Measures - Proposed Reporting Periods and Submission Timeframes for FYs 2016-2018		
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) 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

For data collection, we are proposing that PCHs submit aggregate-level data through the CMS Web-based Measures Tool. This proposal mirrors the requirements we have finalized for the IPFQR Program (77 FR 53655). PCHs would submit all the data required for a particular program year once annually during the data submission windows we proposed above, and would do so via the PCH section on the QualityNet secure Web site. However, the data input forms on the QualityNet Web site for such submission will require aggregate data for each separate quarter. Therefore, PCHs will need to track and maintain quarterly records for their data. We refer readers to FY 2013 IPPS/LTCH PPS final rule (77 FR 53655) for more information on the CMS Web-based aggregated data collection tool used in the IPFQR Program, which we are now proposing to also use in the PCHQR Program. We believe that this option is less burdensome to PCHs than patient level reporting.

We also recognize that aggregate level reporting has the potential to result in less accurate measure rates than patient level reporting; however, we have assessed our infrastructure readiness to collect these measures in the PCHQR Program and believe that an aggregate data submission approach is the most feasible approach at this time.

We welcome public comment on the proposed reporting periods and data collection methods/modes for the clinical process/oncology care measures.

f. Proposed Reporting and Data Submission Requirements for the Proposed SCIP Measures

We are proposing that PCHs report the proposed SCIP measures beginning with January 1, 2015 discharges. We believe that this date will provide enough advance notice

for PCHs to prepare to report the measures, and our belief is based on the experience gained from collecting the SCIP measures for the Hospital IQR Program.

We are proposing to calculate the SCIP measure rates for purposes of the FY 2016 program using patient-level data from the first quarter (Q1) of CY 2015. We recognize that using data from only one quarter may not provide a complete picture of the quality of care provided at a PCH. However, our intent is to align the PCHQR Program's current reporting timeline with the reporting timeline used by the Hospital IQR Program, as well as to leverage the current IT infrastructure to minimize cost and burden. We are proposing to calculate the SCIP measure rates for purposes of the FY 2017 program using the last three quarters (Q2, Q3, and Q4) of CY 2015. This will allow us to calculate measure rates for FY 2018 using data from all four quarters (Q1, Q2, Q3, and Q4) of CY 2016. The table below outlines the proposed reporting periods and submission timeframes for the FY 2016, FY 2017, and FY 2018 program years.

Proposed SCIP Measures - Proposed Reporting Periods and Submission Timeframes for FYs 2016-2018		
Program Year (FY)	Reporting Periods (CY)	Data Submission Deadlines
2016	Q1 2015 discharges (January 1, 2015 – March 31, 2015)	August 15, 2015
2017	Q2 2015 discharges (April 1, 2015 – June 30, 2015)	November 15, 2015
	Q3 2015 discharges (July 1, 2015 – September 30, 2015)	February 15, 2016
	Q4 2015 discharges (October 1, 2015 – December 31, 2015)	May 15, 2016
2018	Q1 2016 discharges (January 1, 2016 – March 31, 2016)	August 15, 2016
	Q2 2016 discharges (April 1, 2016 – June 30, 2016)	November 15, 2016

Proposed SCIP Measures - Proposed Reporting Periods and Submission Timeframes for FYs 2016-2018		
Program Year (FY)	Reporting Periods (CY)	Data Submission Deadlines
	Q3 2016 discharges (July 1, 2016 – September 30, 2016)	February 15, 2017
	Q4 2016 discharges (October 1, 2016 – December 31, 2016)	May 15, 2017

We are proposing that PCHs submit patient level data for each of the SCIP measures to CMS through the QualityNet infrastructure. This is the same procedural/reporting mechanism requirement used for collecting Hospital IQR Program SCIP process of care measures. We have successfully implemented this reporting mechanism in the Hospital IQR Program and intend to use the same reporting mechanism to collect data for the PCHQR Program. We are proposing the patient-level data submission approach for the SCIP measures so that we can compare the data being submitted by PCHs with that being submitted by hospitals under the Hospital IQR Program. We also believe that patient-level data will provide us with more granular information that we can use to better assess the quality of care provided at a PCH.

We welcome public comment on the proposed reporting and submission requirements for the proposed SCIP measures and welcome feedback on using patient level versus other types of data submission.

g. Proposed HCAHPS Requirements

The HCAHPS requirements that we are proposing mirror those used for the Hospital IQR Program (77 FR 53537 through 53538). Similarly, we are proposing that PCHs submit HCAHPS data in accordance with the current HCAHPS Quality Assurance

Guidelines and the quarterly data submission deadlines, both of which are posted at <http://www.hcahpsonline.org>. Like acute care hospitals that submit HCAHPS data under the Hospital IQR Program, we are proposing that PCHs will have approximately 13 weeks after the end of a calendar quarter to submit HCAHPS data for that quarter to the QIO Clinical Warehouse, also referred to as the “HCAHPS data warehouse.”

In order for a PCH to participate in the collection of HCAHPS data, a PCH must either: (1) contract with an approved HCAHPS survey vendor that will conduct the survey and submit data on the PCH’s behalf to the QIO Clinical Warehouse; or (2) self-administer the survey without using a vendor provided that the PCH attends HCAHPS training and meets Minimum Survey Requirements as specified on the HCAHPS Web site at: <http://www.hcahpsonline.org>. A current list of approved HCAHPS survey vendors can be found on the HCAHPS Web site.

We are proposing that a PCH which chooses to contract with a survey vendor must provide the sample frame of HCAHPS-eligible discharges to its survey vendor with sufficient time to allow the survey vendor to begin contacting each sampled patient within 6 weeks of discharge from the hospital. (We refer readers to the Quality Assurance Guidelines located at <http://www.hcahpsonline.org> for details about HCAHPS survey administration.) We would strongly encourage PCHs to submit their entire patient discharge list, excluding patients who had requested “no publicity” status or who are excluded because of State regulations, in a timely manner to their survey vendor to allow adequate time for sample creation, sampling, and survey administration. We emphasize that PCHs must also provide the administrative data that is required for HCAHPS in a

timely manner to their survey vendor. This includes the patient's MS-DRG at discharge, or alternative information that can be used to determine the patient's service line, in accordance with the survey protocols in the most recent HCAHPS Quality Assurance Guidelines.

We note that HCAHPS Quality Assurance Guidelines require that hospitals maintain complete discharge lists that indicate which patients were eligible for the HCAHPS Survey, which patients were not eligible, which patients were excluded, and the reason(s) for ineligibility and exclusion. (We refer readers to the Quality Assurance Guidelines located at <http://www.hcahpsonline.org> for details about HCAHPS eligibility and sample frame creation.) In addition, the PCH must authorize the survey vendor to submit data via My QualityNet, the secure part of the QualityNet Web site, on the PCH's behalf.

We are proposing that the PCHs obtain and submit at least 300 completed HCAHPS surveys in a rolling four-quarter period unless the PCH is too small to obtain 300 completed surveys. We are proposing that the absence of a sufficient number of HCAHPS-eligible discharges will be the only acceptable reason for obtaining and submitting fewer than 300 completed HCAHPS surveys in a rolling four quarter period. We are proposing that if a PCH obtains fewer than 100 completed surveys, the PCH's scores will be accompanied by an appropriate footnote on the Hospital Compare Web site alerting the Web site users that the scores should be reviewed with caution, as the number of surveys may be too low to reliably assess PCH performance.

After the survey vendor submits the data to the QIO Clinical Warehouse, we strongly recommend that PCHs employing a survey vendor promptly review the two HCAHPS Feedback Reports (the Provider Survey Status Summary Report and the Data Submission Detail Report) and the HCAHPS Review and Correction Report that are available. These reports will enable a PCH to ensure that its survey vendor has submitted the data on time, the data has been accepted into the QIO clinical Warehouse, and the data accepted into the QIO Clinical Warehouse are complete and accurate.

In order to ensure compliance with HCAHPS survey and administration protocols, we are proposing that PCHs and survey vendors must participate in oversight activities, which will include onsite visits and/or conference calls. During the oversight process, the HCAHPS Project Team will review the PCH's or survey vendor's survey systems and assess protocols based upon the most recent HCAHPS Quality Assurance Guidelines. All materials relevant to survey administration will be subject to review. The systems and program review includes, but is not limited to: (a) survey management and data systems; (b) printing and mailing materials and facilities; (c) telephone and Interactive Voice Response (IVR) materials and facilities; (d) data receipt, entry and storage facilities; and (e) written documentation of survey processes. As needed, hospitals and survey vendors will be subject to follow-up site visits or conference calls. We point out that the HCAHPS Quality Assurance Guidelines state that hospitals should refrain from activities that explicitly influence how patients respond on the HCAHPS Survey. We are proposing that if we determine that a PCH is not compliant with HCAHPS program requirements, we may determine that the PCH is not submitting

HCAHPS data that meet the requirements of the PCHQR Program. Below is a table outlining the proposed reporting and data submission requirements.

Proposed HCAHPS Measure - Proposed Reporting Periods and Submission Timeframes For FYs 2016-2018		
Program Year (FY)	Reporting Periods (CY)	Data Submission Deadlines
2016	Q2 2014 discharges (April 1, 2014 – June 30, 2014)	October 1, 2014
	Q3 2014 discharges (July 1, 2014 – September 30, 2014)	January 7, 2015
	Q4 2014 discharges (October 1, 2014 – December 31, 2014)	April 1, 2015
2017	Q1 2015 discharges (January 1, 2015 – March 31, 2015)	July 1, 2015
	Q2 2015 discharges (April 1, 2015 – June 30, 2015)	October 7, 2015
	Q3 2015 discharges (July 1, 2015 – September 30, 2015)	January 6, 2016
	Q4 2015 discharges (October 1, 2015 – December 31, 2015)	April 6, 2016
2018	Q1 2016 discharges (January 1, 2016 – March 31, 2016)	July 6, 2016
	Q2 2016 discharges (April 1, 2016 – June 30, 2016)	October 5, 2016
	Q3 2016 discharges (July 1, 2016 – September 30, 2016)	January 4, 2017
	Q4 2016 discharges (October 1, 2016 – December 31, 2016)	April 5, 2017

We strongly encourage those PCHs that are currently administering the HCAHPS Survey to continue to do so. We welcome public comment on our proposed HCAHPS requirements for PCHs.

C. Long-Term Care Hospital Quality Reporting (LTCHQR) Program

1. Statutory History

In accordance with section 1886(m)(5) of the Act, as added by section 3004 of the Affordable Care Act, the Secretary established the Long-Term Care Hospital Quality Reporting (LTCHQR) Program. Under the LTCHQR Program, for the FY 2014 payment determination and subsequent payment determinations, in the case of an LTCH that does not submit data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a rate year, any annual update to a standard Federal rate for discharges for the hospital during the rate year, and after application of section 1886(m)(3) of the Act, shall be reduced by two percentage points.

Section 1886(m)(5)(D)(iii) of the Act requires the Secretary to publish the selected measures for the LTCHQR Program that will be applicable with respect to the FY 2014 payment determination no later than October 1, 2012.

Under section 1886(m)(5)(D)(i) of the Act, the quality measures for the LTCHQR Program are measures selected by the Secretary that have been endorsed by an entity that holds a contract with the Secretary under section 1890(a) of the Act, unless section 1886(m)(5)(D)(ii) of the Act applies. This contract is currently held by the National Quality Forum (NQF). The NQF was established to standardize healthcare quality measurement and reporting through its consensus development process (http://www.qualityforum.org/About_NQF/Mission_and_Vision.aspx). The NQF undertakes review of: (a) new quality measures and national consensus standards for measuring and publicly reporting on performance; (b) regular maintenance processes for

endorsed quality measures; (c) measures with time limited endorsement for consideration of full endorsement; and, (d) ad hoc review of endorsed quality measures, practices, consensus standards, or events with adequate justification to substantiate the review (http://www.qualityforum.org/Measuring_Performance/Ad_Hoc_Reviews/Ad_Hoc_Review.aspx). Additional information regarding NQF and its measure review processes is available at:

http://www.qualityforum.org/Measuring_Performance/Measuring_Performance.aspx.

Section 1886(m)(5)(D)(ii) of the Act provides that an exception may be made in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity that holds a contract with the Secretary under section 1890(a) of the Act. In such a case, section 1886(m)(5)(D)(ii) of the Act authorizes the Secretary to specify a measure(s) that is not so endorsed, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. The LTCHQR Program was implemented in section VII.C. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756).

2. 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 citizens we serve. Quality reporting programs, as well as public reporting of that information, furthers 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 remains a constant 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.nationalprioritiespartnership.org/>), HHS Strategic Plan (<http://www.hhs.gov/secretary/about/priorities/priorities.html>), and the National Quality Strategy (NQS), which is described at:

<http://www.healthcare.gov/center/reports/quality03212011a.html>.

We also consider input from the Measure Applications Partnership (MAP) when selecting measures under the LTCHQR Program. The MAP is composed of multi-stakeholder groups convened by our contractor under section 1890 of the Act (currently the NQF). 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. CMS, in turn, must take this input into consideration in selecting those categories of measures. The NQF provided MAP input to CMS in February of 2013, as required under section 1890A(a)(3) of the Act. This input appears at:

http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx. Measures proposed for the LTCHQR Program in this proposed rule were measures CMS included under its List of Measures Under Consideration (MUC List) for

December 1, 2012¹¹³, a list CMS must make public by December 1 of each year, as part of the pre-rulemaking process, as described in section 1890A(a)(2). The list is discussed in the MAP Pre-Rulemaking Report available at:

http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx (pp. 170-176). The MAP supported the direction of each of the proposed measures described below, noting the measure concepts as promising for several of them, and requiring further testing and development.

In the absence of NQF endorsement for measures we are proposing for the LTCH setting, or measures that are not fully supported by the MAP for the LTCHQR Program, we are proposing measures that most closely align with the national priorities discussed above and for which the MAP supports the measure concept. Further discussion of why these measures are high-priority in the LTCH setting is included for each proposed measure below.

In addition, for measures not endorsed by the NQF, we have sought, to the extent practicable, to adopt measures that have been endorsed or adopted by a national consensus organization, recommended by multi-stakeholder organizations, and/or developed with the input of providers, purchasers/payers, and other stakeholders.

3. Process for Retention of LTCHQR Program Measures Adopted in Previous Payment Determinations

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53637), for the LTCHQR Program, we adopted a policy that once a quality measure is adopted, it is retained for use in subsequent payment determinations, unless otherwise stated. For the

¹¹³ Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72363>

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 payment determinations 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 77 FR 53614 and 53615.

4. Process for Adopting Changes to LTCHQR Program Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616), we finalized 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. Examples of such nonsubstantive changes could be updated diagnosis or procedure codes, medication updates for categories of medications, changes to exclusions to the patient population, or minor changes to definitions. 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. Specific examples of what we might consider substantive are changes in acceptable timing of medication, procedure/process, or test administration, or expansion of the measure to a new setting. The subregulatory process for nonsubstantive changes will include revision of the LTCHQR Program Manual and posting of updates

on our LTCH Quality Reporting Program Web site at: <http://www.cms.gov/LTCH-Quality-Reporting/>.

5. Previously Adopted Quality Measures for the FY 2014 and FY 2015 Payment Determinations and Subsequent Payment Determinations

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53616 through 53623), we retained the application of NQF #0678 to the LTCH setting (initially adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51745 through 51750)) and adopted updated versions of NQF #0138 and NQF #0139, for the FY 2014 and FY 2015 payment determination and subsequent payment determinations as listed in the following table:

Quality Measures Finalized in the FY 2013 IPPS/LTCH PPS Final Rule for the FY 2014 and FY 2015 Payment Determinations and Subsequent Payment Determinations	
NQF Measure ID	Measure Title
NQF #0138	National Health Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure
NQF #0139	National Health Safety Network (NHSN) Central line-associated Blood Stream Infection (CLABSI) Outcome Measure
Application of NQF #0678	Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay)

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53619 through 53623 and 53667 through 53672) for a discussion of the data collection and submission methods for these measures for the FY 2014 payment determination and all subsequent payment determinations and for references to the descriptions and specifications of these measures.

6. Previously Adopted Quality Measures for the FY 2016 Payment Determination and Subsequent Payment Determinations

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53636), we adopted two additional quality measures for the LTCHQR Program for the FY 2016 payment determination and subsequent payment determinations, in addition to the three previously adopted measures (CAUTI measure, CLABSI measure, and Pressure Ulcer measure).

Set out below are the quality measures, adopted in FY 2013 IPPS/LTCH PPS final rule, for the FY 2016 payment determination and subsequent payment determinations.

Quality Measures Finalized in the FY 2013 IPPS/LTCH PPS Final Rule for the FY 2016 LTCHQR Program Payment Determination and Subsequent Payment Determinations	
NQF Measure ID	Measure Title
NQF #0138	National Health Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure*
NQF #0139	National Health Safety Network (NHSN) Central line-associated Blood Stream Infection (CLABSI) Outcome Measure*
Application of NQF #0678	Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay)*
NQF #0680	Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay)**
NQF #0431	Influenza Vaccination Coverage among Healthcare Personnel**
* Adopted for the FY 2014 payment determination and subsequent payment determinations.	
** Adopted for the FY 2016 payment determination and subsequent payment determinations.	

7. Proposed Revisions to Previously Adopted Quality Measures

We are proposing the following revisions to the quality measures we have previously adopted for the LTCHQR Program.

a. Proposed Revisions for Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53630 through 53631) we finalized that for Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431), LTCHs should begin to submit data for January 1, 2014 through December 31, 2014 (CY 2014) for the FY 2016 payment determination. There is unique seasonality in the timing of influenza activity each year. The CDC, the steward of this measure, notes (<http://www.cdc.gov/flu/about/season/flu-season-2012-2013.htm>) that while influenza activity most commonly peaks in January or February in the United States, it can begin as early as October and can continue to occur as late as May. The CDC recommends that people get vaccinated against influenza as long as influenza viruses are circulating. Thus, influenza vaccination season usually begins in early fall.

Therefore, we are proposing that, for the LTCHQR Program, the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431) have its own reporting period to align with the influenza vaccination season, which is defined by the CDC as October 1 (or when the vaccine becomes available) through March 31. Instead of beginning data collection and submission in the middle of the 2013-2014 influenza season, as is the case when reporting begins on January 1, 2014 (as finalized in FY 2013 IPPS/LTCH PPS final rule), we are proposing that data collection begin on October 1, 2014, or when the influenza vaccine becomes available (as defined by the CDC) and continue through March 31, 2015 for the 2014-2015 influenza season. This change will allow LTCHs to collect and report data on influenza vaccination for the

entirety of the 2014-2015 influenza season for the FY 2016 payment determination. This change is presented in the following table for the FY 2016 and FY 2017 payment determinations:

Proposed Timeline for Submission of LTCHQR Program Quality Data for the FY 2016 and FY 2017 Payment Determinations: NQF #0431 Influenza Vaccination Coverage Among Healthcare Personnel		
Data collection timeframe	Final submission deadlines	Payment Determination
October 1, 2014 (or when the influenza vaccine becomes available) – March 31, 2015	May 15, 2015	FY 2016
October 1, 2015 (or when the influenza vaccine becomes available) – March 31, 2016	May 15, 2016	FY 2017

While LTCHs can enter information in CDC’s NHSN (www.cdc.gov/nhsn/) at any point during the influenza season for NQF #0431, data submission is only required once per year, unlike the other measures finalized for the LTCHQR Program that utilize NHSN (CAUTI measure NQF #0138 and CLABSI measure NQF #0139). For example, LTCHs can choose to submit influenza vaccination data for NQF #0431 on a monthly basis. However, each time an LTCH submits these data, it will be asked to provide a cumulative total of vaccinations for the “current” influenza season. Thus, entering this information at the end of the influenza season would yield the same total number of vaccinations. The NHSN system will not track the individual number of vaccinations on a monthly basis, but, rather, will track the cumulative total of vaccinations for the

“current” influenza season. Also, we note that data collection period for this measure is not 12 months, as with other measures, but is approximately 6 months (October 1 (or when the vaccine becomes available) through March 31). The final deadlines associated with submitting data, approximately 45 days after the end of the data collection timeframe for the FY 2016 payment determination and subsequent payment determinations, remain consistent across measures.

We note that these proposed changes are applicable only to NQF #0431 Influenza Vaccination Coverage Among Healthcare Personnel, and not applicable to any other LTCHQR Program measures, proposed or adopted, unless explicitly stated. The specifications for this measure can be found at <http://www.cdc.gov/nhsn/PDFs/HPS-manual/vaccination/HPS-flu-vaccine-protocol.pdf>. We invite public comments on our proposal to revise the data collection and reporting timeline for this influenza vaccination measure (NQF #0431) for FY 2016 and FY 2017 payment determination, and subsequent payment determinations.

b. Proposed Revisions for Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627), we finalized that for NQF #0680, Percentage of Residents or Patients Who Were Assessed and Appropriately Give the Seasonal Influenza Vaccine (Short-Stay), LTCHs should begin to collect and submit data on January 1, 2014 through December 31, 2014 (CY 2014) for the FY 2016 payment determination. This measure, stewarded by CMS,

will be collected using items included in the LTCH CARE Data Set (Version 2.01).¹¹⁴

On February 1, 2013, we solicited public comment on this information collection request through 60-day notice (78 FR 7433 through 7434). On April 12, 2013, we published a 30-day notice to solicit public comment on this information collection request (78 FR 21955 through 21956). Later in 2013, we will release the final data submission specifications and updated LTCHQR Program Manual for the LTCH CARE Data Set (Version 2.01) containing items related to NQF #0680.

In order to allow time and opportunity for LTCHs and vendors to participate in CMS-sponsored training activities pertaining to the implementation of the LTCH CARE Data Set (Version 2.01), as well as time to plan for and incorporate changes into their data collection and entry systems, we are proposing to revise the previously finalized start date of January 1, 2014 for reporting of this measure to April 1, 2014. For CY 2014, data collection will continue through December 31, 2014. We are proposing that data for admissions and discharges for an LTCH during April 1, 2014 through December 31, 2014 will be used for the FY 2016 payment determination. We are also proposing that data for January 1, 2015 through December 31, 2015 (CY 2015) will be used for the FY 2017 payment determination. Thereafter, data for January 1 through December 31 of each year will be used for subsequent payment determinations. The proposed change is illustrated in the table below for the FY 2016 and FY 2017 payment determinations.

¹¹⁴The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938-1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956, published April 12, 2013, solicits public comment on additions and updates to the LTCH CARE Data Set. <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html>

Proposed Timeline for Submission of LTCHQR Program Quality Data for the FY 2016 and FY 2017 Payment Determinations: NQF #0680 Percentage of Residents or Patients Who Were Assessed and Appropriately Give the Seasonal Influenza Vaccine (Short-Stay)		
Data collection timeframes	Submission deadlines	Payment Determination
April 1, 2014 – June 30, 2014	August 15, 2014	FY 2016
July 1, 2014 – September 30, 2014	November 15, 2014	
October 1, 2014 – December 31, 2014	February 15, 2015	
January 1, 2015 – March 31, 2015	May 15, 2015	FY 2017
April 1, 2015 – June 30, 2015	August 15, 2015	
July 1, 2015 – September 30, 2015	November 15, 2015	
October 1, 2015 – December 31, 2015	February 15, 2016	

Further, we are proposing that while an LTCH's compliance with reporting quality data for NQF #0680 will be based on the calendar year, the measure calculation and public reporting of this measure (once public reporting is instated) will be based on the influenza vaccination season starting on October 1 (or when vaccine becomes available) and ending on March 31 of the subsequent year. For example, while reporting compliance is based on April 1, 2014 through December 31, 2014 for the FY 2016 payment determination, calculation of the measure for public reporting purposes (if this proposal is finalized) will be based on the 2014-2015 influenza vaccination season (October 1, 2014 (or when the vaccine becomes available) – March 31, 2015). Similarly for the following year, reporting compliance will be based on January 1, 2015 through December 31, 2015 for the FY 2017 payment determination, with calculation of the measure for public reporting purposes (if this proposal is finalized) will be based on the

2015-2016 influenza vaccination season (October 1, 2015 (or when vaccine becomes available) – March 31, 2016).

All LTCHs will be required to collect data using the LTCH CARE Data Set.¹¹⁵

The Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) System will 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>.

We note that these proposed changes are applicable only 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 not 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 and reporting timeline for this influenza vaccination measure (NQF #0680) for FY 2016 and FY 2017 payment determinations, and subsequent payment determinations.

¹¹⁵ The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938-1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956 published April 12, 2013 solicits public comment on additions and updates to the LTCH CARE Data Set. Available on the Web site at: <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html>.

c. Proposed Revisions for Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678)

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51748 through 51750), we adopted an application of NQF #0678 Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay) for the FY 2014 payment determination, and retained this application of the measure in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53619) for the FY 2015 payment determination and subsequent payment determinations. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51748 through 51750) for a discussion of the rationale, data collection methods, and submission methods finalized for this measure for the FY 2014 payment determination and subsequent payment determinations, and for references to the description and specifications of this measure.

At the time we completed our work on the FY 2013 IPPS/LTCH PPS final rule, NQF #0678 was not yet NQF-endorsed for use in the LTCH setting and was undergoing ad hoc review at the NQF for expansion to the LTCH setting. As a result, we were only able to adopt an application of the endorsed measure in our FY 2013 IPPS/LTCH PPS final rule. NQF #0678 underwent review for expansion to the LTCH setting by the NQF Consensus Standards Approval Committee (CSAC) on July 11, 2012 and was subsequently ratified by the NQF Board of Directors for expansion to LTCH setting on August 1, 2012.^{116,117} The title of the measure was changed to Percent of Residents or

¹¹⁶National Quality Forum, Consensus Standards Approval Committee Wednesday, July 11, 2012. Transcript. Available on the Web site at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=71612>.

Patients with Pressure Ulcers that are New or Worsened (Short-Stay) to reflect this expansion. Updated specifications, reflecting the expansion are available on the NQF Web site at: <http://www.qualityforum.org/QPS/0678>.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616), we stated that we would continue to use the rulemaking process to adopt changes to measures when NQF review substantially changes the measure. We stated that one example of a substantive change would be the change the NQF makes to a previously endorsed measure when it extends that measure to a new setting. Because NQF #0678 has received endorsement for the LTCH setting, we are now proposing to adopt the updated measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) for the FY 2015 payment determination and subsequent payment determinations.

This change would not alter the data collection, data submission, or burden finalized in the FY 2013 IPPS/LTCH PPS final rule since there have been no changes to the data elements in the LTCH CARE Data Set (version 1.01), data submission system (QIES ASAP) and technical submission specifications for the LTCH CARE Data Set used for this measure. The only difference between the previously finalized measure (NQF #0678 Percent of Residents with Pressure Ulcers that are New or Worsened (Short-Stay)) and this expanded measure (NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay)) is the change in name and NQF-

¹¹⁷Press Release: NQF Removes Time-Limited Endorsement Status for 13 Measures, Measures Now Have Endorsed Status. August 1, 2012. Available on the Web site at: http://www.qualityforum.org/News_And_Resources/Press_Releases/2012/NQF_Removes_Time-Limited_Endorsement_for_13_Measures;_Measures_Now_Have_Endorsed_Status.aspx

endorsed expansion of this measure to the LTCH (and IRF) patient population in addition to Skilled Nursing Facility/Nursing Home Short-Stay residents.

We invite public comment on this proposal to adopt NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) for the LTCHQR Program.

8. Proposed New LTCHQR Program Quality Measures for the FY 2017 and FY 2018 Payment Determinations and Subsequent Payment Determinations

a. Considerations in Updating and Expanding Quality Measures under the LTCHQR Program for the FY 2017 Payment Determination and Subsequent Payment Determinations

As noted in section IX.C.2. of the preamble of this proposed rule, we consider input from the MAP

(http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx) in selecting measures for the LTCHQR Program. Measures proposed for the LTCHQR Program in this proposed rule were included on CMS's List of Measures under Consideration for December 1, 2012 (MUC List) and discussed in the MAP

Pre-Rulemaking Report available at:

http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx (pp. 170-176). MAP supported the direction of each proposed measure.

In the absence of any NQF-endorsed measures for the LTCH setting or measures fully supported by the MAP for LTCHQR Program, we are proposing measures that most

closely align with the national priorities discussed in section IX.C.2. of the preamble of this proposed rule and for which there is MAP support for the measure concept. Further discussion of why a particular measure is high priority in the LTCH setting is included for each proposed measure below.

In addition, to the extent practicable, we have for each proposed measure that is not endorsed by the NQF, sought to adopt a measure that has been endorsed or adopted by a national consensus organization, been recommended by multi-stakeholder organizations, and/or been developed with the input of providers, purchasers/payers, and other stakeholders.

b. Proposed New LTCHQR Program Quality Measures for the FY 2017 Payment Determination and Subsequent Payment Determinations

We are proposing the following three new quality measures for the LTCHQR Program to affect the FY 2017 payment determination and subsequent payment determinations:

- (1) Proposed Quality Measure #1: National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716)

NQF #1716 is a standardized infection ratio (SIR) of hospital-onset unique blood source MRSA laboratory-identified events among all inpatients in the facility. It was adopted by the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51630) for the FY 2015 payment determination, with data collection having

begun on January 1, 2013. The measure was developed by the CDC and is NQF-endorsed.

Methicillin-Resistant *Staphylococcus aureus* (*S. aureus*) (MRSA) infections are caused by a strain of *S. aureus* bacteria that has become resistant to antibiotics commonly used to treat these infections. Between 2003 and 2004, an estimated 4.1 million persons in the United States had nasal colonization with MRSA.¹¹⁸ In addition, in 2005 it is estimated that there were 94,000 invasive MRSA infections in the United States associated with about 18,000 deaths.¹¹⁹ Currently, there are eight States that have implemented a MRSA Prevention Collaborative.¹²⁰ For Medicare populations, MRSA is a source of increased cost, lengths of stay, morbidity and mortality, and can be a consequence of poor quality of care.^{121,122}

Older adults and patients in healthcare settings are most vulnerable to MRSA infections, as these patients have weakened immune systems. LTCHs are characterized by having highly acutely ill patients with multiple comorbidities and longer lengths of stay, thereby making LTCH patients at risk for acquisition of an antibiotic-resistant infection like MRSA infection.¹²³ According to analysis of ICD-9 codes reported on

¹¹⁸ Gorwitz RJ, Kruszon-Moran D, McAllister SK, et al. Changes in the prevalence of nasal colonization with *Staphylococcus aureus* in the United States, 2001–2004. *J Infect Dis* 2008; **197**: 1226–34.

¹¹⁹ Department of Health and Human Services. *National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination*. Available at <http://www.hhs.gov/ash/initiatives/hai/infection.html>.

¹²⁰ Centers for Disease Control and Prevention. *State Has Implemented a MRSA Prevention Collaborative*. Available at <http://www.cdc.gov/hai/stateplans/states-w-MRSA-collaborative.html>

¹²¹ Centers for Disease Control and Prevention. *People at Risk of Acquiring MRSA Infections*. Available at <http://www.cdc.gov/mrsa/riskfactors/index.html>.

¹²² Centers for Disease Control and Prevention. *Management of Multidrug-Resistant Organisms in Healthcare Settings, 2006*. Available at <http://www.cdc.gov/hicpac/pdf/guidelines/MDROGuideline2006.pdf>.

¹²³ Furuno JP, Hebden JN, Standiford HC, et al. *Prevalence of methicillin-resistant Staphylococcus aureus and Acinetobacter baumannii in a long-term acute care facility*. *Am J Infect Control* 2008;36:468-71.

Medicare claims, LTCHs reported 5,853 cases of MRSA in 2009. Present on admission indicators are not available on LTCH claims; therefore, we are unable to say whether these conditions are present on admission or acquired during the LTCH stay. Therefore, it was not possible to determine which of these infections occurred in the LTCH. However, we note that on the majority of claims, the primary diagnosis is the admitting diagnosis and is considered to be present on admission and therefore, the secondary diagnoses can be assumed to provide a count of conditions that could have been acquired in the LTCH.¹²⁴ When it was assumed that a MRSA infection recorded in the primary diagnosis code was likely present on admission and a MRSA infection recorded in the secondary diagnosis code was acquired in the LTCH, there were 5,826 reported cases that may have been acquired in the LTCH.¹²⁵ Further, healthcare-associated MRSA infections occur frequently in patients who have invasive devices, such as catheters or ventilators.¹²⁶ We included the proposed MRSA measure in the December 1, 2012 MUC list. The MAP supported the direction of this measure.¹²⁷

We are proposing to use the CDC/NHSN reporting and submission infrastructure for reporting of the proposed NHSN Facility-Wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716). CDC/NHSN is the data collection and

¹²⁴ Centers for Medicare & Medicaid Services Center for Medicare & Medicaid Innovation. *Hospital Acquired Conditions (HAC) – Report to Congress*. Available at <http://innovation.cms.gov/Files/x/HospAcquiredConditionsRTC.pdf>

¹²⁵ Bernard SL, Dalton K, Lenfestey N F, Jarrett NM, Nguyen KH, Sorensen AV, Thaker S, West ND. Study to support a CMS Report to Congress: Assess feasibility of extending the hospital-acquired conditions—present on admission IPPS payment policy to non-IPPS payment environments. Prepared for the Centers for Medicare & Medicaid Services (CMS Contract No. HHSM-500-T00007). 2011.

¹²⁶ Centers for Disease Control and Prevention. *Protect Yourself from MRSA*. Available at <http://www.cdc.gov/features/mrsainhealthcare/>.

¹²⁷ National Quality Forum. *Measure Applications Partnership Pre-Rulemaking Report: 2013 Recommendations of Measures Under Consideration by HHS: February 2013*. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738>.

submission framework currently used for reporting the CAUTI (#0138), CLABSI (#0139), and Influenza Vaccination Coverage Among Healthcare Personnel (#0431) measures. Details related to the procedures for using NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the proposed NHSN Facility-Wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure (NQF #1716) can be found at:

<http://www.qualityforum.org/QPS/1716> and

http://www.cdc.gov/nhsn/PDFs/pscManual/12pscMDRO_CDADcurrent.pdf. For

January 2012 through January 2013, an estimated 42 LTCHs reported laboratory-identified MRSA event data into NHSN.¹²⁸ By building on the CDC/NHSN reporting and submission infrastructure, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program. We refer readers to section IX.C.9. of the preamble to this proposed rule for more information on data collection and submission. We invite public comment on this proposed measure and data collection and submission for the proposed measure for the FY 2017 payment determination and subsequent payment determinations.

(2) Proposed Quality Measure #2: National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717)

This measure is a standardized infection ratio (SIR) of hospital-onset CDI Laboratory-identified events among all inpatients in the facility, and was adopted by the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51630-51631

¹²⁸ Data from CMS-CDC correspondence on February 1, 2013.

for the FY 2015 payment determination, with data collection having begun on January 1, 2013. The measure was developed by the CDC and is NQF-endorsed.

Clostridium difficile (*C. difficile*) can cause a range of serious symptoms including diarrhea, serious intestinal conditions, sepsis, and death.¹²⁹ In the United States, *C. difficile* is responsible for an estimated 337,000 infections and 14,000 deaths annually.¹³⁰ Based on the HHS National Action Plan to Prevent Healthcare-Associated Infections, *C. difficile* rates have increased in recent years.¹³¹ The CDC estimates that *C. difficile* infections cost more than \$1 billion in additional health care costs each year.¹³² In recent years, *C. difficile* infections have become more frequent, more severe and more difficult to treat. Mortality rates for *C. difficile* infections are highest in elderly patients.¹³³ Between 1996 and 2009, rates of *C. difficile* infection among hospitalized patients aged 65 years and older increased 200 percent, while deaths related to *C. difficile* increased 400 percent between 2000 and 2007, which is partly attributed to a stronger germ strain.^{134,135} Further, an estimated 90 percent of the *C. difficile*-related

¹²⁹ McDonald LC, Coignard B, Dubberke E, et al. Recommendations for surveillance of *Clostridium difficile*-associated disease. *Infect Control Hosp Epidemiol* 2007;28:140–145. Available at: <http://www.jstor.org/stable/pdfplus/10.1086/511798.pdf?acceptTC=true>.

¹³⁰ Centers for Disease Control and Prevention. *Investigating Clostridium difficile Infections Across the U.S.* Available at <http://www.cdc.gov/hai/eip/pdf/Cdiff-factsheet.pdf>.

¹³¹ Department of Health and Human Services. *National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination*. Available at <http://www.hhs.gov/ash/initiatives/hai/infection.html>.

¹³² Centers for Disease Control and Prevention. *Making Health Care Safer: Stopping C. difficile Infections*. Available at: <http://www.cdc.gov/VitalSigns/HAI/index.html>.

¹³³ Centers for Disease Control and Prevention. *Investigating Clostridium difficile Infections Across the U.S.* Available at: <http://www.cdc.gov/hai/eip/pdf/Cdiff-factsheet.pdf>.

¹³⁴ Centers for Disease Control and Prevention. *QuickStats: Rates of Clostridium difficile Infection Among Hospitalized Patients Aged ≥65 Years, * by Age Group --- National Hospital Discharge Survey, United States, 1996–2009*. *MMWR*, 60(34); 1171. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6034a7.htm>.

¹³⁵ Centers for Disease Control and Prevention. *Making Health Care Safer: Stopping C. difficile Infections*. Available at: <http://www.cdc.gov/VitalSigns/HAI/index.html>.

deaths occur in patients 65 and older. *C. difficile* is a source of increased costs in patient care, lengths of stay, morbidity and mortality, and can be a consequence of poor quality of care for Medicare patients.¹³⁶

Illness from *C. difficile* most commonly affects older adults in hospitals or in facilities with longer lengths of stay, where germs spread easily, antibiotic use is common, and people are especially vulnerable to infection.¹³⁷ Considering *C. difficile* infections are increasing in LTCHs and that the LTCH population is highly vulnerable to *C. difficile* infection, it is important to measure these rates in LTCHs.¹³⁸ According to analysis of ICD-9 codes reported on Medicare claims, LTCHs reported 12,282 cases of *C. difficile*-associated disease in 2009. Present on admission indicators are not available on LTCH claims, therefore we are unable to say whether these conditions are present on admission or acquired during the LTCH stay. Therefore, it was not possible to determine which of these infections occurred in the LTCH. However, we note that on the majority of claims, the primary diagnosis is the admitting diagnosis and is considered to be present on admission and therefore, the secondary diagnoses can be assumed to provide a count of conditions that could have been acquired in the LTCH.¹³⁹ When it was assumed that a *C. difficile*-associated infection recorded in the primary diagnosis code was likely present

¹³⁶ Dubberke ER, Reske KA, Olsen MA, McDonald LC, Fraser VJ. Short- and long-term attributable costs of *Clostridium difficile*-associated disease in nonsurgical inpatients. *Clin Infect Dis* 2008; 46:497-504. Available at: <http://cid.oxfordjournals.org/content/46/4/497.long>.

¹³⁷ Centers for Disease Control and Prevention. *Frequently Asked Questions about Clostridium difficile for Healthcare Providers*. Available at: http://www.cdc.gov/HAI/organisms/cdiff/Cdiff_faqs_HCP.html.

¹³⁸ Goldstein EJC, Polonsky J, Touzani M, Citron DM. *C. difficile* infection (CDI) in a long-term acute care facility (LTAC). *Anaerobe* 2009;15:241–243. Available at: <http://www.sciencedirect.com/science/article/pii/S1075996409001176>.

¹³⁹ Centers for Medicare & Medicaid Services Center for Medicare & Medicaid Innovation. *Hospital Acquired Conditions (HAC) – Report to Congress*. Available at: <http://innovation.cms.gov/Files/x/HospAcquiredConditionsRTC.pdf>

on admission and a *C. difficile*-associated infection recorded in the secondary diagnoses code may have been acquired in the LTCH, there were 11,384 reported cases that may have been acquired in the LTCH.¹⁴⁰ In addition, there is evidence that *C. difficile* infections are preventable, and therefore surveillance and measuring infection rates is important to reducing infections and improving patient safety.

Currently, there are three States that require hospitals to report *C. difficile* data to NHSN. Fifteen States have implemented a *C. difficile* Prevention Collaborative.¹⁴¹ The goal for this proposed *C. difficile* measure is to provide a common mechanism (CDC/NHSN) for all LTCHs to report and analyze these data that will inform infection control staff of the impact of targeted prevention efforts. We included the proposed *C. difficile* measure in the December 1, 2012 MUC list. The MAP supported the direction of this measure.¹⁴²

We are proposing to use the CDC/NHSN reporting and submission infrastructure for reporting of the proposed NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Outcome Measure (NQF #1717). CDC/NHSN is the data collection and submission framework currently used for reporting the CAUTI, CLABSI and Influenza Vaccination Coverage Among Healthcare Personnel measures. Similar to the NHSN MRSA Bacteremia Outcome Measure we have proposed above, details related to the

¹⁴⁰ Bernard SL, Dalton K, Lenfestey N F, Jarrett NM, Nguyen KH, Sorensen AV, Thaker S, West ND. Study to support a CMS Report to Congress: Assess feasibility of extending the hospital-acquired conditions—present on admission IPPS payment policy to non-IPPS payment environments. Prepared for the Centers for Medicare & Medicaid Services (CMS Contract No. HHSM-500-T00007). 2011.

¹⁴¹Centers for Disease Control and Prevention. *State Has Implemented a C. diff Prevention Collaborative*. Available at: <http://www.cdc.gov/hai/stateplans/states-w-CDI-collaborative.html>.

¹⁴² National Quality Forum. *Measure Applications Partnership Pre-Rulemaking Report: 2013 Recommendations of Measures Under Consideration by HHS: February 2013*. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738>

procedures for using NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the proposed NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Outcome Measure (NQF #1717) can be found at: <http://www.qualityforum.org/QPS/1717> and http://www.cdc.gov/nhsn/PDFs/pscManual/12pscMDRO_CDADcurrent.pdf. For January 2012 through January 2013, an estimated 46 LTCHs reported laboratory-identified *C. Difficile* event data into NHSN.¹⁴³ By building on the CDC/NHSN reporting and submission infrastructure, we intend to reduce the administrative burden related to data collection and submission for this measure under the LTCHQR Program.

We refer readers to section IX.C.9. of the preamble to this proposed rule for more information on data collection and submission. We invite public comment on this proposed measure and data collection and submission for the proposed measure for the FY 2017 payment determination and subsequent payment determinations.

(3) Proposed Quality Measure #3: All-cause Unplanned Readmission Measure for 30 days Post- Discharge from Long-Term Care Hospitals

LTCHs treat patients who, on average, are hospitalized 25 days or greater with medically complex problems, including prolonged mechanical ventilation or multiple organ failure. In 2011, as reported by MedPAC, about 123,000 Medicare beneficiaries received care for almost 140,000 LTCH stays in roughly 424 LTCHs nationwide, with payments of \$5.4 billion.¹⁴⁴ For patients discharged from LTCH settings, the unadjusted

¹⁴³ Data from CMS-CDC correspondence on February 1, 2013.

¹⁴⁴ Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy. Available at: http://www.medpac.gov/documents/Mar13_EntireReport.pdf, March 2013, see Chapter 11, Long-term care hospital services, pg. 237-257.

rate of readmission to LTCHs and IPPS hospitals in the 30 days after an LTCH discharge was about 26 percent in 2010 and 2011.¹⁴⁵ With such a large proportion of patients being readmitted to an acute level of care (that is, to either an LTCH or to an IPPS hospital), we are interested in monitoring the rates for each facility and reducing rates that are inappropriately high. Thus, we are proposing a risk-adjusted measure of readmission rates, the All-cause Unplanned Readmission Measure for 30 days Post Discharge from Long-Term Care Hospitals.

This measure will enhance efforts to promote patient safety, reduce healthcare-associated infections, improve coordination of care and care transitions, and reduce healthcare costs. Readmissions are costly to the Medicare program and have been identified as sensitive to improvements in coordination of care and discharge planning for patients.¹⁴⁶ Literature on readmissions is mainly focused on discharges from short-term acute care hospitals. However, processes that may affect readmission rates, such as discharge planning, communications, and coordination, also occur at other inpatient facilities.

While some readmissions are unavoidable, such as those resulting from the inevitable progression of disease or worsening of chronic conditions, readmissions may also result from poor quality of care or inadequate transitions between care settings. Randomized controlled trials in short-stay acute care hospitals have shown that improvement in the following areas can directly reduce hospital readmission rates: quality of care during the initial admission; improvement in communication with patients,

¹⁴⁵ RTI analysis of 2010-2011 Medicare MedPAR claims data under CMS contract HHSM-500-2008-000211.

¹⁴⁶ Federal Register, Vol. 76, No. 160, Thursday, August 18, 2011 / Rules and Regulations, IV.C.1.a.

their caregivers and their clinicians; patient education; pre-discharge assessment; and coordination of care after discharge. Successful randomized trials have reduced 30-day readmission rates by 20 to 40 percent^{147,148,149,150,151,152,153} and a 2011 meta-analysis of randomized clinical trials found evidence that interventions associated with discharge planning helped to reduce readmission rates,¹⁵⁴ illustrating how hospitals may influence readmission rates through best practices.

Because many studies have shown readmissions to be related to quality of care, and that interventions have been able to reduce 30-day readmission rates, we believe it is appropriate to include All-cause Unplanned Readmission Measure for 30 days Post Discharge from Long-Term Care Hospitals as a quality measure in the LTCHQR Program. Promoting quality improvements leading to successful transitions of care for patients moving from the LTCH setting to the community or another post-acute care

¹⁴⁷ Jack BW, Chetty VK, Anthony D, Greenwald JL, Sanchez GM, Johnson AE, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. *Ann Intern Med* 2009;150(3):178–87.

¹⁴⁸ Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing patients and caregivers to participate in care delivered across settings: the Care Transitions Intervention. *J Am Geriatr Soc* 2004;52(11):1817–25.

¹⁴⁹ Courtney M, Edwards H, Chang A, Parker A, Finlayson K, Hamilton K. Fewer emergency readmissions and better quality of life for older adults at risk of hospital readmission: a randomized controlled trial to determine the effectiveness of a 24-week exercise and telephone follow-up program. *J Am Geriatr Soc* 2009;57(3):395–402.

¹⁵⁰ Garasen H, Windspoll R, Johnsen R. Intermediate care at a community hospital as an alternative to prolonged general hospital care for elderly patients: a randomised controlled trial. *BMC Public Health* 2007;7:68.

¹⁵¹ Koehler BE, Richter KM, Youngblood L, Cohen BA, Prengler ID, Cheng D, et al. Reduction of 30-day postdischarge hospital readmission or emergency department (ED) visit rates in high-risk elderly medical patients through delivery of a targeted care bundle. *J Hosp Med* 2009;4(4):211–218.

¹⁵² Naylor M, Brooten D, Jones R, Lavizzo-Mourey R, Mezey M, Pauly M. Comprehensive discharge planning for the hospitalized elderly. A randomized clinical trial. *Ann Intern Med* 1994;120(12):999–1006.

¹⁵³ Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, et al. Comprehensive discharge planning and home follow-up of hospitalized elders: a randomized clinical trial. *Jama* 1999;281(7):613–20.

¹⁵⁴ Naylor MD, Aiken LH, Kurtzman ET, Olds DM, Hirschman KB. The Importance of Transitional Care in Achieving Health Reform. *Health Affairs* 2011; 30(4):746-754.

setting, and reducing preventable facility-wide readmission rates, is consistent with the NQS aims of safer, better coordinated care and lower costs.

Our approach to developing this measure is consistent with NQF-endorsed Hospital-Wide Risk-Adjusted All-Cause Unplanned Readmission Measure (NQF #1789) (<http://www.qualityforum.org/QPS/1789>) finalized for the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53521 through 53528). We are proposing to use the same statistical approach, the same time window and a similar set of patient characteristics. To the extent appropriate, the proposed LTCH measure is being harmonized with this Hospital-Wide Readmission (HWR) measure¹⁵⁵ and other measures of readmission rates being developed for post-acute care (PAC) settings, including the All-cause Unplanned Readmission Measure for 30 days Post Discharge from Inpatient Rehabilitation Facilities. This reflects MAP recommendations to promote alignment across care settings.¹⁵⁶

LTCH patients, on average, require long stays at a hospital level of care and need care even after discharge. The setting chosen for placement of the discharged patient, and coordination with caregivers after discharge, are important for the stability of these patients. The rate of readmission to an acute level of care (short or long-term) for such patients will be sensitive to appropriate discharge placement. The All-cause Unplanned Readmission Measure for 30 days Post Discharge from Long-Term Care Hospitals

¹⁵⁵ QualityNet. *Hospital-wide All-Cause Unplanned Readmission (HWR) Measure*. Available at <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772504318>. As obtained on March 20, 2013.

¹⁵⁶ National Quality Forum. *Measure Applications Partnership Pre-Rulemaking Report: 2013 Recommendations of Measures Under Consideration by HHS: February 2013*. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738>

assesses return to short-stay acute care hospitals or LTCHs within 30 days of discharge from an LTCH to the community or another care setting of lesser intensity. Patient readmissions are tracked using Medicare FFS claims data for 30 days after discharge, or the date of patient death if the patient dies within 30 days of discharge.

In the Hospital IQR Program, two readmission measurement approaches were taken: (1) measures related to patients with specific medical conditions, such as heart failure, pneumonia, and acute myocardial infarction,¹⁵⁷ and (2) a hospital-wide measure. In LTCHs, patients tend to be complex and not easily classified into specific condition or procedure types. In addition, LTCHs have relatively small numbers of patients. Even ventilator patients, who are reasonably definable, are not numerous enough to provide good stable indicators of quality. Therefore, a hospital-wide all-cause readmission measure reflects a broader assessment of the quality of care in LTCHs, and may consequently better promote quality improvement and inform consumers about quality care.

In applying the All-cause Unplanned Readmission Measure for 30 days Post Discharge from Long-Term Care Hospitals, we will follow patients for 30 days after the LTCH discharge date, or date of death if the patient dies within the 30 day post-discharge period, using Medicare FFS claims data. Because patients differ in morbidity and complexity, the measure is risk-adjusted for patient case-mix. The measure also excludes planned readmissions because these are not considered to be indicative of poor quality care on the part of the LTCH.

¹⁵⁷ Please refer to 77 FR 53377 and table on 77 FR 53531 for current condition-specific readmission measures used in the Hospital IQR Program, available at: <http://www.gpo.gov/fdsys/pkg/FR-2012-08-31/pdf/2012-19079.pdf>.

A model developed by a CMS measure development contractor predicts admission rates while accounting for patient demographics, primary condition in the prior short stay, comorbidities, and a few other patient factors. The use of such risk adjusters will account for case-mix differences that affect patient readmission rates among facilities. While estimating the predictive power of the patient characteristics, the model also estimates a facility specific effect common to patients treated at that facility. Similar to the Hospital IQR Program hospital-wide readmission measure, the proposed LTCHQR Program measure is the ratio of the number of risk-adjusted predicted unplanned readmissions for each individual LTCH, including the estimated facility effect, to the average number of risk-adjusted predicted unplanned readmissions for the same patients treated at a facility with the average effect on readmissions. A ratio above one indicates a higher than expected readmission rate, or lower level of quality, while a ratio below one indicates a lower than expected readmission rate, or higher level of quality. (The construction of the Hospital IQR Program hospital-wide measure and the NQF report may be downloaded from:

http://www.qualityforum.org/Publications/2012/07/Patient_Outcomes_All-Cause_Readmissions_Expedited_Review_2011.aspx.)

The patient population for the All-cause Unplanned Readmission Measure for 30 days Post Discharge from Long-Term Care Hospitals includes LTCH patients who:

- Were discharged alive from the LTCH;
- Had 12 months of Medicare Part A, fee-for-service coverage prior to the LTCH

stay;

- ▣ Had 30 days of Medicare Part A, fee-for-service coverage post discharge;
- Had an IPPS hospital stay within the 30 days prior to the LTCH stay; and
- Were aged 18 years or above when admitted to the LTCH.

As in the Hospital IQR Program hospital-wide readmission measure, patients whose principal diagnosis was cancer and whose treatment was nonsurgical are excluded. Studies of this population that were reviewed for the Hospital IQR Program readmission measure showed them to have a different trajectory of illness and mortality than other patient populations.¹⁵⁸ The measure also excludes patients who were discharged against medical advice.

Readmissions that are not included in the measure are:

- Transfers from an LTCH to another LTCH or IPPS hospital; and
- Readmissions within the 30 day window that are usually considered planned due to the nature of the procedures and principal diagnoses of the readmission.

▣ LTCH stays that are problematic (for example, overlapping admission and discharge dates).

The planned readmission list for the All-cause Unplanned Readmission Measure for 30 days Post Discharge from Long-Term Care Hospitals includes the planned procedures specified in the Hospital-Wide All-Cause Unplanned Readmission (HWR) Measure (NQF #1789) used in the Hospital IQR Program, plus other procedures that were determined in consultation with technical expert panel. The list of procedures considered planned may be found in the LTCH Readmissions Measure Specifications file

¹⁵⁸ National Quality Forum. "Patient Outcomes: All-Cause Readmissions Expedited Review 2011". July 2012. pp12

which will be made available for download at the time of release of this proposed rule at:

<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/>. In addition to the list of planned procedures

there is a list of diagnoses which, if found as the principal diagnosis on the readmission claim, would indicate that the procedure occurred during an unplanned readmission.

A patient discharged from an LTCH is tracked until one of the following occurs:

(1) the 30-day period post-discharge ends; (2) the patient dies; or, (3) the patient is readmitted to an acute level of care (short or long term). If multiple readmissions occur, only the first is considered for this measure. If the first readmission is unplanned, it is counted as a readmission in the measure rate. The occurrence of a planned readmission ends the 30-day window of the index discharge from the LTCH.

Readmission rates are risk-adjusted for patient case-mix characteristics, independent of quality. The risk adjusted model accounts for demographic characteristics, principal diagnosis, co-morbidities, length of stay in the prior IPPS hospital, critical care days in the prior IPPS hospital, number of IPPS hospital stays in the prior year, and the occurrence of various surgery types in the prior IPPS hospital stay.

In modeling LTCH readmissions, all patients are included in a single model, an approach different from the five-cohort approach of the Hospital IQR Program HWR measure, adapted to account for a substantially smaller patient population in the LTCH setting. Separate models for patient types, as was done for the Hospital IQR Program measure, are not feasible. The number of cases is much smaller in the LTCHs than in the IPPS hospitals and patients are generally not as strongly characterized by one major

admitting diagnosis or condition. Patient characteristics are captured by diagnoses and prior surgeries, with a marker for prolonged mechanical ventilation also included.

Because there are approximately 120,000 LTCH admissions per year, and approximately 110,000 of those admissions meet the criteria for inclusion, the proposed measure will use a model that merges two years of Medicare claims data. This approach is similar to that used by the Hospital IQR Program condition-specific readmission measures, which use three years of claims data (77 FR 53523). Merging multiple years of data produces more precise estimates of the effects of all the risk adjusters, and increases the sample size associated with each facility. Larger patient samples are better able to meaningfully distinguish facility performance.

Under the exception authority in section 1886(m)(5)(D)(ii) of the Act, we are proposing to use this measure in the LTCHQR Program. This section provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

In 2012, NQF endorsed two hospital-wide readmission measures, the National Committee for Quality Assurance (NCQA) measure intended for health plans, Plan All-Cause Readmissions (NQF #1768), and CMS' Hospital-Wide All-Cause Unplanned Readmission Measure (HWR) (NQF #1789). NQF #1789 is the model for the All-cause Unplanned Readmission Measure for 30 days Post Discharge from Long-Term Care

Hospital measure we are proposing. The most recent MAP Pre-Rulemaking Report noted that “readmission measures are also examples of measures that MAP recommends be standardized across settings, yet customized to address the unique needs of the heterogeneous Post-Acute Care (PAC)/LTC population. MAP has continually noted the need for care transition measures in PAC/LTC performance measurement programs. Setting-specific admission and readmission measures under consideration would address this need.”¹⁵⁹

We intend to seek NQF endorsement of the All-cause Readmission Measure for 30 days Post Discharge from Long-Term Care Hospital. As this is a claims-based measure not requiring reporting of new data by LTCHs, this measure will not be used to determine LTCH reporting compliance for the LTCHQR Program. We are proposing to begin reporting feedback to LTCHs on performance of this measure in CY 2016. The initial feedback will be based on FY 2013 and FY 2014 Medicare claims data related to LTCH readmissions. The readmission measure will be part of the LTCH public reporting program once public reporting is instated. We intend to provide details pertaining to public reporting, such as LTCH preview of performance results, of this measure in our future rulemaking.

We invite public comment on these proposals.

¹⁵⁹ National Quality Forum. *Measure Applications Partnership Pre-Rulemaking Report: 2013 Recommendations of Measures Under Consideration by HHS: February 2013*. Available at <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738>.

c. Proposed New LTCHQR Program Quality Measure for the FY 2018 Payment Determination and Subsequent Payment Determinations

We are proposing one new quality measure, Application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), for the LTCHQR Program to affect the FY 2018 payment determination and subsequent payment determinations.

This NQF-endorsed measure is an outcome measure that reports the percentage of residents (or patients if finalized for the LTCH setting) who experienced falls with major injury over a 12 month period. This measure was developed by the CMS and is NQF-endorsed for the Nursing Home/Skilled Nursing Facility setting.

Research indicates that fall related injuries are the most common cause of accidental death in people aged 65 and older, with approximately 41 percent of accidental deaths annually.¹⁶⁰ Rates increase to 70 percent of accidental deaths amongst individuals ages 75 and older.¹⁶¹ In addition to death, falls can lead to fracture, soft tissue or head injury, fear of falling, anxiety and depression.¹⁶² Research also indicates that approximately 75 percent of nursing facility residents fall at least once a year; twice the rate of their counterparts in the community.¹⁶³ Similar data are not available for the LTCH setting. Falls also represent a significant cost burden to the entire health care system, with

¹⁶⁰ Currie LM. Fall and injury prevention. *Annu Rev Nurs Res.* 2006;24:39-74.

¹⁶¹ Fuller GF. Falls in the elderly. *Am Fam Physician.* Apr 1 2000;61(7):2159-2168, 2173-2154.

¹⁶² Premier Inc. Causes of Falls. 2013. Available: https://www.premierinc.com/quality-safety/tools-services/safety/topics/falls/causes_of_falls.jsp.

¹⁶³ Rubenstein LZ, Josephson KR, Robbins AS. Falls in the nursing home. *Ann Intern Med.* 1994 Sep 15; 121(6):442-51.

injurious falls accounting for 6 percent of medical expenses among those age 65 and older.¹⁶⁴

According to analysis of ICD-9 codes reported on Medicare claims, LTCHs reported 2,567 major injuries due to falls in 2009. Present on admission indicators are not available on LTCH claims, therefore we are unable to say whether these conditions are present on admission or acquired during the LTCH stay. Therefore, it was not possible to determine which of these falls occurred in the LTCH. However, we note that on the majority of claims, the primary diagnosis is the admitting diagnosis and is considered to be present on admission and therefore, the secondary diagnoses can be assumed to provide a count of conditions that could have been acquired in the LTCH.¹⁶⁵ When it was assumed that a fall recorded in the primary diagnosis code was likely present on admission and that a fall recorded in the secondary diagnosis code was acquired in the LTCH, there were 2,049 reported injuries that may have been acquired in the LTCH.¹⁶⁶

According to Morse (2002), 78 percent of falls are anticipated physiologic falls. Anticipated physiological falls are falls amongst individuals who scored high on a risk assessment scale, meaning their risk could have been identified in advance of the fall.¹⁶⁷

To date, studies have identified a number of risk factors for

¹⁶⁴ Rubenstein LZ, Powers CM, MacLean CH. Quality indicators for the management and prevention of falls and mobility problems in vulnerable elders (ACOVE). *Ann Intern Med.* 2001 Oct 16;135(8 Pt 2):686-93

¹⁶⁵ Centers for Medicare & Medicaid Services Center for Medicare & Medicaid Innovation. *Hospital Acquired Conditions (HAC) – Report to Congress.* Available at <http://innovation.cms.gov/Files/x/HospAcquiredConditionsRTC.pdf>

¹⁶⁶ Bernard SL, Dalton K, Lenfestey N F, Jarrett NM, Nguyen KH, Sorensen AV, Thaker S, West ND. Study to support a CMS Report to Congress: Assess feasibility of extending the hospital-acquired conditions—present on admission IPPS payment policy to non-IPPS payment environments. Prepared for the Centers for Medicare & Medicaid Services (CMS Contract No. HHSM-500-T00007). 2011.

¹⁶⁷ Morse, J. M. (2002) Enhancing the safety of hospitalization by reducing patient falls. *Am J Infect Control* 2002; 30(6): 376-80

falls.^{168,169,170,171,172,173,174,175,176} The identification of such risk factors suggests the potential for health care facilities to reduce and prevent the incidence of falls for their patients.

In light of the evidence discussed above, we are proposing an application of the measure NQF #0674 Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay), for the LTCHQR Program for the FY 2018 payment determination and subsequent payment determinations.

We note that, while NQF #0674 is currently endorsed only for long stay nursing home residents, we believe that an application of this measure would be highly relevant for the LTCH setting. As stated above, many patients receiving care in the LTCH setting are elderly and are at high risk for death and other injuries due to falls. A technical expert panel convened by our measure development contractor discussed potential quality measures for the LTCH setting and stressed that falls with major injury are a major concern in LTCH setting.

¹⁶⁸ Rothschild JM, Bates DW, Leape LL. Preventable medical injuries in older patients. *Arch Intern Med*. 2000 Oct 9; 160(18):2717-28.

¹⁶⁹ Morris JN, Moore T, Jones R, et al. Validation of long-term and post-acute care quality indicators. CMS Contract No: 500-95-0062/T.O. #4. Cambridge, MA: Abt Associates, Inc., June 2003.

¹⁷⁰ Avidan AY, Fries BE, James ML, Szafara KL, Wright GT, Chervin RD. Insomnia and hypnotic use, recorded in the minimum data set, as predictors of falls and hip fractures in Michigan nursing homes. *J Am Geriatr Soc*. 2005 Jun; 53(6):955-62.

¹⁷¹ Fonad E, Wahlin TB, Winblad B, Emami A, Sandmark H. Falls and fall risk among nursing home residents. *J Clin Nurs*. 2008 Jan; 17(1):126-34.

¹⁷² Currie LM. Fall and injury prevention. *Annu Rev Nurs Res*. 2006;24:39-74.

¹⁷³ Ellis AA, Trent RB. Do the risks and consequences of hospitalized fall injuries among older adults in California vary by type of fall? *J Gerontol A Biol Sci Med Sci*. Nov 2001;56(11):M686-692.

¹⁷⁴ Chen XL, Liu YH, Chan DK, Shen Q, Van Nguyen H. *Chin Med J (Engl)*. Characteristics associated with falls among the elderly within aged care wards in a tertiary hospital: a retrospective. 2010 Jul;123(13):1668-72.

¹⁷⁵ Frisina PG, Guellnitz R, Alverzo J. A time series analysis of falls and injury in the inpatient rehabilitation setting. *Rehabil Nurs*. 2010 Jul-Aug;35(4):141-6, 166.

¹⁷⁶ Lee JE, Stokic DS. Risk factors for falls during inpatient rehabilitation. *Am J Phys Med Rehabil*. 2008 May;87(5):341-50; quiz 351, 422.

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 NQF’s consensus endorsed measures and were unable to identify any NQF-endorsed measures for falls with major injury in the LTCH setting. We are unaware of any other measures for falls with major injury that have been endorsed or adopted by another consensus organization for the LTCH setting.

Therefore, we are proposing to adopt an application of the NQF-endorsed measure Percent of Nursing Home Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) for use in the LTCH setting for the LTCHQR Program under the Secretary’s authority to select non-NQF endorsed measures. In the future we will consider applying for NQF review for endorsement of this measure to the LTCH setting as part of the measure expansion process. Additional information regarding NQF #0674, on which our proposed application of the measure will be based, including measure specifications, is available at: <http://www.qualityforum.org/QPS/0674>. The use of different applications of the same quality measure across multiple healthcare settings is also consistent with the 2008 NQF steering committee recommendation that “in the interest of standardization and minimizing the burden for those implementing and using measures, measure harmonization is an important consideration in evaluating and

recommending measures for endorsement.” Data on NQF #0674 is currently collected and reported on Nursing Home Compare as part of the Nursing Home Quality Initiative.¹⁷⁷

We are proposing that data for the proposed application of NQF #0674 will be collected through the LTCH CARE Data Set,¹⁷⁸ with submission through the QIES ASAP System, as described in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53619 through 53621). For more information on LTCHQR Program reporting using the QIES ASAP system, we refer readers to the 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 which assess the presence of falls and falls with major injury, should this proposed application of the measure be adopted. These new items will be applied to all LTCH patients and will not distinguish between long stay versus short stay patients since this categorization is not applicable to the LTCH setting.

The items used for the proposed application of the quality measure will be based on the items from the Minimum Data Set (MDS) 3.0, version 1.13.0 (1/17/13) items J1800 (Any Falls Since Admission/Entry or Reentry or Prior Assessment) and J1900A, B and C (Number of Falls (A: with no injury, B: with injury (except major), C with Major

¹⁷⁷ Nursing Home Quality Initiative, Quality Measures. December 2012. Available: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIQualityMeasures.html>

¹⁷⁸The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938-1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956 published April 12, 2013 solicits public comment on additions on updates to the LTCH CARE Data Set.

injury)) since Admission/Entry or Reentry or Prior Assessment), available at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIMDS30TechnicalInformation.html>. The calculation of the proposed application of the measure will be based on item J1900C, Number of Falls with major injury, since admission. The specifications and data elements for NQF #0674 are available in the MDS 3.0 Quality Measures User's Manual Version 6.0 available on our Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html>.

By building on the existing reporting and submission infrastructure for LTCHs, (the LTCH CARE Data Set, which we began using for data collection on October 1, 2012 for the Pressure Ulcer measure), 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. of the preamble to this proposed rule for more information on data collection and submission.

We invite public comment on this proposed measure and data collection and submission for the proposed measure for the FY 2018 payment determination and subsequent payment determinations.

d. LTCHQR Program Quality Measures and Concepts under Consideration for Future Years Payment Determinations

We are considering the measures and measure topics in the table below for future years in the LTCHQR Program. We invite public comment on these measures and

measure topics, specifically comments regarding the clinical importance, feasibility of data collection and implementation, current use, and usability of data to inform quality improvements in the LTCH setting.

Future Measures and Measure Topics Under Consideration for the LTCH Quality Reporting Program
<p>National Quality Strategy Priority: Safety and Healthcare-Associated Infections HAIs</p> <ul style="list-style-type: none"> ● Surgical Site Infection ● Ventilator-Associated Event ☐ Ventilator Bundle
<p>National Quality Strategy Priority: Safety and Healthcare-Acquired Conditions: Avoidable Adverse Events and Serious Reportable Events</p> <ul style="list-style-type: none"> ● Manifestations of Poor Glycemic Control
<p>National Quality Strategy Priority: Effective Clinical Processes</p> <ul style="list-style-type: none"> ● Severe Sepsis and Septic Shock: Management Bundle ● Application of Venous Thromboembolism Prophylaxis (NQF #0371) ● Ventilator Weaning Rate
<p>National Quality Strategy Priority: Patient Safety</p> <ul style="list-style-type: none"> ● 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)
<p>National Quality Strategy Priority: Patient and Caregiver-Centered Care</p> <ul style="list-style-type: none"> ● Depression Assessment and Management ● Functional Change ● Application of HCAHPS (NQF #0166) ● Application of Pain Management (for example, Percent of Residents Who Self-Report Moderate to Severe Pain (Short-Stay) (NQF #0677))
<p>National Quality Strategy Priority: Communication and Coordination of Care</p> <ul style="list-style-type: none"> ● Application of Medication Reconciliation (NQF #0097) ● Application of Medication Reconciliation Post-Discharge (NQF #0554) ● Reconciled Medication List Received by Discharged Patients (NQF #0646) ● Transition Record with Specified Elements Received by Discharged Patients (NQF #0647) ● Timely Transmission of Transition Record (NQF #0648)

9. Form, Manner, and Timing of Quality Data Submission for the FY 2016 Payment Determination and Subsequent Payment Determinations

a. Background

Section 1886(m)(5)(C) of the Act requires that, for the FY 2014 payment determination and each subsequent payment determination, 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 rate year, the Secretary will reduce any annual update to the standard Federal rate for discharges for the hospital during the rate year by two percentage points.

b. Finalized Timeline for Data Submission Under the LTCHQR Program for the FY 2016 Payment Determination

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53636 through 53637), we finalized the data submission timeline for measures for the FY 2016 payment determination. LTCHs are required to submit data on LTCH admissions and discharges occurring from January 1, 2014 through December 31, 2014 (CY 2014) for the FY 2016 payment determination. We adopted this timeframe because we believe this will provide sufficient time for LTCHs and CMS to put processes and procedures in place to meet the additional quality reporting requirements. We also finalized in this rule the quarterly submission deadlines for the FY 2016 payment determination as approximately 45 days after the end of each quarter, as outlined in the table below. This is the date by which all

data collected during that quarter must be submitted to CMS for measures using the LTCH CARE Data Set and to CDC for measures using the CDC/NHSN.

Finalized Timeline for Submission of LTCHQR Program Quality Data for the FY 2016 Payment Determination	
Data collection timeframe: CY 2014	Submission Deadline
Q1 (January–March 2014)	May 15, 2014
Q2 (April–June 2014)	August 15, 2014
Q3 (July–September 2014)	November 15, 2014
Q4 (October–December 2014)	February 15, 2015

c. Proposed Timeline for Data Submission for the NQF #0431 Influenza Vaccination Coverage Among Healthcare Personnel Measure for the FY 2016 Payment Determination and Subsequent Payment Determinations

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53630 through 53631) we finalized the adoption of the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure for the FY 2016 payment determination. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53636) we also finalized the data collection period for the FY 2016 payment determination to be January 1, 2014 through December 31, 2014. As noted in IX.C.7.a. of the preamble to this proposed rule, there is a unique seasonality in the timing of influenza activity each year. The CDC, the steward of this measure, recommends that people get vaccinated against influenza as long as influenza viruses are circulating. We are proposing that, for the LTCHQR Program, the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431) have its own reporting period to align with the influenza vaccination season, which is defined by the CDC as October 1 (or when the vaccine becomes available) through March 31 of the

subsequent year for the influenza season. This timeline is consistent with how the NQF specifies this measure. Further details related to the procedures for using the CDC/NHSN for data submission and measure specifications for the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure can be found at: <http://www.qualityforum.org/QPS/0431> and <http://www.cdc.gov/nhsn/LTACH/hcp-flu-vac/index.html>.

If our proposal in IX.C.7.a. of the preamble to this proposed rule is finalized, LTCHs would be required to report data on the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure from October 1, 2014 or the date on which the vaccine becomes available, whichever occurs first, through March 31, 2015 for the 2014-2015 influenza season for FY 2016 payment determination. We are also proposing that this October (or when vaccine becomes available) through March reporting period for the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure would apply to the FY 2017 payment determination and subsequent payment determinations.

d. Proposed Timeline for Data Submission for the NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) Measure for the FY 2016 Payment Determination and Subsequent Payment Determinations

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627), we finalized the adoption of 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. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53637) we also finalized the data collection period for the FY 2016 payment determination to begin January 1, 2014 and continue through December 31, 2014. This measure will be collected using the LTCH CARE Data Set. The LTCH CARE Data Set (version 2.01),¹⁷⁹ proposed data collection instrument for this measure, is currently undergoing OMB review under the Paperwork Reduction Act. We anticipate that the review and approval will be completed by summer 2013.

We generally allow 9-12 months for LTCHs to comply with and integrate the requisite changes to new versions of data sets into their existing IT infrastructure, and to train staff members. Because summer 2013 approval of the LTCH CARE Data Set version 2.01 would only allow 6 months for LTCHs to put plans and procedures into place, we are proposing to move the start date for data collection of this measure to April 1, 2014 instead of the previously finalized start date of January 1, 2014. Data collection and submission of this measure will continue through December 31, 2014 for the FY 2016 payment determination. This proposed change would only affect CY 2014 reporting. We are proposing that for all subsequent payment determinations this measure will be collected on a calendar year basis beginning on January 1 and continuing through December 31 of each year.

¹⁷⁹The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938-1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956 published April 12, 2013 solicits public comment on additions and updates to the LTCH CARE Data Set. <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html>.

Timeline for Data Collection of LTCHQR Program Quality Data for the FY 2016 Payment Determination	
NQF Measure ID	Data Collection Timeframe
NQF # 0138*	January 1, 2014- December 31, 2014
NQF # 0139*	January 1, 2014- December 31, 2014
NQF #0678*	January 1, 2014- December 31, 2014
NQF # 0680	April 1, 2014- December 31, 2014**
NQF # 0431	October 1, 2014 (or when vaccine becomes available)-March 31, 2015**

* The data collection period for this measure was finalized in the FY 2013 IPPS/LTCH PPS final rule.

** This data collection timeframe for this measure is proposed in this proposed rule.

Timeline for Submission of LTCHQR Program Quality Data for the FY 2016 Payment Determination and Subsequent Payment Determinations NQF #0138*, NQF #0139*, NQF #0678*	
Data collection timeframe: CY 2014	Final submission deadlines for the LTCHQR Program FY 2016 payment determination
Q1 (January–March 2014)	May 15, 2014
Q2 (April–June 2014)	August 15, 2014
Q3 (July–September 2014)	November 15, 2014
Q4 (October–December 2014)	February 15, 2015

*The data collection period for this measure was finalized in the FY 2013 IPPS/LTCH PPS final rule.

Proposed Timeline for Submission of LTCHQR Program Quality Data for the FY 2016 Payment Determination and Subsequent Payment Determinations: NQF #0680 Percentage of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay)	
Data collection timeframe	Final submission deadlines for the LTCHQR Program FY 2016 payment determination
April 1, 2014- December 31, 2014	February 15, 2015

Proposed Timeline for Submission of LTCHQR Program Quality Data for the FY 2016 Payment Determination and Subsequent Payment Determinations: NQF #0431: Influenza Vaccination Coverage Among Healthcare Personnel	
Data collection timeframe	Final submission deadlines for the LTCHQR Program FY 2016 payment determination

Proposed Timeline for Submission of LTCHQR Program Quality Data for the FY 2016 Payment Determination and Subsequent Payment Determinations: NQF #0431: Influenza Vaccination Coverage Among Healthcare Personnel	
Data collection timeframe	Final submission deadlines for the LTCHQR Program FY 2016 payment determination
October 1 2014 (or when vaccine becomes available)-March 31, 2015	May 15, 2015

We invite public comment on these proposed data collection and quarterly submission timeframes for NQF #0680 and NQF #0431 for the FY 2016 payment determination.

e. Proposed Timeline for Data Submission under the LTCHQR Program for the FY 2017 Payment Determination and Subsequent Payment Determinations

As previously stated, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53636 through 53637), we finalized the data submission timeline for the FY 2016 payment determination. For the FY 2017 payment determination, we are proposing to require data submission for the LTCHQR Program on all LTCH admissions and discharges occurring January 1, 2015 through December 31, 2015 (CY 2015) with the exception of Influenza Vaccination Among Healthcare Personnel (NQF #0431). We are proposing that the data collection timeframe for this measure (NQF #0431) be in alignment with measure specifications per advisement of the CDC, the steward for this NQF-endorsed measure. Please refer to section IX.C.9.c. of the preamble to this proposed rule for additional information on this measure's timelines.

We note that the All-cause Unplanned Readmission Measure for 30 days Post-Discharge from Long-Term Care Hospitals is a Medicare claims-based measure, therefore no new data need to be collected or reported by the facility. We will use

CY 2013 and CY 2014 Medicare claims data to calculate the All-cause Unplanned Readmission Measure for 30 days Post- Discharge from Long-Term Care Hospitals. We are proposing these timeframes because we believe this will provide sufficient time for CMS and LTCHs to put processes and procedures in place to meet the quality reporting requirements under the LTCHQR Program. The proposed data collection reporting periods for the measures applicable to the FY 2017 payment determination are listed in the following table.

Proposed Timeline for Collection of LTCHQR Program Quality Data for the FY 2017 Payment Determination	
NQF Measure ID	Data Collection Timeframe
NQF # 0138	January 1, 2015- December 31, 2015
NQF # 0139	January 1, 2015- December 31, 2015
NQF # 0678	January 1, 2015- December 31, 2015
NQF # 0680	January 1, 2015- December 31, 2015
NQF # 0431	October 1, 2015 (or when vaccine becomes available)-March 31, 2016
NQF # 1716	January 1, 2015- December 31, 2015
NQF # 1717	January 1, 2015- December 31, 2015

For each quarter outlined in the table below during which the LTCHs are required to collect data, we are proposing final submission deadlines occurring approximately 45 days after the end of any given quarter by which all data collected during that quarter must be submitted. We believe that this is a reasonable amount of time to allow LTCHs to submit data and make any necessary corrections. Set out below is the proposed timeline for submission of LTCHQR Program quality data for the FY 2017 payment determination.

Proposed Timeline for Submission of LTCHQR Program Quality Data for the FY 2017 Payment Determination: NQF #0138, NQF #0139, NQF #0678, NQF #0680, NQF #1716, NQF #1717	
Data collection timeframe: CY 2015	Final submission deadlines for the LTCHQR Program FY 2017 payment determination
Q1 (January–March 2015)	May 15, 2015
Q2 (April–June 2015)	August 15, 2015
Q3 (July–September 2015)	November 15, 2015
Q4 (October–December 2015)	February 15, 2016

Proposed Timeline for Submission of LTCHQR Program Quality Data for the FY 2017 Payment Determination: NQF #0431: Influenza Vaccination Coverage Among Healthcare Personnel	
Data collection timeframe	Final submission deadlines for the LTCHQR Program FY 2017 payment determination
October 1 2015 (or when vaccine becomes available)-March 31, 2016	May 15, 2016

We invite public comment on this proposal.

f. Proposed Timeline for Data Submission under the LTCHQR Program for the FY 2018 Payment Determination and Subsequent Payment Determinations

For measures for the FY 2018 payment determination, we are proposing to require data collection on LTCH discharges occurring from January 1, 2016 through December 31, 2016 with the exception of Influenza Vaccination Among Healthcare Personnel (NQF #0431). We are proposing that the data collection timeframe for this measure (NQF #0431) be in alignment with measure specifications per advisement of the CDC, the steward for this NQF-endorsed measure. LTCHs would follow the proposed

deadlines presented in the tables below to complete submission of data for each quarter for each proposed measure for the FY 2018 payment determination. For each quarter outlined in the table below during which LTCHs are required to collect data, we are proposing a final submission deadline occurring approximately 45 days after the end of each quarter by which all data collected during that quarter must be submitted. We believe that this is a reasonable amount of time to allow LTCHs to submit data and make any necessary corrections.

Proposed Timeline for Data Collection of LTCHQR Program Quality Data for the FY 2018 Payment Determination	
NQF Measure ID	Data Collection Timeframe
NQF # 0138	January 1, 2016- December 31, 2016
NQF # 0139	January 1, 2016- December 31, 2016
NQF # 0678	January 1, 2016- December 31, 2016
NQF # 0680	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
NQF #0674	January 1, 2016-December 31, 2016

Proposed Timeline for Submission of LTCHQR Program Quality Data for the FY 2018 Payment Determination and Subsequent Payment Determinations for All Measures Except #0431: Influenza Vaccination Coverage Among Healthcare Personnel	
Data collection timeframe: 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

Proposed Timeline for Submission of LTCHQR Program Quality Data for the FY 2018 Payment Determination and Subsequent Payment Determinations: NQF #0431: Influenza Vaccination Coverage Among Healthcare Personnel	
Data collection timeframe	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

We invite public comment on this proposal.

10. Public Display of Data Quality Measures for the LTCHQR Program

Under section 1886(m)(5)(E) of the Act, the Secretary is required to establish procedures for making any quality data submitted by LTCHs under section 1886(m)(5)(C) of the Act available to the public. Section 1886(m)(5)(E) of the Act requires that such procedures shall ensure that a LTCH has the opportunity to review the data that is to be made public with respect to its facility, prior to such data being made public. The statute also requires that the Secretary report quality measures that relate to services furnished in LTCHs on CMS's Internet Web site. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53637) we received and responded to public comment regarding the procedures we could adopt for 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 preview 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.

11. Proposed LTCHQR Program Submission Waiver Requirements for the FY 2015 Payment Determination and Subsequent Payment Determinations

Our experience with other quality reporting programs has shown that there are times when providers are unable to submit quality data due to extraordinary circumstances beyond their control (for example, natural or man-made disasters). We define a “disaster” as any natural or man-made catastrophe which causes damages of sufficient severity and magnitude to partially or completely destroy or delay access to medical records and associated documentation. Natural disasters could include events such as hurricanes, tornadoes, earthquakes, volcanic eruptions, fires, mudslides, snowstorms, and tsunamis. Man-made disasters could include such events as terrorist attacks, bombings, floods caused by man-made actions, civil disorders, and explosions. A disaster may be widespread or impact multiple structures or be isolated and impact a single site only.

In certain instances of either natural or man-made disasters, an LTCH may have the ability to conduct a full patient assessment, and record and save the associated data either during or before the occurrence of an extraordinary event. In this case, the extraordinary event has not caused the facility’s data files to be destroyed, but it could hinder the LTCH’s ability to meet the quality reporting program’s data submission deadlines. In this scenario, the LTCH would potentially have the ability to report the data

at a later date, after the emergency circumstances have subsided. In such cases, a temporary waiver of the LTCH duty to report quality measure data may be appropriate.

In other circumstances of natural or man-made disaster, an LTCH may not have had the ability to conduct a full patient assessment, and record and save the associated data before the occurrence of an extraordinary event. In such a scenario, the facility does not have data to submit to CMS as a result of the extraordinary event. We believe that it is appropriate, in these situations, to grant a full waiver of the reporting requirements.

We do not wish to penalize LTCHs in these circumstances or to unduly increase their burden during these times. Therefore, we are proposing a process, for the FY 2015 payment determination and subsequent payment determinations, for LTCHs to request and for CMS to grant waivers with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the LTCHs. When a waiver is granted, an LTCH will not incur payment reduction penalties for failure to comply with the requirements of the LTCHQR Program. For LTCHQR Program reporting and submission of quality measure data for the FY 2014 payment determination, we will be issuing guidance on the waiver process via the LTCH Quality Reporting Program Web site at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/>.

Under the proposed process for the FY 2015 payment determination and subsequent payment determinations, an LTCH may request a waiver of the requirement to submit quality data for one or more quarters. We are proposing a process that, in the event that an LTCH seeks to request a waiver for quality reporting purposes for the

FY 2015 payment determination and subsequent payment determinations, the LTCH may request a waiver for one or more quarters by submitting a written request to CMS. We are proposing that the LTCH compose a letter to CMS that documents the waiver request, with the information below, and submit the letter to CMS via email to the LTCH Quality Waiver mailbox at LTCHQRPreconsiderations@cms.hhs.gov.

We note that the subject of the email must read “Disaster Waiver Request” and the letter must contain the following information:

- LTCH CCN;
- LTCH name;
- CEO or CEO-designated personnel contact information including name, telephone number, email address, and mailing address (the address must be a physical address, not a post office box);
- LTCH’s reason for requesting a waiver;
- Evidence of the impact of extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the LTCH believes it will be able to again submit LTCH QRP data and a justification for the proposed date.

We are proposing that the letter documenting the disaster waiver request be signed by the LTCH’s CEO or CEO designated personnel, and must be submitted within 30 days of the date that the extraordinary circumstances occurred. Following receipt of the letter, we would: (1) provide a written acknowledgement, using the contact information provided in the letter, to the CEO or CEO-designated contact notifying them

that the request has been received; and (2) provide a formal response to the CEO or anyCEO-designated LTCH personnel, using the contact information provided in the letter, indicating our decision.

This proposal does not preclude us from granting waivers to LTCHs that have not requested them when we determine that an extraordinary circumstance, such as an act of nature, affects an entire region or locale. If we make the determination to grant a waiver to LTCHs in a region or locale, we are proposing to communicate this decision through routine communication channels to LTCHs and vendors, including, but not limited to, issuing memos, emails, and notices on <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html>.

We invite public comment on this proposal.

12. Proposed LTCHQR Program Reconsideration and Appeals for the FY 2015 Payment Determination and Subsequent Payment Determinations

At the conclusion of any given quality data reporting and submission period, we will review the data received from each LTCH during that reporting period to determine if the LTCH has met the quality data reporting requirements. LTCHs that are found to be noncompliant with the reporting requirements set forth for that reporting cycle could receive a reduction in the amount of 2 percentage points to their annual payment update for the upcoming fiscal year.

We are aware that some of our other quality reporting programs, such as the Hospital IQR Program, include an opportunity for providers and suppliers to request a reconsideration of our initial non-compliance determination. We are also aware, for the

purposes of the LTCHQR Program, that we will be making compliance determinations for the FY 2014 payment determination in the coming months and there is a need for providers to be able to request a reconsideration if the circumstances warrant. Therefore, to be consistent with other established quality reporting programs and to provide an opportunity for providers to seek reconsideration of our initial non-compliance decision, we are proposing a process that will allow LTCHs to request reconsiderations pertaining to their FY 2015 payment determination and that of subsequent payment determinations.

As part of this process, LTCHs that are non-compliant with the reporting requirements during a given reporting cycle will be notified of that finding. The purpose of this notification is to put the LTCH on notice of the following: (1) that the LTCH has been identified as being non-compliant with the LTCHQR Program's reporting requirements for the reporting cycle in question; (2) that the LTCH will be scheduled to receive a reduction in the amount of two percentage points to the annual payment update for the upcoming fiscal year; (3) that the LTCH may file a request for reconsideration if they believe that the finding of non-compliance is erroneous, or that if they were non-compliant, they have a valid and justifiable excuse for this non-compliance; and (4) that the LTCH must follow a defined process on how to file a request for reconsideration, which will be described in the notification.

Upon the conclusion of our review of each request for reconsideration, we will render a decision. We may reverse our initial finding of noncompliance if: (1) the LTCH provides proof of full compliance with all requirements during the reporting period; or (2) the LTCH provides adequate proof of a valid or justifiable excuse for non-compliance

if the LTCH was not able to comply with requirements during the reporting period. We will uphold our initial finding of noncompliance if the LTCH cannot show any justification for noncompliance.

We intend to provide details pertaining to the reconsideration process, and the mechanisms related to provider requests for reconsiderations of their payment determination, such as filing requests, required content, supporting documentation, and mechanisms of notification and final determinations on the LTCHQR Program Web site in spring 2013 prior to any LTCH's need for information on the CMS reconsideration process for the FY 2014 payment determination and subsequent payment determinations at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/>.

We invite public comment on the proposed procedures for reconsideration and appeals for FY 2015 payment determination and subsequent payment determinations.

D. Inpatient Psychiatric Facilities Quality Reporting (IPFOR) Program

1. Statutory Authority

Section 1886(s)(4) of the Act, as added and amended by sections 3401(f) and 10322(a) of the Affordable Care Act, requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units.

Section 1886(s)(4)(A)(i) of the Act requires that, for rate year (RY) 2014 and each subsequent rate year, the Secretary shall reduce any annual update to a standard Federal rate for discharges occurring during such rate year by 2.0 percentage points for any inpatient psychiatric hospital or psychiatric unit that does not comply with quality data submission requirements with respect to an applicable rate year.

We note that section 1886(s)(4)(A)(i) of the Act uses the term “rate year.” Beginning with the annual update of the inpatient psychiatric facility prospective payment system (IPF PPS) that took effect on July 1, 2011 (RY 2012), we aligned the IPF PPS update with the annual update of the ICD-9-CM codes, which are effective on October 1 of each year. The change allows for annual payment updates and the ICD-9-CM coding update to occur on the same schedule and appear in the same **Federal Register** document, thus making updating rules more administratively efficient. To reflect the change to the annual payment rate update cycle, we revised the regulations at 42 CFR 412.402 to specify that, beginning October 1, 2012, the 12-month period of October 1 through September 30 is referred to as a fiscal year (FY) (76 FR 26435). For more information regarding this terminology change, we refer readers to section III. of the RY 2012 IPF PPS final rule (76 FR 26434 through 26435). For purposes of the

discussion below, the term “rate year” and “fiscal year” both refer to the period beginning October 1 and ending September 30. To avoid any confusion that may be caused by using the term “rate year” with respect to the inpatient psychiatric hospitals and psychiatric units quality reporting program, we will use the term “fiscal year” rather than “rate year” throughout this proposed rule, even when we are referring to statutory provisions that refer to “rate year.”

As provided in section 1886(s)(4)(A)(ii) of the Act, the application of the reduction for failure to report under section 1886(s)(4)(A)(i) of the Act may result in an annual update of less than 0.0 percent for a fiscal year, and may result in payment rates under section 1886(s)(1) of the Act being less than such payment rates for the preceding year. In addition, section 1886(s)(4)(B) of the Act requires that the application of the reduction to a standard Federal rate update be noncumulative across fiscal years. Thus, any reduction applied under section 1886(s)(4)(A) of the Act will apply only with respect to the fiscal year rate involved and the Secretary shall not take into account such reduction in computing the payment amount under the system described in section 1886(s)(1) of the Act for subsequent years.

Section 1886(s)(4)(C) of the Act requires that, for FY 2014 (October 1, 2013 through September 30, 2014) and each subsequent year, each psychiatric hospital and psychiatric unit shall submit to the Secretary data on quality measures as specified by the Secretary. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary. Under section 1886(s)(4)(D)(i) of the Act, measures selected for the quality reporting program must have been endorsed by the entity with a contract under

section 1890(a) of the Act. The National Quality Forum (NQF) currently holds this contract. The NQF is a voluntary, consensus-based, standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The NQF was established to standardize health care quality measurement and reporting through its consensus development process. We generally prefer to adopt NQF-endorsed measures in our reporting programs with some exceptions as provided by law.

For purposes of the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program, section 1886(s)(4)(D)(ii) of the Act provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Finally, pursuant to section 1886(s)(4)(D)(iii) of the Act, the Secretary shall publish the measures applicable to the FY 2014 IPFQR Program no later than October 1, 2012.

Section 1886(s)(4)(E) of the Act requires the Secretary to establish procedures for making public the data submitted by inpatient psychiatric hospitals and psychiatric units under the IPFQR Program. Such procedures must ensure that a facility has the opportunity to review its data prior to such data being made public. The Secretary must report quality measures that relate to services furnished by the psychiatric hospitals and units on a CMS Web site.

2. Application of the Payment Update Reduction for Failure to Report for the FY 2014 Payment Determination and Subsequent Years

Beginning in FY 2014, section 1886(s)(4)(A)(i) of the Act requires the application of a 2.0 percentage point reduction to the applicable annual update to a Federal standard rate for those psychiatric hospitals and psychiatric units that fail to comply with the quality reporting requirements implemented in accordance with section 1886(s)(4)(C) of the Act, as detailed below. The application of the reduction may result in an annual update for a fiscal year that is less than 0.0 percent and in payment rates for a fiscal year being less than the payment rates for the preceding fiscal year. Pursuant to section 1886(s)(4)(B) of the Act, any such reduction is not cumulative and it will apply only to the fiscal year involved. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53678), we adopted requirements regarding the application of the payment reduction to the annual update of the standard Federal rate for failure to report data on measures selected for the FY 2014 payment determination and subsequent years and added new regulatory text at 42 CFR 412.424 to codify these requirements.

3. Covered Entities

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645), we established that the IPFQR Program's quality reporting requirements cover those psychiatric hospitals and psychiatric units that are paid under Medicare's IPF PPS (42 CFR 412.404(b)).

Generally, psychiatric hospitals and psychiatric units within acute care and critical access hospitals that treat Medicare patients are paid under the IPF PPS. For more information on the application of and exceptions to payments under the IPF PPS, we refer readers to

section IV. of the November 15, 2004 IPF PPS final rule (69 FR 66926). As we noted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645), we use the term “inpatient psychiatric facility” (IPF) to refer to both inpatient psychiatric hospitals and psychiatric units. This usage follows the terminology we have used in the past in our IPF PPS regulations (42 CFR 412.402).

4. Considerations in Selecting Quality Measures

For purposes of the IPFQR Program, section 1886(s)(4)(D)(i) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act. However, the statutory requirements under section 1886(s)(4)(D)(ii) of the Act provide an exception that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

In implementing the IPFQR Program, our overarching objective is to support the HHS National Quality Strategy’s three-part aim of better health care for individuals, better health for populations, and lower costs for health care services:

<http://www.healthcare.gov/news/reports/quality03212011a.html#na>. Implementation of the IPFQR Program will help achieve the three-part aim by creating transparency around the quality of care provided at IPFs to support patient decision-making and quality improvement. Over time, the IPFQR Program will help align the goals for quality

measurement and improvement at IPFs with those of other providers in the health care system.

We seek to collect data in a manner that balances the need for information related to the full spectrum of quality performance and the need to minimize the burden of data collection and reporting. We have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care provided by IPFs. As we stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645 through 53646), we will use the following considerations for the development and selection of measures:

- Given the availability of well-validated measures and the need to balance breadth with minimizing burden, the measures should address, as fully as possible, the six domains of measurement that arise from the six priorities of the National Quality Strategy (NQS): clinical care; person- and caregiver-centered experience and outcomes; safety; efficiency and cost reduction; care coordination; and community/population health.
- Public reporting should rely on a mix of standards, outcomes, process of care measures, and patient experience of care measures, including measures of care transitions and changes in patient functional status, with an emphasis on measurement as close to the patient-centered outcome of interest as possible.
- The measure sets should evolve so that they include a focused set of measures appropriate to IPFs that reflects the level of care and the most important areas of service and measures for IPFs as well as measures addressing a core set of measure concepts that align quality improvement objectives across all provider and supplier types and settings.

- Measures should address gaps in quality of inpatient psychiatric care.
- As part of our burden reduction efforts, we continuously seek to weigh the relevance and utility of the measures compared to the burden on IPFs submitting data under the IPFQR Program. As appropriate, we will align our measures with other Medicare and Medicaid quality programs and may consider how we can incorporate data reporting by means of electronic reporting mechanisms, so that the collection of performance information is part of care delivery.
- To the extent practicable, measures used by CMS should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. We take into account widely accepted criteria established in medical literature. We consider suggestions and input from technical expert panels (TEPs), convened by CMS contractors, which evaluate IPFQR quality measures for importance, scientific soundness, usability, and feasibility.

We also take into account national priorities and HHS Strategic Plans and Initiatives:

- HHS engaged a wide range of stakeholders to develop the National Quality Strategy, as required by the Affordable Care Act, which pursues three aims (better care, healthy people, and affordable care) that establish a framework with six identifiable priorities <http://www.healthcare.gov/news/reports/quality03212011a.html#na>:
- Ensuring that each person and family is engaged as partners in their care.
- Promoting effective communication and coordination of care.

- Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease.
- Working with communities to promote wide use of best practices to enable healthy living.
- Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models.
- Making care safer by reducing harm caused in the delivery of care.
- We consider recommendations of the Measures Application Partnership (MAP) for the inclusion of clinical quality measures <http://www.qualityforum.org/MAP/>. The MAP is a public-private partnership convened by the NQF for the primary purpose of providing input to HHS on selecting performance measures for quality reporting programs and pay-for-reporting programs.
- HHS is the United States Government's principal department for protecting the health of all Americans. HHS accomplishes its mission through programs and initiatives. The goals of the HHS Strategic Plan for FYs 2010 through 2015 are: Strengthen Health Care; Advance Scientific Knowledge and Innovation; Advance the Health, Safety, and Well-Being of the American People; Increase Efficiency, Transparency, and Accountability of HHS Programs; and Strengthen the Nation's Health and Human Services Infrastructure and Workforce (<http://www.hhs.gov/secretary/about/priorities.html>). HHS will update this strategic plan every 4 years and measure its progress in addressing specific national problems, needs, or mission-related challenges.

HHS prioritizes policy and program interventions to address the leading causes of death and disability in the United States, including heart disease, cancer, stroke, chronic lower respiratory diseases, unintentional injuries, and preventable behaviors. Initiatives such as the HHS Action Plan to Reduce Healthcare-Associated Infections in clinical settings and the Partnership for Patients exemplify these programs.

5. Proposed Quality Measures for the FY 2015 Payment Determination and Subsequent Years

a. Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53646 through 53652), we adopted the following six chart-abstracted IPF quality measures for the FY 2014 payment determination and subsequent years shown in the table below:

Previously Adopted IPFQR Program Quality Measures Beginning with the FY 2014 Payment Determination			
National Quality Strategy Priority	NQF #	Measure ID	Measure Description
Patient Safety	0640	HBIPS-2	Hours of Physical Restraint Use
	0641	HBIPS-3	Hours of Seclusion Use
Clinical Quality of Care	0552	HBIPS-4	Patients Discharged on Multiple Antipsychotic Medications
	0560	HBIPS-5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification
Care Coordination	0557	HBIPS-6	Post-Discharge Continuing Care Plan Created
	0558	HBIPS-7	Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider Upon Discharge

We note that, at the time of the finalization of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53258), providers were using ICD-9-CM codes, but as of October 1, 2014 ICD-10-CM codes will be in effect. We do not at this time anticipate that this change will have substantive effects on any measures.

Measures adopted for the IPFQR Program will remain in the quality reporting program for all subsequent years unless specifically stated otherwise (for example, through removal or replacement). We are not proposing to remove or replace any of the previously adopted measures from the IPFQR Program or add any new measures to the IPFQR Program for the FY 2015 payment determination. We believe that keeping the same measures for the FY 2015 payment determination will allow IPFs one additional year during which they could ramp up recordkeeping and improve quality of care on existing measures. We discussed the collection requirements and submission timeframes for these measures in section VIII.F.7. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53654 through 53658).

b. Proposed New Quality Measures for the FY 2016 Payment Determination and Subsequent Years

We are proposing three new measures for the FY 2016 payment determination and subsequent years for the IPFQR Program. The measures are: (1) SUB-1: Alcohol Use Screening (Submitted for NQF review); (2) SUB-4: Alcohol & Drug Use: Assessing Status After Discharge (Submitted for NQF review); and (3) Follow-Up After Hospitalization for Mental Illness (FUH) (NQF #0576).

The three proposed measures were included in 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,” which is available on the NQF Web site at http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx. We considered the input and recommendations provided by the MAP in selecting measures to propose for the IPFQR Program at this time. The MAP supported the inclusion of the third proposed measure in the IPFQR Program, and supported the direction of the first two measures, noting that their recommendation is contingent on NQF endorsement. The first two measures were submitted to the NQF in 2012. Currently, the dates for their review have not been established.

The first two of these measures have been developed by and are maintained by The Joint Commission (TJC) (the measure steward) and the third measure has been developed by and is maintained by the National Committee for Quality Assurance (NCQA) (the measure steward). These measures are appropriate for the purposes of assessing the quality of inpatient psychiatric services and align with National Quality Strategy goals of promoting effective prevention and treatment practices (clinical quality of care), and promoting effective communication and coordination of care. Technical specifications for measures “SUB-1: Alcohol Use Screening” and “SUB-4: Alcohol & Drug Use: Assessing Status After Discharge” can be found on the TJC Web site at: <https://manual.jointcommission.org/bin/view/Manual/WebHome>. Technical

specifications for the measure “Follow-Up After Hospitalization for Mental Illness” (FUH) (NQF #0576) can currently be found on the NCQA Web site at:

<http://www.ncqa.org/portals/0/Follow-Up%20After%20Hospitalization%20for%20Mental%20Illness.pdf>.

The three proposed measures for FY 2016 and subsequent years are described in more detail below.

(1) SUB-1: Alcohol Use Screening (NQF Review Pending)

Individuals with mental health conditions experience substance use disorders (SUDs) at a much higher rate than the general population. Individuals with the most serious mental illnesses have the highest rates of such disorders. Co-occurring SUDs often go undiagnosed and, without treatment, contribute to a longer persistence of disorders, poorer treatment outcomes, lower rates of medication adherence, and greater impairments to functioning. Accordingly, this proposed measure, and the one immediately following, are intended to assess efforts by IPFs to screen for the most common type of such disorder, alcohol abuse, and to follow up after discharge with individuals who screen positive for alcohol abuse or who received a diagnosis of alcohol or drug disorder during the inpatient stay.

In late 2008, TJC received funding from the Partnership for Prevention and HHS’ Substance Abuse and Mental Health Services Administration (SAMHSA) to develop, specify, and test standardized performance measures addressing alcohol screening and cessation counseling. Four alcohol/substance use performance measures were pilot tested in the spring/summer of 2010. The four alcohol/substance use measures (SUB measure

set) were approved as a core measure set for use in TJC's accreditation programs (http://www.jointcommission.org/core_measure_sets.aspx). The SUB measures can be found in the TJC's Specification Manual for National Hospital Inpatient Quality Measures at: <https://manual.jointcommission.org/bin/view/Manual/WebHome>.

The SUB-1: Alcohol Use Screening proposed measure assesses the number of patients 18 years of age and older who were screened for alcohol use using a validated screening questionnaire for unhealthy drinking during their inpatient stay, and is reported as a percentage. The numerator includes the number of patients who were screened for alcohol use using a validated screening questionnaire for unhealthy drinking. The denominator includes the number of hospitalized inpatients 18 years of age or older. Higher rates on the measure are indicative of better performance. The measure excludes the following populations: patients younger than 18, cognitively impaired patients, and patients admitted for less than 1 day or greater than 120 days.

This measure is specified for collection through chart abstraction. We are proposing the form, manner, and timing of collection in section IX.D.9. of the preamble of this proposed rule. Full specifications for this measure are available at:

<https://manual.jointcommission.org/bin/view/Manual/WebHome>.

The SUB-1: Alcohol Use Screening proposed measure meets the measure selection exception requirements for the IPFQR Program under 1886(s)(4)(D)(ii) of the Act as previously discussed in Section 4 (Considerations in Selecting Quality Measures) of this rule. Although the proposed measure is not currently NQF-endorsed, we considered available measures that have been endorsed or adopted by a consensus

organization and found no other feasible and practical measures on the topic of substance use disorder screening for the inpatient population.

We invite public comment on this proposed measure.

(2) SUB-4: Alcohol and Drug Use: Assessing Status After Discharge (NQF Review Pending)

The SUB-4: Alcohol and Drug Use proposed measure assesses whether discharged patients are contacted between 7 and 30 days after hospital discharge in order to collect post-discharge follow-up information regarding their alcohol or drug use status. The measure applies to patients 18 years of age or older who screened positive for alcohol abuse, or who received a diagnosis of alcohol or drug disorder during their inpatient stay. The numerator includes the number of discharged patients that are contacted between 7 and 30 days after hospital discharge and follow-up information regarding alcohol or drug use status is collected. The denominator includes the number of discharged patients 18 years of age and older who screened positive for alcohol abuse or who received a diagnosis of alcohol or drug use disorder during their hospital stay. Higher rates on the measure are indicative of better performance.

The following patients are excluded from the measure:

- Patients less than 18 years of age;
- Patients who are cognitively impaired;
- Patients who were not screened or refused to be screened for alcohol use;
- Patients who expired;

- Patients who have a duration of stay less than or equal to 1 day or greater than 120 days;

- Patients who do not screen positive for alcohol abuse;
- Patients discharged to another hospital;
- Patients who left against medical advice;
- Patients discharged to another health care facility;
- Patients discharged to home or other health care facility for hospice care;
- Patients who do not reside in the United States;
- Patients who do not have a phone or cannot provide any contact information;
- Patients discharged to a detention facility, jail, or prison; and
- Patients who are readmitted within the follow-up time frame.

This measure is specified for collection through chart abstraction. We are proposing the form, manner, and timing of collection in section IX.D.9. of the preamble of this proposed rule. Full specifications for this measure are available at:

<https://manual.jointcommission.org/bin/view/Manual/WebHome>

The SUB-4: Alcohol and Drug Use: Assessing Status After Discharge proposed measure meets the measure selection exception requirements for the IPFQR Program under section 1886(s)(4)(D)(ii) of the Act as previously discussed in section IX.D.4. of the preamble of this proposed rule. Because this measure is not currently NQF-endorsed, we considered other available measures that have been endorsed or adopted by a consensus organization. We found no other feasible and practical measures on the topic

of post-discharge alcohol and drug assessment for inpatients who screened positive for substance abuse.

We invite public comment on this proposed measure.

(3) Follow-Up After Hospitalization for Mental Illness (FUH) (NQF #0576)

Mental illness accounts for a very large disease burden and it is estimated that half of first-time psychiatric patients are readmitted within two years of hospital discharge. Continuity of treatment and appropriate follow-up care and management of chronic diseases, such as mental illnesses, are known to reduce the risk of repeated hospitalizations. Proper follow-up treatment for psychiatric hospitalization can lead to improved quality of life for patients, families, and society as a whole.

The Follow-Up After Hospitalization for Mental Illness measure assesses the percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental health disorders, and who subsequently had an outpatient visit or an intensive outpatient encounter with a mental health practitioner, or received partial hospitalization services. The measure separately identifies the percentage of patients who received follow-up within 7 and 30 days of discharge. The detailed technical specifications for this measure can be found at:

<http://www.ncqa.org/portals/0/Follow-Up%20After%20Hospitalization%20for%20Mental%20Illness.pdf>.

This measure is specified by the steward for either collection through chart abstraction or calculation using claims/administrative data. We considered using claims/administrative data for patients discharged from IPFs to calculate the measure, and

welcome public feedback on this approach. However, we are proposing to collect chart-abstracted data for this measure in order to maintain consistency with the approach used for existing measures in the IPFQR Program, and solicit comment on this proposal. We also considered using claims/administrative data for patients discharged from IPFs to calculate the measure, and would welcome public feedback on this alternative approach. We are proposing the form, manner, and timing of collection in section IX.D.9. of the preamble of this proposed rule.

The Follow-Up After Hospitalization for Mental Illness (FUH) proposed measure meets the measure selection criteria under section 1886(s)(4)(D)(i) of the Act, because it is NQF-endorsed.

We invite public comment on this proposed measure.

In summary, we are retaining all six of the chart-abstracted measures previously adopted for the FY 2014 payment determination and subsequent years. Also, for the FY 2016 payment determinations and subsequent years, we are proposing the addition of three new chart-abstracted measures for the IPFQR Program: (1) SUB-1: Alcohol Use Screening (NQF review pending); (2) SUB-4: Alcohol & Drug Use: Assessing Status After Discharge (NQF review pending); and (3) Follow-Up After Hospitalization for Mental Illness (FUH) (NQF #0576).

We are proposing the collection requirements for these measures in the “form, manner, and timing” section (section IX.D.9.) of the preamble of this proposed rule. The table below lists the previously adopted measures for the FY 2014 payment determination

and subsequent years and the proposed additional measures for the FY 2016 payment determination and subsequent years.

Previously Adopted and Proposed Quality Measures for the IPFQR Program			
National Quality Strategy Priority	NQF #	Measure ID	Measure Description
Previously Adopted Measures for the FY 2014 Payment Determination and Subsequent Years			
Patient Safety	0640	HBIPS-2	Hours of Physical Restraint Use
	0641	HBIPS-3	Hours of Seclusion Use
Clinical Quality of Care	0552	HBIPS-4	Patients Discharged on Multiple Antipsychotic Medications
	0560	HBIPS-5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification
Care Coordination	0557	HBIPS-6	Post-Discharge Continuing Care Plan Created
	0558	HBIPS-7	Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider Upon Discharge
Proposed New Measures for the FY 2016 Payment Determination and Subsequent Years			
Clinical Quality of Care	Review Pending	SUB-1	Alcohol Use Screening
	Review Pending	SUB-4	Alcohol & Drug Use: Assessing Status After Discharge
	0576	FUH	Follow-Up After Hospitalization for Mental Illness

We invite public comment on these proposals.

c. Maintenance of Technical Specifications for Quality Measures

We will provide a user manual that will contain links to measure specifications, data abstraction information, data submission information, a data submission mechanism known as the Web-based Measure Tool, and other information necessary for IPFs to participate in the IPFQR Program. This manual will be posted on the QualityNet Web

site at: <https://www.QualityNet.org>. We will maintain the technical specifications for the quality measures by updating this manual periodically and including detailed instructions for IPFs to use when collecting and submitting data on the required measures. These updates will be accompanied by notifications to IPFQR Program participants, providing sufficient time between the change and effective dates in order to allow users to incorporate changes and updates to the measure specifications into data collection systems.

Many of the quality measures used in different Medicare and Medicaid reporting programs are NQF-endorsed. As part of its regular maintenance process for NQF-endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes 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.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53652), we stated that 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 IPFQR Program so that these measures remain up-to-date.

Through NQF's measure maintenance process, NQF endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measure. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53653), we adopted a policy to use a subregulatory process to make nonsubstantive updates to NQF-endorsed measures used for the IPFQR Program. We also stated that we expected to make the determination of what constitutes a substantive versus a nonsubstantive change on a case-by-case basis, and provided examples of the types of changes that would fall into each category.

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 non-substantive changes may include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based. As stated in the FY 2013 IPPS/LTCH PPS final rule, we will revise the Specifications Manual so that it clearly identifies the updates and provide links to where additional information on the updates can be found. We also will post the updates on the QualityNet Web site at <https://www.QualityNet.org>. We will provide sufficient lead time for facilities to implement the changes where changes to the data collection systems would be necessary.

We will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the IPFQR 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 believe that the policy finalized in the FY 2013 IPPS/LTCH PPS final rule adequately balances our need to incorporate non-substantive NQF updates to NQF-endorsed IPFQR Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process. These policies regarding what is considered substantive versus non-substantive apply to all measures in the IPFQR Program.

6. Proposed Request for Voluntary Information – IPF Assessment of Patient Experience of Care

As indicated previously, we strive to address each of the six priorities of the HHS National Quality Strategy in our quality reporting programs. One priority area currently

unaddressed in the IPFQR Program is that of patient and family engagement and experience of care. We included on our “List of Measures under Consideration for December 1, 2012,” the measure “Inpatient Consumer Survey of Inpatient Behavioral Healthcare Services” (NQF #0726). The MAP provided input on this measure supporting its inclusion in the IPFQR Program.

We believe that while the specific survey instrument incorporated in that measure addressed an important area of quality care, we are not proposing to adopt the measure at this time because of several issues. These issues include potential reporting and information collection burdens in a new program, and compatibility with the content and format of other similar CMS beneficiary surveys. We intend to pursue the adoption of a standardized measure of patient experience of care for the IPFQR Program in the near future.

In an effort to proceed cautiously with the selection of an assessment instrument and collection protocol, we are instead proposing at this time to collect information from IPFs participating in the IPFQR Program regarding whether the IPF assesses patient experience of inpatient behavioral health services using a standardized instrument (Yes/No). We will also ask those IPFs that answer “Yes” to indicate the name of the survey that they administer. Submission of this information is completely voluntary and would not in any way affect an IPF’s FY 2016 payment determination.

We will use information we collect from this request for voluntary information to assess readiness of IPFs to report patient experience of care measure data in the IPFQR

Program. We intend to propose to make this request for voluntary information a mandatory measure in future rulemaking.

Section IX.D.9. of the preamble of this proposed rule, which covers the form, manner, and timing of data submissions, includes our proposal for collection requirements that would apply to any information IPFs voluntarily submit.

Section X.D.9. also includes more information about the request for voluntary information.

We welcome comments on this approach as well as recommendations concerning future measurement of this domain, including recommendations of specific instruments for surveying patient and family engagement and experience of care in inpatient psychiatric settings.

7. Request for Recommendations for New Quality Measures for Future Years

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the inpatient psychiatric setting. Therefore, through future rulemaking, we intend to propose new measures that will help us further our goal of achieving better health care and improved health for Medicare beneficiaries who obtain inpatient psychiatric services, through the widespread dissemination and use of performance information.

We plan to continue developing a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in IPFs. Accordingly, we are soliciting recommendations concerning future measures to assess the domains that arise from the six NQS priorities: clinical care; person- and

caregiver-centered experience and outcomes; safety; efficiency and cost reduction; care coordination; and community/population health. This approach will enhance better psychiatric care while bringing the IPFQR Program in line with other established quality reporting and performance improvement programs who also aim to align with the NQS priorities such as the Hospital Inpatient Quality Reporting (IQR) Program, the Hospital Outpatient Quality Reporting (OQR) Program, the Hospital Value-Based Purchasing (VBP) Program, the End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and other CMS quality programs. Recommendations for consideration of individual measures should address the importance of the measure, its scientific evidence, its relevance for quality improvement, and the feasibility of collection and reporting.

We welcome all recommendations related to any of the identified domains. However, we are particularly interested in measure and domain recommendations concerning: (1) inpatient psychiatric treatment and quality of care of geriatric patients and other adults, adolescents, and children; (2) quality of prescribing for antipsychotics and antidepressants; (3) readmissions; (4) access to care; (5) screening for suicide and violence; and (6) screening and treatment for nonpsychiatric, comorbid conditions for which patients with mental or substance use disorders are at higher risk. In addition, we seek recommendations on any other measures related to patient experience of care and overall quality of care for IPFs.

We welcome public comment on considerations of additional measure topics for the IPFQR Program in future rulemaking.

8. Proposed Public Display Requirements for the FY 2014 Payment Determination and Subsequent Years

Section 1886(s)(4)(E) of the Act requires the Secretary to establish procedures for making the data submitted under the IPFQR Program available to the public. Such procedures shall ensure that an IPF has the opportunity to review the data that is to be made public with respect to the IPF prior to such data being made public. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53653 through 53654), we finalized our procedures for the FY 2014 payment determination and subsequent years regarding public display. We previously finalized that the data collected under the IPFQR program would be displayed on a CMS Web site and that public display would begin in the first quarter of the calendar year following the respective payment determination year (77 FR 53654). Last year, we also finalized a 30-day preview period that would allow IPFs to review their data before it became public. The previously finalized preview period is September 20 through October 19 of the respective payment determination year (77 FR 53654).

We are proposing to change our finalized policies, however, in an attempt to align the IPF preview and display periods with that of the Hospital IQR Program. We are proposing that for the FY 2014 payment determination and subsequent years, we will publicly display the submitted data on a CMS Web site in April of each calendar year following the start of the respective payment determination year. In other words, the public display period for the FY 2014 payment determination would be April 2014; the public display periods for the FY 2015 and FY 2016 payment determinations would be April 2015 and April 2016 respectively, and so forth.

Accordingly, we also propose that the preview period for the FY 2014 payment determination and subsequent years be modified to 30 days approximately twelve weeks prior to the public display of the data. This is to align with the Hospital IQR Program's preview and display periods and, as a result, reduce burden to facilities. Below, please find a table that displays the new proposed public display timeline. Although we have listed the public display timeline only for the FYs 2014 through 2016 payment determinations, this policy applies to the FY 2014 payment determination and subsequent years.

Proposed Public Display Timeline for the FY 2014 Payment Determination and Subsequent Years		
Payment Determination Year (Fiscal Year)	Reporting Period (Calendar Year)	Public Display (Calendar Year)
FY 2014	Q4 2012 (October 1, 2012 – December 31, 2012) Q1 2013 (January 1, 2013 - March 31, 2013)	April 2014
FY 2015	Q2 2013 (April 1, 2013 – June 30, 2013) Q3 2013 (July 1, 2013 – September 30, 2013) Q4 2013 (October 1, 2013 – December 31, 2013)	April 2015
FY 2016	Q1 2014 (January 1, 2014 – March 31, 2014) Q2 2014 (April 1, 2014 – June 30, 2014) Q3 2014 (July 1, 2014 – September 30, 2014) Q4 2014 (October 1, 2014 - December 31, 2014)	April 2016

We welcome public comment on these proposals.

9. Form, Manner, and Timing of Quality Data Submission for the FY 2014 Payment Determination and Subsequent Years

a. Background

Section 1886(s)(4)(C) of the Act requires that, for the FY 2014 payment determination and each subsequent year, each IPF submit to the Secretary data on quality measures as specified by the Secretary. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary. As required by section 1886(s)(4)(A) of the Act, for any IPF that fails to submit quality data in accordance with section 1886(s)(4)(C) of the Act, the Secretary will reduce any annual update to a standard Federal rate for discharges occurring during such fiscal year by 2.0 percentage points. The complete data submission requirements, submission deadlines, and data submission mechanism, known as the Web-Based Measure Tool, is posted on the QualityNet Web site at: <http://www.qualitynet.org/>. The Web-Based Measure Tool is an Internet database for IPFs to submit their aggregate data. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53654 through 53658), we required that IPFs submit data in accordance with the specifications for the appropriate proposed reporting periods to the Web-Based Measures Tool found in the IPF section on the QualityNet Web site (<http://www.qualitynet.org/>).

b. Procedural Requirements

In order to participate in the IPFQR Program, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53654 through 53655), we required IPFs to comply with certain procedural requirements. We have aligned these procedural requirements with the Hospital IQR Program to avoid imposing additional burden on providers and to increase efficiencies by virtue of allowing providers to use similar submission requirements across programs. Under these adopted policies, IPFs must--

- Register with QualityNet before the IPF begins reporting, regardless of the method used for submitting the data.
- Identify a QualityNet Administrator who follows the registration process located on the QualityNet Web site (<http://www.qualitynet.org/>).
- Complete a Notice of Participation (NOP). IPFs that wish to participate in the IPFQR Program must complete an online NOP. Submission of a NOP is an indication that the IPF agrees to participate in the IPFQR Program and public reporting of their measure rates. The timeframe for completing the NOP is between January 1 and August 15 before each respective payment determination year. For example, for the FY 2015 payment determination year, the timeframe for completing the NOP is between January 1, 2014 and August 15, 2014.
- Any IPF that receives a new CMS Certification Number (CCN) on or after the beginning of the respective payment determination year and wishes to participate in the IPFQR Program, but has not otherwise submitted a NOP using the new CCN, must submit a completed NOP no later than 180 days from the date identified as the open date

(that is, the Medicare acceptance date) on the approved CMS Quality Improvement Evaluation System to participate in the IPFQR Program.

- Withdrawals from the IPFQR Program will be accepted no later than August 15 before the beginning of each respective payment determination year. We believe the August 15 deadline will give us sufficient time to update payment determinations for each respective year. For example, under current policies, the withdrawal period for the FY 2015 payment determination year is between January 1, 2014 and August 15, 2014. If in a given payment determination year, an IPF withdraws from the program, it will receive a reduction of 2.0 percentage points to that year's applicable percentage increase. Once an IPF has submitted a NOP, it is considered to be an active IPFQR Program participant until such time as the IPF submits a withdrawal form to CMS.

- We determine if an IPF has complied with our data submission requirements by validating each IPF's CCN and their aggregated data submission on the QualityNet Web site.

- IPFs must submit the aggregated numerator and denominator data for all age groups, for all measures, to avoid the 2.0 percentage point reduction.

c. Proposed Submission Requirements for the FY 2016 Payment Determination and Subsequent Years

Currently, IPFs choosing to participate in the IPFQR Program must meet the specific data collection and submission requirements as described on the QualityNet Web site at <http://www.qualitynet.org/> and by TJC, the HBIPS measure steward

(77 FR 53655). As we indicated in the FY 2013 IPPS/LTCH PPS final rule, the specifications for the HBIPS measures can be found on the TJC Web site at:

<https://manual.jointcommission.org/bin/view/Manual/WebHome>.

For the FY 2016 payment determination, we are proposing that, for the proposed chart-abstracted measures listed in the preamble of this proposed rule, participating IPFs meet the same specific data collection and submission requirements when reporting quality measure data. The specifications for the SUB-1 and SUB-4 measures can be found on the TJC Web site at:

http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures.aspx. The specifications for the FUH measure are posted on the NCQA

Web site at: [\[Up%20After%20Hospitalization%20for%20Mental%20Illness.pdf\]\(http://www.ncqa.org/portals/0/Follow-Up%20After%20Hospitalization%20for%20Mental%20Illness.pdf\).](http://www.ncqa.org/portals/0/Follow-</p></div><div data-bbox=)

We finalized a policy in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53656) requiring that IPFs submit aggregate data on measures on an annual basis via the Web-Based Measures Tool found in the IPF section on the QualityNet Web site. While this policy applies on an annual basis beginning in FY 2014, it is listed under a sub-heading labeled “Reporting and Submission Requirements for the FY 2014 Payment Determination” (77 FR 53655). To avoid reader confusion, we clarify that these reporting and submission requirements finalized in the FY 2013 IPPS/LTCH PPS final rule apply to all subsequent years unless we change our policy through future rulemaking. It is our intent to require that IPFs submit aggregate data on measures on an annual basis

via the Web-Based Measures Tool found in the IPF section on the QualityNet Web site for the FY 2014 payment determination and subsequent years.

The data input forms on the QualityNet Web site for such submission will require aggregate data for each separate quarter. Therefore, IPFs will need to track and maintain quarterly records for their data.

With respect to the NCQA's FUH measure, we are proposing all-payer Web-based collection to maintain consistency throughout the measures we have selected for the IPFQR Program. However, we welcome comments for alternative forms of data submission.

As noted earlier, NQF #0726 "Inpatient Consumer Survey of Inpatient Behavioral Healthcare Services" is a patient experience measure covering information not measured by existing program measures. While we are not adopting NQF #0726 at this time, we are proposing to request voluntary information about survey administration asking whether the IPF assesses patient experience of inpatient behavioral health services using a standardized instrument. IPFs would only have to provide a "yes" or "no" response. We will also ask those IPFs that answer "yes" to indicate which survey they administer. We are proposing that this information be collected through a Web-based collection tool.

We invite public comment on the proposed submission requirements.

d. Reporting Requirements for the FY 2016 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53657), we established reporting periods and submission timeframes for the FY 2014, FY 2015, and

FY 2016 payment determinations, but we did not require any data validation approach. However, we encouraged the IPFs to use a validation method and conduct their own analysis. Our recommendations remain the same in this proposal. In future years, should we modify the program to require patient-level data, we will consider proposals for an appropriate validation method using rulemaking.

Although in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53657) we adopted policies for the FY 2014 payment determination and subsequent years, we only listed quality reporting periods and submission timeframes for the FY 2014, FY 2015, and FY 2016 payment determinations. We explained that the reporting periods for the FY 2014 and FY 2015 payment determinations were 6 and 9 months, respectively, to allow us to achieve a 12 month (calendar year) reporting period for the FY 2016 payment determination. We also indicated that the submission timeframe is between July 1 and August 15 within the same calendar year that marks the beginning of the appropriate payment determination year. We have included this information in the table below.

Quality Reporting Periods and Submission Timeframes for the FY 2014 Payment Determination and Subsequent Years		
Payment Determination (Fiscal Year)	Reporting Period for Services Provided (Calendar Year)	Data Submission Timeframe
FY 2014	Q4 2012 (October 1, 2012 – December 31, 2012) Q1 2013 (January 1, 2013 - March 31, 2013)	July 1, 2013 – August 15, 2013
FY 2015	Q2 2013 (April 1, 2013 – June 30, 2013) Q3 2013 (July 1, 2013 – September 30, 2013) Q4 2013	July 1, 2014 – August 15, 2014

Quality Reporting Periods and Submission Timeframes for the FY 2014 Payment Determination and Subsequent Years		
Payment Determination (Fiscal Year)	Reporting Period for Services Provided (Calendar Year)	Data Submission Timeframe
	(October 1, 2013 – December 31, 2013)	
FY 2016	Q1 2014 (January 1, 2014 – March 31, 2014) Q2 2014 (April 1, 2014 – June 30, 2014) Q3 2014 (July 1, 2014 – September 30, 2014) Q4 2014 (October 1, 2014 - December 31, 2014)	July 1, 2015 – August 15, 2015

To avoid reader confusion, we are reiterating that the policy we adopted for the FY 2016 payment determination also applies to the FY 2017 payment determination and subsequent years, unless we change it through future rulemaking.

e. Proposed Population, Sampling, and Minimum Case Threshold for the FY 2016 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53657 through 53658), for the FY 2014 payment determination and subsequent years, we finalized our policy that participating IPFs must meet specific population, sample size, and minimum reporting case threshold requirements as specified in TJC's Specifications Manual. We also indicated that the Specifications Manual for the measures is updated at least twice a year (and may be updated more often as necessary), and IPFs must follow the requirements in the most recent manual, which can be found on the TJC Web site at:

<https://manual.jointcommission.org/bin/view/Manual/WebHome>.

We also finalized our policy that the target population for the quality measures includes all patients, not solely Medicare beneficiaries, to improve quality of care. We believe it is important to require IPFs to submit measures on all patients because quality improvement is of industry-wide importance and should not be focused exclusively on a certain subset of patients. In addition, we need this scope of data in order to be able to assess the quality of care being provided to Medicare beneficiaries.

We also finalized our policy that IPFs that have no data to report for a given measure must enter zero for the population and sample counts. For example, an IPF that has no hours of physical restraint use (HBIPS-2) to report for a given quarter is still required to submit a zero for its quarterly aggregate population for HBIPS-2 in order to meet the reporting requirement. We believe it is important for IPFs to submit data on all measures even when the population size for a given measure is zero or small because it provides us with the opportunity to identify, assess, and evaluate the baseline for the number of cases for each measure in future years. This will also assist us in determining the minimum case threshold for future years in the rule. In cases where the measure rates are calculated based on low caseloads, when the submitted data are publicly displayed on the QualityNet Web site, we will clearly note that the affected measure rates were calculated based on low caseloads that may affect the result.

For the HBIPS measures, which we finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53657 through 53658), we will continue to apply our finalized policies for population, sampling, and minimum case threshold outlined above. For the measures we have proposed for the FY 2016 payment determination and subsequent years, we are

proposing that IPFs follow the sampling and population requirements as specified by the appropriate measure steward as outlined below.

The most recent version of the Specifications Manual, including the sampling and population information for the SUB measures, can be found on the TJC Web site at:

http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures.aspx. We note that IPFs are required to report data only for inpatient discharges treated by the IPF, not for acute care hospital discharges that are not treated and billed by the IPFs.

We are proposing that there will be no sampling required for the FUH measure – IPFs are expected to submit all data. We are proposing that IPFs follow the population requirements outlined at: <http://www.ncqa.org/portals/0/Follow-Up%20After%20Hospitalization%20for%20Mental%20Illness.pdf>.

We invite public comment on this proposal.

f. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658), we finalized our DACA policy for the FY 2014 payment determination and subsequent years. We stated that IPFs must acknowledge their data accuracy and completeness once annually using a form provided on the QualityNet Web site. To affirm that the data provided to meet the IPFQR Program data submission requirements are accurate and complete to the best of an IPF's knowledge, an IPF is required to submit the DACA form. We will provide a link to this form once IPFs have completed entry of all aggregated measure data. Data submission is not complete until the IPF submits the DACA form. In the FY 2013

IPPS/LTCH PPS final rule (77 FR 53658), we listed the DACA deadlines for the FY 2014, FY 2015, and FY 2016 payment determinations only, even though our finalized policy was for the FY 2014 payment determination and subsequent years. Set out in the table below are the DACA deadlines we listed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658).

Data Accuracy and Completeness Acknowledgment (DACA) Deadlines for the FY 2014 Payment Determinations and Subsequent Years		
Payment Determination (Fiscal Year)	Reporting Period for Services Provided (Calendar Year)	Data Accuracy and Completeness Acknowledgement Deadline
FY 2014	Q4 2012 (October 1, 2012 – December 31, 2012) Q1 2013 (January 1, 2013 - March 31, 2013)	August 15, 2013
FY 2015	Q2 2013 (April 1, 2013 – June 30, 2013) Q3 2013 (July 1, 2013 – September 30, 2013) Q4 2013 (October 1, 2013 - December 31, 2013)	August 15, 2014
FY 2016	Q1 2014 (January 1, 2014 – March 31, 2014) Q2 2014 (April 1, 2014 – June 30, 2014) Q3 2014 (July 1, 2014 – September 30, 2014) Q4 2014 (October 1, 2014 - December 31, 2014)	August 15, 2015

To avoid reader confusion, we are reiterating that the DACA finalized policies listed above will continue to apply for the FY 2014 payment determination and subsequent years unless and until we change such policies through our rulemaking process. Thus, we will continue with our adopted policy that the deadline for submission

of both measure data and the DACA form is no later than August 15 prior to the applicable IPFQR Program payment determination year.

We have summarized the pertinent IPFQR dates in the table below with regard to data reporting periods, submission deadlines, DACA deadlines, and public display periods.

Data Accuracy and Completeness Acknowledgment (DACA) Deadlines for the FY 2014 Payment Determinations and Subsequent Years				
Payment Determination (Fiscal Year)	Reporting Period for Services Provided (Calendar Year)	Submission Timeframe	DACA Deadline	Public Display
FY 2014	Q4 2012 (October 1, 2012 – December 31, 2012) Q1 2013 (January 1, 2013 - March 31, 2013)	July 1, 2013 – August 15, 2013	August 15, 2013	April 2014
FY 2015	Q2 2013 (April 1, 2013 – June 30, 2013) Q3 2013 (July 1, 2013 – September 30, 2013) Q4 2013 (October 1, 2013 - December 31, 2013)	July 1, 2014 – August 15, 2014	August 15, 2014	April 2015
FY 2016	Q1 2014 (January 1, 2014 – March 31, 2014) Q2 2014 (April 1, 2014 – June 30, 2014) Q3 2014 (July 1, 2014 – September 30, 2014) Q4 2014 (October 1, 2014 -	July 1, 2015 – August 15, 2015	August 15, 2015	April 2016

Data Accuracy and Completeness Acknowledgment (DACA) Deadlines for the FY 2014 Payment Determinations and Subsequent Years				
Payment Determination (Fiscal Year)	Reporting Period for Services Provided (Calendar Year)	Submission Timeframe	DACA Deadline	Public Display
	December 31, 2014)			

Again, we have listed information until FY 2016, but these deadlines apply to the FY 2014 payment determination and subsequent years.

10. Reconsideration and Appeals Procedures for the FY 2014 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658 through 53659), we adopted a reconsideration process whereby IPFs can request a reconsideration of their payment update reduction in the event an IPF believes that its annual payment update has been incorrectly reduced for failure to report quality data under the IPFQR Program. We codified the reconsideration procedures that IPFs must follow at 42 CFR 412.434. We instituted an annual reconsideration process similar to the Hospital IQR Program (74 FR 43892). We do not utilize reconsideration policies and procedures related to the Hospital IQR Program validation requirement because the IPFQR Program does not currently include an annual validation requirement for IPFs.

11. Waivers from Quality Reporting Requirements for the FY 2014 Payment Determination and Subsequent Years

In our experience with other quality reporting and/or performance programs, we have noted occasions when participants have been unable to submit required quality data due to extraordinary circumstances that are not within their control (for example, natural

disasters). It is our goal to avoid penalizing IPFs in such circumstances or to unduly increase their burden during these times. Therefore, in the FY 2013 IPFS/LTCH PPS final rule (77 FR 53659 through 53660), we adopted a policy that, for the FY 2014 payment determination and subsequent years, IPFs may request and we may grant waivers with respect to the reporting of required quality data when extraordinary circumstances beyond the control of the IPF may warrant. When waivers are granted, IPFs will not incur payment reductions for failure to comply with the requirements of the IPFQR Program.

Under the process, in the event of extraordinary circumstances not within the control of the IPF, such as a natural disaster, the IPF may request a reporting extension or a complete waiver of the requirement to submit quality data for one or more quarters. Such IPFs would submit a request form to CMS available on the QualityNet Web site at: <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772379030>.

This process does not preclude us from granting waivers or extensions to IPFs that have not requested them when we determine that an extraordinary circumstance, such as an act of nature (for example, a hurricane or other natural disaster that could reasonably affect an IPF's ability to compile or report data), affects an entire region or locale. If we make the determination to grant a waiver or extension to IPFs in a region or locale, we will communicate this decision through routine communication channels to IPFs and vendors, by means of memoranda, emails, and notices on the QualityNet Web site, among other means.

12. Electronic Health Records (EHRs)

Under the current and proposed chart-abstracted quality measures, IPFs cannot use EHRs (also referred to as electronic medical records) for data collection because the current and proposed measures will be submitted as aggregate data. However, we encourage IPFs to take steps towards adoption of EHRs that will allow for reporting of clinical quality data from EHRs directly to a CMS repository. We encourage IPFs that are implementing, upgrading, or developing EHR systems to ensure that the technology obtained, upgraded, or developed conforms to standards adopted by HHS. Although the IPFQR Program is in its initial implementation stages, we recommend that IPFs ensure that their EHR systems accurately capture quality data and that, ideally, such systems provide point-of-care decision support that promotes optimal levels of clinical performance.

In the future, we will continue to work with standard-setting organizations and other entities to explore processes through which EHRs could speed the collection of data and minimize the resources necessary for quality reporting.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53660), we responded to public comments on the adoption of EHRs for the IPFQR Program in the future and we again invite public comment on this issue.

E. 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 EHR technology (CEHRT). Eligible hospitals 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.

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). The subset of CQMs that we are proposing for voluntary electronic reporting in the Hospital IQR Program in section IX.A.7. of the preamble to this proposed rule is included in Table 10 of the EHR Incentive Program Stage 2 final rule.

We continue to believe there are important synergies with respect to the two programs. We believe the financial incentives under the EHR Incentive Program for the adoption and meaningful use of CEHRT by eligible hospitals and CAHs will encourage the adoption and use of CEHRT for the anticipated 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. Proposed Expanded Electronic Submission Period for CQMs

Section 1886(n)(3)(B)(iii) of the Act requires that, in selecting CQMs for and establishing the form and manner of reporting for the EHR Incentive Program, the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required. To the extent that CQMs are included in both the Hospital IQR Program and the EHR Incentive Program, we expect that the Hospital IQR Program would transition to using CEHRT rather than manual chart abstraction. The beginning of this transition is described in section IX.A.7. of the preamble to this proposed rule with the proposed voluntary electronic reporting of up to 16 CQMs in the Hospital IQR Program, which are also included in the set of CQMs from which hospitals will report for the EHR Incentive Program beginning in FY 2014 (77 FR 54083 through 54087). By using voluntary electronic reporting in FY 2014 for all 16 of the CQMs proposed under the Hospital IQR Program, hospitals can submit once and fulfill the CQM component of MU as well as the reporting requirement for those 16 CQMs in the Hospital IQR Program.

In the EHR Incentive Program Stage 2 final rule (77 FR 54049-54051), for CQM data that is submitted electronically beginning in 2014, we established the submission period as the two months immediately following the end of the FY (October 1 – November 30 for eligible hospitals and CAHs). In response to feedback we have received through various forums, we are proposing to open the submission period for electronically submitted files on January 2. This will allow for better alignment with the

Hospital IQR Program. The proposed expanded submission period would allow more flexibility for eligible hospitals and CAHs to start submitting earlier and more frequently, as patients who fit the denominator criteria of the CQMs that the hospitals will submit are discharged. As established in the EHR Incentive Program Stage 2 final rule, the submission period would end on November 30, and eligible hospitals that are demonstrating MU for the first time in the year immediately preceding any payment adjustment year must submit by July 1. This proposal would not change the reporting periods for CQMs established in the EHR Incentive Program Stage 2 final rule (77 FR 54051).

We also are proposing, beginning in FY 2014, to allow eligible hospitals and CAHs that are demonstrating meaningful use for the first time to report CQMs by attestation or through the electronic reporting methods that we establish for the EHR Incentive Program. In the EHR Incentive Program Stage 2 final rule (77 FR 54049 through 54051), we finalized a policy that first-time meaningful EHR users would be required to report CQMs through attestation. This proposal would change that policy to allow more flexibility for eligible hospitals and CAHs to choose between reporting by attestation or electronically in their first year of MU. For further explanation of reporting CQMs by attestation or electronically under the EHR Incentive Program, we refer readers to the discussion of reporting methods in the EHR Incentive Program Stage 2 final rule (77 FR 54087 through 54089). Regardless of the reporting method selected, however, the July 1 deadline for avoiding the Medicare payment adjustments will remain the same, as established in the EHR Incentive Program Stage 2 final rule (77 FR 54049

through 54051). We emphasize that to avoid a payment adjustment under Medicare, eligible hospitals demonstrating MU for the first time in the year immediately preceding any payment adjustment year must complete their submission of CQM data by July 1.

We note although reporting CQM data by attestation would still be an option for first-time meaningful users under the EHR Incentive Program, it would not fulfill any Hospital IQR Program requirements. We welcome public comment on this proposal.

3. Quality Reporting Data Architecture Category III (QRDA-III) Option in 2014

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 using a method similar to the Hospital IQR Program electronic reporting pilot, which uses QRDA-I (patient-level data). We also stated 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 have determined that the electronic submission of aggregate-level data using QRDA-III will not be feasible in 2014 for eligible hospitals and CAHs under the Medicare EHR Incentive Program. Thus, for the 2014 reporting period under the Medicare EHR Incentive Programs, eligible hospitals and CAHs would have the option to continue to report aggregate CQM results through attestation. We will reassess this

policy for the 2015 and future reporting periods. We note that submissions of aggregate CQM data via attestation would not satisfy the reporting requirements for the Hospital IQR Program. We also note that this proposed policy does not apply to the Medicaid EHR Incentive Program. Therefore, the 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.

As described in section IX.A.9.d. of the preamble of this proposed rule, the Hospital IQR Program intends to continue its policy to accept patient-level data as it transitions to electronic reporting. In order to remain aligned with the Hospital IQR Program, and because over 82 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 the 16 CQMs identified by the Hospital IQR Program in section IX.A.7. of the preamble of this proposed rule. We believe that keeping the two programs aligned will ultimately reduce reporting burden for hospitals. We believe that the proposed extension of the submission period that we are proposing in section IX.E.2. of the preamble of this proposed rule will also help the electronic submission process for hospitals. We welcome public comment on this proposal.

4. Case Number Threshold Exemption--Proposed Requirements Regarding Data Submission

In the EHR Incentive Program Stage 2 final rule (77 FR 54080), we established a case number threshold exemption policy for eligible hospitals and CAHs that experience

a low volume of cases addressed by certain CQMs, and stated that hospitals seeking an exemption under the policy must submit aggregate population and sample size data in the same manner as required in the Hospital IQR Program. Our intent was to reduce the burden on hospitals and CAHs that participate in both programs so they would only need to submit this information once. However, we have determined that this information could be captured in QualityNet for both the EHR Incentive Program and the Hospital IQR Program during the process of electronically submitting CQMs. We are proposing to require that the aggregate population data be entered into QualityNet (for EHR-based reporting) during the process of electronically submitting CQMs. We note that sample size data are not required for electronically submitted CQMs.

We note that, in general, the submission deadline for the aggregate population data is the same as the submission deadline for CQMs (November 30). For eligible hospitals in their first year of demonstrating MU, the aggregate population data would need to be submitted no later than July 1 for hospitals that seek to invoke the case number threshold exemption, as this data would be needed to determine whether the eligible hospital met the CQM reporting requirements for MU.

**X. Proposed Change to the Medicare Hospital Conditions of Participation (CoPs)
Relating to the Administration of Pneumococcal Vaccines**

Among the regulations at 42 CFR Part 482 governing the Conditions of Participation (CoPs) for hospitals to participate in the Medicare program, we have established a condition for Nursing Services under § 482.23. Included in the standards for the nursing services condition is a standard for the preparation and administration of drugs. Section §482.23(c)(3) contains the following provision: “With the exception of influenza and pneumococcal *polysaccharide* [emphasis added] vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient as specified under § 482.12(c).” At the time that this CoP standard was originally promulgated (October 2, 2002), and for several years thereafter, the pneumococcal polysaccharide vaccine (PPSV or Pneumovax 23®, Merck) was the only pneumococcal vaccine approved for adult use. In developing the original standard, it was not the Agency’s intention to specify a particular type or brand of pneumococcal vaccine. Instead, the Agency wanted to allow hospitals the flexibility to have a policy where nurses could administer influenza and pneumococcal vaccines without a prior practitioner order and only after assessing patients for any contraindications to the vaccines being administered.

However, we recently became aware of another pneumococcal vaccine (pneumococcal conjugate vaccine (PCV) or Prevnar 13®, Pfizer), which received FDA

approval for adult use in December 2011. We believe that the availability of another FDA-approved pneumococcal vaccine may have the potential for causing confusion in the hospital community at large by our use of the term “polysaccharide” as a distinguisher for the pneumococcal vaccine in the hospital CoP standard. Indeed, it has come to our attention that some hospitals may be using only the polysaccharide type of pneumococcal vaccine because they believe they are not permitted under the CoPs to stock and use any other type of pneumococcal vaccine. We believe the proposed change would allow for the inclusion of all pneumococcal vaccines approved for use now and in the future. With two types of pneumococcal vaccines currently approved for use with adults, we also believe that patient access to the pneumococcal vaccine would potentially improve because hospitals would now possess the freedom and flexibility to choose which type of pneumococcal vaccine(s) it will now stock and use.

Therefore, in this proposed rule, we are proposing to amend the regulatory language at §482.23(c)(3) to delete the term “polysaccharide”. This proposed deletion would allow a hospital to include any type of pneumococcal vaccine as part of its physician-approved policy for administration by nurses without a prior practitioner order, provided the vaccine has been approved by the FDA for the patient population to which the hospital intends to administer it. In addition, this proposed change would give hospitals the added flexibility to include the administration of any pneumococcal vaccines that are approved in the future by the FDA for administration under this CoP standard.

XI. 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 2013 "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 2014 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>.

XII. 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-](http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html)

[Payment/AcuteInpatientPPS/index.html](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 of the data files requested, 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 2010 Medicare cost reports used to create the proposed FY 2014 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
2013	2010	2014
2012	2009	2013
2011	2008	2012
2010	2007	2011
2009	2006	2010
2008	2005	2009
2007	2004	2008
2006	2003	2007
2005	2002	2006
2004	2001	2005

Media: Internet at:

<http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage>.

Periods Available: FY 2005 through FY 2014 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 2014 IPPS Update.

3. Provider Occupational Mix Adjustment Factors for Each Occupational Category Public Use File

This file contains each hospital's occupational mix adjustment factors by occupational category. Two versions of these files are created each year. They support the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at:

<http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage>.

Period Available: FY 2014 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 2014 IPPS Update.

5. FY 2014 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 2014 IPPS Update.

6. HCRIS Cost Report Data

The data included in this file contain cost reports with fiscal years ending on or after September 30, 1996. These data files contain the highest level of cost report status.

Media: Internet at:

http://www.cms.hhs.gov/CostReports/02_HospitalCostReport.asp and Compact Disc (CD).

File Cost: \$100.00 per year.

7. Provider-Specific File

This file is a component of the PRICER program used in the fiscal intermediary's or the MAC's system to compute DRG/MS-DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

Media: Internet at:

http://www.cms.hhs.gov/ProspMedicareFeeSvcPmtGen/03_psf_text.asp

Period Available: Quarterly Update.

8. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number as published in each year's update of the Medicare hospital inpatient prospective payment system. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG/MS-DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year. They support the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at:

<http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage>

Periods Available: FY 1985 through FY 2014.

9. MS-DRG Relative Weights (Also Table 5 - MS-DRGs)

This file contains a listing of MS-DRGs, MS-DRG narrative descriptions, relative weights, and geometric and arithmetic mean lengths of stay as published in the **Federal Register**. There are two versions of this file as published in the **Federal Register**.

- Notice of proposed rulemaking.
- Final rule.

Media: Internet at:

<http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage>

Periods Available: FY 2005 through FY 2014 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. They support the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at:

<http://www.cms.hhs.gov/AcuteInpatientPPS/HIF/list.asp#TopOfPage>.

Periods Available: FY 1994 through FY 2014 IPPS Update.

11. AOR/BOR Tables

This file contains data used to develop the MS-DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by MS-DRG for length of stay and standardized charges. The BOR tables are “Before Outliers Removed” and the AOR is “After Outliers Removed.” (Outliers refer to statistical outliers, not payment outliers.)

Two versions of this file are created each year. They support the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at:

<http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage>.

Periods Available: FY 2005 through FY 2014 IPPS Update.

12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the hospital inpatient operating and capital prospective payment systems. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, indirect medical education (IME) adjustment, disproportionate share, and the Core-based Statistical Area (CBSA). The file supports the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at:

<http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage>.

Period Available: FY 2014 IPPS Update.

13. Hospital Readmissions Reduction Program File

This file contains information on the calculation of the Hospital Readmissions Reduction Program payment adjustment. Variables include the proxy excess readmission ratios for acute myocardial infarction, pneumonia and heart failure and the proxy readmissions payment adjustment for each provider included in the program.

The file supports the following:

- Notice of proposed rulemaking published in the **Federal Register**.
- Final rule published in the **Federal Register**.

Media: Internet at:

<http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/list.asp#TopOfPage>.

Period Available: FY 2014 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 2015 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, and FY 2014, we received 1, 4, 5, 3, 3, 5, and 5 applications, respectively.

3. ICRs for the Proposed Occupational Mix Adjustment to the Proposed FY 2014 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 2014 wage index. While the preamble 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 Pub. L. 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.3. of the preamble of this proposed rule discusses proposed revisions to the wage index based on hospital redesignations. As stated in that section, under section 1886(d)(10) of the Act, the MGCRB has the authority to accept short-term IPPS hospital applications requesting geographic reclassification for wage index or standardized payment amounts and to issue decisions on these requests by hospitals for geographic reclassification for purposes of payment under the IPPS.

The burden associated with this application process is the time and effort necessary for an IPPS hospital to complete and submit an application for reclassification to the MGCRB. While this requirement is subject to the PRA, the associated burden was previously approved under OCN 0938-0573. However, the information collection expired on December 31, 2011. We are currently seeking to reinstate the information collection and, as required by the PRA, will announce public notice and comment periods in the **Federal Register** separate from this rulemaking.

5. ICRs for Application for GME Resident Slots

The information collection requirements associated with the preservation of resident cap positions from closed hospitals, addressed under section V.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, Pub. L. 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 will no longer be using the 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 are seeking OMB approval for a revised information collection request using the same OMB control number (0938-1022). In the revised request we will add the 5 proposed claims-based measures, if finalized: (1) 30-day risk standardized COPD Readmission; (2) 30-day risk standardized COPD Mortality; (3) 30-day risk standardized Stroke Readmission; (4) 30-day risk standardized Stroke Mortality; and (5) AMI payment per Episode of Care. In addition, we are proposing to remove three chart-abstracted measures: (1) PN-3b: Blood Culture Performed in the Emergency Department Prior to First Antibiotic Received in the Hospital; (2) HF 1: Discharge Instructions; and (3) IMM-1: Immunization for Pneumonia. We are also proposing to remove seven chart-abstracted measures: (1) PN 3b: Blood Culture Performed in the Emergency Department Prior to First Antibiotic Received in the Hospital; (2) HF 1: Discharge Instructions; and (3) IMM 1: Immunization for Pneumonia; (4) AMI-2: Aspirin Prescribed at Discharge; (5) AMI-10: Statin Prescribed at Discharge; (6) HF-3: ACEI or ARB for LVSD; (7) SCIP-Inf-10: Surgery Patients with Perioperative Temperature Management and one structural measure, Systematic Clinical Database Registry for Stroke Care.

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. However, we do believe there will be a reduction in the burden associated with the removal of seven chart-abstracted measures and one structural measure. We estimate a reduction in burden associated with

data collection for chart- abstracted measures and associated forms. For the FY 2015 payment determination, we estimated that the burden for chart abstracted measures and associated forms for each hospital is 1,900 hours annually. For the FY 2016 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.

To support the proposed validation of two additional HAI measures, we also are proposing to add two new HAI Validation Templates for a total of four Validation Templates to be completed by hospitals selected for annual validation. To add these new Templates without increasing burden for the FY 2016 payment determination and future years, we are proposing to randomly assign one-half of the hospitals to submit templates for CLABSI and CAUTI validation and one-half of the hospitals to submit templates for MRSA and CDI validation. We believe this proposal would limit hospital burden because, of the 600 potential, total hospitals selected for annual validation, only up to 300 hospitals would be required to submit for MRSA and CDI validation and up to 300 hospitals would be required to submit for CLABSI and CAUTI validation. We estimate completion of the CLABSI and CAUTI validation templates will take approximately 20 hours each quarter. We estimate completion of the MRSA and CDI validation templates will take approximately 16 hours each quarter. Our proposed validation for the FY 2016 payment determination is for 3 quarters. Therefore, we estimate the total burden for HAI validation to be 60 hours for hospitals validated for CLABSI and CAUTI

and 48 hours for hospitals validated for MRSA and CDI. We estimate the total burden for validation templates for the 600 IQR participating hospitals selected for validation to be 32,000 hours.

Utilizing the estimates above, we estimate an overall reduction in burden from the FY 2015 estimate of 6.3 million hours annually to 5.9 million hours annually for the FY 2016 payment determination year. This burden estimate includes both newly added measures and measure sets and those for which we are requesting renewal. It excludes burden associated with the NHSN and HCAHPS measures, both of which are submitted under separate OMB numbers.

Previously, we required hospitals to provide 12 patient charts per quarter per hospital for HAI validation and 15 patient charts per quarter per hospital for validation of clinical process of care measures, for a total of 27 charts per quarter per hospital and 108 charts per year per hospital. For the FY 2016 payment determination and subsequent years, we are proposing to reduce this requirement by 12 charts per hospital per year.

In addition, we are proposing that the requirement to submit patient charts for validation of Hospital IQR Program data may be met by employing either of the following options each quarter: (1) a hospital may submit paper medical records, which is the form in which we have historically requested them; or (2) a hospital may securely transmit electronic versions of medical information for the FY 2016 payment determination and subsequent years. The intent of this proposal is to offer an additional mode through which hospitals may meet the requirement to submit patient charts. To support this proposal, which has the potential to reduce burden, cost, and environmental

impact, we also are proposing for the FY 2016 payment determination and subsequent years to reimburse hospitals for submission of electronic versions of medical information.

We are proposing a reimbursement rate of \$3.00 per chart taking into account the following considerations:

- Cost estimates are for retrieval of records and not for the maintenance of electronic health records systems, which are supported by CMS by other means.
- The activities associated with submitting an electronic version of a patient medical record include downloading, verifying, and copying records, which must be done for every record separately, and packaging and encrypting CDs or DVDs which must be done only once per DVD or CD sent.
- We assume that an average patient record will be 412 pages in length, that the average capacity of a DVD is 45,000 pages, and that all 27 records submitted in a quarter will fit on one DVD most of the time.
- Based on time and motion studies conducted by our contractor, we estimate that for records of average lengths, the minimum labor time is between 1 and 2 minutes per record.
- To acknowledge that some records may be so large that they require their own DVD, and that some systems may be slower than others, we also estimated a maximum labor of about 12 minutes per record.
- Averaging these two estimates, we achieve an average of less than 7 minutes of labor per record.

- The labor performed can be accomplished by a combination of staff equivalent to a GS-5 administrative secretary and a GS-5 information technologist, earning within the middle range for this grade, which in 2013 was \$38,616 per year. Assuming, 2,080 hours in a work year, we achieve an hourly rate of \$18.57 per hour.

- Applying OMB Circular A-76, we assumed overhead of 36.25 percent, for a fully burdened labor rate of \$25.30 per hour.

- The labor cost associated with each record is \$2.95.

- Supply costs are limited to DVDs and packaging. DVDs cost \$20 per 100, or 20 cents per DVD. A protective shipping container also costs 20 cents each.

- If a hospital submits all records on the same DVD, supply costs will equal approximately 1.4 cents per DVD. If a hospital submits one DVD per record, supply costs will equal approximately 40 cents per record. Averaging these costs results in 21 cents per record.

- Adding supplies to labor yields a total cost of \$3.16 per record.

- Rounding to the nearest whole dollar yields \$3.00 per record.

For the FY 2016 payment determination, we also are encouraging hospitals to voluntarily submit 16 measures electronically for the Hospital IQR Program in a manner that would permit eligible hospitals to align Hospital IQR Program requirements with some requirements under the Medicare EHR Incentive Program. We estimate that the total burden associated with the electronic 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 established in that final rule, beginning in

FY 2014, hospitals that are beyond their first year of meaningful use must electronically report a total of 16 clinical quality measures covering at least three domains using CEHRT that has been certified to the 2014 Edition certification criteria.

In accordance with the estimates in the Medicare EHR Incentive Program Stage 2 final rule, we believe it will take a hospital approximately 2 hours and 40 minutes to select, prepare, and electronically submit the 16 quality measures using CEHRT. In addition, in accordance with the Medicare EHR Incentive Program Stage 2 final rule, we believe an individual with commensurate skills will submit electronic clinical quality measures on behalf of the hospital at a rate of approximately \$59.00 per hour. Therefore, we believe it will cost a hospital approximately \$156.94 ($\59.00×2.66 hours) to report 16 clinical quality measures electronically in CY 2014 (77 FR 54133). Additional information about the chart abstraction burden is detailed in section XI.B.6. of the preamble to this proposed rule.

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) 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 the FY 2013 IPPS/LTCH PPS final rule, we implemented the PCHQR Program to comply with the statutory mandate, and in an effort to improve the quality of care for inpatient cancer patients. It is our aim and goal to encourage PCHs to furnish high quality care in a manner that is effective and meaningful,

while remaining mindful of the reporting burden created by the implementation of this new program. Therefore, we intend to reduce and avoid duplicative reporting efforts, whenever possible, by leveraging existing infrastructure.

In the FY 2013 IPPS/LTCH PPS final rule, for the FY 2014 program year, we adopted five NQF-endorsed quality measures, two of which were developed by the CDC and three of which were developed by the American College of Surgeons' Commission on Cancer (ACoS/CoC) and discussed the information collection requirements for these measures.

Topic	Quality Measures
Cancer-Specific Treatments	Adjuvant Chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer (NQF #0223)
	Combination Chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative Breast Cancer (NQF #0559)
	Adjuvant Hormonal Therapy (NQF #0220)
Healthcare Acquired Infections (HAIs)	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
	National Healthcare Safety Network (NHSN)Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)

In this proposed rule, we are proposing that PCHs submit data on 1 additional measure beginning with FY 2015 and 13 additional measures beginning with FY 2016 (as listed below), for a total of 19 measures (5 previously adopted plus 14 new measures).

Proposed New Measure Beginning with FY 2015
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Measure Domain	NQF Endorsement Number	Measure Name
Patient Safety	0753	Harmonized Procedure Specific Surgical

Proposed New Measures Beginning with FY 2016		
Measure Domain	NQF Endorsement Number	Measure Name
Surgical Care Improvement Project (SCIP)	0218	Surgery Patients Who Received Appropriate VTE Prophylaxis within 24 Hrs Prior to Surgery to 24 Hrs After Surgery End Time
	0284	Surgery Patients on Beta Blocker Therapy Prior to Admission Who Received a Beta Blocker during the Perioperative Period
	0453	Urinary Catheter Removed on Post-Operative Day 1 or Post-Operative Day 2 with Day Surgery Being Day Zero
	0527	Prophylactic Antibiotic Received Within 1 Hr Prior to Surgical Incision
	0528	Prophylactic Antibiotic Selection for Surgical Patients
	0529	Prophylactic Antibiotic Discontinued Within 24 Hrs After Surgery End Time
Clinical Process/Oncology Care	0380	Multiple Myeloma-Treatment with Bisphosphonates
	0382	Oncology-Radiation Dose Limits to Normal Tissues
	0383	Oncology: Plan of Care for Pain
	0384	Oncology: Pain Intensity
	0390	Prostate Cancer-Adjuvant Hormonal Therapy for High-Risk Patients
	0389	Prostate Cancer-Avoidance of Overuse Measure-Bone Scan for Staging Low-Risk Patients

Proposed New Measures Beginning with FY 2016		
Measure Domain	NQF Endorsement Number	Measure Name
Patient Engagement/Patient Experience of Care	0166	HCAHPS Patient Experience of Care Survey

We believe that our proposal to require PCHs to submit data on these additional proposed measures will not prove burdensome. PCHs have familiarity with and experience reporting quality data to CMS during the initial year of the PCHQR program. Therefore, we believe that because a majority of PCHs have demonstrated the ability to report these measures, the reporting requirements we are proposing will not significantly impact PCHs.

The anticipated burden on these PCHs consists of the following: training of appropriate staff members on how to use the NHSN for the reporting of the proposed SSI measure, CMS (QualityNet) for the reporting of the proposed SCIP measures, and the CMS Web Measures Tool for the reporting of the proposed clinical process/oncology care measures; the time required for collection and aggregation of data; and the time required for reporting of the data by the PCH's representative; and the time required to participate and collect HCAHPS data. We have taken into account all these elements in our burden calculation.

We estimate that 11 PCHs will submit data on approximately 63,468 cancer cases annually. It will require, on average, 9.5 hours for a PCH to abstract the information from medical records and submit such information for each case. The time required to administer the HCAHPS is likely to be lower than the time for chart abstraction.

However, the same method was used to ensure a high-end estimate so that facilities will

not experience a higher burden than estimated. In addition, sampling was not considered for this reason. Therefore, this burden represents the “worst-case scenario” of what would be required of each facility. Based on these assumptions, we estimate that the annual hourly burden on each PCH for the collection, submission, and training of personnel for submitting all quality measure data would be approximately 54,822 hours.

8. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section V.H. of the preamble of this proposed rule, we discuss proposed requirements for the Hospital VBP Program. Specifically, in this proposed rule, we are proposing to adopt three new measures for the FY 2016 Hospital VBP Program, including IMM-2: Influenza Immunization and CAUTI, and the Surgical Site Infection (SSI) measure, stratified as SSI-Colon and SSI-Abdominal Hysterectomy. We also are proposing to adopt CLABSI, a measure that we finalized for FY 2015 but did not readopt at that time.

In addition, we are proposing to adopt the three 30-day mortality measures and the AHRQ PSI composite measure for FYs 2017 through 2019 program determinations.

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

In section IX.C. of the preamble of the proposed rule, we discuss the requirements for the LTCHQR Program, established by section 1886(m)(5) of the Act, which was added by section 3004 of the Affordable Care Act.

In the FY 2013 IPPS/LTCH PPS final rule, we finalized the adoption of five quality measures for use in the LTCHQR Program for the FY 2016 payment update determination and subsequent payment determinations. These measures are: (1) NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138); (2) NHSN Central Line-Associated Blood Stream Infection (CLABSI) Outcome Measure (NQF #0139); (3) Application of Percent of Residents with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678); (4) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680); and (5) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53630 through 53631) we finalized that for Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431), LTCHs should begin to submit data from January 1, 2014 through December 31, 2014 (CY 2014) for the FY 2016 payment determination. However, there is unique seasonality in the timing of influenza activity each year. To account for this, we are proposing that, for the LTCHQR Program, this measure *only* (NQF #0431) have its own reporting period to align with the influenza vaccination season, which is defined by the CDC as October 1st (or when the vaccine becomes available) through March 31st.

This proposed change would allow LTCHs to collect and report data on influenza vaccination for the entirety of the 2014-2015 influenza season for the FY 2016 payment determination. Similarly, this change would allow LTCHs to collect and report data on influenza vaccination for the entirety of future influenza seasons for subsequent payment determinations.

While LTCHs can enter information in NHSN at any point during the influenza season for NQF #0431, data submission is only required once per year, unlike the other measures finalized for the LTCHQR Program that utilize CDC/NHSN (CAUTI measure NQF #0138 and CLABSI measure NQF #0139). LTCHs can choose to submit influenza vaccination data on an incremental basis (for example, on a monthly basis), or just once a year. The final deadlines associated with submitting data, approximately 45 days after the end of the data collection timeframe for the FY 2016 payment determination, remain consistent across measures.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627), we finalized that for NQF #0680, Percentage of Residents or Patients Who Were Assessed and Appropriately Give the Seasonal Influenza Vaccine (Short-Stay), LTCHs should begin to collect and submit data on January 1, 2014 through December 31, 2014 (CY 2014) for the FY 2016 payment determination. This measure, stewarded by CMS, will be collected using items included in the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (Version 2.01).¹⁸⁰ On February 1, 2013, we solicited public

¹⁸⁰The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938-1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956, published April 12, 2013, solicits public comment on additions and updates to the LTCH

comment on this information collection request (78 FR 7433 through 7434). On April 12, 2013, we published a 30-day notice to solicit public comment on this information collection request (78 FR 21955 through 21956). Later in 2013, we will release the final data submission specifications and updated LTCHQR Program Manual for the LTCH CARE Data Set (Version 2.01) containing items related to NQF #0680.

In order to allow time and opportunity for LTCHs and vendors to participate in CMS-sponsored training activities pertaining to the implementation of the LTCH CARE Data Set (Version 2.01), as well as time to plan for and incorporate changes into their data collection and entry systems, we are proposing to revise the previously finalized start date of January 1, 2014 for reporting of this measure to April 1, 2014. For CY 2014, data collection will continue through December 31, 2014. We are proposing that data for admissions and discharges for an LTCH during April 1, 2014 through December 31, 2014 will be used for the FY 2016 payment determination. We are also proposing that data for January 1, 2015 through December 31, 2015 (CY 2015) will be used for the FY 2017 payment determination. Thereafter, data for January 1 through December 31 of each year will be used for subsequent payment determinations.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51748 through 51750), we adopted an application of NQF #0678 Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay) for the FY 2014 payment determination, and retained this application of the measure in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53619) for the FY 2015 payment determination and subsequent payment

determinations. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51748 through 51750) for a discussion of the rationale, data collection methods, and submission methods finalized for this measure for the FY 2014 payment determination and subsequent payment determinations, and for references to the description and specifications of this measure.

At the time we completed our work on the FY 2013 IPPS/LTCH PPS final rule, we were only able to adopt an application of the endorsed measure in our final version of the FY 2013 rule. NQF #0678 was subsequently ratified by the NQF Board of Directors for expansion to the LTCH setting on August 1, 2012.^{181,182} Because NQF #0678 has received endorsement for the LTCH setting, we are now proposing to adopt the updated measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) for the FY 2015 payment determination and subsequent payment determinations. This measure will continue to be collected using items included in the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (Version 1.01) for CY 2013 and first quarter of CY 2014. Further, starting April 1, 2014, this measure is proposed to be collected using items included in the LTCH CARE Data Set Version 2.01.¹⁸³

¹⁸¹National Quality Forum, Consensus Standards Approval Committee Wednesday, July 11, 2012. Transcript. Available on the Web site at:

<http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=71612>.

¹⁸²Press Release: NQF Removes Time-Limited Endorsement Status for 13 Measures, Measures Now Have Endorsed Status. August 1, 2012. Available on the Web site at:

http://www.qualityforum.org/News_And_Resources/Press_Releases/2012/NQF_Removes_Time-Limited_Endorsement_for_13_Measures;_Measures_Now_Have_Endorsed_Status.aspx

¹⁸³The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938-1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956, published April 12, 2013, solicits public comment on additions and updates to the LTCH

The changes we have described to the reporting periods for two measures (NQF #0431 and NQF #0680) and the updated NQF-endorsed pressure ulcer measure (NQF #0678) are not new measures. We do not believe that these changes will result in any additional reporting burden on LTCHs.

In section IX.C.8.b. of the preamble of this proposed rule, we are proposing three additional measures for use in the LTCHQR Program for the FY 2017 payment determination and subsequent payment determinations. These proposed measures are: (1) National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus Aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); (2) National Healthcare 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 2017 payment determination, in addition to the CAUTI, CLABSI, and Influenza Vaccination Coverage among Healthcare Personnel measures, we are proposing that LTCHs would report quality data related to the MRSA and CDI measures to the CDC's NHSN data submission system (<http://www.cdc.gov/nhsn/>). The NHSN is a secure, Internet-based surveillance system that is maintained and managed by CDC.

There are currently approximately 440 LTCHs in operation in the United States and, according to the CDC, over 413 of these LTCHs already submit HAI data to NHSN. We believe that any burden increase related to complying with the LTCHQR Program

requirements for submission of the MRSA and CDI measures will be minimal for those LTCHs that are already familiar with the NHSN submission process, for several reasons. First, these LTCHs will have already completed initial setup and become familiar with reporting data in the NHSN system due to the requirement to report CAUTI and CLABSI measures beginning on October 1, 2012 for the FY 2014 payment determination and continuing reporting for CY 2013 for the FY 2015 payment determination. Second, as of January 2013, there are approximately 42 LTCHs reporting MRSA measure data and approximately 46 facilities reporting *Clostridium Difficile* measure data into NHSN. Third, there has been no change in the registration and training requirements for providers that are already acquainted with the NHSN. Therefore, we believe that most LTCH providers should be very comfortable using the NHSN for continuing with the reporting of data for CAUTI and CLABSI measures for CY 2014 for FY 2016 payment update determination. Further, we believe that by the time (October 1, 2014 or when vaccine becomes available) reporting for NQF #0431 begins for the FY 2016 payment determination, a vast majority of LTCH providers should be very comfortable using the NHSN.

The most significant burden associated with the quality measures is the time and effort associated with collecting and submitting the data on the CAUTI, CLABSI, Influenza Vaccination Coverage among Healthcare Personnel, MRSA, and *Clostridium Difficile* measures to NHSN for LTCHs that are not currently reporting any measures data.

There are currently approximately 440 LTCHs in the United States paid under the CMS LTCH PPS. We estimate that each LTCH will execute approximately 12 NHSN submissions (6 CAUTI events and 6 CLABSI events) per month (144 events per LTCH annually). This equates to a total of approximately 63,360 submissions of HAI data to NHSN from all LTCHs per year. We estimate that each NHSN assessment will take approximately 25 minutes to complete. This time estimate consists of 10 minutes of clinical time (for example, nursing time) needed to collect the clinical data and 15 minutes of clerical time necessary to enter the data into the NHSN database. Based on this estimate, we expect each LTCH will expend 300 minutes (5 hours) per month and 60 hours per year reporting to NHSN.

Therefore, the total estimated annual hourly burden on all LTCHs in the United States for reporting to NHSN is 26,400 hours. The estimated cost per submission is estimated at \$12.07. These costs are estimated using an hourly wage for a registered nurse of \$41.59 and a medical billing clerk/data entry person of \$20.57 (U.S. Bureau of Labor Statistics data). Therefore, we estimate that the annual cost per each LTCH will be \$1,739 and the total yearly cost to all LTCHs for the submission of CAUTI and CLABSI data to NHSN will be \$765,019¹⁸⁴. While these requirements are subject to the Paperwork Reduction Act, we believe the associated burden hours are accounted for in the information collection request currently approved under OMB control number 0920-0666.

¹⁸⁴ Nursing Time—24 hours @ \$41.59 per hour = \$998.16; \$998.16 x 440 LTCHs = approximately \$439,140; Administrative Time—36 hours @ \$20.57 per hour = \$740.52; \$740.52 x 440 LTCHs = approximately \$325,829; TOTAL = \$439,140 + \$325,829 = \$765,019.

We estimate that each LTCH will execute only one NHSN submission per year (total number of vaccinations) as required by the CDC for the NHSN-reported Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431). This equates to a total of approximately 440 submissions of vaccination data to NHSN from all LTCHs per year. We estimate that each NHSN submission will take approximately 15 minutes to complete. This time estimate consists of 15 minutes of clerical time necessary to enter the data into the NHSN database. Based on this estimate, we expect each LTCH will expend 15 minutes per year reporting to NHSN. Therefore, the total estimated annual burden on all LTCHs in the United States for reporting this measure to NHSN is 110 hours. The estimated cost per submission is estimated at \$3.90. The cost is estimated using an hourly wage for a medical billing clerk/data entry person of \$15.59 (U.S. Bureau of Labor and Statistics data). We estimate the annual cost per each LTCH will be \$3.90 and the total yearly cost to all LTCHs for the submission of the Influenza Coverage Among Healthcare Personnel measure (NQF #0431) will be \$1,715.

Similar to the submission of CAUTI and CLABSI data, we estimate that each LTCH will execute approximately 12 NHSN submissions (6 MRSA events and 6 *C. Difficile* events) per month (144 events per LTCH annually). This equates to a total of approximately 63,648 submissions of HAI data to NHSN from all LTCHs per year. We estimate that each NHSN assessment will take approximately 25 minutes to complete. This time estimate consists of 10 minutes of clinical time (for example, nursing time) needed to collect the clinical data and 15 minutes of clerical time necessary to enter the

data into the NHSN. Based on this estimate, we expect each LTCH will expend 300 minutes (5 hours) per month and 60 hours per year reporting to NHSN.

Therefore, the total estimated annual hourly burden on all LTCHs in the United States for reporting to NHSN is 26,400 hours. The estimated cost per submission is estimated at \$12.07. These costs are estimated using an hourly wage for a registered nurse of \$41.59 and a medical billing clerk/data entry person of \$20.57 (U.S. Bureau of Labor Statistics data). Therefore, we estimate that the annual cost per each LTCH will be \$1,739 and the total yearly cost to all LTCHs for the submission of CAUTI and CLABSI data to NHSN will be \$765,019.¹⁸⁵

We estimate that the total annual cost to all LTCHs for submission of NHSN data will be \$1,531,753 or \$3,481 per LTCH annually.

We are proposing to adopt the updated measure NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) for the FY 2015 payment determination and subsequent payment determinations. This change would not alter the data collection, data submission, or burden finalized in the FY 2013 IPPS/LTCH PPS final rule and PRA package for LTCH CARE Data Set (Version 1.01)¹⁸⁶ since there have been no changes to the data elements, data submission system (QIES ASAP) and technical submission specifications for the LTCH CARE Data Set used for this measure for CY 2013 and first quarter of CY 2014. The only difference between the previously

¹⁸⁵ Nursing Time—24 hours @ \$41.59 per hour = \$998.16; \$998.16 x 440 LTCHs = approximately \$439,140; Administrative Time—36 hours @ \$20.57 per hour = \$740.52; \$740.52 x 440 LTCHs = approximately \$325,829; TOTAL = \$439,140 + \$325,829 = \$765,019.

¹⁸⁶The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938-1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956, published April 12, 2013, solicits public comment on additions and updates to the LTCH CARE Data Set. <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html>.

finalized measure and the proposed measure is the change in name and NQF-endorsed expansion of this measure to the LTCH (and IRF) patient populations in addition to Skilled Nursing Facility/Nursing Home Short-Stay residents. Therefore, the burden on providers for reporting of data for NQF #0678 remains unchanged.¹⁸⁷

In order to allow time and opportunity for LTCHs and vendors to participate in CMS-sponsored training activities pertaining to the implementation of the LTCH CARE Data Set (Version 2.01), as well as time to plan for and incorporate changes into their data collection and entry systems, we are proposing to revise the previously finalized start date for Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680) of January 1, 2014 to April 1, 2014. For CY 2014, data collection will continue through December 31, 2014. We are proposing that data for admissions and discharges for an LTCH during April 1, 2014 through December 31, 2014 will be used for the FY 2016 payment determination. Three items will be included on the LTCH CARE Data Set Version 2.01 for this measure. We have also removed several items from the administrative, functional status, and skin conditions sections of the LTCH CARE Data Set Version 1.01 to create the LTCH CARE Data Set Version 2.01¹⁸⁸, so we anticipate that increase in burden due to the addition of items for NQF #0680 will be minimal. Later in 2013, we

¹⁸⁷The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938-1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956, published April 12, 2013, solicits public comment on additions and updates to the LTCH CARE Data Set. <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html>.

¹⁸⁸The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938-1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956 published April 12, 2013 solicits public comment on additions and updates to the LTCH CARE Data Set. <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html>.

will release the final data submission specifications and updated LTCHQR Program Manual for the LTCH CARE Data Set (Version 2.01) containing items related to NQF #0680.

As previously mentioned, there are currently approximately 440 LTCHs in the United States paid under the LTCH PPS. We estimate that the total number of LTCH discharges per year is 202,050¹⁸⁹ (134,700 Medicare beneficiaries and 67,350 non-Medicare beneficiaries). Therefore, the total number of discharges estimated for each LTCH is 457 annually and 38 monthly. We estimate that the total number of LTCH CARE Data Sets (LCDS) submitted by all LTCHs per year is 404,100 which equates to a total of 914 total LCDS submissions for each LTCH on an annual basis. The average number of LCDS submitted by each LTCH on a monthly basis is 76.

We estimate that the total time required to complete an LCDS per patient to be approximately 32 minutes,¹⁹⁰ which includes 11 minutes for the admission assessment, 11 minutes for the discharge assessment and 10 minutes for data entry. Therefore, each LTCH will spend approximately 1,216 minutes per month, or approximately 20.27 hours per month submitting the LCDS. We expect each LTCH to spend approximately 243 hours per year engaged in data collection and submission of the LCDS. Therefore, the total estimated burden to all LTCHs for reporting the LCDS is 106,920 hours per year.¹⁹¹

¹⁸⁹ MedPAC Report to Congress, March 2012, page 261. Available at: http://www.medpac.gov/documents/Mar12_EntireReport.pdf.

¹⁹⁰ This time estimate includes the time required to complete both the required and voluntary questions on the LTCH CARE Data Set.

¹⁹¹ 32 minutes/form x 38 forms per LTCH per month = 1,216 minutes per LTCH per month; 1,216 minutes / 60 minutes per hour = 20.27 hours per LTCH per month; 20.27 hours per LTCH per month x 12 months/year = 243 hours per each LTCH/year; 243 hours/each LTCH per year x 440 LTCHs in U.S. = 106,920 hrs/all LTCHs/year.

We estimate that the total annual cost to each LTCH will be approximately \$6,751 to submit the LCDS. That estimate is based on the hourly wage for a registered nurse to complete the LCDS at \$33.23 per hour and for an administrative assistant to transmit the LCDS at \$15.59.¹⁹² As previously stated, we estimate a total of 457 annual discharges (914 LCDS submissions) for each LTCH on an annual basis and that it will take 22 minutes total (11 minutes each) to complete the admissions and discharge assessments per patient. That is, 10,054 minutes of time, or 167.57 hours, that a registered nurse in each LTCH will spend completing the LCDS annually. For a registered nurse to spend 167.57 hours per year completing the LCSDs at a rate of \$33.23 per hour, the associated cost for each LTCH will be approximately \$5,568 and, for approximately 440 LTCHs, a total of \$2,449,920 nursing wages per year.

Similarly, we previously estimated that it will take approximately 10 minutes per patient for data entry by an administrative assistant, resulting in approximately 4,570 minutes that each LTCH will spend transmitting the LCDS per year, or 76 administrative hours per year. At a rate of \$15.59, that equates to approximately \$1,185 for each LTCH and \$521,330 for all LTCHs per year. Therefore, we estimate that the total annualized cost to each LTCH will be approximately \$6,751 and \$2,971,250 to all LTCHs.

While these requirements are subject to the Paperwork Reduction Act, we believe the associated burden hours are accounted for in the information collection request currently under consideration for approval under OMB control number 0920-0666.

¹⁹² The mean hourly wage of \$15.59 per hour for a Medical Secretary was obtained from the U.S. Bureau of Labor Statistics. We refer readers to: <http://www.bls.gov/oes/current/oes436013.htm>.

We also are proposing the All-Cause Unplanned Readmission Measure for 30 days Post Discharge from Long-Term Care Hospitals which we do not believe would increase LTCH provider burden because it is a Medicare FFS claims-based measure and does not require reporting of data other than submission of Medicare FFS claims data (LTCHs submit these data to CMS for payment purposes).

In section IX.C.8.c. of the preamble of this proposed rule, we are proposing one additional quality measure for use in the LTCHQR Program for the FY 2018 payment determination and subsequent payment determinations. We are proposing that LTCHs report data for an application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure beginning January 1, 2016. It is our intent to foster alignment between measures by expanding preexisting data collection and submission methods to reduce the administrative burden related to data collection and submission. This measure will be collected using the LTCH CARE Data Set. The items used for the proposed application of the NQF #0674 will be based on the items from the Minimum Data Set (MDS) 3.0, version 1.13.0 (1/17/13) items J1800 (Any Falls Since Admission/Entry or Reentry or Prior Assessment) and J1900A, B and C (Number of Falls (A: with no injury, B: with injury (except major), C with Major injury)) since Admission/Entry or Reentry or Prior Assessment), available at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIMDS30TechnicalInformation.html>. The calculation of the proposed application of the measure will be based on item J1900C, Number of Falls with major injury, since admission/entry or reentry or prior assessment.

The specifications and data elements for NQF #0674 are available in the MDS 3.0

Quality Measures User's Manual Version 6.0 available on our Web site at:

<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html>.

We believe that the initial registration for use of the LTCH CARE Data Set, along with any necessary training, occurred for most LTCHs prior to the reporting of the Pressure Ulcer measure which began on October 1, 2012. Therefore, we believe the burden will be minimal related to the addition of this proposed quality measure into the LTCH CARE Data Set.

Therefore, we do not expect the addition of the NQF #0674 Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) measure to increase the burden substantially. Further, LTCHs will have been reporting data for the LTCHQR Program using the LTCH CARE Data Set for more than 2 years by the time the data collection begins for this measure.

At this time, we have not completed the revision of the information collection instrument (LTCH CARE Data Set) that LTCHs would be required to submit to report the proposed measure (NQF #0674) for the FY 2018 payment determination and subsequent payment determinations. Because the forms are still under development, we cannot make a complete burden estimate at this time for the inclusion of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) measure in the LTCH CARE Data Set. Once the forms are available, we will prepare and submit the required information collection request, which will fully set forth the anticipated burden

to LTCHs as a result of the new data items that need to be added to the LTCH CARE Data Set.

10. ICRs for the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

In section VIII.F. of the preamble of the FY 2013 IPPS/LTCH PPS final rule, we discussed the implementation of the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program pursuant to the Secretary's authority under section 1886(s)(4) of the Act. We previously adopted six measures for the FY 2014 IPFQR Program payment determination and subsequent years. In section IX.D. of the preamble of this proposed rule, we are proposing that, for the FY 2016 payment determination and subsequent years, IPFs must submit aggregate data on three additional measures, for a total of nine measures. In addition, we are proposing a request for voluntary information.

To reduce the burden on IPFs, we are not proposing to make changes to the administrative, reporting or submission requirements for the existing six measures previously finalized in last year's rule (77 FR 53654 through 53657). However, there will be new reporting and submission requirements associated with the three proposed additional measures and the proposed request for voluntary information for the FY 2016 payment determination and subsequent years.

We believe that the proposed measures will help improve the quality of care provided by IPFs as we work to make quality data more transparent to the public. As required by the Act, we will share the information collected under the IPFQR Program with the public. These data will be displayed on the CMS Web site.

We have estimated the burden associated with IPFs complying with the requirements of the IPFQR Program. In our burden estimate calculation, we have included the time that would be spent for: (1) the submission of voluntary information; (2) chart abstraction; and (3) training personnel on the collection of chart-abstracted data, aggregation of the data, and for protocols to submit the aggregate-level data through QualityNet. We estimate that the annual hourly burden on each IPF for the collection, submission, and training of personnel for submitting all quality measures, including 30 minutes needed for the voluntary submission, is approximately 1,030 hours in a year for each IPF. Therefore, the average hourly burden on each IPF is approximately 86 hours per month. At this time, we have no way to estimate how many IPFs will participate in the program. Therefore, we cannot estimate the aggregate impact.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS-1599-P

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov

C. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the “DATES” section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects**42 CFR Part 412**

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant program—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons stated in the preamble of this proposed rule, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR chapter IV as follows:

**PART 412--PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT
HOSPITAL SERVICES**

1. The authority citation for Part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), and sec. 124 of Pub. L. 106-113 (113 Stat. 1501A-332).

2. Section 412.3 is added to read as follows:

§ 412.3 Admissions.

(a) For purposes of payment under Medicare Part A, an individual is considered an inpatient of a hospital, including a critical access hospital, if formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner in accordance with paragraph (b) of this section and §§ 482.24(c), 482.12(c), and 485.638(a)(4)(iii) of this chapter for a critical access hospital.

(b) The order must be furnished by a qualified and licensed practitioner who has admitting privileges at the hospital as permitted by State law, and who is responsible for the inpatient care of the patient at the hospital. The practitioner may not delegate the decision (order) to another individual who is not responsible for the care of that patient, is not authorized by the State to admit patients, or has not been granted admitting privileges applicable to that patient by the hospital's medical staff.

(c) Except as specified in paragraph (c)(2) of this section—

(1) When a patient enters a hospital for a surgical procedure not specified by Medicare as inpatient only under § 419.22(n) of this chapter, a diagnostic test, or any other treatment, and the physician expects to keep the patient in the hospital for only a limited period of time that does not cross 2 midnights, the services are generally inappropriate for inpatient payment under Medicare Part A, regardless of the hour that the patient came to the hospital or whether the patient used a bed. Surgical procedures, diagnostic tests, and other treatment are generally appropriate for inpatient hospital payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights. The expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs

and symptoms, current medical needs, and the risk of an adverse event. The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration.

(2) If an unforeseen circumstance, such as a beneficiary's death or transfer, result 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.

3. Section 412.46 is revised to read as follows:

§ 412.46 Medical review requirements.

(a) Physician acknowledgement. (1) Basis. Because payment under the prospective payment system is based in part on each patient's principal and secondary diagnoses and major procedures performed, as evidenced by the physician's entries in the patient's medical record, physicians must complete an acknowledgement statement to this effect.

(2) Content of physician acknowledgement statement. When a claim is submitted, the hospital must have on file a signed and dated acknowledgement from the attending physician that the physician has received the following notice:

Notice to Physicians: Medicare payment to hospitals is based in part on each patient's principal and secondary diagnoses and the major procedures performed on the patient, as attested to by the patient's attending physician by virtue of his or her signature in the medical record. Anyone who misrepresents, falsifies, or conceals essential information

required for payment of Federal funds, may be subject to fine, imprisonment, or civil penalty under applicable Federal laws.

(3) Completion of acknowledgement. The acknowledgement must be completed by the physician at the time that the physician is granted admitting privileges at the hospital, or before or at the time the physician admits his or her first patient. Existing acknowledgements signed by physicians already on staff remain in effect as long as the physician has admitting privileges at the hospital.

(b) Physician's order and certification regarding medical necessity. No presumptive weight shall be assigned to the physician's order under § 412.3 or the physician's certification under subpart B of part 424 of the chapter in determining the medical necessity of inpatient hospital services under section 1862(a)(1) of the Act. A physician's order or certification will be evaluated in the context of the evidence in the medical record.

4. Section 412.64 is amended—

a. By adding paragraph (d)(1)(v).

b. In paragraph (h)(4) introductory text, by removing the date “October 1, 2013” and adding in its place the date “October 1, 2014”.

c. In paragraph (h)(4)(vi), by removing the date “October 1, 2013” and adding in its place the date “October 1, 2014”.

The addition reads as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *

(1) * * *

(v) For fiscal year 2014, the percentage increase in the market basket index less a multifactor productivity adjustment (as determined by CMS) and less 0.3 percentage point for prospective payment hospitals (as defined in § 413.40(a) of this chapter) for hospitals in all areas.

* * * * *

§412.101 [Amended]

5. Section 412.101 is amended—

a. In paragraph (b)(2)(i), by removing the term “FY 2013” and adding in its place the term “FY 2014.”

b. In paragraph (b)(2)(ii), by removing the phrase “For FY 2011 and FY 2012,” and adding in its place the phrase “For FY 2011, FY 2012, and FY 2013,”.

c. In paragraph (c)(1), by removing the term “FY 2013” and adding in its place the term “FY 2014.”

d. In paragraph (c)(2) introductory text, by removing the phrase “For FY 2011 and FY 2012,” and adding in its place the phrase “For FY 2011, FY 2012, and FY 2013,”.

e. In paragraph (d), by removing the term “FY 2013” and adding in its place the term “FY 2014.”

6. Section 412.106 is amended by adding paragraphs (f), (g), and (h) to read as follows:

§412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(f) Empirically justified Medicare DSH payments. Effective for discharges on or after October 1, 2013, the amounts otherwise payable to a hospital under paragraph (d) of this section are reduced by 75 percent.

(g) Additional payment for uncompensated care. (1) Payment rules. Hospitals that qualify for payments under this section for fiscal year 2014 and each subsequent year, will receive an additional amount equal to the product of the following three factors:

(i) Factor 1. For FY 2014 and each subsequent fiscal year, a factor equal to the difference between:

(A) The most recently available estimates, as calculated by CMS' Office of the Actuary, of the aggregate amount of payments that would be made to such hospitals under paragraphs (a) through (e) of this section if paragraph (f) of this section did not apply for the fiscal year; and

(B) The most recently available estimates, as calculated by CMS' Office of the Actuary, of the aggregate amount of payments that are made to such hospitals pursuant to paragraph (f) of this section for the fiscal year.

(ii) Factor 2. 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 (and subtracting from the factor 0.1 percentage point for fiscal year 2014 and 0.2 percentage point for each of fiscal years 2015, 2016, and 2017), as determined by comparing:

(A) 18 percent, the percent of such individuals who are uninsured in 2013, based on the March 20, 2010 estimate of the “Insured Share of the Nonelderly Population Including All Residents” by the Congressional Budget Office; and

(B) The percent of such individuals who are uninsured in the applicable fiscal year, based on the most recent estimate of the “Insured Share of the Nonelderly Population Including All Residents” by the Congressional Budget Office available at the time of development of the annual final rule for the hospital inpatient prospective payment system.

(iii) Factor 3. A factor equal to the percent, for each inpatient prospective payment system hospital, that represents the quotient of:

(A) The amount of uncompensated care for such hospital as estimated by CMS.

(B) The aggregate amount of uncompensated care as estimated by CMS for all hospitals that are estimated to receive a payment under this section.

(C) Beginning with fiscal year 2014, 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.

(iv) The final values for each of the three factors are determined for each fiscal year at the time of development of the annual final rule for the hospital inpatient prospective payment system, and these values are used for both interim and final payment determinations.

(2) Preclusion of administrative and judicial review. There is no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the following:

(i) Any estimate of the Secretary for the purpose of determining the factors in section paragraph (g)(1) of this section; and

(ii) Any period selected by the Secretary for such purposes.

(h) Manner and timing of payments. (1) Interim payments are made on a periodic basis during the payment year to each hospital that is estimated to be eligible for payments under this section at the time of the annual final rule for the hospital inpatient prospective payment system, subject to the final determination of eligibility at the time of cost report settlement for each hospital.

(2) Final payment determinations are made at the time of cost report settlement, based on the final determination of each hospital's eligibility for payment under this section.

§412.108 [Amended]

7. Section 412.108 is amended—

a. In paragraph (a)(1) introductory text, by removing the phrase “before October 1, 2012” and adding in its place the phrase “before October 1, 2013”.

b. In paragraph (c)(2)(iii) introductory text, by removing the phrase “before October 1, 2012” and adding in its place the phrase “before October 1, 2013”.

8. Section 412.140 is amended by revising the section heading and paragraphs (a)(3) introductory text and (b) and adding paragraph (f) to read as follows:

§ 412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Reporting (IQR) Program.

(a) * * *

(3) Submit a completed Notice of Participation Form to CMS if the hospital is participating in the program for the first time, has previously withdrawn from the program and would like to participate again, or has received a new CMS Certification Number (CCN).

* * * * *

(b) Withdrawal from the Hospital IQR Program. CMS will accept Hospital IQR Program withdrawal forms from hospitals on or before—

(1) Prior to the FY 2016 payment determination, August 15 of the fiscal year preceding the fiscal year for which a Hospital IQR determination will be made.

(2) Beginning with the FY 2016 payment determination, May 15 of the fiscal year preceding the fiscal year for which a Hospital IQR payment determination will be made.

* * * * *

(f) Patient experience of care data (HCAHPS survey). HCAHPS is the Hospital Consumer Assessment of Healthcare Providers and Systems survey that measures patient experience of care after a recent hospital stay.

(1) Approved HCAHPS survey vendors and self-administering hospitals must fully comply with all HCAHPS oversight activities, including allowing CMS and its HCAHPS Project Team to perform site visits at the hospitals' and survey vendors' company locations.

(2) CMS approves an application for an entity to administer the HCAHPS survey as an approved HCAHPS survey vendor on behalf of one or more hospitals when an applicant has met the Minimum Survey Requirements and Rules of Participation listed in the most recently available version of the HCAHPS Quality Assurance Guidelines, available on the official HCAHPS On-Line Web site, and agree to comply with the survey administration protocols contained in the most recently available version of the HCAHPS Quality Assurance Guidelines and as updated through HCAHPS Bulletins and announcements on the official HCAHPS On-Line Web site. An entity must be an approved HCAHPS survey vendor in order to administer and submit HCAHPS data to CMS on behalf of one or more hospitals.

9. Section 412.150 is amended by adding paragraph (c) to read as follows:

§ 412.150 Basis and scope of subpart.

* * * * *

(c) Section 1886(p) of the Act requires the Secretary to establish an adjustment to hospital payments for hospital-acquired conditions, or a Hospital-Acquired Condition

Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions, effective for discharges beginning on October 1, 2014. The rules for determining the payment adjustment under the Hospital-Acquired Condition Reduction Program are specified in §§412.170 and 412.172.

10. Section 412.152 is amended by revising the definition of “Base operating DRG payment amount” to read as follows:

§ 412.152 Definitions for the Hospital Readmissions Reduction Program.

* * * * *

Base operating DRG payment amount is the wage-adjusted DRG operating payment plus any applicable new technology add-on payments under subpart F of this part. This amount is determined without regard to any payment adjustments under the Hospital Value-Based Purchasing Program, as specified under § 412.162. This amount does not include any additional payments for indirect medical education under § 412.105, the treatment of a disproportionate share of low-income patients under § 412.106, outliers under subpart F of this part, and a low volume of discharges under § 412.101. With respect to a sole community hospital that receives payments under § 412.92(d) or a Medicare-dependent, small rural hospital that receives payments under § 412.108(c) for FY 2013, 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. With respect to a hospital that is paid under section 1814(b)(3) of the Act, this amount is an amount equal to the wage adjusted DRG payment amount plus new technology payments

that would be paid to such hospitals, absent the provisions of section 1814(b)(3) of the Act.

* * * * *

11. Section 412.154 is amended by revising paragraph (d)(2) to read as follows:

§ 412.154 Payment adjustments under the Hospital Readmissions Reduction Program.

* * * * *

(d) * * *

(2)(i) Maryland’s annual report to the Secretary and request for exemption from the Hospital Readmissions Reduction Program must be resubmitted and reconsidered annually.

(ii) Beginning with the FY 2015 program year—

(A) The State must submit a preliminary report to CMS no later than January 15 of each year for the Secretary to consider, through the annual proposed rule, its exemption from the Hospital Readmissions Reduction Program for the upcoming Federal fiscal year.

(B) The State must submit a final report to CMS no later than June 1 of each year for the Secretary to consider, through the annual final rule, its exemption from the Hospital Readmissions Reduction Program in the upcoming Federal fiscal year.

(C) The reports required under paragraphs (d)(2)(ii)(A) and (B) of this section must include information as specified by CMS.

* * * * *

12. Section 412.160 is amended by revising the definitions of “Achievement threshold” and “Benchmark” to read as follows:

§ 412.160 Definitions for the Hospital Value-Based Purchasing (VBP) Program

* * * * *

Achievement threshold (or achievement performance standard) means the median (50th percentile) of hospital performance on a measure during a baseline period with respect to a fiscal year, for Hospital VBP Program measures other than the Medicare Spending per Beneficiary measure, and the (50th percentile) of hospital performance on a measure during the performance period with respect to a fiscal year, for the Medicare Spending per Beneficiary measure.

* * * * *

Benchmark means the arithmetic mean of the top decile of hospital performance on a measure during the baseline period with respect to a fiscal year, for Hospital VBP Program measures other than the Medicare Spending per Beneficiary measure, and the arithmetic mean of the top decile of hospital performance on a measure during the performance period with respect to a fiscal year, for the Medicare Spending per Beneficiary measure.

* * * * *

13. An undesignated center heading and §§ 412.170 and 412.172 are added to subpart I to read as follows:

Payment Adjustments under the Hospital-Acquired Condition Reduction Program

§ 412.170 Definitions for the Hospital-Acquired Condition Reduction Program.

As used in this section and § 412.172, the following definitions apply:

Applicable hospital is a hospital described in section 1886(d)(1)(B) of the Act (including a hospital in Maryland that is paid under the waiver 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).

Applicable period is, with respect to a fiscal year, the 2-year period (specified by the Secretary) from which data are collected in order to calculate the total hospital-acquired condition score under the Hospital-Acquired Condition Reduction Program.

Hospital-acquired condition is 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.

§ 412.172 Payment adjustments under the Hospital-Acquired Condition Reduction Program.

(a) Scope. This section sets forth the requirements for determining the payment adjustments under the Hospital-Acquired Condition Reduction Program for hospitals that meet the criteria described under paragraph (e) of this section.

(b) Payment adjustment. With respect to all discharges from an applicable hospital occurring during FY 2015 or a subsequent year, the amount of payment under this section, or section 1814(b)(3) of the Act as applicable, for such discharges during the

fiscal year will be equal to 99 percent of the amount of payment that would otherwise apply to these discharges under this section or section 1814(b)(3) of the Act (determined after the application of the payment adjustment under the Hospital Readmissions Reduction Program under § 412.154 and the adjustment made under the Hospital Value-Based Purchasing Program under § 412.162 and section 1814(l)(4) of the Act but without regard to section 1886(p) of the Act).

(c) Hospitals paid under section 1814(b)(3) of the Act (certain Maryland hospitals). 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 from the application of the payment adjustments under this section. The State must submit an annual report to CMS that describes 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 Hospital-Acquired Conditions Reduction Program as applied to hospitals described in section 1886(d)(1)(B) of the Act.

(1) CMS will establish criteria for evaluation of Maryland's annual report to determine whether the State will be exempted from the application of the payment adjustments under this section for a given fiscal year.

(2) Maryland's annual report and request for exemption from the Hospital-Acquired Condition Reduction Program must be resubmitted and reconsidered annually.

(d) Risk adjustment. In carrying out the provisions of paragraph (e) of this section, CMS will establish and apply an appropriate risk-adjustment methodology.

(e) Criteria for applicable hospitals. (1) General. With respect to a subsection (d) hospital, CMS will identify the top quartile of all subsection (d) hospitals with respect to hospital-acquired conditions as measured during the applicable period.

(2) Use of total hospital-acquired condition scores. CMS will use total hospital-acquired condition scores to identify applicable hospitals. CMS will identify the 25 percent of hospitals with the highest total scores.

(3) Methodology for calculating total hospital-acquired condition scores. CMS will calculate the total hospital-acquired condition scores by weighing the selected measures according to the established methodology.

(f) Reporting of hospital-specific information. CMS will make information available to the public regarding hospital-acquired condition rates of all hospitals under the Hospital-Acquired Reduction Program.

(1) CMS will provide each hospital with confidential hospital-specific reports and discharge level information used in the calculation of its total hospital-acquired condition score.

(2) Hospitals will have a period of 30 days after the receipt of the information provided under paragraph (f)(1) of this section to review and submit corrections for the hospital-acquired condition domain score for each condition that is used to calculate the score for the fiscal year.

(3) The administrative claims data used to calculate a hospital's total hospital-acquired condition score for the condition for a fiscal year are not subject to review and correction under paragraph (f)(2) of this section.

(4) CMS will post the total hospital-acquired condition score for the applicable conditions for a fiscal year for each hospital on an appropriate Web site.

(g) Limitations on review. There is no administrative or judicial review under § 412.170 and this section for the following:

- (1) The criteria describing applicable hospitals.
- (2) The applicable period.
- (3) The specification of hospital-acquired conditions.
- (4) The provision of reports to hospitals and the information made available to the public.

14. Section 412.523 is amended by—

- a. Revising paragraph (c)(3) introductory text.
- b. Adding paragraph (c)(3)(x).
- c. Redesignating paragraph (c)(4) as paragraph (c)(5).
- d. Adding a new paragraph (c)(4).

The additions read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) Computation of the standard Federal rate. Subject to the provisions of paragraph (c)(4) of this section, the standard Federal rate is computed as follows:

* * * * *

(x) For long-term care hospital prospective payment system fiscal year beginning October 1, 2013, and ending September 30, 2014. The standard Federal rate for the long-term care hospital prospective payment system beginning October 1, 2013, and ending September 30, 2014, is the standard Federal rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.8 percent, and further adjusted, as appropriate, as described in paragraph (d) of this section.

(4) For fiscal year 2014 and subsequent fiscal years—(i) In the case of a long-term care hospital that does not submit quality reporting data to CMS in the form and manner and at a time specified by the Secretary, the annual update to the standard Federal rate specified in paragraph (c)(3) of this section is further reduced by 2.0 percentage points.

(ii) Any reduction of the annual update to the standard Federal rate under paragraph (c)(4)(i) of this section 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.

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

15. The authority citation for Part 482 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

16. Section 482.23 is amended by revising paragraph (c)(3) introductory text to read as follows:

§482.23 Condition of participation: Nursing services.

* * * * *

(c) * * *

(3) With the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient as specified under § 482.12(c).

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

17. 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)).

18. Section 485.620 is amended by revising paragraph (a) to read as follows:

§ 485.620 Condition of participation: Number of beds and length of stay.

(a) Standard: Number of beds. Except as permitted for CAHs having distinct part units under § 485.647, the CAH maintains no more than 25 inpatient beds. Inpatient beds may be used for either inpatient or swing-bed services.

* * * * *

19. Section 485.635 is amended by revising paragraphs (a)(3)(vii), (b)(1), and (c)(1) to read as follows:

§ 485.635 Condition of participation: Provision of services.

(a) * * *

(3) * * *

(vii) Procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of § 483.25(i) of this chapter is met with respect to inpatients receiving posthospital SNF care.

* * * * *

(b) * * *

(1) General: (i) The CAH provides those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These CAH services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

(ii) The CAH furnishes acute care inpatient services.

* * * * *

(c) * * *

(1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including—

(i) Services of doctors of medicine or osteopathy;

(ii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH; and

(iii) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.

* * * * *

PART 489--PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

20. The authority citation for Part 489 continues to read as follows:

Authority: Secs. 1102 1819, 1820(E), 1861, 1864(M), 1866, 1869, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i-3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395(hh)).

21. In § 489.24, the paragraph (f) heading is revised to read as follows:

§ 489. 24 Special responsibilities of Medicare hospitals in emergency cases.

* * * * *

(f) Recipient hospital responsibilities. * * *

* * * * *

(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 24, 2013

Marilyn Tavenner,
Acting Administrator, Centers for
Medicare & Medicaid Services

Dated: April 25, 2013

Kathleen Sebelius,
Secretary.

BILLING CODE 4120-01-P

Note: The following addendum and appendices 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, 2013 and Payment Rates for LTCHs Effective for Discharges Occurring on or after October 1, 2013

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 2014 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 2014. 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, 2013.

In addition, we are setting forth a description of the methods and data we used to determine the proposed standard Federal rate that would be applicable to Medicare LTCHs for FY 2014.

In general, except for SCHs and hospitals located in Puerto Rico, for FY 2014, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

Currently, SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge.

We note that section 606 of the American Taxpayer Relief Act of 2012 (ATRA) extended the MDH program from the end of FY 2012 (that is, for discharges occurring before October 1, 2012) to the end of FY 2013 (that is, for discharges occurring before October 1, 2013). Under prior law, the MDH program was to be in effect through the end of FY 2012 only. Absent additional legislation further extending the MDH program, the MDH program will expire for discharges beginning in FY 2014. Therefore, due to the expiration of the MDH program beginning with FY 2014, we are not including hospitals that are currently MDHs (until October 1, 2013) in our update of the hospital-specific rates for FY 2014.

For hospitals located in Puerto Rico, the payment per discharge is based on the sum of 25 percent of an updated Puerto Rico-specific rate based on average costs per case

of Puerto Rico hospitals for the base year and 75 percent of the Federal national rate. (We refer readers to section II.D.3. of this Addendum for a complete description.)

As discussed below in section II. of this Addendum, we are proposing to make changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2014. 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 2014. 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 2014. In section V. of this Addendum, we are proposing to make changes in the determination of the standard Federal rate for LTCHs paid under the LTCH PPS for FY 2014. 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 2014

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 2014.

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.
- A proposed update of 1.8 percent for all areas (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less an adjustment of 0.4 percentage point for MFP and less 0.3 percentage point), as required by section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. For hospitals that fail to submit data, in a form and manner, and at the time, specified by the Secretary relating to the quality of inpatient care furnished by the hospital, pursuant to section 1886(b)(3)(B)(viii) of the Act, the proposed update is –0.2 percent (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less an adjustment of 0.4 percentage point for MFP, and less 0.3 percentage point).
- A proposed update of 1.8 percent to the Puerto Rico-specific standardized amount (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less an adjustment of 0.4 percentage point for MFP and less 0.3 percentage point), in

accordance with section 1886(d)(9)(C)(i) of the Act, as amended by section 401(c) of Pub. L. 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 2013 budget neutrality factor and applying a revised factor.

- An adjustment to ensure the effects of the rural community hospital demonstration program required under section 410A of Pub. L. 108-173, as amended by sections 3123 and 10313 of Pub. L. 111-148, which extended the demonstration program for an additional 5 years, are budget neutral as required under section 410A(c)(2) of Pub. L. 108-173.

- An adjustment to remove the FY 2013 outlier offset and apply an offset for FY 2014, 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 Pub. L. 110-90 until FY 2013.

- As discussed below and in section V.N. of the preamble of this proposed rule, a proposed adjustment to offset the cost of the policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A.

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 2013, for FY 2014, consistent with current law, we are proposing to continue to apply the rural floor budget neutrality adjustment to hospital wage indices 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 2014 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 one additional year, through September 30, 2014.

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 2014 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 2014, we are proposing to rebase and revise the national and Puerto Rico-specific labor-related and nonlabor-related shares from the percentages established for FY 2013. 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: "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 proportion of hospitals' costs that are attributable to wages and wage-related costs as the "labor-related share." For FY 2014, as discussed in section IV.B.4. of the preamble of this proposed rule, we are proposing a labor-related share of 69.6 percent for the national standardized amounts and 63.2 percent for the Puerto Rico-specific standardized amount. Consistent with section 1886(d)(3)(E)

of the Act, we are the wage index to a labor-related share of 62 percent for all IPPS hospitals whose wage index values are less than or equal to 1.0000. For all IPPS hospitals whose wage indices are greater than 1.0000, we are proposing to apply the wage index to a labor-related share of 69.6 percent of the national standardized amount. For FY 2014, all Puerto Rico hospitals have a proposed wage index less than 1.0 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 below 1.0000. Therefore, the national labor-related share would be 62 percent because the proposed wage index for all Puerto Rico hospitals is less than 1.0.

When we divide the proposed average hourly rate of every hospital in Puerto Rico by the proposed Puerto Rico- Specific national average hourly rate (the sum of all salaries and hours for all hospitals only in Puerto Rico), we determine a proposed Puerto Rico Specific wage index above or below 1.0000, depending on the hospital. 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 Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Section 1886(d)(9)(A)(ii)(II) of the Act equalizes the Puerto Rico-specific urban and rural area rates. Accordingly, we are proposing to calculate the proposed FY 2014 national standardized amount and Puerto Rico-specific rate irrespective of whether a hospital is located in an urban or rural location.

3. Updating the Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, in this proposed rule, we are proposing to replace 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. As discussed in section V.A. 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 2014 applicable percentage increase (which is based on the first quarter 2013 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 2014) of 0.4 percent, which is calculated based on IHS Global Insight, Inc.'s (IGI's) first quarter 2013 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 2014 by the estimated market basket percentage increase less 0.3 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 2013 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 2014 is 2.5 percent. Thus, for FY 2014, the proposed update to the average standardized amount is 1.8 percent for hospitals in all areas (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less a proposed adjustment of 0.4 percentage point for MFP and less 0.3 percentage point). For hospitals that do not submit quality data pursuant to section 1886(b)(3)(B)(viii) of the Act, the estimated update to the proposed operating standardized amount is -0.2 percent (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less a proposed adjustment of 0.4 percentage point for MFP, and less 0.3 percentage point). The proposed standardized amounts 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 Pub. L. 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 an applicable percentage increase to the Puerto Rico-specific standardized amount of 1.8 percent.

Although the update factors for FY 2014 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 2014 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 2014 standardized amount to remove the effects of the FY 2013 geographic reclassifications and outlier payments before applying the proposed FY 2014 updates. We then apply budget neutrality offsets

for outliers and geographic reclassifications to the standardized amount based on proposed FY 2014 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 rate setting 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 2014, we are continuing 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 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 V.G. of the preamble of this proposed rule for full details of our implementation of 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 V.H. 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.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, for FY 2014 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 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 2014 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. The data from the proposed applicable period for FY 2014 have not yet been through the review and correction process required by section 1886(q)(6) of the Act. For the final rule, we intend 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 2014 as hospitals will have had the opportunity to review and correct these data before the data are made public under our policy regarding the reporting of hospital-specific readmission rates consistent with section 1886(q)(6) of the Act. We discuss our proposed policy regarding the reporting of

hospital-specific readmission rates for FY 2014 in section V.G.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 proposed hospital VBP payment adjustment factors for FY 2014 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 2014 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 OPSS/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 establishes a new section 1886(r) of the Act that modified the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving DSH adjustments will receive 25 percent of the amount they previously would have received under the current statutory formula for Medicare DSH payments. 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 2014 and subsequent years, we are proposing to include estimated DSH payments that will be paid in accordance with section 1886(r)(1) of the Act and also to include estimates of the additional payments made to hospitals receiving Medicare DSH as described by section 1886(r)(2) of the Act. That is, we are proposing to include estimated Medicare DSH payments at 25 percent of what would otherwise be paid and also the estimated additional payments for hospitals receiving Medicare DSH on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

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 1.0, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with 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 1.0 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2014, we are proposing to adjust 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.F. of the preamble of this proposed rule.

For FY 2014, 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 2012 discharge data to simulate payments and compared aggregate payments using the FY 2013 labor-related share percentages, the FY 2013 relative weights, and the FY 2013 pre-reclassified wage data and applied the proposed FY 2014 hospital readmissions payment adjustments and estimated FY 2014 hospital VBP payment adjustments to aggregate payments using the FY 2013 labor-related share percentages, the proposed FY 2014 relative weights, and the FY 2013 pre-reclassified wage data and applied the same hospital readmissions payment adjustments and estimated hospital VBP payment adjustments. Based on this comparison, we computed a proposed budget neutrality adjustment factor equal to 0.997583. 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 0.997583 to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2013.

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. We first determined a proposed MS- DRG reclassification and recalibration budget neutrality factor of 0.997583 (by using the same methodology described above to determine the proposed MS-DRG reclassification and recalibration budget neutrality factor for the Puerto Rico standardized amount and hospital-specific rates). Secondly, to compute a proposed budget neutrality factor for wage index and labor-related share changes, we used FY 2012 discharge data to simulate payments and compared aggregate payments using the proposed FY 2014 relative weights and the FY 2013 pre-reclassified wage indices, applied the FY 2013 labor-related share of 68.8 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0) and applied the proposed FY 2014 hospital readmissions payment adjustment and the FY 2014 estimated hospital VBP payment adjustment when estimating aggregate payments using the proposed FY 2014 relative weights and the proposed FY 2014 pre-reclassified wage indices, applied the proposed labor-related share for FY 2014 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 2014 hospital readmissions payment adjustments and estimated FY 2014 hospital VBP payment adjustments. In addition, we applied the proposed MS-DRG reclassification and recalibration budget neutrality factor (derived in the first step) to the rates that were used to simulate payments for this comparison of aggregate payments from FY 2013 to FY 2014. By applying this methodology, we

determined a proposed budget neutrality factor of 0.999766 for changes to the wage index. Finally, we multiplied the proposed MS-DRG reclassification and recalibration budget neutrality factor of 0.997583 (derived in the first step) by the proposed budget neutrality factor of 0.999766 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 factor of 0.99735.

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 2014, we used FY 2012 discharge data to simulate payments and compared total IPPS payments with proposed FY 2014 relative weights, proposed FY 2014

labor-related share percentages, and proposed FY 2014 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 2014 hospital readmissions payment adjustments and the estimated FY 2014 hospital VBP payment adjustments to total IPPS payments with proposed FY 2014 relative weights, proposed FY 2014 labor-related share percentages, and proposed FY 2014 wage data after such reclassifications and applied the same hospital readmissions payment adjustments and the estimated hospital VBP payment adjustments. Based on these simulations, we calculated a proposed adjustment factor of 0.990971 to ensure that the effects of these provisions are budget neutral, consistent with the statute.

The proposed FY 2014 budget neutrality adjustment factor is applied to the standardized amount after removing the effects of the FY 2013 budget neutrality adjustment factor. We note that the proposed FY 2014 budget neutrality adjustment reflects proposed FY 2014 wage index reclassifications approved by the MGCRB or the Administrator.

c. Proposed Rural Floor Budget Neutrality Adjustment

As noted above, as discussed in section III.G. 2.b. of the preamble of this proposed rule, in the FY 2012 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). We make an adjustment to the wage index to ensure that aggregate payments to hospitals after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105-33) and the imputed floor under § 412.64(h)(4) of the regulations are not affected. In addition, we note in section III.G.2.b. of the preamble of this proposed rule, we are proposing to extend the imputed floor using the higher of the value determined under the original methodology or the alternative methodology for FY 2014. 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. Also, consistent with section 3141 of the Affordable Care Act and as discussed in section III.G. of this proposed rule, the budget neutrality adjustment for the rural and imputed floors is a national adjustment to the wage index.

Since FY 2012, there has been one hospital in rural Puerto Rico. Therefore, similar to our calculation in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593 and 51788) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53689), for FY 2014, we are proposing to calculate a national rural Puerto Rico wage index (used to adjust the labor-related share of the national standardized amount for hospitals located in Puerto Rico which receive 75 percent of the national standardized amount) and a rural Puerto Rico-specific wage index (which is used to adjust the labor-related share of the Puerto Rico-specific standardized amount for hospitals located in Puerto Rico that receive 25

percent of the Puerto Rico-specific standardized amount). Because this rural Puerto Rico hospital still has no established wage data, our calculation is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). A complete discussion regarding the computation of the rural Puerto Rico wage index can be found in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51594).

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 2012 discharge data and proposed FY 2014 post-reclassified national and Puerto Rico-specific wage indices to simulate IPPS payments. First, we compared the national and Puerto Rico-specific simulated payments without the national rural floor and imputed floor and Puerto Rico-specific rural floor applied to the national and Puerto Rico-specific simulated payments with the national rural floor and imputed floor and Puerto Rico-specific rural floor applied to determine the proposed national rural budget neutrality adjustment factor of 0.990189 and the proposed Puerto Rico-specific budget neutrality adjustment factor of 0.990877. The national adjustment is applied to the national wage indices to produce a national rural floor budget neutral wage index and the Puerto Rico-specific adjustment is applied to the Puerto Rico-specific wage indices to produce a Puerto Rico-specific rural floor budget neutral wage index.

d. Proposed Case-Mix Budget Neutrality Adjustment

Below we summarize the proposed recoupment adjustment to the FY 2014 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 Pub. L. 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 proposals 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. We note that section II.D. of the preamble of this proposed rule also includes a discussion on documentation and coding effects that occurred through FY 2010, including a request for public comments as to whether any portion of the proposed -0.8 percent recoupment adjustment discussed below should be reduced and instead applied as a prospective adjustment for the cumulative MS-DRG documentation and coding effect through FY 2010.

(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 Pub. L. 110-90 to require the Secretary to make a recoupment adjustment totaling \$11 billion by FY 2017. Our actuaries estimate 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 rate adjustments over more than one year, in order to moderate the effect on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, we are proposing a -0.8 percent adjustment to the standardized amount in FY 2014. We note that, as section 631 of the ATRA instructs CMS to make a recoupment adjustment

only to the standardized amount, this proposed adjustment would not apply to the Puerto Rico-specific rate.

e. Proposed Adjustment to Offset the Cost of the Policy Proposal on Admission and Medical Review Criteria for Hospital Inpatient Services under Medicare Part A

In the Medicare Part B Inpatient Billing in Hospitals proposed rule that went on display at the Office of the Federal Register on March 13, 2013, and that appeared in the **Federal Register** on March 18, 2013 (78 FR 16632), we proposed to revise our Part B inpatient billing policy to allow payment of all hospital services that were furnished and would have been reasonable and necessary if the beneficiary had been treated as an outpatient, rather than admitted to the hospital as an inpatient, except for those services specifically requiring an outpatient status. This policy would apply when CMS or a Medicare review contractor determines that the hospital admission was not reasonable and necessary or when a hospital determines after a beneficiary has been discharged that the beneficiary should have received hospital outpatient services rather than hospital inpatient services. We also proposed to continue applying the timely filing restriction to the billing of all Part B inpatient services, under which claims for Part B services must be filed within 1 year from the date of service. As we discuss in section V.N. of the preamble to this proposed rule, in addition to evaluating our policy related to Part B inpatient billing following denials of Part A inpatient claims on the basis that the inpatient admission was not reasonable and necessary or following self-audit, we also believe it is important to consider whether we can provide more clarity regarding the relationship between inpatient admission decisions and Medicare payment. Toward that

end, in section V.N.3. of the preamble of this proposed rule, we present a proposal that would clarify that a beneficiary becomes a hospital inpatient when formally admitted following the physician order for hospital inpatient admission, and would also clarify when we believe hospital inpatient admissions are reasonable and necessary based on how long beneficiaries have spent, or are reasonable expected to spend, in the hospital as inpatients. Under this proposal, Medicare's external review contractors would presume that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than one Medicare utilization day (defined by encounters crossing 2 "midnights") in the hospital receiving medically necessary services. Similarly, we would presume that generally services spanning less than 2 midnights should have been provided on an outpatient basis, unless there is clear physician documentation in the medical record supporting the physician's order and expectation that the beneficiary required an inpatient level of care. (For a complete discussion on our proposed inpatient admission guidelines, including our proposed time-based presumption of medical necessity for hospital inpatient services based on the beneficiary's length of stay as part of our medical review criteria for payment of hospital inpatient services under Medicare Part A, we refer readers to section V.N.3 of this proposed rule.)

Our actuaries project a net increase in IPPS expenditures as a result of the proposed policy that medical review of inpatient admissions will include a presumption that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined by encounters crossing 2 "midnights") in the hospital receiving medically necessary services, discussed in section

V.N.3. of the preamble of this proposed rule (as summarized above). These additional expenditures result from an expected net increase in hospital inpatient encounters due to some encounters spanning more than 2 midnights moving to the IPPS from the OPPS, and some encounters of less than 2 midnights moving from the IPPS to the OPPS. In making this projection, the actuaries analyzed Medicare claims data for extended hospital outpatient encounters and shorter stay hospital inpatient encounters, and estimated the number of encounters that are expected to shift from outpatient to inpatient and vice versa (that is, the number that are expected to shift from inpatient to outpatient). In section V.N.5. of the preamble of this proposed rule, we discuss that our actuaries estimate that this projected net increase in inpatient encounters would increase IPPS expenditures by approximately \$220 million. In light of the widespread impact on the IPPS of the proposed policy and the systemic nature of the issue, we believe it is appropriate to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to offset to offset the estimated \$220 million in additional IPPS expenditures associated with this proposed policy by proposing to reduce the national standardized amount, the Puerto Rico-specific standardized amount, and hospital-specific rates by 0.2 percent (or 0.998 adjustment). We refer readers to section V.N.4. of the preamble of this proposed rule for a complete discussion on this proposed adjustment to offset the estimated cost of the proposed time-based presumption of medical necessity for hospital inpatient services based on the beneficiary's length of stay as part of our medical review criteria for hospital inpatient services under Medicare Part A.

f. Proposed Rural Community Hospital Demonstration Program Adjustment

As discussed in section V.K. of the preamble to this proposed rule, section 410A of Pub. L. 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 Pub. L. 108-173 requires that “[i]n conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented.”

Sections 3123 and 10313 of the Affordable Care Act extended the demonstration 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 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 that the language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that “aggregate payments made by the Secretary do not exceed the amount which the

Secretary would have paid if the demonstration...was not implemented,” but does not identify the range across which aggregate payments must be held equal.

For FY 2014, for the 23 hospitals participating in the demonstration program, 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 V.K. of the preamble of this proposed rule. For this proposed rule, the estimated amount for the proposed adjustment to the national IPPS payment rates for FY 2014 is \$46,515,865. (The estimated amount for the adjustment to the national IPPS payment rates for FY 2013 was \$34,288,129.) Accordingly, to account for the estimated costs of the demonstration program, for FY 2014, we computed a factor of 0.999834 for the rural community hospital demonstration program budget neutrality adjustment that would be applied to the IPPS standard Federal payment rate.

We note that if updated data became available prior to the publication of the FY 2014 IPPS/LTCH PPS final rule, we are proposing to use that data, to the extent appropriate, to estimate the costs of the demonstration program in FY 2014. Therefore, this estimated budget neutrality offset amount may change in the final rule to reflect the updated data.

In addition, if settled cost reports for all of the demonstration hospitals that participated in the applicable fiscal year (2007, 2008, 2009 or 2010) are made available prior to the FY 2014 IPPS/LTCH PPS final rule, we are proposing to incorporate into the FY 2014 budget neutrality offset amount any additional amounts by which the final settled costs of the demonstration in any of these years (as described previously)

exceeded the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule.

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 2014 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 2014 Outlier Fixed-Loss Cost Threshold

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53691 through 53696), we received comments from the public concerning our methodology for calculating the outlier threshold. Specifically, many commenters expressed concern that CMS is still not reaching the 5.1 percent target for outlier payments and believed there is still room for improvement. The commenters made various suggestions to improve the current methodology used to calculate the outlier threshold. In that final rule we responded that we appreciate the commenters providing multiple alternative methodologies to adjust the CCRs used in our outlier fixed-loss cost threshold. Due to the many options the commenters presented, we stated that the most prudent approach was to study the merits of each methodology and, if appropriate, make a proposal in the FY 2014 IPPS/LTCH

PPS proposed rule if we believe making a change to our current methodology would improve our methodology for projecting the outlier fixed-loss cost threshold. Since publication of the FY 2013 IPPS/LTCH PPS final rule, we have studied the merits of the commenters' suggestions to improve the outlier threshold methodology. Below we discuss our proposed outlier methodology for FY 2014 with revisions from the prior fiscal year.

As we have done in the past, to calculate the proposed FY 2014 outlier threshold, we simulated payments by applying proposed FY 2014 payment rates and policies using cases from the FY 2012 MedPAR file. Therefore, in order to determine the proposed FY 2014 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2012 to FY 2014. Since FY 2005, we have used the same methodology to inflate charges. For FY 2014 and subsequent years, we are proposing to further refine our current methodology which uses more recent data that reflect the rate-of-change in hospital charges under the new outlier policy. In the FY 2005 IPPS final rule (69 FR 49277), to compute the 1-year average annualized rate-of-change in charges per case, we stated that we were taking the unprecedented step of comparing the average charge per case from the most recent 6 month period of charge data available to the average charge per case from the same 6 month period from the prior year rather than using a full year of charge data. At that time, we noted that we adopted this methodology to calculate the outlier threshold for FY 2005 as a result of the special circumstances surrounding the revisions to the outlier payment methodology; specifically the exceptionally high rate of hospital charge inflation that was reflected in the data for

FYs 2001, 2002, and 2003. We also noted that we would continue to consider other methodologies for determining charge inflation when calculating the outlier threshold in the future. We refer the reader to the FY 2005 IPPS final rule for a complete discussion on this methodology.

For FY 2014, if we were to propose to continue to use our current methodology that we adopted in FY 2005, we would have computed the 1-year average annualized rate-of-change in charges per case by comparing the last quarter of FY 2011 in combination with the first quarter of FY 2012 (July 1, 2011, through December 31, 2011) to the last quarter of FY 2012 in combination with the first quarter of FY 2013 (July 1, 2012, through December 31, 2012). This rate-of-change was 4.7 percent (1.046908) or 9.6 percent (1.096016) over 2 years. After nine years of using the same methodology, the special circumstances of the exceptionally high rate of hospital charge inflation that was reflected in the data for FYs 2001, 2002, and 2003 may not be as applicable. We believe the policies that we implemented in the FY 2003 Outlier final rule (outlier reconciliation and no longer assigning the statewide average CCR for those hospitals that fall below a CCR floor) have helped control inflation of hospital charges.

Therefore, instead of comparing periods of the most recent 6 months of charge data, we are proposing to adopt a new methodology to inflate charges that use periods of 1-year of the most recent charge data. 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 since a 6 month measure inherently uses fewer claims than a 1-year measure, which 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 proposed methodology, to compute the 1-year average annualized rate-of-change in charges per case for FY 2014, we are proposing to compare the second quarter of FY 2011 through the first quarter of FY 2012 (January 1, 2011, through December 31, 2011) to the second quarter of FY 2012 through the first quarter of FY 2013 (January 1, 2012, through December 31, 2012). This rate-of-change was 4.8 percent (1.048458) or 9.9 percent (1.099264) over 2 years.

As we have done in the past, we are proposing to establish the proposed FY 2014 outlier threshold using hospital CCRs from the December 2012 update to the Provider-Specific File (PSF) -- the most recent available data at the time of this proposed rule. For FY 2014, we are also proposing to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below). In the FY 2007 IPPS final rule (71 FR 48150), we worked with the Office of Actuary to develop the current methodology used to adjust the CCRs. We have used this same methodology to adjust the CCRs from FY 2007 through FY 2013.

Over the years, many commenters have stated that our current methodology is unnecessary complicated. In addition, as mentioned above, in the FY 2013 IPPS/LTCH PPS final rule, commenters made various suggestions to improve the current methodology used to calculate the outlier threshold and we stated that we would study the merits of each methodology and, if appropriate, make a proposal in the FY 2014 IPPS/LTCH PPS proposed rule if we believe making a change to our current methodology would improve our projection of the outlier fixed-loss cost threshold. In that same final

rule, some commenters suggested the use of historical CCR data from the PSF to compute a rate-of-change in CCRs. Under this approach, the commenters compared 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. The commenters stated that although this adjustment would be based on 1 year's data, the commenters believed that the use of historical data to adjust the CCRs is consistent with CMS' estimation of charge inflation. After reviewing the commenters' suggestion, we agree that the use of historical data to adjust the CCRs is simpler and is consistent with CMS' estimation of charge inflation.

Therefore, for FY 2014, we are proposing to adjust the CCRs from the December 2012 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the December 2011 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2012 update of the PSF. We note that we used total transfer-adjusted cases from FY 2012 to determine the national average case-weighted CCRs for both sides of the comparison. We believe 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 2011 operating national average case-weighted CCR of 0.303178 and a December 2012 operating national average case-weighted CCR of 0.295049. We then calculate the

percentage change between the two national operating case-weighted CCRs by subtracting the December 2011 operating national average case-weighted CCR from the December 2012 operating national average case-weighted CCR and then dividing by the December 2011 national operating average case-weighted CCR. This resulted in a national operating CCR adjustment factor of 0.973187.

We used the same methodology proposed above to also adjust the capital CCRs. Specifically, we calculated a December 2011 capital national average case-weighted CCR of 0.025994 and a December 2012 capital national average case-weighted CCR of 0.0249373. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the December 2011 capital national average case-weighted CCR from the December 2012 capital national average case-weighted CCR and then dividing by the December 2011 capital national average case-weighted CCR. This resulted in a national capital CCR adjustment factor of 0.959337.

Consistent with our methodology in the past and as stated in the FY 2009 IPPS final rule (73 FR 48763), we continue to believe it is appropriate to apply only a 1-year adjustment factor to the CCRs. On average, it takes approximately 9 months for a fiscal intermediary or MAC to tentatively settle a cost report from the fiscal year end of a hospital's cost reporting period. The average "age" of hospitals' CCRs from the time the fiscal intermediary or the MAC inserts the CCR in the PSF until the beginning of FY 2009 is approximately 1 year. Therefore, as stated above, we believe a 1-year adjustment factor to the CCRs is appropriate.

As stated above, for FY 2014, we applied the proposed FY 2014 rates and policies using cases from the FY 2012 MedPAR files in calculating the proposed outlier threshold.

As discussed in section III.B.3. of the preamble to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 and 50161) and in section III.G.3. of the preamble of this proposed rule, in accordance with section 10324(a) of the Affordable Care Act, beginning in FY 2011, we created a wage index floor of 1.00 for all hospitals located in States determined to be frontier States. We noted that the frontier State floor adjustments will be calculated and applied after rural and imputed floor budget neutrality adjustments are calculated for all labor market areas, in order to ensure that no hospital in a frontier State will receive a wage index lesser than 1.00 due to the rural and imputed floor adjustment. In accordance with section 10324(a) of the Affordable Care Act, the frontier State adjustment will not be subject to budget neutrality, and will only be extended to hospitals geographically located within a frontier State. However, for purposes of estimating the proposed outlier threshold for FY 2014, it was necessary to apply this provision by adjusting the wage index of those eligible hospitals in a frontier State when calculating the outlier threshold that results in outlier payments being 5.1 percent of total payments for FY 2014. If we did not take into account this provision, our estimate of total FY 2014 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 2014 outlier payments, we are not proposing to make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. We continue to believe that, due to the policy implemented in the June 9, 2003 Outlier final rule (68 FR 34494), CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year. We also noted 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 V.G. and V.H., respectively, of the preamble of this proposed rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe 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.

Using this proposed methodology, we are proposing an outlier fixed-loss cost threshold for FY 2014 equal to the prospective payment rate for the DRG, plus any IME and DSH payments, and any add-on payments for new technology, plus \$24,140.

We note that the proposed FY 2014 threshold is higher than the FY 2013 final outlier threshold of \$21,821. We believe that the decrease in DSH payments due to the implementation of section 1886(r)(1) of the Act contributed to a higher proposed fixed-loss outlier threshold for FY 2014. We note that the additional payments based on uncompensated care made to hospitals receiving Medicare DSH under section 1886(r)(2) of the Act are not taken into consideration when determining outlier payments because we did not propose to make this payment on a per discharge basis. However, when computing a claim by claim outlier threshold, we calculate DSH payments under section 1886(d)(5)(f) of the Act with the reduction under section 1886(r)(1) (the original DSH amount multiplied by 0.25). Therefore, we believe that, decreasing DSH payments decreases total funds to typical cases, which is used to compute the claim by claim outlier threshold thus leading to an increase in outlier payments. This requires that we raise the

outlier threshold to decrease the amount of outlier dollars 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 2014 will result in outlier payments that will equal 5.1 percent of operating DRG payments and 5.49 percent of capital payments based on the Federal rate.

In accordance with section 1886(d)(3)(B) of the Act, we are proposing to reduce the FY 2014 standardized amount by the same percentage to account for the projected proportion of payments paid as outliers.

The outlier adjustment factors that would be applied to the standardized amount based on the FY 2014 outlier threshold are as follows:

	Operating Standardized Amounts	Capital Federal Rate
National	0.948997	0.945149
Puerto Rico	0.952600	0.944392

We are proposing to apply the outlier adjustment factors to the proposed FY 2014 rates after removing the effects of the FY 2013 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 1.152 or capital CCRs greater than 0.166, 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, 2013, 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-2013-IPPS-Final-Rule-Home-Page-Items/FY2013-Final-Rule-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 2014 when hospital-specific CCRs based on the latest settled cost report are either not available or are outside the range noted above. Table 8C listed in section VI. of this Addendum (and available via the Internet) contains the proposed statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that we published a manual update (Change Request 3966) to our outlier policy on October 12, 2005, which updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update covered an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their fiscal intermediary or MAC on a possible alternative operating and/or capital CCR as explained in Change Request 3966. Use of an alternative CCR developed by the hospital in conjunction with the fiscal intermediary or MAC can avoid possible overpayments or underpayments at cost report settlement, thus ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR ratio at any time as long as the guidelines of Change Request 3966 are followed. 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 2012 and FY 2013 Outlier Payments

In the FY 2013 IPPS final rule (77 FR 53697 through 53698), we stated that, based on available data, we estimated that actual FY 2012 outlier payments would be approximately 5.0 percent of actual total MS-DRG payments. This estimate was computed based on simulations using the FY 2011 MedPAR file (discharge data for FY 2011 claims). That is, the estimate of actual outlier payments did not reflect actual FY 2012 claims, but instead reflected the application of FY 2012 payment rates and policies to available FY 2011 claims.

Our current estimate, using available FY 2012 claims data, is that actual outlier payments for FY 2012 were approximately 5.47 percent of actual total MS-DRG payments. Thus, the data indicate that, for FY 2012, the percentage of actual outlier payments relative to actual total payments is higher than we projected for FY 2012. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not plan to make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2012 are equal to 5.1 percent of total MS-DRG payments.

We currently estimate that, using the latest CCRs from the March 2013 update of the PSF, actual outlier payments for FY 2013 will be approximately 5.17 percent of actual total MS-DRG payments, approximately 0.1 percentage point higher than the 5.1 percent we projected when setting the outlier policies for FY 2013. This estimate of

5.17 percent is based on simulations using the FY 2012 MedPAR file (discharge data for FY 2012 claims).

5. Proposed FY 2014 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 2014. The proposed Puerto Rico-specific amounts are shown in Table 1C listed and published in section VI. of this Addendum (and available via the Internet). The proposed amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is the labor-related share of 69.6 percent, and Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are proposing to apply a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we will apply a labor-related share of 62 percent for all hospitals whose wage indices are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the proposed standardized amounts reflecting the applicable percentage increase of 1.8 percent for FY 2014, and a proposed update of -0.2 percent for hospitals that fail to submit quality data consistent with section 1886(b)(3)(B)(viii) of the Act.

Under section 1886(d)(9)(A)(ii) of the Act, the Federal portion of the Puerto Rico payment rate is based on the discharge-weighted average of the national large urban standardized amount (this amount is set forth in Table 1A). The proposed labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2014 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the Internet). This table also includes the proposed Puerto Rico standardized amounts. The proposed labor-related share applied to the Puerto Rico-specific standardized amount is the 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 Pub. L. 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 2013 national standardized amount. The second column shows the proposed changes from the FY 2013 standardized amounts for hospitals that satisfy the quality data submission requirement and, therefore, receive the full proposed update of 1.8 percent. The third column shows the proposed changes for hospitals receiving the proposed reduced update of -0.2 percent. The first row of the table shows the proposed updated (through FY 2013) average standardized amount after restoring the FY 2013 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 Pub. L. 110-90. The MS-DRG reclassification and recalibration wage index budget

neutrality factors are cumulative. Therefore, those FY 2013 factors are not removed from this table.

**COMPARISON OF FY 2013 STANDARDIZED AMOUNTS TO THE PROPOSED
FY 2014 STANDARDIZED AMOUNT WITH FULL AND REDUCED UPDATE**

	Full Update (1.8 percent); Wage index is greater than 1.0000; Labor/Non- Labor Share Percentage (69.6/30.4)	Full Update (1.8 percent); Wage index is less than or equal to 1.0000; Labor/Non- Labor Share Percentage (62/38)	Reduced Update (-0.2 percent); Wage index is greater than 1.0000; Labor/Non- Labor Share Percentage (69.6/30.4)	Reduced Update (-0.2 percent); Wage index is less than or equal to 1.0000; Labor/Non- Labor Share Percentage (62/38)
FY 2013 Base Rate after removing: 1. FY 2013 Geographic Reclassification Budget Neutrality (0.991276) 2. FY 2013 Rural Community Hospital Demonstration Program Budget Neutrality (0.999677) 3. Cumulative FY 2008, FY 2009, FY 2012, FY 2013 Documentation and Coding Adjustment as Required under Sections 7(b)(1)(A) and 7(b)(1)(B) of Pub. L. 110-90 (0.9478) 4. FY 2013 Operating Outlier Offset (0.948999)	Labor: \$4,176.63 Nonlabor: \$1,824.27	Labor: \$3,720.56 Nonlabor: \$2,280.34	Labor: \$4,176.63 Nonlabor: \$1,824.27	Labor: \$3,720.56 Nonlabor: \$2,280.34
Proposed FY 2014 Update Factor	1.018	1.018	0.998	0.998

Proposed FY 2014 MS-DRG Recalibration and Wage Index Budget Neutrality Factor	0.997350	0.997350	0.997350	0.997350
Proposed FY 2014 Reclassification Budget Neutrality Factor	0.990971	0.990971	0.990971	0.990971
Proposed FY 2014 Rural Community Demonstration Program Budget Neutrality Factor	0.999834	0.999834	0.999834	0.999834
Proposed FY 2014 Operating Outlier Factor	0.948997	0.948997	0.948997	0.948997
Proposed Adjustment to Offset the Cost of the Policy Proposal on Admission and Medical Review Criteria for Hospital Inpatient Services under Medicare Part A	0.998	0.998	0.998	0.998
Cumulative Factor: FY 2008, FY 2009, FY 2012, and FY 2013 Documentation and Coding Adjustment as Required under Sections 7(b)(1)(A) and 7(b)(1)(B) of Pub. L. 110-90 and Proposed Documentation and Coding Recoupment Adjustment as required under Section 631 of the American Taxpayer Relief Act of 2012	0.9403	0.9403	0.9403	0.9403
Proposed National Standardized Amount for FY 2014	Labor: \$3,741.72 Nonlabor: \$1,634.32	Labor: \$3,333.14 Nonlabor: \$2,042.90	Labor: \$3,668.21 Nonlabor: \$1,602.21	Labor: \$3,267.66 Nonlabor: \$2,002.76

The following table illustrates the proposed changes from the FY 2013 Puerto Rico-specific payment rate for hospitals located in Puerto Rico. The second column shows the proposed changes from the FY 2013 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 2013 Puerto Rico specific payment rate for hospitals with a Puerto Rico-specific wage index less than 1.0000. The first row of the table shows the proposed updated (through FY 2013) Puerto Rico-specific payment rate after restoring the FY 2013 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 factor is cumulative and is not removed from this table.

COMPARISON OF FY 2013 PUERTO RICO-SPECIFIC PAYMENT RATE TO THE PROPOSED FY 2014 PUERTO RICO-SPECIFIC PAYMENT RATE

	Update (1.8 percent); Wage index is greater than 1.0000; Labor/Non- Labor Share Percentage (63.2/36.8)	Update (1.8 percent); Wage index is less than or equal to 1.0000; Labor/Non-Labor Share Percentage (62/38)
FY 2013 Puerto Rico Base Rate, after removing: 1. FY 2013 Geographic Reclassification Budget Neutrality (0.991276) 2. FY 2013 Rural Community Hospital Demonstration Program Budget Neutrality (0.999677)		

	Update (1.8 percent); Wage index is greater than 1.0000; Labor/Non- Labor Share Percentage (63.2/36.8)	Update (1.8 percent); Wage index is less than or equal to 1.0000; Labor/Non-Labor Share Percentage (62/38)
3. FY 2013 Puerto Rico Operating Outlier Offset (0.944760)	Labor: \$1,700.33 Nonlabor: \$990.07	Labor: \$1,668.05 Nonlabor: \$1,022.35
Proposed FY 2014 Update Factor	1.018	1.018
Proposed FY 2014 MS-DRG Recalibration Budget Neutrality Factor	0.997583	0.997583
Proposed FY 2014 Reclassification Budget Neutrality Factor	0.990971	0.990971
Proposed FY 2014 Rural Community Hospital Demonstration Program Budget Neutrality Factor	0.999834	0.999834
Proposed FY 2014 Puerto Rico Operating Outlier Factor	0.952600	0.952600
Proposed Adjustment to Offset the Cost of the Policy Proposal on Admission and Medical Review Criteria for Hospital Inpatient Services under Medicare Part A	0.998	0.998
Proposed Puerto Rico-Specific Payment Rate for FY 2014	Labor: \$1,626.53 Nonlabor: \$947.09	Labor: \$1,595.64 Nonlabor: \$977.98

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 2014. 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 2014 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. For FY 2011 and in prior fiscal years, we used the most recent cost-of-living adjustment (COLA) factors obtained from the U.S. Office of Personnel Management (OPM) Web site at:

<http://www.opm.gov/oca/cola/rates/asp> to update this nonlabor portion.

In the FY 2013 IPPS/LTCH PPS proposed and final rules (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively), we explained that statutory changes transitioned the Alaska and Hawaii COLAs to locality pay. We further explained that, beginning in FY 2012, as OPM transitioned away from COLAs, we continued to use the same “frozen” COLA factors that were used to adjust payments in FY 2011 (based on OPM’s 2009 COLA factors) to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii while we explored alternatives for updating the COLA factors in the future. In the FY 2013 IPPS/LTCH PPS final rule, for FY 2013, we continued to use the same COLA factors used to adjust payments in FY 2012 (which are based on OPM’s 2009 COLA factors). We also established a methodology to update the COLA factors for Alaska and Hawaii that were published by 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, we are proposing to update 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. Specifically, under our methodology, we are using a comparison of the growth in the Consumer Price Indices (CPIs) in Anchorage and Honolulu relative to the growth in the overall CPI as published by the Bureau of Labor

Statistics (BLS) to update the COLA adjustment factors for all areas in Alaska and Hawaii, respectively. As discussed in the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28145 through 28146), because BLS publishes CPI data for only Anchorage, Alaska and Honolulu, Hawaii, our methodology for updating the COLA factors uses a comparison of the growth in the CPIs for those cities relative to the growth in the overall CPI to update the COLA adjustment factors for all areas in Alaska and Hawaii, respectively. We believe that the relative price differences between these cities and the United States (as measured by the CPIs mentioned above) are generally appropriate proxies for the relative price differences between the “other areas” of Alaska and Hawaii and the United States.

The CPIs for “All Items” that BLS publishes for Anchorage, Alaska, Honolulu, Hawaii, and for the average U.S. city are based on a different mix of commodities and services than is reflected in the nonlabor related share of the IPPS market basket. As such, under the methodology we established to update the COLA factors, we calculated a “reweighted CPI” using the CPI for commodities and the CPI for services for each of the geographic areas to mirror the composition of the IPPS market basket nonlabor-related share. The current composition of BLS’ CPI for “All Items” for all of the respective areas is approximately 40 percent commodities and 60 percent services. However, the nonlabor-related share of the proposed IPPS market basket is comprised of approximately 60 percent commodities and 40 percent services. We note that, if finalized, we do not anticipate that the proposals in section IV. of the preamble of this proposed rule (proposing to revise and rebase the IPPS market basket for FY 2014) would alter the

commodities/services weights of the nonlabor-related share of the IPPS market basket. Therefore, under the methodology we established in the FY 2013 IPPS/LTCH PPS final rule, we have created reweighted indexes for Anchorage, Alaska, Honolulu, Hawaii, and the average U.S. city using the respective CPI commodities index and CPI services index and applying the approximate 60/40 weights from the proposed IPPS market basket. We believe that this methodology is appropriate because we would continue to make a COLA adjustment for hospitals located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standardized amount by a COLA factor.

Under the COLA factor update methodology we established in the FY 2013 IPPS/LTCH PPS final rule, we further exercised our discretionary authority to adjust payments made to hospitals located in Alaska and Hawaii by incorporating a 25-percent cap on the CPI-updated COLA factors used to adjust the nonlabor-related portion of the standardized amounts, which is consistent with a statutorily mandated 25-percent cap that was applied to OPM's published COLA factors. We believe that this is appropriate because our proposed CPI-updated COLA factors for FY 2014 use the 2009 OPM COLA factors as a basis. In addition, we are proposing to continue to establish COLA factors that are rounded to 2 decimal places, which is consistent with the number of decimal places in the 2009 OPM COLA factors that are used as the basis for calculating the proposed FY 2014 COLA factors. This policy also would maintain consistency with the rounding used for the 25-percent cap on the COLA factors (that is, a COLA factor of no more than 1.25).

Applying this methodology, we are proposing to establish the COLA factors for FY 2014 that would adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii as shown in the table below.

**Proposed FY 2014 Cost-of-Living Adjustment Factors:
Alaska and Hawaii Hospitals**

Area	Proposed 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

Each of the COLA factors was calculated using data through 2012 as these are the latest historical CPI data published by the BLS. The reweighted CPI for Honolulu, Hawaii grew faster than the reweighted CPI for average U.S. city over the time period from 2009 to 2012, with a growth rate of 8.9 percent and 8.3 percent, respectively. As a result, for FY 2014, we calculated proposed COLA factors for the City and County of Honolulu, the County of Kauai, the County of Maui, and the County of Kalawao to be 1.26 compared to the FY 2013 COLA factor of 1.25. However, as stated above, our COLA factor update methodology caps COLA factors at 1.25. In addition, the proposed

COLA factor calculated for the County of Hawaii for FY 2014 is 1.19 compared to the FY 2013 COLA factor of 1.18.

The reweighted CPI for Anchorage, Alaska grew slower than the reweighted CPI for average U.S. city over the time period from 2009 to 2012, with a growth rate of 8.0 percent and 8.3 percent, respectively. However, applying this slower relative growth rate to the FY 2009 COLA factors for each of the Alaska areas results in no proposed change to the COLA factors for the Alaska areas for FY 2014 (1.25 for “All other” areas of Alaska and 1.23 for the three specified urban areas of Alaska (Anchorage, Fairbanks and Juneau)) as compared to the FY 2013 COLA factors.

C. Calculation of the Proposed Prospective Payment Rates

General Formula for Calculation of the Prospective Payment Rates for FY 2014

In general, the operating prospective payment rate for all hospitals paid under the IPPS located outside of Puerto Rico, except SCHs, for FY 2014 equals the Federal rate. (As noted above, due to the expiration of the MDH program, beginning with FY 2014, we are not including MDHs in our discussion of the update of the hospital-specific rates for FY 2014.)

Currently, SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2014 equals the higher of the applicable Federal rate, or the hospital-specific rate as described below. The prospective payment rate for hospitals located in Puerto Rico for FY 2014 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 (full update for hospitals submitting quality data; update including a -2.0 percent adjustment for hospitals that did not submit these data).

Step 2--Multiply the labor-related portion of the standardized amount by the applicable wage index for the geographic area in which the hospital is located or the area to which the hospital is reclassified.

Step 3--For hospitals in Alaska and Hawaii, multiply the nonlabor-related portion of the standardized amount by the applicable cost-of-living adjustment factor.

Step 4--Add the amount from Step 2 and the nonlabor-related portion of the standardized amount (adjusted, if applicable, under Step 3).

Step 5--Multiply the final amount from Step 4 by the relative weight corresponding to the applicable MS-DRG (Table 5 listed in section VI. of this Addendum and available via the Internet).

The Federal rate as determined in Step 5 may then be further adjusted if the hospital qualifies for either the IME or DSH adjustment. In addition, for hospitals that

qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b), the payment in Step 5 would be increased by the formula described in section V.C. of the preamble of this proposed rule. Finally, the base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively.

2. Hospital-Specific Rate (Applicable Only to SCHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that currently SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment. For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996 and FY 2006 Hospital-Specific Rate for FY 2013

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs equals the applicable

percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the proposed applicable percentage increase to the hospital-specific rates applicable to SCHs is 1.8 percent (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less a proposed adjustment of 0.4 percentage point for MFP and less 0.3 percentage point) for hospitals that submit quality data or -0.2 percent (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent, less 2.0 percentage points for failure to submit data under the Hospital IQR Program, less a proposed adjustment of 0.4 percentage point for MFP, and less 0.3 percentage point) for hospitals that fail to submit quality data. For a complete discussion of the applicable percentage increase applicable to the hospital-specific rates for SCHs, we refer readers to section V.A. of the preamble of this proposed rule.

In addition, because SCHs use the same MS-DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the 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 hospital-specific rate is adjusted by the proposed MS-DRG reclassification and

recalibration budget neutrality factor of 0.997583, as discussed in section III. of this Addendum. The resulting rate is used in determining the payment rate an SCH will receive for its discharges beginning on or after October 1, 2013. We note that, in this proposed rule, for FY 2014, 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 proposals 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. We note that section II.D. of the preamble of this proposed rule also includes a discussion on documentation and coding effects that occurred through FY 2010, including a request for public comments as to whether any portion of the proposed -0.8 percent recoupment adjustment discussed in section II.D.6. of the preamble of this proposed rule should be reduced and instead applied as a prospective adjustment for the cumulative MS-DRG documentation and coding effect through FY 2010.

c. Proposed Adjustment to Offset the Cost of the Admission and Medical Review

Criteria for Hospital Inpatient Services under Medicare Part A Proposal and Clarification

As discussed previously, in section V.N.5. of the preamble of this proposed rule, our actuaries project additional IPPS expenditures would result from our proposed policy that medical review of inpatient admissions will include a presumption that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined by encounters crossing 2 “midnights”) in the hospital receiving medically necessary services (which is presented in section V.N.3. of

the preamble of this proposed rule). We believe it is appropriate to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to propose reductions of 0.2 percent (or 0.998 adjustment) to the IPPS rates, including the proposed FY 2014 hospital-specific rate for SCHs, to offset our estimate of the increase in IPPS payments. We refer readers to section V.N. of the preamble of this proposed rule for a complete discussion of our policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A.

3. General Formula for Calculation of Prospective Payment Rates for Hospitals Located in Puerto Rico Beginning on or after October 1, 2013, and before October 1, 2014

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 average standardized amount.

Step 2--Multiply the labor-related portion of the standardized amount by the applicable wage index for the geographic area in which the hospital is located or the area to which the hospital is reclassified.

Step 3--Add the amount from Step 2 and the nonlabor-related portion of the national average standardized amount.

Step 4--Multiply the amount from Step 3 by the applicable MS-DRG relative weight (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 for a given discharge for a hospital located in Puerto Rico. This rate is then further adjusted if the hospital qualifies for either the IME or DSH adjustment.

c. Proposed Adjustment to Offset the Cost of the Admission and Medical Review

Criteria for Hospital Inpatient Services under Medicare Part A Proposal and Clarification

As discussed previously, in section V.N.5. of the preamble of this proposed rule, our actuaries project additional IPPS expenditures would result from our proposed policy that medical review of inpatient admissions will include a presumption that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined by encounters crossing 2 “midnights”) in the hospital receiving medically necessary services (which is presented in section V.N.3. of the preamble of this proposed rule). We believe it is appropriate to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to propose reductions of 0.2 percent (or 0.998 adjustment) to the IPPS rates, including the FY 2014 national standardized amount and the Puerto Rico standardized amount, to offset our estimate of the increase in IPPS payments. We refer readers to section V.N. of the preamble of this proposed rule for a complete discussion of our policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A.

III. Proposed Changes to Payment Rates for Acute Care Hospital Inpatient

Capital-Related Costs for FY 2014

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 2014, which would be effective for discharges occurring on or after October 1, 2013.

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 Pub. L. 108-173, the methodology for operating payments made to hospitals located in Puerto Rico under the IPPS was revised to make payments based on a blend of 25 percent of the applicable standardized amount specific to Puerto

Rico hospitals and 75 percent of the applicable national average standardized amount. In conjunction with this change to the operating blend percentage, effective with discharges occurring on or after October 1, 2004, we also revised the methodology for computing capital payments 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 are proposing to use to determine the capital Federal rate for FY 2014. In particular, we explain why the proposed FY 2014 capital Federal rate would increase approximately 1.5 percent, compared to the FY 2013 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 1.1 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 2014 under that framework is 0.9 percent based on the best data available at this time. The proposed update factor under that framework is based on a projected 1.2 percent increase in the proposed revised and rebased FY 2010-based CIPI (discussed in more detail in section IV.D. of the preamble of this proposed rule), 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 2012 DRG reclassification and recalibration, and a forecast error correction of -0.3 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 2014 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 2014.

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 2014, 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 2014. 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 2014 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 2012 DRG reclassification and recalibration as part of our update for FY 2014. We estimate that FY 2012 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 2014.

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 -0.3 percentage point was calculated for the proposed FY 2014 update. That is, current historical data indicate that the forecasted FY 2012 rate-of-increase of the FY 2006-based CIPI (1.5 percent) used in calculating the FY 2012 update factor slightly overstated the actual realized FY 2012 price increases of the FY 2006-based CIPI (1.2 percent) by 0.3 percentage point because the prices associated with both the depreciation and interest cost

categories grew more slowly than anticipated. Historically, when forecast error of the CPII is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended under this framework. Therefore, we are proposing to make a - 0.3 percentage point adjustment for forecast error in the update for FY 2014.

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 CPII 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 2014 (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 2014, 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 2006 and extending through FY 2011. Based on these data, we estimated that case-mix constant intensity declined during FYs 2006 through 2011. 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 2014. Therefore, we are proposing to make a 0.0 percentage point adjustment for intensity in the update for FY 2014.

Above, we described the basis of the components used to develop the proposed 0.9 percent capital update factor under the capital update framework for FY 2014 as shown in the table below.

Proposed CMS FY 2014 Update Factor to the Capital Federal Rate

Capital Input Price Index*	1.2
Intensity:	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	-0.5
Projected Case-Mix Change	0.5
Subtotal	1.2
Effect of FY 2012 Reclassification and Recalibration	0.0
Forecast Error Correction	-0.3

Total Update	0.9
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*The capital input price index is based on the proposed revised and rebased FY 2010-based CIPI discussed in section IV.D. of the preamble of this proposed rule.

b. Comparison of CMS and MedPAC Update Recommendation

In its March 2013 Report to Congress, MedPAC did not make a specific update recommendation for capital IPPS payments for FY 2014. (We refer readers to MedPAC's Report to the Congress: Medicare Payment Policy, March 2013, 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 2013, we estimated that outlier payments for capital will equal 6.38 percent of inpatient capital-related payments based on the capital Federal rate in FY 2013. 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 5.49 percent for inpatient capital-related payments based on the proposed capital Federal rate in FY 2014. Therefore, we are proposing to apply an outlier adjustment factor of 0.9451

in determining the proposed capital Federal rate for FY 2014. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2014 will be somewhat lower than the percentage for FY 2013. This decrease in estimated capital outlier payments is primarily due to the proposed increase in the outlier threshold used to identify outlier cases for both inpatient operating and inpatient capital-related payments, which is discussed in section II.A. of this Addendum. That is, because the outlier threshold used to identify outlier cases would be higher, cases would receive lower outlier payments and fewer cases would qualify for outlier payments.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The proposed FY 2014 outlier adjustment of 0.9451 is a 0.95 percent change from the FY 2013 outlier adjustment of 0.9362. Therefore, the proposed net change in the outlier adjustment to the capital Federal rate for FY 2014 is 1.0095 ($0.9451 / 0.9362$). Thus, the proposed outlier adjustment would increase the FY 2014 capital Federal rate by 0.95 percent compared to the FY 2013 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 2014, we compared (separately for the national capital rate and the Puerto Rico capital rate) estimated aggregate capital Federal rate payments based on the FY 2013 MS-DRG classifications and relative weights and the FY 2013 GAF to estimated aggregate capital Federal rate payments based on the FY 2013 MS-DRG classifications and relative weights and the proposed FY 2014 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 0.9998 for FY 2014 to the previous cumulative FY 2013 adjustment factor of 0.9904, yielding an adjustment factor of 0.9902 through FY 2014. For the Puerto Rico GAFs, we are proposing to apply an incremental budget neutrality adjustment factor of 0.9990 for FY 2014 to the previous cumulative FY 2013 adjustment factor of 1.0095, yielding a cumulative adjustment factor of 1.0084 through FY 2014.

We then compared estimated aggregate capital Federal rate payments based on the FY 2013 MS-DRG relative weights and the proposed FY 2014 GAFs to estimated aggregate capital Federal rate payments based on the cumulative effects of the proposed FY 2014 MS-DRG classifications and relative weights and the proposed FY 2014 GAFs. The proposed incremental adjustment factor for DRG classifications and changes in

relative weights is 0.9990 both nationally and for Puerto Rico. The proposed cumulative adjustment factors for MS-DRG classifications and proposed changes in relative weights and for proposed changes in the GAFs through FY 2014 are 0.9892 nationally and 1.0074 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 2014 geographic reclassification decisions made by the MGCRB compared to FY 2013 decisions. However, it does not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Proposed Capital Federal Rate for FY 2014

For FY 2013, we established a capital Federal rate of \$425.49 (77 FR 53706).

We are proposing to establish an update of 0.9 percent in determining the FY 2014 capital Federal rate for all hospitals. In addition, as discussed in greater detail in section IV.C. of the preamble of this proposed rule, we are proposing to make a reduction of 0.2 percent to the capital IPPS rates, to offset the estimated additional IPPS expenditures that are projected to result from our policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A.

As a result of the proposed 0.9 percent update, the proposed budget neutrality factors, and the proposed 0.2 percent reduction to offset the estimated additional IPPS expenditures projected to result from our policy proposal on admission and medical review criteria for hospital inpatient services discussed above, we are proposing to establish a national capital Federal rate of \$432.03 for FY 2014. The proposed national capital Federal rate for FY 2014 was calculated as follows:

- The proposed FY 2014 update factor is 1.009, that is, the proposed update is 0.9 percent.
- The proposed FY 2014 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 proposed changes in the GAFs is 0.9988.

- The proposed FY 2014 outlier adjustment factor is 0.9451.
- A proposed adjustment factor of 0.9980 (that is, a reduction of 0.2 percent) to offset the estimated additional IPPS expenditures that are projected to result from our policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A.

(We note, in section VI.D. of the preamble of this proposed rule, we discuss the MS-DRG documentation and coding adjustment, including our proposed -0.8 percent recoupment adjustment to the operating IPPS standardized amount in FY 2014 under the provisions of section 631 of the ATRA, as well as additional prospective adjustments for the MS-DRG documentation and coding effect through FY 2010 authorized under section 1886(d)(3)(A)(vi) of the Act. Although we are not proposing an additional prospective adjustment in FY 2014 for the cumulative MS-DRG documentation and coding effects through FY 2010, we are soliciting public comments as to whether any portion of the proposed -0.8 percent recoupment adjustment to the operating IPPS standardized amount should be reduced and instead applied as a prospective adjustment to the operating IPPS standardized amount (and hospital-specific rates) for the cumulative MS-DRG documentation and coding effect through FY 2010. We discuss in that same section that if we were to attribute a portion of the proposed -0.8 percent recoupment adjustment to the operating IPPS standardized amount for FY 2014 as a prospective adjustment, under the Secretary's broad authority under section 1886(g) of the Act, we also would make an appropriate adjustment to the national capital IPPS Federal rate (and note that the capital IPPS Puerto Rico rate would not be affected).

Because the proposed capital Federal rate has already been adjusted for differences in case-mix, wages, cost-of-living, indirect medical education costs, and payments to hospitals serving a disproportionate share of low-income patients, we are not proposing to make additional adjustments in the capital Federal rate for these factors, other than the proposed budget neutrality factor for proposed changes in the MS-DRG classifications and relative weights and for proposed changes in the GAFs. (As noted previously in this section, there is no need for an exceptions payment adjustment budget neutrality factor in determining the FY 2014 capital Federal rate.)

We are providing the following chart that shows how each of the proposed factors and proposed adjustments for FY 2014 affects the computation of the proposed FY 2014 national capital Federal rate in comparison to the FY 2013 national capital Federal rate. The proposed FY 2014 update factor has the effect of increasing the capital Federal rate by 0.9 percent compared to the FY 2013 capital Federal rate. The proposed GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.12 percent. The proposed FY 2014 outlier adjustment factor has the effect of increasing the capital Federal rate by 0.95 percent compared to the FY 2013 capital Federal rate. The proposed adjustment to account for the estimated additional IPPS expenditures that are projected to result from our policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A has the effect of decreasing the capital Federal rate by 0.2 percent compared to the FY 2013 capital Federal rate. The combined effect of all the proposed changes would increase the

national capital Federal rate by 1.54 percent compared to the FY 2013 national capital Federal rate.

**Comparison of Factors and Adjustments:
FY 2013 Capital Federal Rate and
Proposed FY 2014 Capital Federal Rate**

	FY 2013	Proposed FY 2014	Change	Percent Change
Update Factor ¹	1.0120	1.0090	1.0090	0.90
GAF/DRG Adjustment Factor ¹	0.9998	0.9988	0.9988	-0.12
Outlier Adjustment Factor ²	0.9362	0.9451	1.0095	0.95
Adjustment for admission and medical review criteria ³	N/A	0.9980	0.9980	-0.20
Capital Federal Rate	\$425.49	\$432.03	1.0154	1.54

¹ The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rates. Thus, for example, the incremental change from FY 2013 to FY 2014 resulting from the application of the proposed 0.9988 GAF/DRG budget neutrality adjustment factor for FY 2014 is a net change of 0.9988 (or -0.12 percent).

² The outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the proposed FY 2014 outlier adjustment factor is 0.9451/0.9362, or 1.0095 (or 0.95 percent).

³ The proposed adjustment to account for the estimated additional IPPS expenditures that are projected to result from our policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A (discussed in section VI.C. of the preamble of this proposed rule).

6. 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 proposed national GAF and for the proposed Puerto Rico GAF, and the proposed budget neutrality factor for MS-DRG reclassifications and recalibration (which is the same nationally and for Puerto Rico) is discussed above in section III.A.3. of this Addendum.

In computing the payment for a particular Puerto Rico hospital, the Puerto Rico portion of the capital rate (25 percent) is multiplied by the Puerto Rico-specific GAF for the labor market area in which the hospital is located, and the national portion of the capital rate (75 percent) is multiplied by the national GAF for the labor market area in

which the hospital is located (which is computed from national data for all hospitals in the United States and Puerto Rico).

For FY 2013, the special capital rate for hospitals located in Puerto Rico was \$207.25 (77 FR 53707). With the changes we are proposing to make to the other factors used to determine the capital Federal rate (including the proposed adjustment to account for the estimated additional IPPS expenditures that are projected to result from our policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A (discussed in section V.N. of the preamble of this proposed rule), the proposed FY 2014 special capital rate for hospitals in Puerto Rico is \$212.50.

B. Calculation of the Proposed Inpatient Capital-Related Prospective Payments for FY 2014

For purposes of calculating payments for each discharge during FY 2014, the capital Federal rate is adjusted as follows: (Standard Federal Rate) x (DRG weight) x (GAF) x (COLA for hospitals located in Alaska and Hawaii) x (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 2014 are in section II.A. of this Addendum. For FY 2014, a case would qualify as a cost outlier if the cost for the case plus the (operating) IME and DSH payments is greater than the

prospective payment rate for the MS-DRG plus the proposed fixed-loss amount of \$24,140.

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 this proposed rule, we are proposing to rebase and revise the CIPI to a FY 2010 base year to reflect the more current structure of capital costs in hospitals. A complete discussion of this rebasing is provided in section IV.D. of the preamble of this proposed rule. The CIPI was last rebased to FY 2006 in the FY 2010 IPPS/RV 2010 LTCH PPS final rule (74 FR 44021).

2. Forecast of the CIPI for FY 2014

Based on the latest forecast by IHS Global Insight, Inc. (first quarter of 2013), we are forecasting the proposed FY 2010-based CIPI to increase 1.2 percent in FY 2014.

This reflects a projected 1.8 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 2.8 percent increase in other capital expense prices in FY 2014, partially offset by a projected 2.3 percent decline in vintage-weighted interest expenses in FY 2014. The weighted average of these three factors produces the forecasted 1.2 percent increase for the proposed FY 2010-based CIPI as a whole in FY 2014.

IV. Proposed Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2014

Historically, certain hospitals and hospital units excluded from the prospective payment system received payment for inpatient hospital services they furnished on the basis of reasonable costs, subject to a rate-of-increase ceiling. An annual per discharge limit (the target amount as defined in § 413.40(a)) was set for each hospital or hospital unit based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. The updated target amount for that period was multiplied by the Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) on total inpatient operating costs for a hospital's cost reporting period. Prior to October 1, 1997, these payment provisions applied consistently to certain categories of excluded providers, which included rehabilitation hospitals and units (now referred to as IRFs), psychiatric hospitals and units (now referred to as IPFs), LTCHs, children's hospitals, and cancer hospitals.

Payments for services furnished in children's hospitals and cancer hospitals that are excluded from the IPPS continue to be subject to the rate-of-increase ceiling based on the hospital's own historical cost experience. (We note that, in accordance with § 403.752(a), RNHCIs are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

We are proposing that the FY 2014 rate-of-increase percentage for updating the target amounts for the 11 cancer hospitals, children's hospitals, and RNHCIs would be the estimated percentage increase in the FY 2014 IPPS operating market basket, in

accordance with applicable regulations at § 413.40. As described in section IV. of the preamble of this proposed rule, we are proposing to revise and rebase 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 children's hospitals, 11 cancer hospitals, and RNHCIs for FY 2014 and subsequent fiscal years. Accordingly, the FY 2014 rate-of-increase percentage to be applied to the target amount for these cancer hospitals, children's hospitals, and RNHCIs would be the FY 2014 percentage increase in the FY 2010-based IPPS operating market basket. Based on IHS Global Insight, Inc.'s 2013 first quarter forecast, we estimate that the FY 2010-based IPPS operating market basket update for FY 2014 is 2.5 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 2014.

IRFs, IPFs, and LTCHs were previously paid under the reasonable cost methodology. However, the statute was amended to provide for the implementation of prospective payment systems for IRFs, IPFs, and LTCHs. In general, the prospective payment systems for IRFs, IPFs, and LTCHs provide transitioning periods of varying lengths of time during which a portion of the prospective payment was based on cost-based reimbursement rules under 42 CFR Part 413 (certain providers do not receive a transition period or may elect to bypass the transition as applicable under 42 CFR Part 412, Subparts N, O, and P.) We note that all of the various transitioning periods provided for under the IRF PPS, the IPF PPS, and the LTCH PPS have ended.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VIII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule for the update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2014. 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 2014

A. Proposed LTCH PPS Standard Federal Rate for FY 2014

1. Background

In section VIII. 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 2014.

Under § 412.523(c)(3)(ii) of the regulations, for LTCH PPS rate years beginning RY 2004 through RY 2006, we updated the standard Federal rate annually by a factor to adjust for the most recent estimate of the increases in prices of an appropriate market basket of goods and services for LTCHs. We established this policy of annually updating the standard Federal rate because, at that time, we believed that was the most appropriate method for updating the LTCH PPS standard Federal rate for years after the initial implementation of the LTCH PPS in FY 2003. Thus, under § 412.523(c)(3)(ii), for RYs 2004 through 2006, the annual update to the LTCH PPS standard Federal rate was equal to the previous rate year's Federal rate updated by the most recent estimate of increases in the appropriate market basket of goods and services included in covered inpatient LTCH services.

In determining the annual update to the standard Federal rate for RY 2007, based on our ongoing monitoring activity, we believed that, rather than solely using the most recent estimate of the LTCH PPS market basket update as the basis of the annual update factor, it was appropriate to adjust the standard Federal rate to account for the effect of documentation and coding in a prior period that was unrelated to patients' severity of

illness (71 FR 27818). Accordingly, we established under § 412.523(c)(3)(iii) that the annual update to the standard Federal rate for RY 2007 was zero percent based on the most recent estimate of the LTCH PPS market basket at that time, offset by an adjustment to account for changes in case-mix in prior periods due to the effect of documentation and coding that were unrelated to patients' severity of illness. For RY 2008 through FY 2011, we also made an adjustment for the effect of documentation and coding that was unrelated to patients' severity of illness in establishing the annual update to the standard Federal rate as set forth in the regulations at §§ 412.523(c)(3)(iv) through (c)(3)(vii). For FYs 2012 and 2013, 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 VIII.C.2.b. 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 VIII.C.2.b. 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 2013, 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 2.6 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)(ix) of the regulations, we established an annual update of 1.8 percent to the standard Federal rate for FY 2013 (77 FR 53708 through 53711 and 53481).

For FY 2014, as discussed in greater detail in section VIII.C.2.e. 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 MFP adjustment 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)(D) of the Act. In addition, as discussed in greater detail in section VIII.C.2.c., beginning in

FY 2014, the proposed annual update will be further reduced by 2.0 percentage points for LTCHs that fail to submit quality reporting data in accordance with 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 1.8 percent provided the LTCH submits quality reporting data for FY 2014 in accordance with the LTCHQR Program under section 1886(m)(5) of the Act, which is based on the full estimated increase in the LTCH PPS market basket of 2.5 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 0.3 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(D) of the Act. As discussed in greater detail in section VIII.C.2.c., for LTCHs that fail to submit quality reporting data for FY 2014 in accordance with the LTCHQR Program, the proposed annual update will be further reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

Accordingly, we are proposing an annual update to the LTCH PPS standard Federal rate of -0.2 percent for LTCHs that fail to submit quality reporting data for FY 2014. This is calculated based on the full estimated increase in the LTCH PPS market basket of 2.5 percent, less a proposed MFP adjustment of 0.4 percentage point, less an additional adjustment of 0.3 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 2014 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 2014, we applied the annual update to the LTCH PPS standard Federal rate from the previous year. In determining the proposed standard Federal rate for FY 2014, we also are proposing to make certain regulatory adjustments. Specifically, we are proposing to apply an adjustment factor under the second 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 VIII.C.3. of the preamble of this proposed rule. In addition, in determining the proposed FY 2014 standard Federal rate, we are proposing to apply a budget neutrality adjustment factor for the changes related to the area wage adjustment (that is, changes to the wage data and labor-related share) in accordance with § 412.523(d)(4).

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53708 through 53710 and 53481), we established an annual update to the LTCH PPS standard Federal rate of 1.8 percent for FY 2013 based on the full estimated LTCH PPS market basket increase of 2.6 percent, less the MFP adjustment of 0.7 percentage point consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.1 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(C) of the Act. Accordingly, at § 412.523(c)(3)(ix), we established an annual update to the standard Federal rate for FY 2013 of 1.8 percent. That is, we applied an update factor of 1.018 to the FY 2012 Federal rate of \$40,222.05

to determine the FY 2013 standard Federal rate. Effective December 29, 2012, we also adjusted the standard Federal rate for FY 2013 by the one-time prospective adjustment factor for FY 2013 of 0.98734 under § 412.523(d)(3)(ii) (this adjustment was not applied to payments for discharges occurring before December 29, 2012, consistent with the statute). Furthermore, for FY 2013, we applied an area wage level budget neutrality factor of 0.999265 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 2013 of \$40,397.96 (calculated as $\$40,222.05 \times 1.018 \times 0.98734 \times 0.999265$). Furthermore, consistent with the statute, the one-time prospective adjustment factor of 0.98734 applied to the standard Federal rate for FY 2013 is not applied to payments for discharges occurring before December 29, 2012. Thus, payment for discharges occurring on or after October 1, 2012, and on or before December 28, 2012, does not reflect that adjustment and instead are paid based on a standard Federal rate of \$40,915.95 (calculated as $\$40,397.96$ divided by 0.98734).

In this proposed rule, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 1.8 percent (that is, an update factor of 1.018) for FY 2014, based on the full estimated increase in the LTCH PPS market basket of 2.5 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 0.3 percentage point required by sections 1886(m)(3)(A)(ii) and(m)(4)(D) of the Act, provided the LTCH submits quality data in

accordance with the LTCHQR Program under section 1886(m)(5) of the Act. Therefore, under proposed § 412.523(c)(3)(x), we are proposing to apply a factor of 1.018 to the FY 2013 standard Federal rate of \$40,397.96 (as established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53710)) to determine the proposed FY 2014 standard Federal rate. For LTCHs that fail to submit quality reporting data for FY 2014 under the LTCHQR Program, under proposed § 412.523(c)(3)(x) in conjunction with proposed § 412.523(c)(4), we are proposing to reduce the annual update to the LTCH PPS standard Federal rate by an additional 2.0 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 -0.2 percent (that is, 1.8 percent minus 2.0 percentage points = -0.2 percent or an update factor of 0.9980) for FY 2014 for LTCHs that fail to submit quality reporting data for FY 2014 under the LTCHQR Program. We also are proposing to establish that the standard Federal rate for FY 2014 would be further adjusted by a proposed adjustment factor of 0.98734 for FY 2014 under the second year of the 3-year phase-in of the one-time prospective adjustment at § 412.523(d)(3)(ii). In addition, for FY 2014, we are proposing to apply an area wage level budget neutrality factor of 1.000433 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 for FY 2014 of \$40,622.06 (calculated as $\$40,397.96 \times 1.018 \times 0.98734 \times 1.000433$) for discharges occurring on or after October 1, 2013, and on or before

September 30, 2014, provided the LTCH submits quality reporting data for FY 2014 in accordance with the LTCHQR Program under section 1886(m)(5) of the Act. For LTCHs that fail to submit quality reporting data for FY 2014 in accordance with the LTCHQR Program under section 1886(m)(5) of the Act, we are proposing to establish a standard Federal rate for FY 2014 of \$39,823.99 (calculated as $\$40,397.96 \times 0.998 \times 0.98734 \times 1.000433$) for discharges occurring on or after October 1, 2013, and on or before September 30, 2014.

B. Proposed Adjustment for Area Wage Levels under the LTCH PPS for FY 2014

1. Background

Under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal rate to account for differences in LTCH area wage levels at § 412.525(c). The labor-related share of the LTCH PPS standard Federal rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

When we implemented the LTCH PPS, we established a 5-year transition to the full area wage index level adjustment. The area wage level adjustment was completely phased-in for cost reporting periods beginning in FY 2007. Therefore, for cost reporting periods beginning on or after October 1, 2006, the applicable LTCH wage index values are the full LTCH PPS wage index values calculated based on acute care hospital

inpatient wage index data without taking into account geographic reclassification under section 1886(d)(8) and section 1886(d)(10) of the Act. For additional information on the phase-in of the area wage level adjustment under the LTCH PPS, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56015 through 56019) and the RY 2008 LTCH PPS final rule (72 FR 26891).

2. Proposed Geographic Classifications/Labor Market Area Definitions

As discussed in the August 30, 2002 LTCH PPS final rule, which implemented the LTCH PPS (67 FR 56015 through 56019), in establishing an adjustment for area wage levels, the labor-related portion of a LTCH's Federal prospective payment is adjusted by using an appropriate wage index based on the labor market area in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment at existing § 412.525(c) is made on the basis of the location of the LTCH in either an urban area or a rural area as defined in § 412.503. Currently under the LTCH PPS at § 412.503, an “urban area” is defined as a Metropolitan Statistical Area (which would include a metropolitan division, where applicable) as defined by the Executive OMB and a “rural area” is defined as any area outside of an urban area.

In the RY 2006 LTCH PPS final rule (70 FR 24184 through 24185), in regulations at § 412.525(c), we revised the labor market area definitions used under the LTCH PPS effective for discharges occurring on or after July 1, 2005, based on the Executive OMB's CBSA designations, which are based on 2000 Census data. We made this revision because we believe that the CBSA-based labor market area definitions will ensure that the LTCH PPS wage index adjustment most appropriately accounts for and

reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We note that these are the same CBSA-based designations implemented for acute care hospitals under the IPPS at § 412.64(b) (69 FR 49026 through 49034). (For further discussion of the CBSA-based labor market area (geographic classification) definitions currently used under the LTCH PPS, we refer readers to the RY 2006 LTCH PPS final rule (70 FR 24182 through 24191).) We have generally updated the LTCH PPS CBSA-based labor market area definitions 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 beginning October 1, 2010, and adopted their continued use for FY 2012 and FY 2013 (76 FR 51808 and 77 FR 53710, respectively). In the FY 2013 IPPS/LTCH PPS final rule, we explained that in 2013 OMB planned to announce new area delineations based on its 2010 standards and the 2010 Census data and, therefore, for the FY 2013 LTCH area wage level adjustment, we would continue to use the same labor market areas that we adopted for FY 2012 (77 FR 53710). In fact, on February 28, 2013, OMB issued OMB Bulletin No. 13-01, announcing revisions to the delineation of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and

guidance on uses of the delineation of these 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, this 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 in the **Federal Register** on June 28, 2010 (75 FR 37246 through 37252) and Census Bureau data.

In order to implement these changes for the LTCH PPS (as in the case of the IPPS, as discussed in section III.B. of the preamble of this proposed rule), it is necessary to identify the new area designations 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, there are new CBSAs, urban counties that have become rural, rural counties that have become urban, and existing CBSAs that have been split apart.

Because the update was not issued until February 28, 2013, and the changes made by the update and their ramifications must be extensively reviewed and verified, we were unable to undertake such a lengthy process before publication of this FY 2014 proposed rule. By the time the update was issued, the FY 2014 IPPS/LTCH PPS proposed rule was in the advanced stages of development. We had already developed the FY 2014 proposed LTCH PPS wage indexes based on the previous OMB definitions that are currently used under the LTCH PPS. We note that CMS was faced with a similar

situation 10 years ago, when OMB announced changes resulting from the 2000 Census in June 2003. At that time, CMS proposed and implemented the changes under the IPPS for FY 2005, followed by the adoption under the LTCH PPS in RY 2006 (as noted previously). Similarly, to allow for sufficient time to assess the new changes and their ramifications, consistent with the proposal under the IPPS discussed in section III.B. of the preamble of this proposed rule, we intend to propose the adoption of the newest CBSA designations and the corresponding changes to the wage index based on those CBSA changes under the LTCH PPS for FY 2015 through notice and comment rulemaking. We refer readers to the RY 2006 LTCH PPS final rule (70 FR 24182 through 24191) for further information on the CBSA-based labor market area definitions currently used under the LTCH PPS. In addition, we refer readers to the FY 2005 IPPS final rule (69 FR 49026 through 49032) for those interested in learning about the issues that may need to be addressed in developing a proposal to implement the latest OMB update to the CBSA designations for FY 2015, and some of the policy decisions that may need to be taken into consideration in the development of such a proposal.

For FY 2014, we are proposing to continue to use the same labor market areas that were used under the LTCH PPS for FY 2013 (77 FR 53710) as we assess the new changes to the CBSA designations and their effect on LTCH PPS payments. This is consistent with the proposed approach being taken under the IPPS, and as noted previously, the LTCH PPS currently uses the same CBSA-based designations implemented for acute care hospitals under the IPPS.

3. Proposed LTCH PPS Labor-Related Share

Under the adjustment for differences in area wage levels at § 412.525(c), the labor-related share of a LTCH's PPS Federal prospective payment is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs (Wages and Salaries, Employee Benefits, Professional Fees: 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. Specifically, we determined the LTCH PPS labor-related share for FY 2013 based on the relative importance of the labor-related share of operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Business Support Services, and All Other: Labor-Related Services) and the labor-related share of capital costs of the LTCH-specific market basket based on FY 2009 data, as we believed these were the best data available to reflect the cost

structure of LTCHs. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479 and 53710 through 53711), we established a labor-related share under the LTCH PPS for FY 2013 of 63.096 percent based on IGI's second quarter 2012 forecast of the FY 2009-based LTCH-specific market basket for FY 2013, as these were the most recent available data at that time that reflected the cost structure of LTCHs. (For additional details on the development of the LTCH PPS labor-related share for FY 2013, we refer readers to section VII.C.3.f. of the preamble of the FY 2013 IPPS/LTCH PPS final rule.)

Consistent with our historical practice, we are proposing to determine the LTCH PPS labor-related share for FY 2014 based on the proposed FY 2014 relative importance of each labor-related cost category, and would reflect the different rates of price change for these cost categories between the base year (FY 2009) and FY 2014. For this proposed rule, we are proposing to determine the LTCH PPS labor-related share for FY 2014 based on IGI's first quarter 2013 forecast of the FY 2009-based LTCH-specific market basket as this is currently the best available data. In addition, consistent with our proposal to update the labor-related share with the most recent available data, we are proposing that if more recent data become available, we would use those data in determining the labor-related share under the LTCH PPS for FY 2014 in the final rule.

The table below shows the proposed FY 2014 labor-related share relative importance using IGI's first quarter 2013 forecast of the FY 2009-based LTCH-specific market basket. The sum of the proposed relative importance for FY 2014 for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Business Support Services, and All Other: Labor-related Services)

would be 58.495 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 9.179 percent of the proposed FY 2009-based LTCH-specific market basket in FY 2014, we are proposing to take 46 percent of 9.179 percent to determine the proposed labor-related share of capital-related costs for FY 2014, which would result in 4.222 percent (0.46×9.179). We would then add that proposed 4.222 for the capital-related cost amount to the proposed 58.495percent for the operating cost amount to determine the total proposed labor-related share for FY 2014. Thus, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of BIPA, to determine appropriate adjustments under the LTCH PPS, we are proposing a labor-related share under the LTCH PPS in FY 2014 of 62.717 percent. This proposed labor-related share is determined using the same methodology as employed in calculating all previous LTCH labor-related shares.

**PROPOSED FY 2014 LABOR-RELATED SHARE
RELATIVE IMPORTANCE BASED ON
THE FY 2009-BASED LTCH-SPECIFIC MARKET BASKET**

	Proposed FY 2014 Labor-Related Share Relative Importance
Wages and Salaries	45.130
Employee Benefits	8.134
Professional Fees: Labor-Related	2.214
Administrative and Business Support Services	0.502
All Other: Labor-Related Services	2.515
Subtotal	58.495

	Proposed FY 2014 Labor-Related Share Relative Importance
Labor-Related Portion of Capital Costs (46%)	4.222
Total Labor-Related Share	62.717

4. Proposed LTCH PPS Wage Index for FY 2014

Historically, under the LTCH PPS, we have established LTCH PPS wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on a LTCH's actual location without regard to the urban or rural designation of any related or affiliated provider.

In the FY 2013 LTCH PPS final rule (77 FR 53711 through 53712), we calculated the FY 2013 LTCH PPS wage index values using the same data used for the FY 2013 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2009), without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act, as these were the most recent complete data available at that time. In that same final rule, we indicated that we computed the FY 2013 LTCH PPS wage index values consistent with the urban and rural geographic classifications (labor market areas) and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments under the LTCH PPS). 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 wage index values in areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable wage index values under the LTCH PPS for FY 2014, 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 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 2010, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act. We are proposing to use FY 2010 data because these data are the most recent complete data available. These are the same data used to compute the proposed FY 2014 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this proposed rule. (For our rationale for using IPPS hospital wage data as a proxy for determining the wage index values used under the LTCH PPS, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44024 through 44025).)

The proposed FY 2014 LTCH PPS wage index values were computed consistent with the urban and rural geographic classifications (labor market areas) discussed above in section V.B.2. of the Addendum to this proposed rule and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS). As with the IPPS wage index,

wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus or campuses are located (as discussed in section III.G. of the preamble of this proposed rule). Furthermore, in determining the proposed FY 2014 LTCH PPS wage index values in this proposed rule, we are proposing to continue to use our existing policy for determining wage index values in areas where there are no IPPS wage data. We established a methodology for determining LTCH PPS wage index values for areas that have no IPPS wage data in the RY 2009 LTCH PPS final rule, and we are proposing to continue to use this methodology for FY 2014. (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 areas without IPPS hospital wage data (or IPPS hospitals) for FY 2014. However, we calculate LTCH PPS wage index values for these areas using our established methodology in the event that, in the future, a LTCH should open in one of those areas. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data is determined by using an average of all of the urban areas within the State, and the LTCH PPS wage index value for rural areas with no IPPS wage data is determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2010 IPPS wage data that we used to determine the proposed FY 2014 LTCH PPS wage index values in this proposed rule, there are no IPPS wage

data for the urban area Hinesville-Fort Stewart, GA (CBSA 25980). Consistent with the methodology discussed above, we calculated the proposed FY 2014 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 2010 IPPS wage data that we are using to determine the proposed FY 2014 LTCH PPS wage index values in this proposed rule, there are no rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate a LTCH PPS wage index value for rural areas with no IPPS wage data for FY 2014. We note that, as IPPS wage data are dynamic, it is possible that rural areas without IPPS wage data will vary in the future.

The proposed FY 2014 LTCH wage index values that would be applicable for LTCH discharges occurring on or after October 1, 2013, through September 30, 2014, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of the Addendum of this proposed rule and available via the Internet on the CMS Web site.

5. Proposed Budget Neutrality Adjustment for Changes to the Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the wage index values or labor-related share are made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage level adjustment budget neutrality factor that will be applied to the standard Federal rate to ensure that any changes to the area wage level adjustment are budget neutral such that any changes to the wage index values or labor-related share will not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we 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).)

As we did for FY 2013, in accordance with § 412.523(d)(4), for FY 2014, 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 the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). Specifically, we are proposing to determine an area wage

level adjustment budget neutrality factor that would be applied to the standard Federal rate under § 412.523(d)(4) for FY 2014 using the following methodology:

Step 1—We simulated estimated aggregate LTCH PPS payments using the FY 2013 wage index values (as established in Tables 12A and 12B listed in the Addendum to the FY 2013 IPPS/LTCH PPS final rule and available via the Internet on the CMS Web site) and the FY 2013 labor-related share of 63.096 percent (as established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479 and 53710 through 53711)).

Step 2—We simulated estimated aggregate LTCH PPS payments using the proposed FY 2014 wage index values (as shown in Tables 12A and 12B listed in the Addendum to this proposed rule and available via the Internet on the CMS Web site) and the proposed FY 2014 labor-related share of 62.717 percent (based on the latest available data as discussed previously in section V.B.3. of this Addendum).

Step 3—We calculated the ratio of these estimated total LTCH PPS payments by dividing the estimated total LTCH PPS payments using the FY 2013 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS payments using the proposed FY 2014 area wage level adjustments (calculated in Step 2) to determine the proposed area wage level adjustment budget neutrality factor for FY 2014.

Step 4—We then applied the proposed FY 2014 area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2014 LTCH PPS standard Federal rate after the application of the proposed FY 2014 annual update (discussed in section V.A.2. of the Addendum to this proposed rule). For this proposed

rule, using the steps in the methodology described above, we determined a proposed FY 2014 area wage level adjustment budget neutrality factor of 1.000433. Accordingly, in section V.A.2. of the Addendum to this proposed rule, to determine the proposed FY 2014 LTCH PPS standard Federal rate, we are proposing to apply a proposed area wage level adjustment budget neutrality factor of 1.000433, in accordance with § 412.523(d)(4). The proposed FY 2014 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 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.

As discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53481 through 53482 and 53712 through 53713), historically, 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). We explained that we did not believe it was appropriate to use either the 2010 or 2011 reduced COLA factors to adjust the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska and Hawaii for Medicare payment purposes. In addition, we believe that it was appropriate to use “frozen” COLA factors to adjust payments, while we explored alternatives for updating the COLA factors in the future.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53712 through 53713), 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). In that same final rule, 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. 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). As also explained in that same final rule, we believe that using these updated COLA factors will 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).)

In this proposed rule, for FY 2014, 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 adjustments under the LTCH PPS, we are proposing to update 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 for purposes of making a COLA for LTCHs located in Alaska and Hawaii under § 412.525(b). Specifically, the methodology uses 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 BLS. As discussed in that same final rule (77 FR 53481 through 53482), because BLS publishes CPI data for only Anchorage, Alaska and Honolulu, Hawaii, our methodology uses a comparison of the growth in the Consumer Price Indices (CPIs) for those cities relative to the growth in the overall CPI to update the COLA factors for all areas located in Alaska and Hawaii, respectively. We believe that the relative price differences between these cities and the United States (as measured by the CPIs mentioned above) are generally appropriate and necessary proxies for the relative price differences between the “other areas” of Alaska and Hawaii and the United States.

The “CPI for All Items” that BLS publishes for Anchorage, Honolulu, and for the average U.S. city are based on a different mix of commodities and services than is reflected in the nonlabor-related share of the IPPS market basket. We note that the mix of commodities and services for the nonlabor-related share based on the LTCH market basket is similar to that of the nonlabor-related share of the IPPS market basket. As such,

under the methodology we established to update the COLA factors, we calculated a “reweighted CPI” using the CPI for commodities and the CPI for services for each of the geographic areas to mirror the composition of the IPPS market basket nonlabor-related share. Furthermore, we note that, if finalized, we do not anticipate that the proposals in section IV. of this preamble to revise and rebase the IPPS market basket for FY 2014 would alter the commodity/services weights for the nonlabor-related share of the IPPS market basket.

The current composition of BLS’ CPI for All Items for all of the respective areas is approximately 40 percent commodities and 60 percent services. However, the nonlabor-related share of the proposed IPPS market basket is comprised of approximately 60 percent commodities and 40 percent services. Therefore, under the methodology we established in the FY 2013 IPPS/LTCH PPS final rule we have created reweighted indexes for Anchorage, Alaska and Honolulu, Hawaii, and the average U.S. city using the respective CPI commodities index and CPI services index and applying the approximate 60/40 weights from the proposed IPPS market basket. We believe that this method of reweighting is appropriate because we would continue to make a COLA for LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the LTCH PPS standard Federal rate by a COLA factor.

Under the COLA factor update methodology we established in the FY 2013 IPPS/LTCH PPS final rule, we further exercised our discretionary authority to adjust payments made to LTCHs located in Alaska and Hawaii by incorporating a 25-percent cap on the CPI-updated COLA factors used to adjust the nonlabor-related portion of the

LTCH PPS standard Federal rate, which is consistent with a statutorily mandated 25-percent cap that was applied to OPM's published COLA factors. We believe that this is appropriate because our proposed CPI-updated COLA factors for FY 2014 uses the 2009 OPM COLA factors as a basis. In addition, we are proposing to continue to establish COLA factors that are rounded to 2 decimal places, which is consistent with the number of decimal places in the 2009 OPM COLA factors that are used as the basis for calculating the proposed FY 2014 COLA factors. This policy would also maintain consistency with the rounding used for the 25-percent cap on the COLA factors (that is, a COLA factor of no more than 1.25).

Applying this methodology, we are proposing to establish the COLA factors for FY 2014 that would adjust the nonlabor-related portion of the standard Federal rate for LTCHs located in Alaska and Hawaii as shown in the table below.

**Proposed Cost-of-Living Adjustment Factors for Alaska and Hawaii
Hospitals for the LTCH PPS for FY 2014**

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

Each of the COLA factors were calculated using data through 2012, as these are the latest historical CPI data published by the BLS. The reweighted CPI for Honolulu, Hawaii grew faster than the reweighted CPI for the average U.S. city over the time period

from 2009 to 2012, with a growth rate of 8.9 percent and 8.3 percent, respectively. As a result, for FY 2014, we calculated proposed COLA factors for the City and County of Honolulu, the County of Kauai, the County of Maui, and the County of Kalawao to be 1.26 compared to the FY 2013 COLA factor of 1.25. However, as stated above, our COLA factor update methodology caps the COLA factors at 1.25. In addition, the proposed COLA factor calculated for the County of Hawaii for FY 2014 is 1.19 compared to the FY 2013 COLA factor of 1.18.

The reweighted CPI for Anchorage, Alaska grew slower than the reweighted CPI for the average U.S. city over the time period from 2009 to 2012, with a growth rate of 8.0 percent and 8.3 percent, respectively. However, applying this slower relative growth rate to the FY 2009 COLA factors for each of the Alaska areas results in no proposed change to the COLA factors for the Alaska areas for FY 2014 (1.25 for “All other areas of Alaska” and 1.23 for the three specified urban areas of Alaska (Anchorage, Fairbanks, and Juneau) as compared to the FY 2013 COLA factors.

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 a LTCH can incur under the LTCH PPS for a case

with unusually high costs before the LTCH will receive any additional payments. We calculate the fixed-loss amount by estimating aggregate payments with and without an outlier policy. The fixed-loss amount results in estimated total outlier payments being projected to be equal to 8 percent of projected total LTCH PPS payments. Currently, MedPAR claims data and CCRs based on data from the most recent Provider-Specific File (PSF) (or from the applicable statewide average CCR if a LTCH's CCR data are faulty or unavailable) are used to establish a fixed-loss threshold amount under the LTCH PPS.

2. Determining LTCH CCRs under the LTCH PPS

a. Background

The following is a discussion of CCRs that are used in determining payments for HCO and SSO cases under the LTCH PPS, at § 412.525(a) and § 412.529, respectively. Although this section is specific to HCO cases, because CCRs and the policies and methodologies pertaining to them are used in determining payments for both HCO and SSO cases (to determine the estimated cost of the case at § 412.529(d)(2)), we are discussing the determination of CCRs under the LTCH PPS for both of these types of cases simultaneously.

In determining both HCO payments (at § 412.525(a)) and SSO payments (at § 412.529), we calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. In general, we use the LTCH's overall CCR, which is computed based on either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting

period, in accordance with § 412.525(a)(4)(iv)(B) and § 412.529(f)(4)(ii) for HCOs and SSOs, respectively. (We note that, in some instances, we use an alternative CCR, such as the statewide average CCR in accordance with the regulations at § 412.525(a)(4)(iv)(C) and § 412.529(f)(4)(iii), or a CCR that is specified by CMS or that is requested by the hospital under the provisions of the regulations at § 412.525(a)(4)(iv)(A) and § 412.529(f)(4)(i).) Under the LTCH PPS, a single prospective payment per discharge is made for both inpatient operating and capital-related costs. Therefore, we compute a single “overall” or “total” LTCH-specific CCR based on the sum of LTCH operating and capital costs (as described in Section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100-4)) as compared to total charges. Specifically, a LTCH's CCR is calculated by dividing a LTCH's total Medicare costs (that is, the sum of its operating and capital inpatient routine and ancillary costs) by its total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges).

b. LTCH Total CCR Ceiling

Generally, a LTCH is assigned the applicable statewide average CCR if, among other things, a LTCH's CCR is found to be in excess of the applicable maximum CCR threshold (that is, the LTCH CCR ceiling). This is because CCRs above this threshold are most likely due to faulty data reporting or entry, and, therefore, CCRs based on erroneous data should not be used to identify and make payments for outlier cases. Thus, under our established policy, generally, if a LTCH's calculated CCR is above the applicable ceiling, the applicable LTCH PPS statewide average CCR is assigned to the

LTCH instead of the CCR computed from its most recent (settled or tentatively settled) cost report data.

In accordance with § 412.525(a)(4)(iv)(C)(2) for HCOs and § 412.529(f)(4)(iii)(B) for SSOs, in this proposed rule, using our established methodology for determining the LTCH total CCR ceiling (described above), based on IPPS total CCR data from the December 2012 update of the PSF, we are proposing to establish a total CCR ceiling of 1.259 under the LTCH PPS that would be effective for discharges occurring on or after October 1, 2013 through September 30, 2014.

Consistent with our historical policy of using the best available data, we also are proposing that if more recent data became available, we would use such data to establish a total CCR ceiling for FY 2014 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 fiscal intermediary or MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for a LTCH in one of the following circumstances: (1) new LTCHs that have not yet submitted their first Medicare cost report (for this purpose, consistent with current policy, a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose CCR is in

excess of the LTCH CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the fiscal intermediary or MAC may consider in determining a LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as a LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data, 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 2012 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, 2013 through September 20, 2014, in Table 8C listed in section VI. of the Addendum to this proposed rule (and available via the Internet). Furthermore, consistent with our historical practice of using the best available data, we also are proposing that if more recent data become available, we would use such data to establish LTCH PPS statewide average total CCRs for urban and rural hospitals that would be effective for FY 2014 in the final rule. All areas in the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for

determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although Connecticut has areas that are designated as rural, there are no short-term, acute care IPPS hospitals or LTCHs located in those areas as of March 2013.

Therefore, consistent with our existing methodology, we are proposing to use the national average total CCR for rural IPPS hospitals for rural Connecticut 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 2014

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 2013 IPPS/LTCH PPS final rule (77 FR 53715), we presented our policies regarding the methodology and data we would use to establish the fixed-loss amount of \$15,408 for FY 2013. In general, for FY 2014, we are proposing to continue to use our existing methodology to calculate a fixed-loss amount for FY 2014 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 that proposed 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).) Using our existing methodology, we are proposing a fixed-loss amount of \$14,139 for FY 2014.

In this proposed rule, we are proposing to continue to use our existing methodology to calculate the fixed-loss amount for FY 2014 (based on the data and the rates and policies presented in this proposed rule) in order to maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments. Consistent with our historical practice of using the best data available, in determining the fixed-loss amount for FY 2014, we are proposing to use the most recent available LTCH claims data and CCR data at this time. Specifically, for this proposed rule, we are proposing to use LTCH claims data from the December 2012 update of the FY 2012 MedPAR file and CCRs from the December 2012 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 2014 because these data are the most recent complete LTCH data available at this time.

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 \$14,139 for FY 2014. Thus, we are proposing to make an additional payment for an HCO case that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted Federal LTCH payment for the MS-LTC-DRG and the fixed-loss amount of \$14,139). We also note that the proposed fixed-loss amount of

\$14,139 for FY 2014 is lower than the FY 2013 fixed-loss amount of \$15,408. Based on our payment simulations using the most recent available data at this time, the decrease in the proposed fixed-loss amount for FY 2014 is necessary to maintain the existing requirement that estimated outlier payments would equal 8 percent of estimated total LTCH PPS payments. (For further information on the existing 8 percent HCO “target” requirement, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56022 through 56024).) Maintaining the fixed-loss amount at the current level would result in HCO payments that are less than the current regulatory 8-percent requirement because a higher fixed-loss amount would result in fewer cases qualifying as outlier cases. In addition, maintaining the higher fixed-loss amount would result in a decrease in the amount of the additional payment for an HCO case because the maximum loss that a LTCH must incur before receiving an HCO payment (that is, the fixed-loss amount) would be larger. For these reasons, we believe that lowering the fixed-loss amount is appropriate and necessary to maintain that estimated outlier payments would equal 8 percent of estimated total LTCH PPS payments as required under § 412.525(a).

4. Application of Outlier Policy to SSO Cases

As we discussed in the August 30, 2002 final rule (67 FR 56026), under some rare circumstances, a LTCH discharge could qualify as an SSO case (as defined in the regulations at § 412.529 in conjunction with § 412.503) and also as an HCO case. In this scenario, a patient could be hospitalized for less than five-sixths of the geometric average length of stay for the specific MS-LTC-DRG, and yet incur extraordinarily high treatment costs. If the estimated costs exceeded the HCO threshold (that is, the SSO

payment plus the fixed-loss amount), the discharge is eligible for payment as an HCO.

Thus, for an SSO case in FY 2014, 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 \$14,139 and the amount paid under the SSO policy as specified in § 412.529).

E. Computing the Proposed Adjusted LTCH PPS Federal Prospective Payments for FY 2014

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 2014 values are shown in Tables 12A and 12B listed in section VI. of the Addendum of this proposed rule and are available via the Internet). The 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 2014 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 2014 of \$40,622.06 (provided the LTCH submits quality reporting data for FY 2014 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 2014 in the following example:

Example:

During FY 2014, a Medicare patient is in a LTCH located in Chicago, Illinois (CBSA 16974) and discharged on January 1, 2014. The proposed FY 2014 LTCH PPS wage index value for CBSA 16974 is 1.0446 (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 28 (Spinal Procedures with MCC), which has a relative weight for FY 2014 of 1.6023 (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 2014 in accordance with the LTCHQR Program under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted Federal prospective payment for this Medicare patient in FY 2014, we compute the wage-adjusted proposed Federal prospective payment amount by multiplying the unadjusted proposed FY 2014 standard Federal rate (\$40,622.06, for LTCHs that submit quality reporting data for FY 2014 in accordance with the LTCHQR Program under section 1886(m)(5) of the Act) by the proposed labor-related share (62.717 percent) and the proposed wage index value (1.0446). This wage-adjusted amount is then added to the proposed nonlabor-related portion of the unadjusted proposed standard Federal rate (37.283 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 (1.6023) to calculate the total adjusted proposed Federal LTCH PPS prospective payment for FY 2014 (\$66,909.36). The table below illustrates the components of the calculations in this example.

Unadjusted Proposed Standard Federal Prospective Payment Rate (provided the LTCH submits quality data in accordance with the LTCHQR Program under section 1886(m)(5) of the Act)	\$40,622.06
Proposed Labor-Related Share	x 0.62717
Labor-Related Portion of the Proposed Federal Rate	= \$25,476.94
Proposed Wage Index (CBSA 16974)	x 1.0446
Proposed Wage-Adjusted Labor Share of Federal Rate	= \$26,613.21
Proposed Nonlabor-Related Portion of the Federal Rate (\$40,622.06 x 0.37283)	+ \$15,145.12
Adjusted Proposed Federal Rate Amount	= \$41,758.33
Proposed MS-LTC-DRG 28 Relative Weight	x 1.6023
Total Adjusted Proposed Federal Prospective Payment	= \$66,909.37

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 and 2013, for the FY 2014 rulemaking cycle, the IPPS and LTCH tables will not be published as part of the annual IPPS/LTCH PPS proposed and final rulemakings and will be available only through the Internet. Specifically, IPPS Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 5, Supplement to 5, 6G, 6H, 6I, 6J, 6K, 7A, 7B, 8A, 8B, 9A, 9C, 10, 15, and 16 and LTCH PPS Tables 8C, 11, 12A, 12B, 13A, and 13B will be available only through the Internet. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E, displayed at the end of this section, will continue to be published in the **Federal Register** as part of the annual proposed and final rules. As discussed in section II.G.9. and 11. of the preamble of this proposed rule, Tables 6A through 6F will not be issued with this FY 2014 proposed rule because there are no changes to the ICD-9-CM codes. As discussed in section V.C. of the preamble of this proposed rule, effective FY 2014 and forward, the low-volume hospital definition and payment adjustment methodology under section 1886(d)(12) of the Act returns to the pre-Affordable Care Act definition and payment adjustment methodology (we refer readers to section V.C. for complete details on the low-volume hospital payment adjustment). Therefore, we are no longer including a table (previously Table 14) in this proposed rule that lists the low-volume payment adjustments.

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

The following IPPS tables for this FY 2014 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 2014 IPPS Proposed Rule Home Page” or “Acute Inpatient--Files for Download”.

Table 2.—Proposed Acute Care Hospitals Case-Mix Indexes for Discharges Occurring in Federal Fiscal Year 2012; Proposed Hospital Wage Indexes for Federal Fiscal Year 2014; Hospital Average Hourly Wages for Federal Fiscal Years 2012 (2008 Wage Data), 2013 (2009 Wage Data), and 2014 (2010 Wage Data); and 3-Year Average of Hospital Average Hourly Wages

Table 3A.—Proposed FY 2014 and 3-Year* Average Hourly Wage for Acute Care Hospitals in Urban Areas by CBSA

Table 3B.—Proposed FY 2014 and 3-Year* Average Hourly Wage for Acute Care Hospitals in Rural Areas by CBSA

Table 4A.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Urban Areas by CBSA and by State--FY 2014

Table 4B.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals in Rural Areas by CBSA and by State--FY 2014

Table 4C.—Proposed Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals That Are Reclassified by CBSA and by State--FY 2014

Table 4D.—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 2014

Table 4E.—Urban CBSAs and Constituent Counties for Acute Care Hospitals--FY 2014

Table 4F.—Proposed Puerto Rico Wage Index and Capital Geographic Adjustment Factor (GAF) for Acute Care Hospitals by CBSA--FY 2014

Table 4J.—Proposed Out-Migration Adjustment for Acute Care Hospitals—FY 2014

Table 5.—List of Proposed Medicare Severity Diagnosis-Related Groups (MS-DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay--FY 2014

Supplement to Table 5--List of MS-DRGs and Relative Weighting Factors Using 15 Cost-to-Charge Ratios (Not Proposed)—FY 2014

Table 6G.—Proposed Additions to the CC Exclusions List--FY 2014

Table 6H – Proposed Deletions from the CC Exclusions List – FY 2014

Table 6I.—Proposed Major CC List—FY 2014

Table 6J.—Proposed Complete CC List—FY 2014

Table 6K.—Proposed Complete List of CC Exclusions—FY 2014

Table 7A.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2012 MedPAR Update—December 2012 GROUPER V30.0 MS-DRGs

Table 7B.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2012 MedPAR Update—December 2012 GROUPER V31.0 MS-DRGs

Table 8A.—Proposed FY 2014 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)

Table 8B.—Proposed FY 2014 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals

Table 9A.—Hospital Reclassifications and Redesignations--FY 2014

Table 9C.—Hospitals Redesignated as Rural under Section 1886(d)(8)(E) of the Act--FY 2014

Table 10.—Proposed New Technology Add-On Payment Thresholds ^{1,2} for Applications for FY 2015

Table 15.—Proposed FY 2014 Proxy Readmissions Adjustment Factors

Table 16.—Proposed Proxy Hospital Inpatient Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2014

The following LTCH PPS tables for this FY 2014 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-1599-P.

Table 8C.—Proposed FY 2014 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, 2013 through September 30, 2014 under the LTCH PPS

Table 12A.—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2013 through September 30, 2014

Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2013 through September 30, 2014

Table 13A.—Proposed Composition of Low-Volume Quintiles for MS-LTC-DRGs—FY 2014

Table 13B.—Proposed No-Volume MS-LTC-DRG Crosswalk for FY 2014

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 2014

Full Update (1.8 Percent)		Reduced Update (-0.2 Percent)	
Labor-related	Nonlabor-related	Labor-related	Nonlabor-related
\$3,741.72	\$1,634.32	\$3,668.21	\$1,602.21

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 2014

Full Update (1.8 Percent)		Reduced Update (-0.2 Percent)	
Labor-related	Nonlabor-related	Labor-related	Nonlabor-related
\$3,333.14	\$2,042.90	\$3,267.66	\$2,002.76

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 2014

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
¹ National	Not Applicable	Not Applicable	\$3,333.14	\$2,042.90
Puerto Rico	\$1,626.53	\$947.09	\$1,595.64	\$977.98

¹ For FY 2014, there are no CBSAs in Puerto Rico with a proposed national wage index greater than 1.

TABLE 1D.—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2014

	Rate
National	\$432.03
Puerto Rico	\$212.50

**TABLE 1E.—PROPOSED LTCH STANDARD FEDERAL PROSPECTIVE
PAYMENT RATE--FY 2014**

	Full Update (1.8 Percent)	Reduced Update* (-0.2 Percent)
Standard Federal Rate	\$40,622.06	\$39,823.99

* For LTCHs that fail to submit quality reporting data for FY 2014 in accordance with the LTCH Quality Reporting Program, the proposed 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 2014 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 \$110 million decrease in FY 2014 operating payments (or -0.1 percent change) and an estimated \$101 million increase in FY 2014 capital payments (or 1.1 percent change). These proposed changes are relative to payments made in FY 2013. The impact analysis of the proposed capital payments can be found in section I.K. of this Appendix. In addition, as described in section I.L. of this Appendix, LTCHs are expected to experience an increase in payments by \$62 million in FY 2014 relative to FY 2013.

Our operating impact estimate includes the proposed -0.8 percent documentation and coding adjustment applied to the IPPS standardized amount, as part of the recoupment required under section 631 of the ATRA. It includes the proposed -0.2 percent adjustment applied to the IPPS standardized amount, the hospital-specific rate, and the Puerto Rico-specific rate to offset the cost of the policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A. In addition, our operating payment impact estimate includes the proposed 1.8 percent hospital update to the standardized amount (which includes the estimated 2.5 percent market basket update less 0.4 percentage point for the proposed multifactor productivity adjustment and less 0.3 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.

B. Need

This proposed rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This proposed rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS payment system.

C. Objectives of the IPPS

The primary objective of the IPPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe the 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 31 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, 45 such hospitals in Maryland remain excluded from the IPPS pursuant to the waiver under section 1814(b)(3) of the Act.

As of March 2013, there are 3,404 IPPS acute care hospitals included in our analysis. This represents approximately 55 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,328 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, and 11 cancer hospitals, which are paid under separate payment systems. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts for these IPPS-excluded hospitals and units are not included in this proposed rule. The impact of the proposed update and proposed policy changes to the LTCH PPS for FY 2014 is discussed in section I.L. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of March 2013, there were 97 children's hospitals, 11 cancer hospitals, 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, 234 rehabilitation hospitals and 898 rehabilitation units, and 437 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 472 psychiatric hospitals and 1,155 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.L. of this Appendix.

For children's hospitals, the 11 cancer hospitals, and RNHCIs, the proposed update of the rate-of-increase limit (or target amount) is the estimated FY 2014 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 this proposed rule, we are proposing to rebase

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 2014 and subsequent years for children's hospitals, the 11 cancer hospitals, 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 2013 first quarter forecast of the proposed FY 2010-based market basket increase, we are estimating that the proposed FY 2014 update based on the IPPS operating market basket is 2.5 percent (that is, the current estimate of the market basket rate-of-increase).

However, the Affordable Care Act requires an adjustment for multifactor productivity (currently proposed to be 0.4 percentage point) and a 0.3 percentage point reduction to the market basket update resulting in a proposed 1.8 percent applicable percentage increase for IPPS hospitals subject to a reduction of 2.0 percentage points if the hospital fails to submit quality data under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act. Children's hospitals, the 11 cancer hospitals, and RNHCIs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. Therefore, for RNHCIs, children's hospitals, and the 11 cancer hospitals paid under § 413.40 of the regulations, the proposed update is the proposed percentage increase in the FY 2014 IPPS operating market basket, estimated at 2.5 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 proposed payment rate updates for the IPPS for FY 2014 for operating costs of acute care hospitals. The proposed FY 2014 updates to the capital payments to acute care hospitals are discussed in section I.K. of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2014 operating payments will

decrease by 0.1 percent compared to FY 2013. In addition to the applicable percentage increase, this amount reflects the proposed FY 2014 recoupment adjustment for documentation and coding described in section II.D. of the preamble of this proposed rule and the proposed adjustment to offset the cost of the policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A: a -0.8 percent adjustment to the IPPS national standardized amounts for the proposed documentation and coding adjustment and a -0.2 percent adjustment to the IPPS national standardized amount, the Puerto Rico-specific rate and the hospital-specific rate for the policy proposal on admission and medical review criteria. 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 proposed changes in payments per case presented below are taken from the FY 2012 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 2012 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 2014 are discussed in section I.K. of this Appendix.

We discuss the following proposed changes below:

- The effects of the application of the proposed documentation and coding adjustment, the proposed adjustment to offset the costs of the policy proposal on admission and medical review criteria 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, including the proposed methodology to calculate the MS-DRG cost based relative weights using 19 departmental CCRs instead of the current 15 departmental CCRs.
- The effects of the proposed changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2010, compared to the FY 2009 wage data and the proposed changes in the labor related share from 68.8 percent for FY 2013 to the proposed 69.6 percent for FY 2014 for hospitals with a wage index greater than 1.0.
- The effects of the proposed recalibration of the MS-DRG relative weights as required by section 1886(d)(4)(C) of the Act, including the proposed wage and recalibration budget neutrality factors.
- The effects of the geographic reclassifications by the MGCRB as of publication of this proposed rule that would be effective for FY 2014.
- The effects of the proposed rural floor and imputed floor with the application of the national budget neutrality factor applied to the wage index.
- 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 cannot 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 Pub. L. 108-173, which provides for an increase in a hospital's wage index if the hospital qualifies by meeting a threshold percentage of residents of the county where the hospital is located who commute to work at hospitals in counties with higher wage indexes.

- The 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 hospital's base operating DRG amount by an adjustment factor to account for a hospital's excess readmissions.

- The effects of the expiration of the special payment status for MDHs under section 606 of the ATRA under which MDHs that currently receive the higher of payments made under the Federal standardized amount or the payments made under the Federal standardized amount plus 75 percent of the difference between the Federal standardized amount and the hospital-specific rate will be paid based on the Federal standardized amount starting in FY 2014.

- The effects of the proposed 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 total estimated change in payments based on the proposed FY 2014 policies relative to payments based on FY 2013 policies that include the applicable

percentage increase of 1.8 percent (or 2.5 percent market basket update with a proposed reduction of 0.4 percentage point for the multifactor productivity adjustment, and a 0.3 percentage point reduction, as required under the Affordable Care Act).

To illustrate the impact of the proposed FY 2014 changes, our analysis begins with a FY 2013 baseline simulation model using: the proposed FY 2014 applicable percentage increase of 1.8 percent and the proposed documentation and coding adjustment of 0.8 percent to the Federal standardized amount and the proposed adjustment 0.2 percent to the Federal standardized amount, the hospital-specific rate, and the Puerto Rico-specific rate for the policy proposal on admission and medical review criteria; the FY 2013 MS-DRG GROUPER (Version 30.0); the most current CBSA designations for hospitals based on OMB's MSA definitions; the FY 2013 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 Pub. L. 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, 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.) At the time that this impact was prepared, 52 hospitals did not receive the full market basket rate-of-increase

for FY 2013 because they failed the quality data submission process or did not choose to participate. For purposes of the simulations shown below, we modeled the proposed payment changes for FY 2014 using a reduced update for these 52 hospitals. However, we do not have enough information at this time to determine which hospitals will not receive the full update factor for FY 2014.

Each proposed policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2014 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 2013 to FY 2014. Three factors not discussed separately have significant impacts here. The first factor is the update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are proposing to update the standardized amounts for FY 2014 using a proposed applicable percentage increase of 1.8 percent. This includes our forecasted IPPS operating hospital market basket increase of 2.5 percent with a proposed reduction of 0.4 percentage point for the multifactor productivity adjustment and a 0.3 percentage point reduction as required under the Affordable Care Act. (Hospitals that fail to comply with the quality data submission requirements would receive a proposed update of -0.2 percent (this proposed update includes the 2.0 percentage point reduction for failure to submit these data)). Under section 1886(b)(3)(B)(iv) of the Act, the updates to the hospital-specific amounts for SCHs also are equal to the applicable percentage increase, or 1.8 percent. In addition, we

are proposing to update the Puerto Rico-specific amount by an applicable percentage increase of 1.8 percent.

A second significant factor that affects the changes in hospitals' payments per case from FY 2013 to FY 2014 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 2013 that are no longer reclassified in FY 2014. Conversely, payments may increase for hospitals not reclassified in FY 2013 that are reclassified in FY 2014.

A third significant factor is that we currently estimate that actual outlier payments during FY 2013 will be 5.2 percent of total MS-DRG payments. When the FY 2013 final rule was published, we projected FY 2013 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 2013 (as discussed in the Addendum to this proposed rule) are reflected in the analyses below comparing our current estimates of FY 2013 payments per case to estimated FY 2014 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 2014. 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 3,404 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 2,481 hospitals located in urban areas included in our analysis. Among these, there are 1,367 hospitals located in large urban areas (populations over 1 million), and 1,114 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 923 hospitals in rural areas. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The final groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2013 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 2,495; 1,377; 1,118; and 909, 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 2,378 nonteaching hospitals in our analysis, 782 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 former MDHs). There were 207 RRCs, 329 SCHs, 192 former MDHs, and 124 hospitals that are both SCHs and RRCs, and 11 hospitals that were former MDHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare utilization expressed as a percent of total patient days. These data were taken from the FY 2011 or FY 2010 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 2014. 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 2014 Weights and DRG Changes with Application of Recalibration Budget Neutrality ³ (3)	Proposed FY 2014 Wage Data with Application of Wage Budget Neutrality ⁴ (4)	Proposed FY 2014 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality ⁵ (5)	Proposed FY 2014 MGCRB Reclassifications ⁶ (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality ⁷ (7)	Proposed Application of the Frontier Wage Index ⁸ (8)	Proposed FY 2014 Out-Migration Adjustment ⁹ (9)	Expiration of MDH Status ¹⁰ (10)	Proposed Hospital Readmissions Reduction Program ¹¹ (11)	Proposed Changes to Medicare DSH ¹² (12)	All Proposed FY 2014 Changes ¹³ (13)
All Hospitals	3,404	0.8	0	0	0.1	0	0	0.1	0	-0.1	-0.2	-0.9	-0.1
By Geographic Location:													
Urban hospitals	2481	0.8	0	0	0.1	-0.2	0	0.1	0	0	-0.2	-0.8	0.1
Large urban areas	1367	0.8	0	0.1	0.2	-0.3	0	0	0	0	-0.2	-0.7	0.5
Other urban areas	1114	0.8	0.1	-0.1	0	-0.1	0.1	0.2	0	-0.1	-0.1	-1.1	-0.4
Rural hospitals	923	1.2	-0.5	-0.2	-0.6	1.7	-0.3	0.1	0.1	-1.2	-0.2	-0.9	-1.9
Bed Size (Urban):													
0-99 beds	622	0.8	0.3	0	0.3	-0.4	0.1	0.2	0	-0.4	-0.1	0.6	0.9
100-199 beds	762	0.8	-0.1	0	-0.1	-0.1	0.3	0.1	0	0	-0.2	-1.1	-0.5
200-299 beds	464	0.8	-0.1	0	0	0	0	0.1	0	0	-0.2	-0.7	-0.1
300-499 beds	418	0.8	0.1	0	0.1	-0.2	0	0.1	0	0	-0.2	-0.8	0.1
500 or more beds	215	0.8	0.2	0.1	0.4	-0.2	-0.1	0	0	0	-0.2	-1	0.4
Bed Size (Rural):													
0-49 beds	339	1.1	-0.8	-0.3	-1	0.5	-0.3	0.1	0.2	-2	-0.3	0.3	-2.4

	No. of Hospitals ¹ (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment ² (2)	Proposed FY 2014 Weights and DRG Changes with Application of Recalibration Budget Neutrality ³ (3)	Proposed FY 2014 Wage Data with Application of Wage Budget Neutrality ⁴ (4)	Proposed FY 2014 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality ⁵ (5)	Proposed FY 2014 MGCRB Reclassifications ⁶ (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality ⁷ (7)	Proposed Application of the Frontier Wage Index ⁸ (8)	Proposed FY 2014 Out-Migration Adjustment ⁹ (9)	Expiration of MDH Status ¹⁰ (10)	Proposed Hospital Readmissions Reduction Program ¹¹ (11)	Proposed Changes to Medicare DSH ¹² (12)	All Proposed FY 2014 Changes ¹³ (13)
50-99 beds	328	1.2	-0.7	-0.2	-0.8	1.2	-0.3	0	0.2	-3.3	-0.3	-0.1	-3.3
100-149 beds	151	1.2	-0.6	-0.3	-0.7	1.9	-0.3	0.1	0	-0.3	-0.3	-1	-1.1
150-199 beds	59	1.1	-0.2	-0.2	-0.3	2.2	-0.4	0.1	0	0	-0.2	-1.5	-1.1
200 or more beds	46	1.2	-0.1	-0.3	-0.2	2.4	-0.3	0	0	0	-0.2	-1.9	-1.2
Urban by Region:													
New England	120	0.8	-0.1	0.4	0.4	0.7	4.4	0	0	0	-0.2	-1.5	0.2
Middle Atlantic	318	0.8	0	0.7	0.7	0.3	-0.3	0	0	0	-0.3	-0.1	1.6
South Atlantic	375	0.8	0	-0.4	-0.3	-0.4	-0.4	0	0	-0.1	-0.1	-0.4	0
East North Central	395	0.8	0	-0.2	-0.1	-0.2	-0.5	0	0	0	-0.2	-0.7	-0.2
East South Central	149	0.8	0.1	-0.5	-0.2	-0.3	-0.4	0	0	0	-0.2	-0.9	-0.3
West North Central	165	0.8	0.2	-0.2	0	-0.7	-0.5	0.8	0	-0.1	-0.1	-0.8	-0.2
West South Central	371	0.8	0.1	-0.3	0	-0.6	-0.5	0	0	0	-0.1	-0.8	-0.1
Mountain	156	0.9	0.2	-0.1	0.1	-0.1	0	0.2	0	0	-0.1	0.8	1.2
Pacific	381	0.8	0	0.5	0.5	-0.1	0.7	0	0	0	-0.1	-3.2	-1.5
Puerto Rico	51	1	-0.1	0.2	0.5	-0.8	0	0	0	0	0	34.5	35.7

	No. of Hospitals ¹ (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment ² (2)	Proposed FY 2014 Weights and DRG Changes with Application of Recalibration Budget Neutrality ³ (3)	Proposed FY 2014 Wage Data with Application of Wage Budget Neutrality ⁴ (4)	Proposed FY 2014 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality ⁵ (5)	Proposed FY 2014 MGRB Reclassifications ⁶ (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality ⁷ (7)	Proposed Application of the Frontier Wage Index ⁸ (8)	Proposed FY 2014 Out-Migration Adjustment ⁹ (9)	Expiration of MDH Status ¹⁰ (10)	Proposed Hospital Readmissions Reduction Program ¹¹ (11)	Proposed Changes to Medicare DSH ¹² (12)	All Proposed FY 2014 Changes ¹³ (13)
Rural by Region:													
New England	23	1	-0.3	0.2	-0.1	3.2	-0.5	0	0	-3.9	0	-0.8	-2.9
Middle Atlantic	69	1.2	-0.5	-0.2	-0.6	1.6	-0.3	0	0.1	-2.1	-0.2	0.3	-1.2
South Atlantic	165	1.1	-0.5	-0.3	-0.7	2.1	-0.4	0	0.1	-1	-0.3	-0.9	-1.8
East North Central	119	1.2	-0.3	-0.3	-0.6	1.3	-0.3	0	0.1	-2.1	-0.2	-0.3	-1.6
East South Central	171	0.9	-0.4	-0.5	-0.7	2.5	-0.5	0	0.1	-0.6	-0.4	-2	-3.5
West North Central	100	1.4	-0.3	0.1	-0.2	0.4	-0.1	0.3	0.1	-0.8	-0.1	-0.7	-0.4
West South Central	181	1	-0.6	-0.5	-0.9	2.2	-0.4	0	0.1	-0.4	-0.4	-1.2	-2.7
Mountain	65	1.5	-0.4	-0.1	-0.4	0.2	-0.1	0.4	0	-0.1	-0.1	-0.9	0
Pacific	29	1.4	-0.6	0.2	-0.4	1.1	-0.2	0	0	-0.1	-0.1	-0.7	-0.3
Puerto Rico	1	1	3.3	-0.5	3.4	-0.9	-0.4	0	0	0	0	0	4.6
By Payment Classification:													
Urban hospitals	2495	0.8	0	0	0.1	-0.2	0	0	0	0	-0.2	-0.8	0.1
Large urban areas	1377	0.8	0	0.1	0.2	-0.2	0	0	0	0	-0.2	-0.7	0.5

	No. of Hospitals ¹ (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment ² (2)	Proposed FY 2014 Weights and DRG Changes with Application of Recalibration Budget Neutrality ³ (3)	Proposed FY 2014 Wage Data with Application of Wage Budget Neutrality ⁴ (4)	Proposed FY 2014 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality ⁵ (5)	Proposed FY 2014 MGRB Reclassifications ⁶ (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality ⁷ (7)	Proposed Application of the Frontier Wage Index ⁸ (8)	Proposed FY 2014 Out-Migration Adjustment ⁹ (9)	Expiration of MDH Status ¹⁰ (10)	Proposed Hospital Readmissions Reduction Program ¹¹ (11)	Proposed Changes to Medicare DSH ¹² (12)	All Proposed FY 2014 Changes ¹³ (13)
Other urban areas	1118	0.8	0.1	-0.1	0	0	0.1	0.1	0	0	-0.1	-1.1	-0.4
Rural areas	909	1.2	-0.4	-0.2	-0.6	1.4	-0.3	0.2	0.1	-1.2	-0.2	-0.9	-1.9
Teaching Status:													
Nonteaching	2378	0.9	-0.1	-0.1	-0.2	0.2	0	0	0	-0.3	-0.2	-0.9	-0.8
Fewer than 100 residents	782	0.8	0	0	0	-0.1	0	0.1	0	0	-0.1	-0.9	-0.1
100 or more residents	244	0.8	0.2	0.2	0.5	-0.2	0	0	0	0	-0.2	-0.7	0.8
Urban DSH:													
Non-DSH	706	0.8	0	0	0.1	0.1	0	0	0	-0.2	-0.2	0	0.2
100 or more beds	1562	0.8	0.1	0	0.1	-0.2	0	0	0	0	-0.2	-1	0
Less than 100 beds	330	0.9	-0.4	0.1	-0.3	0.2	0.1	0.2	0	-0.5	-0.2	1.1	1.2
Rural DSH:													
SCH	260	1.5	-0.8	0	-0.8	0.1	-0.1	0	0	-0.2	-0.2	-0.1	-1.3
RRC	223	1.2	-0.3	-0.2	-0.4	2	-0.3	0.4	0	-0.3	-0.2	-1.9	-1.6
100 or more beds	29	0.8	-0.5	-0.3	-0.6	1.2	-0.4	0	0.1	-1.5	-0.3	1.5	0.2
Less than 100 beds	294	0.8	-0.7	-0.5	-0.9	0.8	-0.5	0	0.4	-4.9	-0.4	1.1	-3.6

	No. of Hospitals ¹ (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment ² (2)	Proposed FY 2014 Weights and DRG Changes with Application of Recalibration Budget Neutrality ³ (3)	Proposed FY 2014 Wage Data with Application of Wage Budget Neutrality ⁴ (4)	Proposed FY 2014 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality ⁵ (5)	Proposed FY 2014 MGRB Reclassifications ⁶ (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality ⁷ (7)	Proposed Application of the Frontier Wage Index ⁸ (8)	Proposed FY 2014 Out-Migration Adjustment ⁹ (9)	Expiration of MDH Status ¹⁰ (10)	Proposed Hospital Readmissions Reduction Program ¹¹ (11)	Proposed Changes to Medicare DSH ¹² (12)	All Proposed FY 2014 Changes ¹³ (13)
Urban teaching and DSH:													
Both teaching and DSH	826	0.8	0.1	0.1	0.3	-0.3	0	0.1	0	0	-0.2	-0.9	0.4
Teaching and no DSH	135	0.8	0	0.2	0.2	0.3	0.1	0	0	0	-0.2	0	0.7
No teaching and DSH	1066	0.8	-0.1	-0.1	-0.1	0	0.2	0	0	0	-0.2	-1.2	-0.6
No teaching and no DSH	468	0.8	0.1	0	0.1	-0.2	-0.1	0.1	0	0	-0.2	0	0.3
Special Hospital Types:													
RRC	207	0.8	-0.1	-0.1	-0.1	2.9	-0.4	0.5	0.1	-0.5	-0.2	-1.9	-1.4
SCH	329	1.5	-0.6	0	-0.6	0	-0.1	0	0	-0.1	-0.2	-0.2	-0.5
Former MDH	192	0.8	-0.7	-0.6	-1.1	1.1	-0.4	0	0.3	-9.9	-0.5	0.3	-8.5
SCH and RRC	124	1.5	-0.3	0	-0.3	0.5	-0.1	0	0	0	-0.2	-1.1	-0.1
Former MDH and RRC	11	0.8	-0.4	0.3	0	2	-0.6	0	0.1	-15.7	-0.2	-0.8	-12.4
Type of Ownership:													
Voluntary	1944	0.8	0	0.1	0.1	0	0	0.1	0	-0.1	-0.2	-0.9	-0.1

	No. of Hospitals ¹ (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment ² (2)	Proposed FY 2014 Weights and DRG Changes with Application of Recalibration Budget Neutrality ³ (3)	Proposed FY 2014 Wage Data with Application of Wage Budget Neutrality ⁴ (4)	Proposed FY 2014 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality ⁵ (5)	Proposed FY 2014 MGRB Reclassifications ⁶ (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality ⁷ (7)	Proposed Application of the Frontier Wage Index ⁸ (8)	Proposed FY 2014 Out-Migration Adjustment ⁹ (9)	Expiration of MDH Status ¹⁰ (10)	Proposed Hospital Readmissions Reduction Program ¹¹ (11)	Proposed Changes to Medicare DSH ¹² (12)	All Proposed FY 2014 Changes ¹³ (13)
Proprietary	895	0.8	0.1	-0.1	0	0.1	0	0.1	0	-0.1	-0.2	-1.4	-0.9
Government	546	0.9	0	-0.2	-0.1	-0.1	-0.1	0	0	-0.1	-0.1	0.3	1.1
Medicare Utilization as a Percent of Inpatient Days:													
0-25	368	0.8	0.2	0.3	0.5	-0.3	-0.1	0	0	0	-0.1	4.4	6
25-50	1807	0.8	0.1	0	0.1	-0.2	0	0.1	0	0	-0.2	-1.5	-0.6
50-65	967	0.9	-0.2	-0.1	-0.2	0.6	0.1	0	0	-0.4	-0.2	-0.9	-0.8
Over 65	171	1	-0.4	-0.3	-0.7	0.8	-0.3	0	0.1	-1.6	-0.4	-0.6	-1.9
FY 2014 Reclassifications by the Medicare Geographic Classification Review Board:													
All Reclassified Hospitals	762	0.9	-0.1	0	0	2.1	0.2	0	0	-0.2	-0.2	-1.2	-0.5
Non-Reclassified Hospitals	2642	0.8	0	0	0.1	-0.7	-0.1	0.1	0	-0.1	-0.2	-0.7	0

	No. of Hospitals ¹ (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment ² (2)	Proposed FY 2014 Weights and DRG Changes with Application of Recalibration Budget Neutrality ³ (3)	Proposed FY 2014 Wage Data with Application of Wage Budget Neutrality ⁴ (4)	Proposed FY 2014 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality ⁵ (5)	Proposed FY 2014 MGRB Reclassifications ⁶ (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality ⁷ (7)	Proposed Application of the Frontier Wage Index ⁸ (8)	Proposed FY 2014 Out-Migration Adjustment ⁹ (9)	Expiration of MDH Status ¹⁰ (10)	Proposed Hospital Readmissions Reduction Program ¹¹ (11)	Proposed Changes to Medicare DSH ¹² (12)	All Proposed FY 2014 Changes ¹³ (13)
Urban Hospitals Reclassified	451	0.8	0	0.1	0.1	1.9	0.4	0	0	0	-0.2	-1.1	-0.2
Urban Nonreclassified Hospitals, FY 2014	1990	0.8	0.1	0	0.2	-0.7	-0.1	0.1	0	0	-0.2	-0.8	0.2
All Rural Hospitals Reclassified FY 2014	311	1.1	-0.3	-0.3	-0.5	2.7	-0.3	0	0	-0.8	-0.2	-1.6	-1.7
Rural Nonreclassified Hospitals FY 2014	552	1.2	-0.6	-0.2	-0.8	-0.2	-0.3	0.1	0.2	-1.7	-0.3	0.2	-2.2
All Section 401 Reclassified Hospitals	47	1.3	-0.4	-0.3	-0.6	-0.3	0	2.1	0	-2.4	-0.2	-0.2	-1.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	61	1	-0.8	-0.7	-1.3	4.1	-0.4	0	0	-3.9	-0.2	0	-2.6

	No. of Hospitals ¹ (1)	Proposed Hospital Rate Update and Documentation and Coding Adjustment ² (2)	Proposed FY 2014 Weights and DRG Changes with Application of Recalibration Budget Neutrality ³ (3)	Proposed FY 2014 Wage Data with Application of Wage Budget Neutrality ⁴ (4)	Proposed FY 2014 DRG, Rel. Wts., Wage Index Changes with Wage and Recalibration Budget Neutrality ⁵ (5)	Proposed FY 2014 MGRB Reclassifications ⁶ (6)	Proposed Rural Floor and Imputed Floor with Application of National Rural Floor Budget Neutrality ⁷ (7)	Proposed Application of the Frontier Wage Index ⁸ (8)	Proposed FY 2014 Out-Migration Adjustment ⁹ (9)	Expiration of MDH Status ¹⁰ (10)	Proposed Hospital Readmissions Reduction Program ¹¹ (11)	Proposed Changes to Medicare DSH ¹² (12)	All Proposed FY 2014 Changes ¹³ (13)
Specialty Hospitals													
Cardiac specialty Hospitals	15	0.8	1.1	0.3	1.5	-0.8	-0.2	0.7	0	0	-0.1	-0.1	1.4

¹ Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2012, and hospital cost report data are from reporting periods beginning in FY 2010 and FY 2009.

² This column displays the payment impact of the proposed hospital rate update, the documentation and coding adjustment and the adjustment to offset the costs of the proposed inpatient status policy including the 1.8 percent adjustment to the national standardized amount (the estimated 2.5 percent market basket update reduced by the proposed 0.4 percentage point for the multifactor productivity adjustment and the 0.3 percentage point reduction under the Affordable Care Act) and the 0.8 percent documentation and coding adjustment to the national standardized amount and the 0.2 percent adjustment for the policy proposal on admission and medical review criteria applied to the national standardized amount, hospital-specific rate and the Puerto Rico-specific amount.

³ This column displays the payment impact of the proposed changes to the Version 31.0 GROUPER, the proposed changes to the relative weight methodology that uses 19 CCRs as opposed to 15 CCRs, and the proposed recalibration of the MS-DRG weights based on FY 2012 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 0.997583 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 2010 cost report data and proposed changes to the labor-related share. 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 0.999766

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 0.99783 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). The effects demonstrate the proposed FY 2014 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2014. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the proposed geographic budget neutrality factor of 0.990971.

⁷ This column displays the effects of the proposed rural floor and imputed floor. 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 proposed imputed floor) applied to the wage index is 0.990189.

⁸ This column shows the impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0.

⁹ This column displays the impact of section 1886(d)(13) of the Act, as added by section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if the hospital qualifies by meeting a threshold percentage of residents of the county where the hospital is located who commute to work at hospitals in counties with higher wage indexes.

¹⁰ This column displays the impact of the expiration of MDH status for FY 2014, a non-budget neutral payment provision.

¹¹ This column displays the impact of the implementation of the Hospital Readmissions Reduction Program, section 3025 of the Affordable Care Act, a non-budget neutral provision that adjusts a hospital's payment for excess readmissions.

¹² This column 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 shows the proposed changes in payments from FY 2013 to FY 2014. It reflects the impact of the proposed FY 2014 hospital update, the proposed adjustment for documentation and coding, and the proposed adjustment for the policy proposal on admission and medical review criteria. It also reflects proposed changes in hospitals' reclassification status in FY 2014 compared to FY 2013. It incorporates all of the proposed changes displayed in Columns 2, 5, 6, 7, 8, 9, 10, 11 and 12 (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 , Documentation and Coding Adjustment and Adjustment for the Policy Proposal on Admission and Medical Review Criteria (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 2.5 percent market basket update, the proposed reduction of 0.4 percentage point for the multifactor productivity adjustment, and the 0.3 percentage point reduction in accordance with the Affordable Care Act. In addition, this column includes the proposed FY 2014 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. Finally, we are proposing a -0.2 percent adjustment to offset the cost of the policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A that is applied to the national standardized amount, the hospital-specific rate, and the Puerto Rico specific rate. As a result, we are proposing to make a 0.8 percent update to the national standardized amount.

This column also includes the proposed 1.6 percent update to the hospital-specific rates, which includes the proposed 1.8 percent for the hospital update and proposed -0.2 percent adjustment to offset the cost of the policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A.

Overall, hospitals would experience a 0.8 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 1.6 percent increase in payments; therefore, hospital categories with SCHs paid under the hospital-specific rate would experience increases in payments of more than 0.8 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 2014 MS-DRG relative weights will be 100 percent cost-based and 100 percent MS-DRGs. For FY 2014, the MS-DRGs are calculated using the FY 2012 MedPAR data grouped to the Version 31.0 (FY 2014) MS-DRGs. In addition, for FY 2014, we are proposing to move from 15 departmental CCRs to 19 departmental CCRs to calculate the cost-based relative weights. The four additional CCRs of implantable devices, CT scan, MRI, and cardiac catheterization have generally increased the relative weight values for surgical MS-DRGs and decreased the relative weight values for medical 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 proposed changes due to the MS-DRGs and relative weights would result in a 0.0 percent change in payments with the application of the proposed recalibration budget neutrality factor of 0.997583 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 proposed changes to the relative weight methodology. Rural hospitals would experience a 0.5 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 0.2 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 and the proposed change to the labor-related share with the application of the proposed wage budget neutrality factor. Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the proposed wage index for acute care hospitals for FY 2014 is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2009 and before October 1, 2010. The estimated impact of the updated wage data and the proposed labor-related share on hospital payments is isolated in Column 4 by holding the other payment parameters constant in this simulation. That is, Column 4 shows the

proposed percentage change in payments when going from a model using the FY 2013 wage index, based on FY 2009 wage data, the FY 2013 labor-related share of 68.8 percent and having a 100-percent occupational mix adjustment applied, to a model using the proposed FY 2014 pre-reclassification wage index with the proposed labor-related share of 69.6 percent, also having a 100-percent occupational mix adjustment applied, based on FY 2010 wage data (while holding other payment parameters such as use of the Version 31.0 MS-DRG GROUPER constant). The proposed occupational mix adjustment is based on the 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 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 2014, 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 0.999766, and the overall proposed payment change is zero percent.

Column 4 shows the impacts of updating the wage data using FY 2010 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. Among the regions, the largest increase is in the urban Middle Atlantic region, which would experience 0.7 percent increase. The largest decline from updating the wage data and the proposed change in the labor-related share to 69.9 percent is seen in the rural West South Central region, rural East South Central, rural Puerto Rico and Urban East South Central (-0.5 percent decrease).

In looking at the wage data itself, the national average hourly wage increased 2.0 percent compared to FY 2013. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the national 2.0 percent increase in average hourly wage. Of the 3,382 hospitals with wage data for both FYs 2013 and 2014, 1,626, or 48.1 percent, would experience an average hourly wage increase of 2.0 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 2014 relative to FY 2013. Among urban hospitals, none would experience an increase or decrease of more than 5 percent. Among rural hospitals, none would experience an increase or decrease of more than 5 percent. However, 918 rural hospitals would experience increases or decreases of less than 5 percent, while 2,464 urban hospitals would experience increases or decreases of less than 5 percent. 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 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 10 percent	0	0
Increase or decrease less than 5 percent	2,464	918
Decrease more than 5 percent and less than 10 percent	0	0
Decrease more than 10 percent	0	0

d. Combined Effects of the Proposed MS-DRG and Wage Index Changes (Column 5)

Section 1886(d)(4)(C)(iii) of the Act requires that changes to MS-DRG reclassifications and the relative weights cannot increase or decrease aggregate payments. In addition, section 1886(d)(3)(E) of the Act specifies that any updates or adjustments to the wage index are to be budget neutral. We computed a proposed wage budget neutrality factor of 0.999766 and a proposed recalibration budget neutrality factor of 0.997583 (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 0.997350, or approximately -0.27 percent, which is applied to the proposed 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. 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 0.1 percent change in payments.

We estimate that the combined impact of the proposed changes to the relative weights and MS-DRGs and the updated wage data and the proposed change in the labor-related share with budget neutrality applied would result in 0.1 percent increase in payments for urban hospitals and 0.6 percent decrease in payments for rural hospitals primarily due to the proposed changes to the relative weights. Urban Middle Atlantic

hospitals would experience a 0.7 percent increase in payments due to proposed increases in their wages compared to the national average, while the rural West South Central area would experience a 0.9 percent decrease in payments because of below average increases in wages and due to the proposed changes to the relative weights.

e. Effects of Proposed MGCRB Reclassifications (Column 6)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on other bases than where they are geographically located). The proposed changes in Column 6 reflect the per case payment impact of moving from this baseline to a simulation incorporating the proposed MGCRB decisions for FY 2014 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 0.990971 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 1.7 percent. By region, all the rural hospital categories, with the exception of one rural Puerto Rico hospital, would experience increases in payments due to MGCRB reclassifications. Rural hospitals in the New England region would experience a 3.2 percent increase in payments and rural hospitals in the Mountain region would experience a 0.2 percent increase in payments. Urban hospitals in New England and the Middle Atlantic would experience an increase in payments of 0.7 percent and 0.3 percent, respectively, largely due to reclassifications of hospitals in Connecticut and New Jersey.

Table 9A listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site reflects the reclassifications for FY 2014.

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/RV 2010 LTCH PPS final rule, the FYs 2011, 2012, and 2013 IPPS/LTCH PPS final rules, and this proposed rule, section 4410 of Pub. L. 105-33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index received by rural hospitals in the same State. We apply a uniform budget neutrality adjustment to the wage index. In addition, the imputed floor, which is 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 had been receiving 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 are proposing to extend the imputed rural floor, as calculated under the original methodology and the alternative methodology.

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 2014 rural floor budget neutrality factor to be applied to the wage index of 0.990189, which will reduce wage indexes by 0.98 percent.

Column 7 shows the projected impact of the proposed rural floor and proposed imputed floor with the proposed national rural floor budget neutrality factor applied to the proposed wage index. The column compares the proposed post-reclassification FY 2014 wage index of providers before the rural floor and imputed floor adjustment and the proposed post-reclassification FY 2014 wage index of providers with the proposed rural floor and imputed floor adjustment. 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 434 hospitals benefit from the proposed rural and imputed floors while the remaining 2,970 IPPS hospitals in our model have their proposed wage index

reduced by the proposed rural floor budget neutrality adjustment of 0.990189 (or 0.98 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 other urban areas (populations of 1 million or fewer) would experience a 0.1 percent increase in payments because those providers benefit from the rural floor. Urban hospitals in the New England region can expect a 4.4 percent increase in payments primarily due to the application of the proposed rural floor in Massachusetts and Connecticut. All 60 urban providers in Massachusetts are expected to receive the proposed rural floor wage index value, including proposed rural floor budget neutrality, of 1.3108 increasing payments to Massachusetts by an estimated \$169 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, beginning with the FY 2012 wage index, the rural floor for the State is established by the conversion of a CAH to an IPPS hospital that is geographically located in rural Massachusetts. We estimate that Massachusetts hospitals would receive approximately a 5.6 percent increase in IPPS payments due to the application of the proposed rural floor. In addition, 27 out of 32 hospitals in Connecticut would benefit

from the proposed rural floor, which would increase payments to the State by an estimated \$75 million.

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. Urban Puerto Rico hospitals would receive a proposed rural floor as a result of a one IPPS hospital located in rural Puerto Rico setting the rural floor. We are proposing to apply a proposed rural floor budget neutrality factor to the Puerto Rico-specific wage index of 0.990877 or -0.9 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 proposed application of the proposed rural floor with rural floor budget neutrality.

There are 35 hospitals in New Jersey that benefit from the extension of the proposed imputed floor and would receive the proposed imputed floor wage index value, including the proposed rural floor budget neutrality, of 1.1144, which we estimate would increase their payments by approximately \$15 million. Urban Middle Atlantic hospitals would experience a 0.3 percent decrease in payments, which reflects the proposed increase in payments for New Jersey hospitals receiving the proposed imputed floor and a

proposed decrease for other urban hospitals in the in the Middle Atlantic region. Four Rhode Island hospitals would benefit from the proposed imputed rural floor calculated under the alternative methodology and would receive an additional \$3.5 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 2014. Column 3 displays the percentage of total payments each State would receive or contribute to fund the proposed rural floor and imputed floor with national budget neutrality. The column compares the proposed post-reclassification FY 2014 wage index of providers before the proposed rural floor and imputed floor adjustment and the proposed post-reclassification FY 2013 wage index of providers with the proposed rural floor and imputed floor adjustment. 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.

FY 2014 Proposed IPPS Estimated Payments Due to Proposed Rural Floor and Imputed Floor with National Budget Neutrality				
State	Number of Hospitals (1)	Number of Hospitals Receiving 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	93	3	-0.5	-\$7.7

FY 2014 Proposed IPPS Estimated Payments Due to Proposed Rural Floor and Imputed Floor with National Budget Neutrality				
State	Number of Hospitals (1)	Number of Hospitals Receiving 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)
Alaska	6	4	3.3	\$4.7
Arizona	57	7	-0.4	-\$6.7
Arkansas	45	0	-0.5	-\$5.0
California	308	178	0.9	\$86.4
Colorado	46	7	0.1	\$1.5
Connecticut	32	27	4.9	\$75.0
Delaware	6	0	-0.6	-\$2.3
Washington, D.C.	7	0	-0.5	-\$2.5
Florida	168	5	-0.4	-\$29.6
Georgia	107	0	-0.5	-\$12.3
Hawaii	14	0	-0.4	-\$1.2
Idaho	14	0	-0.3	-\$1.0
Illinois	127	5	-0.6	-\$26.8
Indiana	89	4	-0.5	-\$12.9
Iowa	34	0	-0.5	-\$4.2
Kansas	55	0	-0.4	-\$3.7
Kentucky	65	1	-0.4	-\$7.6
Louisiana	99	4	-0.5	-\$6.5
Maine	20	0	-0.5	-\$2.4
Massachusetts	61	60	5.6	\$169.1
Michigan	95	0	-0.5	-\$22.1
Minnesota	51	0	-0.5	-\$9.0
Mississippi	65	1	-0.5	-\$5.1
Missouri	77	0	-0.4	-\$10.7
Montana	12	4	-0.1	-\$0.4
Nebraska	23	0	-0.4	-\$2.5
Nevada	24	19	1.6	\$10.9
New Hampshire	13	9	0.8	\$3.6
New Jersey	64	35	0.4	\$14.8
New Mexico	25	0	-0.3	-\$1.5
New York	166	2	-0.6	-\$46.5
North Carolina	87	0	-0.4	-\$15.2
North Dakota	6	1	-0.3	-\$0.9
Ohio	137	3	-0.4	-\$17.7
Oklahoma	86	2	-0.4	-\$5.4

FY 2014 Proposed IPPS Estimated Payments Due to Proposed Rural Floor and Imputed Floor with National Budget Neutrality				
State	Number of Hospitals (1)	Number of Hospitals Receiving 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)
Oregon	33	0	-0.5	-\$4.5
Pennsylvania	157	6	-0.5	-\$21.8
Puerto Rico	52	13	0	\$0.0
Rhode Island	11	4	0.5	\$1.7
South Carolina	57	5	-0.3	-\$5.0
South Dakota	19	0	-0.3	-\$1.0
Tennessee	97	11	-0.3	-\$7.6
Texas	322	3	-0.5	-\$31.9
Utah	32	0	-0.4	-\$2.0
Vermont	6	0	-0.4	-\$0.8
Virginia	78	1	-0.4	-\$10.5
Washington	49	5	-0.2	-\$3.6
West Virginia	30	3	-0.3	-\$2.3
Wisconsin	66	2	-0.4	-\$7.3
Wyoming	11	0	-0.1	-\$0.2

g. Effects of the Proposed Application of the Frontier State Wage Index (Column 8)

Section 10324(a) of Affordable Care Act requires that we establish a minimum post-reclassified wage-index of 1.00 for all hospitals located in “frontier States.” The term “frontier States” is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, four States (Montana, North Dakota, South Dakota, and Wyoming) are considered frontier States and 46 hospitals located in those States will receive a frontier wage index of 1.0000. Although Nevada is also, by definition, a frontier State and was assigned a frontier floor value of 1.0000 for FY 2012, its FY 2013 rural floor value of

1.0256 was greater and, therefore, was the State's minimum wage index for FY 2013. For FY 2014, its proposed post-reclassification wage index is also above 1.0000, hospitals located in Nevada would not experience a change in payment as a result of this provision. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately \$63 million or approximately 0.1 percent.

Urban hospitals located in the West North Central region and urban hospitals located in the Mountain region would receive an increase in payments by 0.8 percent and 0.2 percent, respectively because many of the hospitals located in this region are frontier hospitals. Similarly, rural hospitals located in the Mountain region and rural hospitals in the West North Central region would experience an increase in payments by 0.4 percent and 0.3 percent, respectively.

h. Effects of the Proposed Wage Index Adjustment for Out-Migration (Column 9)

Section 1886(d)(13) of the Act, as added by section 505 of Pub. L. 108-173, provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment are to receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. Overall, rural hospitals would experience a 0.1 percent increase in payments as a result of the proposed out-migration wage adjustment. Rural DSH providers with less than 100

beds would experience a 0.4 percent increase in payments. There are 210 providers that would receive the proposed out-migration wage adjustment in FY 2014. This out-migration wage adjustment is not budget neutral, and we estimate the impact of these providers receiving the proposed out-migration increase to be approximately \$17 million.

i. Effects of the Expiration of MDH Special Payment Status (Column 10)

Column 10 shows our estimate of the changes in payments due to the expiration of MDH status, a nonbudget neutral payment provision. MDH status had previously expired for FY 2013 under section 3124 of the Affordable Care Act, but was extended for an additional year through FY 2013 under section 606 of the ATRA. Hospitals that qualified to be MDHs receive the higher of payments made under the Federal standardized amount or the payments made under the Federal standardized amount plus 75 percent of the difference between the Federal standardized amount and the hospital-specific rate (a hospital-specific cost-based rate). Because this provision was not budget neutral, the expiration of this payment provision results in a 0.1 percent decrease in payments overall. There are currently 192 MDHs, of which 134 are estimated to be paid under the blended payment of the Federal standardized amount and hospital-specific rate for FY 2013. Because those 134 MDHs will no longer receive the blended payment and will be paid only under the Federal standardized amount in FY 2014, it is estimated that those hospitals will experience an overall decrease in payments of approximately \$127 million.

MDHs were generally rural hospitals, so the expiration of the MDH program will result in an overall decrease in payments to rural hospitals of 1.2 percent. Rural New

England hospitals can expect a decrease in payments of 3.9 percent because 8 out of the 23 rural New England hospitals are MDHs that will lose this special payment status under the expiration of the program at the end of FY 2013. MDHs can expect a decrease in payments of 9.9 percent.

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 is based on a hospital's risk-adjusted readmission rate during a 3-year period for three applicable conditions: Acute Myocardial Infarction, Heart Failure, and Pneumonia. This provision is not budget neutral. A hospital's readmission adjustment is the higher of a ratio of the hospital's aggregate payments for excess readmissions to their aggregate payments for all discharges, or a floor, which has been defined in statute as 0.98 (or a 2.0 percent reduction) for FY 2014. A hospital's base operating DRG payment (that is, wage-adjusted DRG payment amount, as discussed in section V.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 2,173 hospitals will have their base operating DRG payments reduced by their hospital-specific proposed readmissions adjustment, resulting in a 0.2 percent

decrease, or approximately \$175 million, in payments to hospitals overall for FY 2014 relative to no provision.

Urban hospitals in the Middle Atlantic, rural hospitals in the East South Central region, West South Central region, rural DSH hospitals and hospitals with Medicare utilization of over 65 percent would experience the highest decreases of 0.4 percent among the different hospital categories. Rural New England hospitals would experience the no change in payments. Puerto Rico hospitals 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 proposed effects of the implementation of 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 current statutory formula for Medicare DSH payments. 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 and additional statutory adjustments, will become 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 DSHs. The reduction to Medicare DSH payments is not budget neutral.

We are proposing that the amount to be distributed on the basis of uncompensated care, which is 75 percent of what otherwise would have been paid for Medicare DSH payment adjustments (that is, Factor 1), is adjusted to 88.8 percent of that amount for changes in the percentage of individuals under age 65 who are uninsured and additional statutory adjustments (that is, Factor 1 multiplied by Factor 2). As a result, we project that the reduction of Medicare DSH payments, together with the introduction of the new uncompensated care payment, will reduce payments overall by 0.9 percent as compared to Medicare DSH payments prior to the implementation of section 3133 of the Affordable Care Act. The proposed uncompensated care payment has redistributive effects based on a disproportionate share hospital's low income insured patient days (sum of Medicaid patient days and Medicare SSI patient days) relative to all disproportionate share hospitals Medicaid patient days and Medicare SSI patient days, and the payment amount is not tied to a hospital's discharges. Urban hospitals located in the Pacific would experience the largest decreases in payments of 3.2 percent, as these hospitals have lower uncompensated care relative to other hospital categories. Hospitals with low Medicare utilization with Medicare days that are less than 25 percent of total inpatient days would experience a 4.4 percent increase in payment.

1. Effects of All Proposed FY 2014 Changes (Column 13)

Column 13 shows our estimate of the changes in payments per discharge from FY 2013 and FY 2014, resulting from all proposed changes reflected in this proposed rule for FY 2014. 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 0.1 percent for FY 2014 relative to FY 2013. As discussed in section II.D. of the preamble of this proposed rule, this column includes the proposed FY 2014 documentation and coding 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 1.8 percent to the national standardized amount. This annual hospital update includes the proposed 2.5 percent market basket update, the proposed reduction of 0.4 percentage point for the multifactor productivity adjustment, and the 0.3 percentage point reduction under section 3401 of the Affordable Care Act. Finally, it includes the proposed -0.2 percent adjustment of the national standardized amount, the hospital-specific payment rate, and the Puerto Rico-specific rate to offset the costs of the policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A. As described in Column 2, the proposed annual hospital update, combined with the proposed documentation and coding adjustment and the adjustment to offset the cost of the policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A, would result in a 0.8 percent increase in payments in FY 2014 relative to FY 2013. Column 5 shows an increase in payments by 0.1 percent due to the effects of the cumulative DRG and wage budget neutrality. Column 8 describes an estimated 0.1 percent increase in payments due to the proposed frontier State wage index. Column 10 describes the estimated 0.1 percent decrease in payments due to the expiration of the MDH status under section 606 of the ATRA. Column 11 shows the estimated 0.2 percent

decrease in payments due to the proposed reductions in payments under the Hospital Readmissions Reduction Program, which reduce a hospital's base operating DRG payments by a readmission adjustment factor based on a hospital's performance on readmissions for specified conditions. Column 12 shows the estimated 0.9 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. The impact of moving from our estimate of FY 2013 outlier payments, 5.2 percent, to the estimate of FY 2014 outlier payments, 5.1 percent, would result in a decrease of 0.1 percent in FY 2014 payments relative to FY 2013. 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 13 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 0.1 percent for FY 2014. The proposed payment decrease among the hospital categories is largely attributed to the reduction in Medicare DSH payment adjustments and the redistribution of a portion of the Medicare DSH payments as an additional payment for a hospital's relative uncompensated care amount. Hospitals in urban areas would

experience a 0.1 percent increase in payments per discharge in FY 2014 compared to FY 2013. Hospital payments per discharge in rural areas are estimated to decrease by -1.9 percent in FY 2014 as compared to FY 2013 largely due to the expiration of MDH status and reductions to Medicare DSH payments.

Among urban census divisions, the Urban Pacific hospitals would experience an estimated 1.5 percent decrease in payments, more than the national average, because many of the urban providers in this region would see reductions to their Medicare DSH payments. Urban hospitals in the Middle Atlantic would experience a 1.6 percent increase in payments.

Among the rural regions, the hospitals in the East South Central region would experience the estimated decreases in payments of 3.5 percent, due to the expiration of MDH status and reductions to Medicare DSH payments. Rural hospitals in the Mountain region are estimated to experience no change in payments.

Among special categories of hospitals, former MDHs would receive an estimated payment decrease of 8.5 percent due to the expiration of the MDH special payment status. SCHs are paid the higher of their Federal rate and the hospital-specific rate. Overall, SCHs are estimated to experience a payment decrease of 0.5 percent due to the proposed changes to the relative weights methodology and minor reductions under the rural floor budget neutrality and changes to Medicare DSH.

Rural hospitals reclassified for FY 2014 would receive an estimated 1.7 percent payment decrease. Rural hospitals that are not reclassifying are estimated to receive a payment decrease of 2.2 percent due to lower wage data, the application of the proposed

rural floor budget neutrality and expiration of MDH status. Urban reclassified hospitals would experience an estimated payment decrease of 0.2 percent due to decreases in payments under the Medicare DSH changes. Urban nonreclassified hospitals would experience an estimated payment increase of 0.2 percent.

Cardiac hospitals are expected to experience a payment increase of 1.4 percent in FY 2014 relative to FY 2013 primarily due to the proposed changes in the relative weights and the proposed application of the frontier State wage index.

3. Impact Analysis of Table II

Table II presents the projected impact of the proposed changes for FY 2014 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 2013 with the average payments per discharge for FY 2014, as calculated under our models. Thus, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the proposed changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 13 of Table I.

**TABLE II.--IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2014
ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM
(PAYMENTS PER DISCHARGE)**

	Number of Hospitals (1)	Proposed Average FY 2013 Payment Per Discharge (2)	Proposed Average FY 2014 Payment Per Discharge (3)	All Proposed FY 2014 Changes (4)
All Hospitals	3,404	10,891	10,880	-0.1

	Number of Hospitals (1)	Proposed Average FY 2013 Payment Per Discharge (2)	Proposed Average FY 2014 Payment Per Discharge (3)	All Proposed FY 2014 Changes (4)
By Geographic Location:				
Urban hospitals	2,481	11,305	11,315	0.1
Large urban areas	1,367	11,978	12,033	0.5
Other urban areas	1,114	10,488	10,443	-0.4
Rural hospitals	923	8,110	7,957	-1.9
Bed Size (Urban):				
0-99 beds	622	8,742	8,825	0.9
100-199 beds	762	9,538	9,488	-0.5
200-299 beds	464	10,234	10,223	-0.1
300-499 beds	418	11,637	11,653	0.1
500 or more beds	215	13,815	13,870	0.4
Bed Size (Rural):				
0-49 beds	339	6,537	6,379	-2.4
50-99 beds	328	7,551	7,304	-3.3
100-149 beds	151	7,859	7,772	-1.1
150-199 beds	59	8,970	8,870	-1.1
200 or more beds	46	9,829	9,710	-1.2
Urban by Region:				
New England	120	12,354	12,376	0.2
Middle Atlantic	318	12,367	12,560	1.6
South Atlantic	375	10,289	10,288	0
East North Central	395	10,498	10,475	-0.2
East South Central	149	9,895	9,865	-0.3
West North Central	165	11,069	11,051	-0.2
West South Central	371	10,371	10,358	-0.1
Mountain	156	11,613	11,751	1.2
Pacific	381	14,431	14,208	-1.5
Puerto Rico	51	5,505	7,469	35.7
Rural by Region:				
New England	23	10,960	10,642	-2.9
Middle Atlantic	69	8,618	8,519	-1.2
South Atlantic	165	7,771	7,628	-1.8
East North Central	119	8,310	8,180	-1.6
East South Central	171	7,452	7,193	-3.5
West North Central	100	8,610	8,574	-0.4
West South Central	181	7,047	6,858	-2.7
Mountain	65	9,061	9,065	0
Pacific	29	10,996	10,961	-0.3
Puerto Rico	1	2,799	2,927	4.6
By Payment Classification:				
Urban hospitals	2,495	11,295	11,305	0.1
Large urban areas	1,377	11,967	12,021	0.5
Other urban areas	1,118	10,468	10,424	-0.4

	Number of Hospitals (1)	Proposed Average FY 2013 Payment Per Discharge (2)	Proposed Average FY 2014 Payment Per Discharge (3)	All Proposed FY 2014 Changes (4)
Rural areas	909	8,241	8,087	-1.9
Teaching Status:				
Nonteaching	2,378	9,128	9,057	-0.8
Fewer than 100 residents	782	10,676	10,670	-0.1
100 or more residents	244	15,902	16,036	0.8
Urban DSH:				
Non-DSH	706	9,423	9,445	0.2
100 or more beds	1,562	11,763	11,764	0
Less than 100 beds	330	8,061	8,157	1.2
Rural DSH:				
SCH	260	8,158	8,052	-1.3
RRC	223	9,048	8,902	-1.6
100 or more beds	29	7,100	7,117	0.2
Less than 100 beds	294	6,414	6,187	-3.6
Urban teaching and DSH:				
Both teaching and DSH	826	12,856	12,902	0.4
Teaching and no DSH	135	10,466	10,543	0.7
No teaching and DSH	1,066	9,658	9,595	-0.6
No teaching and no DSH	468	9,036	9,062	0.3
Special Hospital Types:				
RRC	207	9,347	9,214	-1.4
SCH	329	8,825	8,782	-0.5
Former MDH	192	6,817	6,236	-8.5
SCH and RRC	124	9,924	9,918	-0.1
Former MDH and RRC	11	8,586	7,520	-12.4
Type of Ownership:				
Voluntary	1,944	11,020	11,005	-0.1
Proprietary	895	9,759	9,670	-0.9
Government	546	11,776	11,902	1.1
Medicare Utilization as a Percent of Inpatient Days:				
0-25	368	14,920	15,810	6
25-50	1,807	11,442	11,378	-0.6
50-65	967	8,932	8,861	-0.8
Over 65	171	7,914	7,767	-1.9
FY 2014 Reclassifications by the Medicare Geographic Classification Review Board:				
All Reclassified Hospitals	762	10,510	10,454	-0.5
Non-Reclassified Hospitals	2,642	11,022	11,026	0
Urban Hospitals Reclassified	451	11,271	11,252	-0.2
Urban Nonreclassified Hospitals, FY 2014:	1,990	11,336	11,356	0.2
All Rural Hospitals Reclassified FY 2014:	311	8,609	8,460	-1.7
Rural Nonreclassified Hospitals FY 2014:	552	7,439	7,275	-2.2
All Section 401 Reclassified Hospitals:	47	9,523	9,382	-1.5

	Number of Hospitals (1)	Proposed Average FY 2013 Payment Per Discharge (2)	Proposed Average FY 2014 Payment Per Discharge (3)	All Proposed FY 2014 Changes (4)
Other Reclassified Hospitals (Section 1886(d)(8)(B))	61	7,754	7,549	-2.6
Specialty Hospitals				
Cardiac specialty Hospitals	15	11,720	11,888	1.4

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 2014	\$26
FY 2015	\$28
FY 2016	\$30
FY 2017	\$33
FY 2018	\$36

In section V.I. of the preamble of this proposed rule, we are proposing to implement the HAC Reduction Program. We refer readers to section I.H.6. of this Appendix A for a discussion of the impact of this proposed implementation.

2. Effects of Proposed Policy Relating to New Medical Service and Technology Add-On Payments

In section II.I. of the preamble to this proposed rule, we discuss the five applications for add-on payments for new medical services and technologies for FY 2014, as well as the status of the four new technologies that were approved to receive new technology add-on payments in FY 2013. As explained in that section, add-on payments for new technology under section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.I.4. of the preamble of this proposed rule, we have yet to determine whether any of the five applications we received for consideration for new technology add-on payments for FY 2014 will meet the specified criteria. Consequently, it is premature to estimate the potential payment impact of these five applications for any potential new technology add-on payments for FY 2014. We note that if any of the five applications are found to be eligible for new technology

add-on payments for FY 2014, in the FY 2014 IPPS/LTCH PPS final rule, we would discuss the estimated payment impact for FY 2014 in that final rule.

In the preamble to this proposed rule, we are proposing to continue making new technology add-on payments in FY 2014 for three of the four new technologies (Voraxaze®, Dificid™ and the Zenith® F. Graft) that were approved to receive new technology add-on payments in FY 2013. 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 2014 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 2014 payments by \$6,300,000. For Dificid™, based on the applicant's estimate from FY 2013, we currently estimate that new technology add-on payments for Dificid™ will increase overall FY 2014 payments by \$34,839,784. 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.

3. Effects of the Proposed Payment Adjustment for Low-Volume Hospitals for FY 2014

In section V.C. of the preamble to this proposed rule, we discuss the provisions of the ATRA (Pub. L. 112-240) which extended for an additional year, through FY 2013,

the temporary changes to the low-volume hospital definition and methodology for determining the payment adjustment made by the Affordable Care Act for FYs 2011 and 2012. In accordance with section 1886(d)(12) of the Act, beginning with FY 2014, 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. Therefore, effective for FY 2014 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 2012 claims data (December 2012 update of the MedPAR file), we estimate that approximately 600 hospitals qualify as a low-volume hospital in FY 2013, and with the statutory changes to the low-volume hospital payment adjustment for FY 2014, we estimate only approximately 6 hospitals will continue to qualify as a low-volume hospital in FY 2014. We project that the expiration of the temporary changes to the low-volume hospital definition and payment adjustment methodology made by the Affordable Care Act and extended by the ATRA will result in a decrease in payments of approximately \$288 million in FY 2014 as compared to the payments these hospitals would have otherwise received in FY 2014 in the absence of the statutory changes to the low-volume hospital payment adjustment for FY 2014. This estimate accounts for our projection of the 6 IPPS low-volume hospitals remaining in FY 2014

that will continue to receive a low-volume hospital payment adjustment of an additional 25 percent.

4. Effects of Extension of the MDH Program through FY 2013

In section V.F. of the preamble of this proposed rule, we briefly discuss the statutory extension of the MDH program through FY 2013 made by section 606 of the ATRA. We refer readers to a March 7, 2013 notice that we published in the **Federal Register** to announce the extension of the MDH program for FY 2013 in accordance with this ATRA provision, where we also stated the impact on Medicare expenditures of the statutory extension (78 FR 14689).

5. Effects of Changes under the FY 2014 Hospital Value-Based Purchasing (VBP) Program

Section 1886(o)(1)(B) of the Act directs the Secretary to begin making value-based incentive payments under the Hospital VBP Program to hospitals 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 2014 through a reduction to the FY 2014 base operating MS-DRG payment for each discharge of 1.25 percent, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2014 is 1.25 percent, for FY 2015 is 1.5 percent, for FY 2016 is 1.75 percent, and for FY 2017 and subsequent years is 2 percent. We 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 finalized numerous policies related to the FY 2014 Hospital VBP Program in the CY 2012 OPPI/ASC final rule with comment period (76 FR 74527 through 74547) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53567 through 53614), including an additional measure in the Clinical Process of Care domain, minimum numbers of cases and measures for the Outcome domain, performance and baseline periods for FY 2014 measures, performance standards, domain weighting, and requirements for the review and corrections processes. We also refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26495 through 26511) where we finalized three 30-day mortality measures, to be placed in the new Outcome domain for the FY 2014 Hospital VBP Program.

In section V.H. of the preamble of this proposed rule, we estimate the available pool of funds for value-based incentive payments in the FY 2014 Hospital VBP Program, which, in accordance with section 1886(o)(7)(C)(ii) of the Act, will be 1.25 percent of base operating DRG payments, or a total of approximately \$1.1 billion. This estimated available pool for FY 2014 is based on the historical pool of hospitals that were eligible to participate in the FY 2013 Hospital VBP Program and the payment information from the December 2012 update to the FY 2012 MedPAR file. We intend to provide an update to this estimate, which will be based on the March 2013 update to the FY 2012 MedPAR file, in the FY 2014 IPPS/LTCH PPS final rule.

The estimated impacts of the FY 2014 Hospital VBP Program by hospital characteristic, found in the table below, are based on historical TPSs. We used the FY 2013 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 March 2013 update to the FY 2012 MedPAR file. The proxy adjustment factors can be found in Table 16 associated with this proposed rule (available on the CMS Web site). The impact analysis shows that, for the FY 2014 Hospital VBP Program, the number of hospitals that would receive an increase in base operating DRG payment amount is slightly higher than the number of hospitals that would receive a decrease. Approximately 44 percent of hospitals would have a change in base operating DRG payment amount that is between -0.2 percent and +0.2 percent. Urban hospitals in the West South Central region and rural hospitals in the East North Central region would have the highest average increase in base operating DRG payment amount while both urban and rural hospitals in the Middle Atlantic and Pacific would receive an average decrease in base operating DRG payment amount. As the percent of disproportionate share (DSH) payments increases, we would see a decrease in base operating DRG payment amounts, while as the Medicare utilization (MCR) percent increases, we would see an increase in base operating DRG payment amount. Nonteaching hospitals would have an average positive adjustment to the base operating DRG payment amount, 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 2014 Hospital VBP Program**

		Number of Hospitals	Case Weighted Average (in percent)
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		Number of Hospitals	Case Weighted Average (in percent)
BY GEOGRAPHIC LOCATION:			
	All Hospitals	2,984	0.000%
	Large Urban	1,226	-0.003%
	Other Urban	1,015	0.002%
	Rural Area	740	0.005%
	Urban hospitals	2,241	-0.001%
	0-99 beds	465	0.149%
	100-199 beds	717	0.014%
	200-299 beds	435	0.015%
	300-499 beds	421	-0.010%
	500 or more beds	203	-0.048%
	Rural hospitals	740	0.005%
	0-49 beds	162	0.049%
	50-99 beds	324	-0.029%
	100-149 beds	150	0.027%
	150-199 beds	57	-0.004%
	200 or more beds	47	0.021%
BY REGION:			
	Urban By Region	2,241	-0.001%
	New England	113	-0.020%
	Middle Atlantic	295	-0.066%
	South Atlantic	356	0.049%
	East North Central	373	0.024%
	East South Central	129	0.019%
	West North Central	155	0.002%
	West South Central	314	0.042%
	Mountain	155	-0.013%
	Pacific	351	-0.078%
	Rural By Region	740	0.005%
	New England	21	-0.103%

		Number of Hospitals	Case Weighted Average (in percent)
	Middle Atlantic	64	-0.115%
	South Atlantic	143	0.021%
	East North Central	117	0.104%
	East South Central	114	0.064%
	West North Central	85	-0.032%
	West South Central	114	-0.053%
	Mountain	54	-0.017%
	Pacific	28	-0.100%
	Puerto Rico		
	By MCR Percent		
	0-25	288	-0.082%
	25-50	1,715	-0.003%
	50-65	853	0.019%
	Over 65	79	0.081%
	BY DSH Percent:		
	0-25	1,429	0.033%
	25-50	1,257	-0.010%
	50-65	157	-0.120%
	Over 65	138	-0.187%
	BY TEACHING STATUS:		
	Teaching	971	-0.031%
	Non-Teaching	2,010	0.033%

We intend to provide an updated impact analysis in the FY 2014 IPPS/LTCH PPS final rule. However, actual FY 2014 Hospital VBP Program TPSs will not be reviewed and corrected by hospitals until after the FY 2014 IPPS/LTCH PPS final rule has been published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2013 Hospital VBP Program will be used for that

updated impact analysis. The updated impact analysis for the final rule will reflect estimated annual base operating DRG payment amount changes based on the December 2012 update to the FY 2012 MedPAR file.

6. Effects of Proposed Implementation of the HAC Reduction Program

In section V.I. of the preamble of this proposed rule, we are proposing measures, scoring, and 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 beginning on October 1, 2014 and for subsequent program years.

We note that there is no payment impact for FY 2014. 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 tables and analyses that we are presenting below show the distributional effect of the measures and scoring system for this program included in this proposed rule.

The four tables below show the following data distribution:

- The first table presents data on hospitals in the top (that is, worst performing) quartile for the Domain 1-Proposed Approach and the Domain 1-Alternative Approach scores, with hospital scores segregated by hospital types.

- The second table presents data on hospitals in the top (that is, worst performing) quartile for Domain 2 scores, with hospital scores segregated by hospital types.
- The third table presents data on hospitals in top (that is, worst performing) quartile for Total HAC Scores for the Domain 1–Proposed Approach and the Domain 1-Alternative Approach, with hospital scores segregated by hospital types.
- The fourth table presents data on (1) hospitals that have complete data for Domain 1 (that is, data for at least three measures for the Domain 1-Proposed Approach or on hospitals that have enough data to calculate PSI 90 for the Domain 1-Alternative Approach), with hospital scores segregated by hospital type; and (2) hospitals that have complete data for Domain 2 (that is, at least one measure for Domain 2), with hospital scores segregated by hospital types.

The data for these data tables are derived from 3,445 IPPS hospitals (minus CAHs) for the time period of July 1, 2009 to June 30, 2011. The data source for Domain 1 is the Standard Analytic File (SAF) claims data, and the data source for Domain 2 is the chart-abstracted data on CDC’s National Healthcare Safety Network (NHSN). The data used to determine teaching status and for-profit/not-for-profit/government-owned status in the fourth table is derived from American Hospital Association (AHA) 2010 Annual Survey of Hospital data, while the data used to determine DSH status in the fourth table is derived from the CMS FY 2013 IPPS Impact File. Maryland hospitals were excluded from the data in the fourth table because Maryland hospitals were not required to submit POA data in their claims and, therefore,

no AHRQ measures could be calculated. Finally, the data source for the Region/Division categories of all four tables is the Citation of Region/Division data available on the Web site at https://www.census.gov/geo/www/us_regdiv.pdf, and the data source for the Urban/Rural categories for all four tables is the Urban/Rural data from the U.S. department of Agriculture's Economic Research Service, which is available on the Web site at: <http://www.ers.usda.gov/data-products/rural-urban-continuum-codes.aspx> .

**HOSPITALS IN TOP QUARTILE (WORST PERFORMING) FOR DOMAIN 1–PROPOSED APPROACH SCORE AND
DOMAIN 1–ALTERNATIVE APPROACH SCORE**

Hospital Category	In Top Quartile Domain 1-Proposed Approach Score			Not in Top Quartile Domain 1-Proposed Approach Score			Domain 1-Proposed Approach Totals	In Top Quartile Domain 1-Alternative Approach Score			Not in Top Quartile Domain 1-Alternative Approach Score			Domain 1 Alternative Approach Totals
	No. of Hospitals	Percent of Total	Percent of Hospital Type	No. of Hospitals	Percent of Total	Percent of Hospital Type		No. of Hospitals	Percent of Total	Percent of Hospital Type	No. of Hospitals	Percent of Total	Percent of Hospital Type	
Teaching status														
Teaching	149	19.2	55.2	121	4.6	44.8	270	154	17.9	57	116	4.5	43	270
Non-teaching	614	79	20.2	2,423	91.2	79.8	3,037	690	80.4	22.7	2,347	91.1	77.3	3,037
No information	14	1.8	10.9	114	4.3	89.1	128	14	1.6	10.9	114	4.4	89.1	128
Total	777		22.6	2,658			3,435	858		25	2,577			3,435
DSH Status														
DSH	639	82.2	24.2	2,002	75.3	75.8	2,641	703	81.9	26.6	1,938	75.2	73.4	2,641
Non-DSH	130	16.7	17.6	610	22.9	82.4	740	147	17.1	19.9	593	23	80.1	740
No information	8	1	14.8	46	1.7	85.2	54	8	0.9	14.8	46	1.8	85.2	54
Total	777		22.6	2,658			3,435	858		25.1	2,577			3,435

Hospital Category	In Top Quartile			Not in Top Quartile			Domain 1-Proposed Approach Totals	In Top Quartile			Not in Top Quartile			Domain 1 Alternative Approach Totals
	Domain 1-Proposed Approach Score			Domain 1-Proposed Approach Score				Domain 1-Alternative Approach Score			Domain 1-Alternative Approach Score			
	No. of Hospitals	Percent of Total	Percent of Hospital Type	No. of Hospitals	Percent of Total	Percent of Hospital Type		No. of Hospitals	Percent of Total	Percent of Hospital Type	No. of Hospitals	Percent of Total	Percent of Hospital Type	
Bed Size														
Under 50	60	7.7	9.1	596	22.4	90.9	656	73	8.5	11.1	583	22.6	88.9	656
50-99	143	18.4	21.1	535	20.1	78.9	678	159	18.5	23.5	519	20.1	76.5	678
100 – 199	190	24.5	21.5	694	26.1	78.5	884	224	26.1	25.3	660	25.6	74.7	884
200 – 299	118	15.2	23.6	381	14.3	76.4	499	135	15.7	27.1	364	14.1	72.9	499
300 – 399	90	11.6	34.2	173	6.5	65.8	263	90	10.5	34.2	173	6.7	65.8	263
400 – 499	57	7.3	46	67	2.5	54	124	62	7.2	50	62	2.4	50	124
500 or more	105	13.5	51.7	98	3.7	48.3	203	101	11.8	49.8	102	4	50.2	203
No information	14	1.8	10.9	114	4.3	89.1	128	14	1.6	10.9	114	4.4	89.1	128
Total	777		22.6	2,658			3,435	858		25	2,577			3,435
Ownership														
For-profit	133	17.1	17.6	621	23.4	82.4	754	157	18.3	20.8	597	23.2	79.2	754

Hospital Category	In Top Quartile			Not in Top Quartile			Domain 1-Proposed Approach Totals	In Top Quartile			Not in Top Quartile			Domain 1 Alternative Approach Totals
	Domain 1-Proposed Approach Score			Domain 1-Proposed Approach Score				Domain 1-Alternative Approach Score			Domain 1-Alternative Approach Score			
	No. of Hospitals	Percent of Total	Percent of Hospital Type	No. of Hospitals	Percent of Total	Percent of Hospital Type		No. of Hospitals	Percent of Total	Percent of Hospital Type	No. of Hospitals	Percent of Total	Percent of Hospital Type	
Government	115	14.8	20.6	443	16.7	79.4	558	135	15.7	24.2	423	16.4	75.8	558
Non-profit	515	66.3	25.8	1,480	55.7	74.2	1,995	552	64.3	27.7	1,443	56	72.3	1,995
No information	14	1.8	10.9	114	4.3	89.1	128	14	1.6	10.9	114	4.4	89.1	128
Total	777		22.6	2,658		858	3,435	858		25	2,577			3,435
Region/Division														
Northeast	151	19.4	28.3	382	14.4	71.7	533	137	16	25.7	396	15.4	74.3	533
New England	37	4.8	25.9	106	4	74.1	143	37	4.3	25.9	106	4.1	74.1	143
Mid-Atlantic	114	14.7	29.2	276	10.4	70.8	390	100	11.7	25.6	290	11.3	74.4	390
Midwest	188	24.2	23.5	613	23.1	76.5	801	201	23.4	25.1	600	23.3	74.9	801
East North Central	124	16	23.6	402	15.1	76.4	526	137	16	26	389	15.1	74	526
West North Central	64	8.2	23.3	211	7.9	76.7	275	64	7.5	23.3	211	8.2	76.7	275

The first table above shows the characteristics of the worst performing hospitals for the Domain 1–Proposed Approach score and for the Domain 1–Alternative Approach score. In the first table, of the hospitals in the top quartile for Domain 1-Proposed Approach, 19.2 percent were teaching hospitals, 79.0 percent were nonteaching hospitals, 82.2 percent were disproportionate share hospitals, 16.7 percent were nondisproportionate share hospitals, 50.6 percent were hospitals with a bed size of 199 or smaller, and 66.3 percent were nonprofit. In the first table, of the hospitals in the top quartile for Domain 1-Alternative Approach, 17.9 percent were teaching hospitals, 80.4 percent were nonteaching hospitals, 81.9 percent were disproportionate share hospitals, 17.1 percent were nondisproportionate share hospitals, 53.1 percent were hospitals with a bed size of 199 or smaller, and 64.3 percent were nonprofit. Altogether, 3,435 hospitals had complete data for the Domain 1–Proposed Approach score and the Domain 1-Alternative Approach score. Among these hospitals, the majority (3,037 for both approaches) were nonteaching hospitals, with the majority of these nonteaching hospitals (2,423, or 79.8 percent, for the proposed approach, and 2,347, or 77.3 percent, for the alternative approach) not in the top quartile score. A minority of the hospitals (270 for both approaches) were teaching hospitals; less than half of these hospitals (121, or 44.8 percent, for the proposed approach, and 116, or 43.0 percent, for the alternative approach) were not in the top quartile score. Of those hospitals that were not in the top quartile score, the nonteaching hospitals were the majority (2,423, or 91.2 percent, for the proposed approach, and 2,347, or 91.1 percent, for the alternative approach). Most of these hospitals were DSHs (2,641 for both approaches), with a minority being non-DSHs

(40 for both approaches). The majority of the DSHs (2,002, or 75.8 percent, for the proposed approach, and 1,938, or 73.4 percent, for the alternative approach) were not in the top quartile score. Slightly less than a quarter of the DSHs (639, or 24.2 percent, for the proposed approach, and 703, or 26.6 percent, for the alternative approach) were in the top quartile (that is, worst performing) score.

In terms of bed size for both the Domain 1-Proposed Approach and the Domain 1-Alternative Approach, the majority of hospitals had less than 300 beds and the majority of these were not in the top quartile score. The majority (884 for both approaches) of hospitals with less than 300 beds were in the 100 – 199 bed size range. Of those 884 hospitals, the majority (694, or 78.5 percent, for the proposed approach, and 600, or 74.7 percent for the alternative approach) were not in the top quartile score. The minority of hospitals for both approaches had greater than 300 beds. The hospitals with 300 – 399 bed size range (263 for both approaches) had a majority of hospitals (173, or 65.8 percent, for both approaches) not in the top quartile score. For the Domain 1-Proposed Approach, the hospitals with 400 – 499 bed size range (124) also had a majority of hospitals (67, or 54.0 percent) not in the top quartile score; however, hospitals with a 500 or more bed size range (203) had a slight majority (105, or 51.7 percent) in the top quartile (that is, worst performing) score. For the Domain 1-Alternative Approach, hospitals with 400 – 499 bed size range (124) had an equal number of hospitals (62, or 50 percent) in the top quartile (that is, worst performing) score as not in the top quartile score, while hospitals with a 500 or more bed size range had an extremely slight majority

(102 or 50.2 percent) not in the top quartile score compared to hospitals in the top quartile (that is, worst performing) score (101, or 49.8 percent).

In terms of ownership, for both the Domain 1-Proposed Approach and the Domain 1-Alternative Approach, more than half of the total of these 3,435 hospitals were nonprofit (1,995). Of these nonprofit hospitals, the majority (1,480, or 74.2 percent for the proposed approach, and 1,443, or 72.3 percent for the alternative approach) were not in top quartile score, while for-profit hospitals (754 for both approaches) also had a majority (621, or 82.4 percent, for the proposed approach, and 597, or 79.2 percent, for the alternative approach) not in top quartile score.

In terms of region/division for both the Domain 1-Proposed Approach and the domain 1-Alternative Approach, of the total 3,435 hospitals, the Northeast region had a total of 533 hospitals with a minority (143) in New England region and a majority (390) in Mid-Atlantic region. The Midwest region had a total of 801 hospitals, with a majority (526) in the East North Central region and the minority (275) in the West North Central region. The South region had the majority of hospitals by a region (1,446), with the South Atlantic region (551) and the West South Central region (566) having similar numbers of hospitals and the East South Central region having the minority of hospitals (329) of the South region. The West region had a total of 655 hospitals, with a majority in the Pacific region (415) and the minority in the Mountain region (240). The South region had the largest number of hospitals (278, or 35.8 percent for the proposed approach, and 309, or 36.0 percent, for the alternative approach) in the top quartile score. For the Domain 1-Proposed Approach, the Northeast New England region had the lowest

number of hospitals (37, or 4.8 percent) in the top quartile score, with the Mountain region (58, or 7.5 percent) and the East South Central region (59, or 7.6 percent) having the next lowest number of hospitals in the top quartile score. For the Domain 1-Alternative Approach, the New England region had the lowest number of hospitals (37, or 4.3 percent) in the top quartile score, with the East South Central region (61, or 7.1 percent) and the West North Central region (64, or 7.5 percent) having the next lowest number of hospitals in the top quartile score. For both approaches, the South region had the largest number (1,168, or 43.9 for the proposed approach, and 1,137, or 44.1 percent for the alternative approach) not in the top quartile score, with the New England region having the lowest number of hospitals (106, or 4.0 for the proposed alternative, and 106, or 4.1 percent for the alternative approach) not in the top quartile score. The Mountain region (182, or 6.8 percent for the proposed approach, and 158, or 6.1 percent for the alternative approach) and the West North Central region (211, or 7.9 percent in the proposed approach, and 211, or 8.2 percent for the alternative approach) having the next lowest amount of hospitals not in the top quartile score.

In terms of urban/rural location of the total 3,435 hospitals, for the Domain 1-Proposed approach and the Domain 1-Alternative Approach, the majority of hospitals (2,461) were urban, and a minority of hospitals (964) being rural. Of the total urban hospitals (2,461), for the Domain 1-Proposed approach, there were 1,860 urban hospitals (75.6 percent) not in top quartile score; the 1,860 urban hospitals also were the majority (70.0 percent) of hospitals not in top quartile score. There were 601 urban hospitals (24.4 percent) in the top quartile score for the Domain 1-Proposed Approach; the 601 urban

hospitals also were the majority (77.3 percent) of hospitals in the top quartile. For the Domain 1-Alternative Approach, there were 1,772 urban hospitals (72.0 percent) not in the top quartile score; the 1,772 urban hospitals also were the majority of hospitals (68.8 percent) not in the top quartile score. There were 689 urban hospitals (28.0 percent) in the top quartile score for the Domain 1-Alternative Approach; the 689 urban hospitals also were the majority of hospitals (80.3 percent) in the top quartile score.

HOSPITALS IN TOP QUARTILE (WORST PERFORMING) FOR DOMAIN 2 SCORE

Hospital Type	In Top Quartile Domain 2 Score			Not in Top Quartile Domain 2 Score			Totals
	No. of Hospitals	Percent of Total	Percent of Hospital Type	No. of Hospitals	Percent of Total	Percent of Hospital Type	
Teaching status							
Teaching	104	14.9%	38.5%	166	6.0%	61.5%	270
Non-teaching	585	84.2%	19.2%	2,456	89.3%	80.8%	3,041
No information	7	1.0%	5.2%	127	4.6%	94.8%	134
Total	696	-	20.2%	2,749	-	-	3,445
DSH Status							
DSH	566	81.3%	21.4%	2,076	75.5%	78.6%	2,642
Non-DSH	129	18.5%	17.4%	612	22.3%	82.6%	741
No information	1	0.1%	1.6%	61	2.2%	98.4%	62
Total	696	-	20.2%	2,749	-	-	3,445
Bed Size							
Under 50	17	2.4%	2.6%	641	23.3%	97.4%	658
50 - 99	54	7.8%	8.0%	624	22.7%	92.0%	678
100 – 199	208	29.9%	23.5%	676	24.6%	76.5%	884
200 – 299	203	29.2%	40.7%	296	10.8%	59.3%	499
300 – 399	96	13.8%	36.4%	168	6.1%	63.6%	264
400 – 499	41	5.9%	33.1%	83	3.0%	66.9%	124
500 or more	70	10.1%	34.3%	134	4.9%	65.7%	204
No information	7	1.0%	5.2%	127	4.6%	94.8%	134
Total	696	-	20.2%	2,749	-	-	3,445
Ownership							

	In Top Quartile Domain 2 Score			Not in Top Quartile Domain 2 Score			
For-profit	138	19.8%	18.3%	617	22.4%	81.7%	755
Government	100	14.4%	17.9%	459	16.7%	82.1%	559
Non-profit	451	64.8%	22.6%	1,546	56.2%	77.4%	1,997
No information	7	1.0%	5.2%	127	4.6%	94.8%	134
Total	696	-	20.2%	2,749	-	-	3,445
Region/Division							
Northeast	145	20.8%	27.1%	391	14.2%	72.9%	536
New England	34	4.9%	23.8%	109	4.0%	76.2%	143
Mid-Atlantic	111	15.9%	28.2%	282	10.3%	71.8%	393
Midwest	129	18.5%	16.1%	673	24.5%	83.9%	802
East North Central	97	13.9%	18.4%	430	15.6%	81.6%	527
West North Central	32	4.6%	11.6%	243	8.8%	88.4%	275
South	271	38.9%	18.7%	1,176	42.8%	81.3%	1,447
South Atlantic	132	19.0%	24.0%	419	15.2%	76.0%	551
East South Central	50	7.2%	15.2%	280	10.2%	84.8%	330
West South Central	89	12.8%	15.7%	477	17.4%	84.3%	566
West	151	21.7%	22.9%	509	18.5%	77.1%	660
Mountain	39	5.6%	16.1%	203	7.4%	83.9%	242
Pacific	112	16.1%	26.8%	306	11.1%	73.2%	418
Total	696	-	20.2%	2,749	-	79.8%	3,445
Urban/Rural							
Urban	640	92.0%	25.9%	1,828	66.5%	74.1%	2,468
Rural	55	7.9%	5.7%	911	33.1%	94.3%	966
No information	1	0.1%	9.1%	10	0.4%	90.9%	11
Total	696	-	20.2%	2,749	-	79.8%	3,445

The second table above shows the characteristics of the worst performing hospitals for the Domain 2 score. In the second table, of the hospitals in the top quartile for the Domain 2 score, 14.9 percent were teaching hospitals, 84.2 percent were nonteaching hospitals, 81.3 percent were disproportionate share hospitals, 18.5 percent were nondisproportionate share hospitals, 40.1 percent were hospitals with a bed size of 199 or smaller, and 64.8 percent were nonprofit. Altogether, 3445 hospitals had complete data for the Domain 2 score. Among these hospitals, the majority (3,041) were nonteaching hospitals, with the majority of these nonteaching hospitals (2,456, or 80.8 percent) not in the top quartile score. A minority of the hospitals (270) were teaching hospitals; more than half of these (166, or 61.5 percent) were not in the top quartile score for Domain 2. Of those hospitals not in the top quartile score, these nonteaching hospitals were the majority (2,456, or 89.3 percent). Most of the total 3,445 hospitals were DSHs (2,642), with a minority of the hospitals being non-DSHs (741). The majority of the DSHs (2,076, or 78.6 percent) were not in the top quartile for the Domain 2 score. While less than a quarter of DSHs (566, or 21.4 percent) were in the top quartile (that is, worst performing) Domain 2 score.

In terms of bed size, for the Domain 2 score, the majority of hospitals had less than 300 beds. The majority of these hospitals with less than 300 beds were not in the top quartile for the Domain 2 score. The majority of the hospitals (884) with less than 300 beds were in the 100 – 199 bed size range. Of those 884 hospitals, the majority (676, or 76.5 percent) were not in the top quartile of the Domain 2 score. The minority of

hospitals had greater than 300 beds. The hospitals with 300 – 399 bed size range (264) had a majority of hospitals (168, or 63.6 percent) not in the top quartile score, along with the hospitals with 400 – 499 bed size range (124) also having a majority of hospitals (83, or 66.9 percent) not in the top quartile of the Domain 2 score. Hospitals with a 500 or more bed size range (204) also had a majority not in the top quartile score (134, or 65.7 percent), with a double digit minority (70, or 34.3 percent) in the top quartile (that is, worst performing) Domain 2 score.

In terms of ownership, for the Domain 2 score, more than half of the total of the 3,445 hospitals were nonprofit hospitals (1,997). Of these 1,997 nonprofit hospitals, the majority (1,546, or 77.4 percent) were not in the top quartile score, while the for-profit hospitals (755) also had a majority (617, or 81.7 percent) not in the top quartile score for Domain 2.

In terms of region/division of the total 3,445 hospitals for Domain 2, the Northeast region had a total of 536 hospitals with a minority (143) in the New England region and a majority (393) in Mid-Atlantic region. The Midwest region had a total of 802 hospitals, with a majority (527) in the East North Central region and the minority (275) in the West North Central region. The South region had the majority of hospitals by a region (1,447), with the South Atlantic region (551) and the West South Central region (566) having similar amounts of hospitals and the East South Central region having the minority of hospitals (330) of the South region. The West region had a total of 660 hospitals, with a majority in the Pacific region (418) and the minority in the Mountain region (242). The South region had the largest number of hospitals (271, or

38.9 percent) in the top quartile score of Domain 2. The West North Central region had the lowest number of hospitals (32, or 4.6 percent) in the top quartile score of Domain 2, with the New England region (34, or 4.9 percent) and the Mountain region (39, or 5.6 percent) having the next lowest number of hospitals in the top quartile score of Domain 2. The South region had the largest number of hospitals (1,176, or 42.8 percent) not in the top quartile of the Domain 2 score, with the New England region having the lowest number of hospitals (109, or 4.0 percent) not in the top quartile of the Domain 2 score. The Mountain region (203, or 7.4 percent) and the West North Central region (243, or 8.8 percent) having the next lowest number of hospitals not in the top quartile of the Domain 2 score.

In terms of urban/rural location of the total 3,445 hospitals, for Domain 2, the majority of hospitals (2,468) were urban, with a minority of hospitals (966) being rural. Of the total 2,468 urban hospitals, there were 1,828 urban hospitals (74.1 percent) not in top quartile of the Domain 2 score. The 1,828 urban hospitals also were the majority of hospitals (66.5 percent) not in top quartile of the Domain 2 score. There were 640 urban hospitals (25.9 percent) in the top quartile of the Domain 2 score. The 640 urban hospitals also were the majority of hospitals (92.0 percent) in the top quartile of the Domain 2 score.

HOSPITALS IN TOP QUARTILE (WORST PERFORMING) FOR TOTAL HAC SCORE--DOMAIN 1 – PROPOSED APPROACH AND DOMAIN 1 – ALTERNATIVE APPROACH

Hospital Type	In Top Quartile for Total HAC Score for Domain 1 - Proposed Approach			Not in Top Quartile for Total HAC Score for Domain 1 – Proposed Approach			Domain 1 Proposed Approach Totals	In Top Quartile for Total HAC Score for Domain 1 - Alternative Approach			Not in Top Quartile for Total HAC Score for Domain 1 – Alternative Approach			Domain 1 Alternative Approach Totals
	No. of Hospitals	Percent of Total	Percent of Hospital Type	No. of Hospitals	Percent of Total	Percent of Hospital Type		No. of Hospitals	Percent of Total	Percent of Hospital Type	No. of Hospitals	Percent of Total	Percent of Hospital Type	
Teaching status														
Teaching	153	17.8	56.7	117	4.5	43.3	270	138	16.5	51.1	132	5.1	48.9	270
Non-teaching	691	80.5	22.8	2,346	91.0	77.2	3,037	687	82.2	22.6	2,350	90.4	77.4	3,037
No information	14	1.6	10.9	114	4.4	89.1	128	11	1.3	8.6	117	4.5	91.4	128
Total	858		25.0	2,577			3,435	836		24.3	2,599			3,435
DSH Status														
DSH	713	83.1	27.0	1,928	74.8	73.0	2,641	687	82.2	26.0	1,954	76.0	74.0	2,641
Non-DSH	140	16.3	18.9	600	23.3	81.1	740	144	17.2	20.2	569	22.1	79.8	713
No information	5	0.6	9.3	49	1.9	90.7	54	5	0.6	9.3	49	1.9	90.7	54
Total	858		25.0	2,577			3,435	836		24.5	2,572			3,408
Bed Size														
Under 50	47	5.5	7.2	609	23.6	92.8	656	69	8.3	10.5	587	22.6	89.5	656
50-99	105	12.2	15.5	573	22.2	84.5	678	144	17.2	21.2	534	20.5	78.8	678

100 – 199	237	27.6	26.8	647	25.1	73.2	884	234	28.0	26.5	650	25.0	73.5	884
200 – 299	186	21.7	37.3	313	12.1	62.7	499	148	17.7	29.7	351	13.5	70.3	499
300 – 399	105	12.2	39.9	158	6.1	60.1	263	86	10.3	32.7	177	6.8	67.3	263
400 – 499	59	6.9	47.6	65	2.5	52.4	124	57	6.8	46.0	67	2.6	54.0	124
500 or more	105	12.2	51.7	98	3.8	48.3	203	87	10.4	42.9	116	4.5	57.1	203
No information	14	1.6	10.9	114	4.4	89.1	128	11	1.3	8.6	117	4.5	91.4	128
Total	858		25.0	2,577			3,435	836		24.3	2,599			3,435
Ownership														
For-profit	166	19.3	22.0	588	22.8	78.0	754	162	19.4	21.5	592	22.8	78.5	754
Government	136	15.9	24.4	422	16.4	75.6	558	139	16.6	24.9	419	16.1	75.1	558
Non-profit	542	63.2	27.2	1,453	56.4	72.8	1,995	524	62.7	26.3	1,471	56.6	73.7	1,995
No information	14	1.6	10.9	114	4.4	89.1	128	11	1.3	8.6	117	4.5	91.4	128
Total	858		25.0	2,577			3,435	836		24.3	2,599			3,435
Region/Division														
Northeast	168	19.6	31.5	365	14.2	68.5	533	155	18.5	29.1	378	14.5	70.9	533
New England	41	4.8	28.7	102	4.0	71.3	143	39	4.7	27.3	104	4.0	72.7	143
Mid-Atlantic	127	14.8	32.6	263	10.2	67.4	390	116	13.9	29.7	274	10.5	70.3	390
Midwest	176	20.5	22.0	625	24.3	78.0	801	184	22.0	23.0	617	23.7	77.0	801
East North Central	127	14.8	24.1	399	15.5	75.9	526	130	15.6	24.7	396	15.2	75.3	526
West North Central	49	5.7	17.8	226	8.8	82.2	275	54	6.5	19.6	221	8.5	80.4	275
South	326	38.0	22.5	1,120	43.5	77.5	1,446	303	36.2	21.0	1,143	44.0	79.0	1,446
South Atlantic	154	17.9	27.9	397	15.4	72.1	551	137	16.4	24.9	414	15.9	75.1	551
East South Central	62	7.2	18.8	267	10.4	81.2	329	59	7.1	17.9	270	10.4	82.1	329
West South Central	110	12.8	19.4	456	17.7	80.6	566	107	12.8	18.9	459	17.7	81.1	566
West	188	21.9	28.7	467	18.1	71.3	655	149	23.2	29.6	461	17.7	70.4	655
Mountain	56	6.5	23.3	184	7.1	76.7	240	63	7.5	26.3	177	6.8	73.8	240
Pacific	132	15.4	31.8	283	11.0	68.2	415	131	15.7	31.6	284	10.9	68.4	415
Total	858		25.0	2,577		75.0	3,435	836			2,599			3,435

Urban/Rural														
Urban	731	85.2	29.7	1,730	67.1	70.3	2,461	691	82.7	28.1	1,770	68.1	71.9	2,461
Rural	127	14.8	13.2	837	32.5	86.8	964	145	17.3	15.0	819	31.5	85.0	964
No information	0	0.0	0.0	10	0.4	100.0	10	0	0.0	0.0	10	0.4	100.0	10
Total	858		25.0	2,577		75.0	3,435	836		24.3	2,599		75.7	3,435

The third table above shows the characteristics of the worst performing hospitals by the Total HAC Score for Domain 1-Proposed Approach and for Domain 1-Alternative Approach. In the third table, of the hospitals in the top quartile for total HAC score (Domain 1-Proposed Approach), 17.8 percent were teaching hospitals, 80.5 percent were nonteaching hospitals, 83.1 percent were disproportionate share hospitals, 16.3 percent were nondisproportionate share hospitals, 45.3 percent were hospitals with a bed size of 199 or smaller, and 63.2 percent were nonprofit. In the third table, of the hospitals in the top quartile for total HAC score (Domain 1-Alternative Approach), 16.5 percent were teaching hospitals, 82.2 percent were nonteaching hospitals, 82.2 percent were disproportionate share hospitals, 17.2 percent were nondisproportionate share hospitals, 53.5 percent were hospitals with a bed size of 199 or smaller, and 62.7 percent were nonprofit. Altogether, 3,435 hospitals had complete data for both the Domain 1-Proposed Approach, and the Domain 1-Alternative Approach. Among these hospitals, the majority (3,037) were nonteaching hospitals, with the majority of these nonteaching hospitals (2,346, or 77.2 percent for the proposed approach, and 2,350, or 77.4 percent for the alternative approach) not in the top quartile total HAC score. A minority of these hospitals (270) were teaching hospitals and slightly more than half of these hospitals (153, or 56.7 percent for the proposed approach, and 138, or 51.1 percent in the alternative approach) were in the top quartile (that is, worst performing) for the Domain 1-Proposed Approach Score and the Domain 1-Alternative Approach score. Of those hospitals not in the top quartile score, the nonteaching hospitals were the majority (2,346, or 91.0 percent for the proposed approach, and 2,350, or 90.4 percent for the

alternative approach). Of the total 3,435 hospitals, the majority were DSHs (2,641), with a minority being non-DSHs (740 for the proposed approach and 713 for the alternative approach). The majority of the DSHs (1,928, or 73.0 for the proposed approach, and 1,954 or 74.0 percent for the alternative approach) were not in the top quartile for the total HAC score. While slightly more than a quarter of DSHs (713, or 27.0 percent for the proposed approach, and 687, or 26.0 percent for the alternative approach) were in the top quartile (that is, worst performing) for the total HAC score.

In terms of bed size, for the Domain 1-Proposed Approach and the Domain 1-Alternative Approach, the majority of hospitals had less than 300 beds. The majority of these hospitals with less than 300 beds were in not in the top quartile for the total HAC score. The majority of hospitals (884) with less than 300 beds were in the 100 – 199 bed size range. Of those 884 hospitals, the majority of hospitals (647, or 73.2 percent for the proposed approach, and 650, or 73.5 percent for the alternative approach) were not in the top quartile of total HAC score. The minority of hospitals had greater than 300 beds. Of those hospitals with greater than a 300-bed size range, the hospitals with the 300 – 399 bed size range (263) had a majority of hospitals (158, or 60.1 percent for the proposed approach, and 177, or 67.3 percent, for the alternative approach) not in the top quartile of total HAC score. The hospitals with 400 – 499 bed size range (124) also had a slight majority of hospitals (65, or 52.4 percent, for the proposed approach, and 67, or 54.0 percent, for the alternative approach) not in the top quartile of the total HAC score. Hospitals with a 500 or more bed size range (203) had a slight majority in the top quartile' section (that is, worst performing) of 105 (or 51.7 percent) for the proposed

approach, and 87 (or 42.9 percent) of hospitals for the alternative approach, with a double digit minority (98, or 48.3 percent) not in the top quartile for the Domain 1–Proposed Approach total HAC score, and a slight majority (116, or 57.1 percent) not in the top quartile for the Domain 1-Alternative Approach total HAC score.

In terms of ownership, for the Domain 1-Proposed Approach and Domain 1-Alternative Approach total HAC score, more than half of the total 3435 hospitals were non-profit hospitals (1,995). Of these 1,995 nonprofit hospitals, the majority (1,453, or 72.8 percent, for the proposed approach, and 1,471, or 73.7 percent for the alternative approach) were not in top quartile of the total HAC score, while the 754 for-profit hospitals also had a majority (588, or 78.0 percent, for the proposed approach, and 592, or 78.5 percent for the alternative approach) not in the top quartile of the total HAC score.

In terms of region/division of the total 3,435 hospitals for Domain 1-Proposed Approach and the Domain 1-Alternative Approach, the Northeast region had a total of 533 hospitals, with a minority (143) in the New England region and a majority (390) in Mid-Atlantic region. The Midwest region had a total of 801 hospitals, with a majority (526) in the East North Central region and the minority (275) in the West North Central region. The South region had the majority of hospitals by a region (1,446), with the South Atlantic region (551) and the West South Central region (566) having similar numbers of hospitals and the East South Central region having the minority of hospitals (329) of the South region. The West region had a total of 655 hospitals, with a majority in the Pacific region (415) and the minority in the Mountain region (240). The South

region had the largest number of hospitals (326, or 38.0 percent, for the proposed approach, and 303, or 36.2 percent, for the alternative approach) in the top quartile of the total HAC score. The New England region had the lowest number of hospitals (41, or 4.8 percent, for the proposed approach, and 39, or 4.7 percent, for the alternative approach) in the top quartile for the total HAC score, with the West North Central region (49, or 5.7 percent for the proposed approach, and 54, or 6.5 percent, for the alternative approach) and the Mountain region (56, or 6.5 percent) having the next lowest number of hospitals in the top quartile of the Domain 1-Proposed Approach total HAC score and the East South Central region (59 or 7.1 percent) having the next lowest number in the top quartile for the Domain 1-Alternative Approach total HAC score. The South region had the largest number of hospitals (1,120, or 43.5 percent, for the proposed approach, and 1,143, or 44.0 percent, for the alternative approach) not in the top quartile of the total HAC score, with the New England region having the lowest number of hospitals (102, or 4.0 percent, for the proposed approach, and 104, or 4.0 percent, for the alternative approach) not in the top quartile of the total HAC score. The Mountain region (184, or 7.1 percent, for the proposed approach, and 177, or 6.8 percent for the alternative approach) and the West North Central region (226, or 8.8 percent, for the proposed approach, and 221, or 8.5 percent for the alternative approach) had the next lowest number of hospitals not in the top quartile of the total HAC score.

In terms of urban/rural location of the total 3,435 hospitals for the Domain 1-Proposed Approach total HAC score and the Domain 1-Alternative Approach total HAC score, the majority of hospitals (2,461) were urban, with a minority of hospitals (964)

being rural. Of the total 2,461 urban hospitals, there were 1,730 urban hospitals (70.3 percent) not in the top quartile of the total HAC score for the Domain 1-Proposed Approach, and 1,770 urban hospitals (71.9 percent) not in the top quartile of the total HAC score for the Domain 1-Alternative Approach. The 1,730 urban hospitals also were the majority (67.1 percent) of hospitals not in the top quartile of Domain 1-Proposed Approach total HAC score, and the 1,770 urban hospitals also were the majority (68.1 percent) of hospitals not in the top quartile of Domain 1-Alternative Approach total HAC score. There were 731 urban hospitals (29.7 percent) in the top quartile of the Domain 1-Proposed Approach total HAC score, with also a majority of hospitals (85.2 percent) in the top quartile. There were 691 urban hospitals (28.1 percent) in the top quartile of the Domain 1- Alternative Approach total HAC score, with also a majority of hospitals (82.7 percent) in the top quartile.

HOSPITALS' COMPLETENESS OF DATA FOR DOMAINS 1 AND 2

Hospital has complete data for Domain 1 (that is, data for at least 3 measures for the Domain 1-Proposed Approach or enough data to calculate PSI 90 for the Domain 1-Alternative Approach)	Hospital has complete data for Domain 2 (that is, has data for at least 1 measure for the domain)						Total No. of Hospitals by Type	Total Percent by Hospital Type
	Yes			No				
	No. of Hospitals	Percent of Total	Percent of Hospital Type	No. of Hospitals	Percent of Total	Percent of Hospital Type		
YES								
Teaching	265	13.8%	98.1%	5	0.3%	1.9%	270	7.9%
Non-teaching	1643	85.3%	54.1%	1394	92.4%	45.9%	3037	88.4%
No information	19	1.0%	14.8%	109	7.2%	85.2%	128	3.7%
<i>Subtotal</i>	1,927			1,508			3,435	
DSH	1,564	81.2%	59.2%	1,077	71.4%	40.8%	2641	76.9%
Non-DSH	359	18.6%	48.5%	381	25.3%	51.5%	740	21.5%
No information	4	0.2%	7.4%	50	3.3%	92.6%	54	1.6%
<i>Subtotal</i>	1,927			1,508			3,435	

	Hospital has complete data for Domain 1 (that is, data for at least 3 measures for the Domain 1-Proposed Approach or enough data to calculate PSI 90 for the Domain 1-Alternative Approach)	Hospital has complete data for Domain 2 (that is, has data for at least 1 measure for the domain)						Total No. of Hospitals by Type	Total Percent by Hospital Type
		Yes			No				
		No. of Hospitals	Percent of Total	Percent of Hospital Type	No. of Hospitals	Percent of Total	Percent of Hospital Type		
	For-profit	365	18.9%	48.4%	389	25.8%	51.6%	754	22.0%
	Government	221	11.5%	39.6%	337	22.3%	60.4%	558	16.2%
	Non-profit	1,322	68.6%	66.3%	673	44.6%	33.7%	1995	58.1%
	No information	19	1.0%	14.8%	109	7.2%	85.2%	128	3.7%
	<i>Subtotal</i>	1,927			1,508			3,435	
	< 50 beds	12	0.6%	1.8%	644	42.7%	98.2%	656	19.1%
	50-99 beds	164	8.5%	24.2%	514	34.1%	75.8%	678	19.7%
	100 - 199 beds	665	34.5%	75.2%	219	14.5%	24.8%	884	25.7%
	200 - 299 beds	486	25.2%	97.4%	13	0.9%	2.6%	499	14.5%
	300 - 399 beds	259	13.4%	98.5%	4	0.3%	1.5%	263	7.7%
	400 - 499 beds	121	6.3%	97.6%	3	0.2%	2.4%	124	3.6%
	500+ beds	201	10.4%	99.0%	2	0.1%	1.0%	203	5.9%
	No information	19	1.0%	14.8%	109	7.2%	85.2%	128	3.7%

	Hospital has complete data for Domain 1 (that is, data for at least 3 measures for the Domain 1-Proposed Approach or enough data to calculate PSI 90 for the Domain 1-Alternative Approach)	Hospital has complete data for Domain 2 (that is, has data for at least 1 measure for the domain)						Total No. of Hospitals by Type	Total Percent by Hospital Type
		Yes			No				
		No. of Hospitals	Percent of Total	Percent of Hospital Type	No. of Hospitals	Percent of Total	Percent of Hospital Type		
	<i>Subtotal</i>	1,927			1,508			3,435	
	NO								
	Teaching	0	0.0%	0.0%	0	0.0%	0.0%	0	0.0%
	Non-teaching	0	0.0%	0.0%	4	40.0%	100.0%	4	40.0%
	No information	0	0.0%	0.0%	6	60.0%	100.0%	6	60.0%
	<i>Subtotal</i>	0			10			10	
	DSH	0	0.0%	0.0%	1	10.0%	0.0%	1	10.0%
	Non-DSH	0	0.0%	0.0%	1	10.0%	100.0%	1	10.0%
	No information	0	0.0%	0.0%	8	80.0%	100.0%	8	80.0%
	<i>Subtotal</i>	0			10			10	
	For-profit	0	0.0%	0.0%	1	10.0%	100.0%	1	10.0%
	Government	0	0.0%	0.0%	1	10.0%	100.0%	1	10.0%

Hospital has complete data for Domain 1 (that is, data for at least 3 measures for the Domain 1-Proposed Approach or enough data to calculate PSI 90 for the Domain 1-Alternative Approach)		Hospital has complete data for Domain 2 (that is, has data for at least 1 measure for the domain)						Total No. of Hospitals by Type	Total Percent by Hospital Type
		Yes			No				
		No. of Hospitals	Percent of Total	Percent of Hospital Type	No. of Hospitals	Percent of Total	Percent of Hospital Type		
	Non-profit	0	0.0%	0.0%	2	20.0%	100.0%	2	20.0%
	No information	0	0.0%	0.0%	6	60.0%	100.0%	6	60.0%
	<i>Subtotal</i>	0			10			10	
	< 50 beds	0	0.0%	0.0%	2	20.0%	100.0%	2	20.0%
	50-99 beds	0	0.0%	0.0%	0	0.0%	0.0%	0	0.0%
	100 - 199 beds	0	0.0%	0.0%	0	0.0%	0.0%	0	0.0%
	200 - 299 beds	0	0.0%	0.0%	0	0.0%	0.0%	0	0.0%
	300 - 399 beds	0	0.0%	0.0%	1	10.0%	100.0%	1	10.0%
	400 - 499 beds	0	0.0%	0.0%	0	0.0%	0.0%	0	0.0%
	500+ beds	0	0.0%	0.0%	1	10.0%	100.0%	1	10.0%
	No information	0	0.0%	0.0%	6	60.0%	100.0%	6	60.0%
	<i>Subtotal</i>	0	0.0%	0.0%	10			10	

The fourth table above contains information on hospitals that had complete data for Domain 1 (that is, had complete data for at least 3 measures for the Domain 1-Proposed Approach or had enough data to calculate PSI 90 for the Domain 1-Alternative Approach) and hospitals that had complete data for Domain 2 (that is, had data for at least 1 measure for the domain). Altogether, 3,435 hospitals had complete data for Domain 1, regardless of whether the proposed approach or the alternative approach was selected.¹⁹³ Among these hospitals, 3,037 (88.4 percent) were nonteaching hospitals, while 270 (7.9 percent) were teaching hospitals. Most of these hospitals were DSHs (2,641, or 76.9 percent), slight more than a fifth (740, or 21.5 percent) were non-DSHs. More than half of these 3,435 hospitals were non-profit (1,995, or 58.1 percent). For-profit hospitals accounted for slightly more than one-fifth (754, or 22 percent) of the 3,435 hospitals with complete data for Domain 1, while 16.2 percent (558) were government hospitals.¹⁹⁴ In terms of bed size, almost 40 percent of the 3,435 hospitals were small facilities, with fewer than 100 beds. Slightly, more than a quarter (884, or 25.7 percent) had 100 to 199 beds, while the remaining 31.7 percent had at least 200 beds. We have no information about the teaching status, ownership, or bed size for

¹⁹³ The reason that there were 3,435 hospitals with complete data for Domain 1, regardless of options, has to do with the minimum measure criterion for Domain 1, Option 1. In particular, a hospital had to have complete data for at least 3 measures in Domain 1-Proposed Approach to have a Domain 1 score calculated. According to the data that CMS used to develop the scoring method for implementing section 3008 of the Affordable Care Act, 3,435 hospitals had complete data for at least 3 measures in Domain 1-Proposed Approach to calculate a Domain 1 score. As for Domain 1-Alternative Approach, for hospitals that did not have enough cases to calculate any one of the eight component indicators for PSI 90, the rate for that component indicator was substituted by the national rate for that component indicator to calculate the hospital's rate for PSI 90.

¹⁹⁴ Government hospitals include military hospitals, hospitals run by the U.S. Department of Veteran Affairs, U.S. Department of Justice, and the Indian Health Service.

128 of the 3,435 hospitals that had complete data for Domain 1, or the DSH status of 54 of these hospitals.

Of the 3,435 hospitals with complete data for Domain 1, more than half (1,927, or 56.1 percent) also had complete data for Domain 2. Among the 1,927 hospitals with complete data for both domains, the majority were nonteaching hospitals (1,643, or 85.3 percent), DSHs (1,564, or 81.2 percent), and nonprofit hospitals (1,322, or 68.6 percent). More than 40 percent of these 1,927 hospitals had fewer than 200 beds, a quarter (486, or 25.2 percent) had 200 to 299 beds, while more than 30 percent had 300 or more beds. Among the 1,508 hospitals with complete data for Domain 1 but not for Domain 2, the vast majority were nonteaching hospitals (1,394, or 92.4 percent); almost three-quarters of these hospitals were DSHs (1,077, or 71.4 percent). Nonprofit hospitals (673, or 44.6 percent) and small hospitals with fewer than 50 beds (644, or 42.7 percent) accounted for a considerable minority among these 1,508 hospitals.

In addition, among the 3,435 hospitals with complete data for Domain 1, the proportion of teaching hospitals that also had complete data for Domain 2 far exceeded that of those that did not (98.1 percent versus 1.9 percent). The proportion of nonteaching hospitals that had complete data was also higher than the proportion of those hospitals that did not, but the difference was smaller (54.1 percent versus 45.9 percent). DSHs were 18.4 percent more likely to have complete data for both domains than for only Domain 1; non-DSHs, on the other hand, were 3 percent more likely to have complete data for only Domain 1 than for both domains. For-profit and government hospitals were more likely to have complete data for Domain 1 only (51.6 percent and

60.4 percent, respectively) than for both domains (48.4 percent and 39.6 percent, respectively), while nonprofit hospitals were less likely to have complete data for Domain 1 only than for both domains (66.3 percent versus 33.7 percent). In terms of bed size, hospitals with more beds were more likely to have complete data for both domains, while those with fewer than 100 beds were more likely to have complete data for Domain 1 only than for both domains.

Among the 3,435 hospitals in our analysis, none had complete data for only Domain 2 but not Domain 1. Ten of the 3,435 hospitals had no complete data for either Domain 1 or Domain 2. Among these 10 hospitals, none were teaching hospitals and 4 were nonteaching hospitals. One hospital was a DSH; another was not. One hospital was a for-profit hospital, one was a government hospital, and two were nonprofit hospitals. Two of the 10 hospitals had fewer than 50 beds, 1 hospital had 300 to 399 beds, and another was a large hospital with at least 500 beds. Of these 10 hospitals, there were 6 hospitals for which we had no information about their teaching status, ownership, or bed size, and 8 hospitals for which we have no information about whether or not they were DSH.

7. Effects of the Policy Changes Relating to Payments for GME and IME

In section V.J.2. of the preamble of this proposed rule, we discuss our proposal to include labor and delivery days in the Medicare utilization calculation. We are proposing, consistent with the inpatient day counting rules for DSH as clarified in the FY 2010 IPPS/RV 2010 LTCH PPS final rule, that effective for cost reporting periods beginning on or after October 1, 2013, for purposes of applying the Medicare utilization

ratio, we would include labor and delivery inpatient days in the numerator (to the extent that there are any labor and delivery inpatient days associated with Medicare beneficiaries), and all labor and delivery inpatient days in the denominator (associated with all inpatients of the hospital). In addition to payments for direct GME, we believe this proposal also would affect other Medicare policies where either the number of inpatient days or a ratio of Medicare inpatient days to total inpatient days is used to determine eligibility or payment. However, this proposal would not impact Medicare payments calculated on a reasonable cost basis for routine inpatient services, which are apportioned in accordance with 42 CFR 413.53(a)(1). We believe including labor and delivery days in the Medicare utilization calculation would result in a savings of approximately \$15 million for FY 2014.

In section V.J.3. of the preamble of this proposed rule, in accordance with section 5506 of the Affordable Care Act which instructs the Secretary to establish a process to increase the FTE resident caps for other hospitals based upon the FTE resident caps in teaching hospitals that closed “on or after a date that is 2 years before the date of enactment” (that is March 23, 2008), we notify the public of the closure of one teaching hospital and the initiation of another round of the section 5506 application and selection process to redistribute FTE resident slots. We are initiating “Round 4” of section 5506, to redistribute the FTE resident slots of the Peninsula Hospital Center in Far Rockaway, NY, which closed on April 9, 2012. We are merely using this proposed rule as a vehicle to initiate another round of the section 5506 application and selection process, which is

an ongoing provision triggered each time a teaching hospital closes. Therefore, there is no impact for this provision.

In section V.J.4. of the preamble of this proposed rule, we are proposing that another IPPS or IPPS-excluded hospital may not count the resident(s) training at the CAH for IME and/or direct GME purposes, even if that hospital is paying for the residents' salary and fringe benefits. Specifically, we are proposing that, effective for portions of cost reporting periods occurring on or after October 1, 2013, a hospital may not claim the FTE residents that are training at a CAH for IME and/or direct GME purposes. However, under policies that were applicable prior to October 1, 2013 and that continue to apply on and after October 1, 2013, the CAH may incur the costs of training the FTE residents for the time that the FTE residents rotate to the CAH, and receive payment based on 101 percent of its Medicare reasonable costs under 42 CFR 413.70.

We do not believe that there is any financial impact of this proposed policy, as we are not precluding all Medicare payment for residents training at CAHs. Rather, we are precluding payment to one group of providers (that is, hospitals), but continuing to allow payment to another group (that is, CAHs). Under current policy, either a hospital could receive IME and direct GME payment for the time spent by residents training at a CAH if the hospital incurred the cost of that training, or the CAH could receive payment under § 413.70 if the CAH incurred the training cost. Under the proposed policy, hospitals would no longer be allowed to receive IME and direct GME payment for the costs associated with training residents at a CAH. However, CAHs could continue to receive

payment under § 413.70 for the allowable costs associated with training residents at a CAH in approved residency training programs.

In section V.J.5. of the preamble of this proposed rule, we discuss the provisions of section 711 of the Medicare Modernization Act (Pub. L. 108-173) which amended section of 1886(h)(2)(D)(iv)(I) of the Act to freeze annual CPI-U updates to hospital-specific PRAs for direct GME payment purposes for those PRAs that exceed the ceiling for FYs 2004 through 2013. Therefore, the “freeze” for PRAs that exceed the ceiling expires beginning in FY 2014. That is, for cost reporting periods beginning on or after October 1, 2013, the usual full CPI-U update, as determined under 42 CFR 413.77(c)(1) would apply to all PRAs for direct GME payment purposes. We note that we are not making any proposals related to this provision in this proposed rule. We are merely providing notice to the public that a statutory provision will no longer apply in FY 2014.

8. Effects of Implementation of Rural Community Hospital Demonstration Program

In section V.K. of the preamble of this proposed rule, we discuss our implementation of section 410A of Pub. L. 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 V.K. of the preamble of this proposed rule, in the

IPPS final rules for each of the previous 9 fiscal years, we have estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration. In order to achieve budget neutrality, we are proposing to adjust the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we are proposing to apply budget neutrality across the payment system as a whole rather than merely across the participants of this demonstration. We believe that the language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that “aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration . . . was not implemented” but does not identify the range across which aggregate payments must be held equal.

We are proposing to adjust the national IPPS rates according to the methodology set forth elsewhere in this proposed rule. 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 16 additional hospitals participating as a result of the expansion of the demonstration under the Affordable Care Act is \$46,515,865. In addition, in this FY 2014 proposed rule, we are proposing that if settled cost reports for all of the demonstration hospitals that participated in the applicable fiscal year (2007, 2008, 2009, or 2010) are made available prior to the FY 2014 IPPS/LTCH PPS final rule, we would incorporate into the FY 2014 budget neutrality offset amount any additional amounts by which the final settled costs of

the demonstration for the year (FY 2007, 2008, 2009, or 2010) exceeded the budget neutrality offset amount applicable to such year as finalized in the respective year's IPPS final rule. The estimated amount of \$46,515,865 that we are proposing for FY 2014 does not account for any differences between the cost of the demonstration program for hospitals participating in the demonstration for FYs 2007 through 2010 and the amounts that were offset by the budget neutrality adjustment for these years because the specific numeric value associated with this component of the adjustment to the national IPPS rates cannot be known at this time. This is because the large majority of settled cost reports beginning in FYs 2007 through 2010 for the hospitals participating in the demonstration during those years also are not available at this time.

9. Effects of the Extended Effective Date for Policy on Hospital Services Furnished under Arrangements

In section V.M. of the preamble of this proposed rule, we discuss our proposed change in the implementation date of our revised policy, as outlined in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51711) under which we limit the circumstances under which a hospital may furnish services to Medicare beneficiaries "under arrangements." We are proposing to change the implementation date of the requirement to be effective for services provided on or after January 1, 2015 (instead of effective with cost reporting periods beginning on or after October 1, 2013). Because there are hospitals in the midst of significant building projects that, when completed, will enable the hospital to provide routine services in compliance with the requirements of this revised policy, we believe it is appropriate to further delay the effective date. We expect that, with the additional time

before the revised “under arrangement” policy becomes effective, hospitals will complete the work needed to ensure compliance with the new requirement. Effective for services provided on or after January 1, 2015, all hospitals would need to be in full compliance with the revised policy for services furnished under arrangement. We have determined that the impact of this proposed effective date change would be negligible.

I. Effects of Proposal Relating to the Furnishing of Acute Care Inpatient Services by CAHs

In section VII.B.2. of the preamble of this proposed rule, we discuss our proposal to revise the requirements under the CoPs for CAHs to specify that CAHs must provide acute care inpatient services. We estimate that the costs to CAHs to implement this proposal would be minimal. The vast majority of CAHs, approximately 99 percent, already are providing acute care inpatient services. In fact, we believe that most CAHs would not consider the proposal a change in policy. We believe most CAHs will view this proposal as a clarification that confirms their usual and customary business practices. We welcome public comments on our assumptions and estimates.

J. Effects of Proposed Changes to the CoPs for Hospitals Relating to the Administration of Pneumococcal Vaccines

In section X. of the preamble of this proposed rule, we discuss our proposal to amend the standard under the CoPs for hospitals relating to the administration of pneumococcal vaccine by nursing staff. We are proposing to delete the term “polysaccharide” vaccine in the standard to allow hospitals to include any type of

pneumococcal vaccine as part of its physician-approved policy for administration by nurses without a prior practitioner order.

While we expect this proposed change to have a positive effect on hospitals by providing them with additional regulatory flexibility in this area, it is difficult to estimate this positive effect in terms of actual cost savings for hospitals. We believe that the proposed change would carry the additional benefit of improving patient access to pneumococcal vaccines if hospitals choose to exercise the potential regulatory flexibility proposed and purchase and stock more than one type of pneumococcal vaccine as a result. This benefit would be particularly apparent if there were a shortage of one type of the pneumococcal vaccine in the future. In conclusion, while we cannot estimate any cost savings that would result from this proposed change, we are confident that it would not impose any burden on hospitals.

K. Effects of Proposed Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented below, we used data from the December 2012 update of the FY 2012 MedPAR file and the December 2012 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 2012 update of the most recently available hospital cost report data (FYs 2010 and 2011) 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 2012 update of the FY 2012 MedPAR file, we simulated payments under the capital IPPS for FY 2013 and FY 2014 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 2014 is as follows:

(Standard Federal Rate) x (DRG weight) x (GAF) x (COLA for hospitals located in Alaska and Hawaii) x (1 + DSH Adjustment Factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may also receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the GAF and the hospital's case-mix. We then added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- We estimate that the Medicare case-mix index would increase by 0.5 percent in both FYs 2013 and 2014.
- We estimate that Medicare discharges would be approximately 12.3 million in FY 2013 and 12.7 million in FY 2014.
- 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 0.90 percent for FY 2014.

- In addition to the proposed FY 2014 update factor, the proposed FY 2014 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality adjustment factor of 0.9988, a proposed outlier adjustment factor of 0.9451, and a proposed adjustment factor of 0.9980 to offset the estimated additional IPPS expenditures that are projected to result from our policy proposal on admission and medical review criteria for hospital inpatient services under Medicare Part A, as discussed in section VI.C. of the preamble of this proposed rule.

2. Results

We used the actuarial model described above to estimate the potential impact of our proposed changes for FY 2014 on total capital payments per case, using a universe of 3,404 hospitals. As described above, the individual hospital payment parameters are taken from the best available data, including the December 2012 update of the FY 2012 MedPAR file, the December 2012 update to the PSF, and the most recent cost report data from the December 2012 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2013 and estimated total payments per case for FY 2014 based on the proposed FY 2014 payment policies. Column 2 shows estimates of payments per case under our model for FY 2013. Column 3 shows estimates of payments per case under our model for FY 2014. Column 4 shows the proposed total percentage change in payments from FY 2013 to FY 2014. The proposed change represented in Column 4 includes the proposed 0.90 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 2014 are expected to increase as compared to capital payments per case in FY 2013. The proposed capital Federal rate for FY 2014 would increase approximately 1.5 percent as compared to the FY 2013 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 effect 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.

We are estimating a slight decrease in outlier payments in FY 2014 as compared to FY 2013. This is primarily because of the proposed increase to the proposed outlier fixed-loss amount (discussed in section II.A.4.f. of the Addendum to this proposed rule).

The net impact of these proposed changes is an estimated 1.1 percent change in capital payments per discharge from FY 2013 to FY 2014 for all hospitals (as shown below in Table III).

The geographic comparison shows that, on average, with the exception of one region, all hospitals are expected to experience an increase in capital IPPS payments per case in FY 2014 as compared to FY 2013. These expected increases are primarily due to the proposed increase in the capital Federal rate, but are somewhat offset by the projected decrease in payments because of the proposed GAFs, and the projected decrease in

outlier payments. Capital IPPS payments per case for both large urban hospitals and other urban hospitals are estimated to increase 1.2 percent. Rural hospitals, on average, are expected to experience a 0.6 percent increase in capital payments per discharge from FY 2013 to FY 2014. The factors contributing to the difference in the projected increase in capital IPPS payments per discharge for urban hospitals as compared to rural hospitals are a decrease in capital payments to rural hospitals due to proposed changes to the GAF, a relatively larger decrease in projected outlier payments to rural hospitals, and a relatively lower projected increase in capital payments to rural hospitals due to the proposed changes to the MS-DRG relative weights.

The comparisons by region show that the estimated increases in capital payments per discharge from FY 2013 to FY 2014 in urban areas ranges from a 2.3 percent increase for the New England urban region to a 0.6 percent increase for the Mountain urban region. Similarly, for rural regions, the New England rural region is expected to experience the largest increase in capital IPPS payments per discharge at 1.7 percent. Unlike most other urban and rural regions, for both the New England urban and rural region, a large part of the expected increase in capital IPPS payments per discharge is due to the proposed GAFs, which are consistent with the proposed changes in the wage index for hospitals located in the New England area, as discussed in section I. of this Appendix.

Whereas all urban regions and most rural regions are estimated to experience an increase in capital IPPS payments per discharge, the Mountain rural region is expected to experience a 0.1 percent decrease in capital IPPS payments per discharge – the only region not expected to experience an increase. This is mainly due both to projected

decreases in capital payments in FY 2014 resulting from the proposed changes to the GAFs, as well as proposed changes to the outlier threshold.

All but one of the hospitals located in Puerto Rico are in urban areas. Hospitals located in the Puerto Rico urban region are expected to experience a 2.1 percent increase in capital IPPS payments per discharge in FY 2014 as compared to FY 2013. This larger than average projected increase in capital IPPS payments per discharge is mostly due to the proposed GAFs, which are consistent with the proposed changes in the wage index for hospitals located in the Puerto Rico urban areas, as discussed in section I. of this Appendix.

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 2013 to FY 2014. The proposed increase in capital payments for both government and proprietary hospitals is estimated at 1.0 percent, and voluntary hospitals are estimated to experience a 1.3 percent increase in capital payments per case from FY 2013 to FY 2014.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2014. 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 2014, we show the average capital payments per case for reclassified hospitals for FY 2014. Urban reclassified hospitals are expected to experience a 1.6 percent increase in capital payments, whereas urban nonreclassified

hospitals are expected to experience an increase of 1.1 percent. The proposed estimated percentage increase for rural reclassified hospitals is 1.1 percent. However, rural nonreclassified hospitals are expected to experience a 0.2 percent decrease in capital payments per case. Other reclassified hospitals (that is, hospitals reclassified under section 1886(d)(8)(B) of the Act) are expected to experience a 1.3 percent increase in capital payments from FY 2013 to FY 2014.

TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE
[FY 2013 PAYMENTS COMPARED TO FY 2014 PAYMENTS]

	Number of hospitals	Average FY 2013 payments/case	Average FY 2014 payments/case	Change
By Geographic Location:				
All hospitals	3,404	816	826	1.1
Large urban areas (populations over 1 million)	1,367	903	914	1.2
Other urban areas (populations of 1 million or fewer)	1,114	794	803	1.2
Rural areas	923	564	568	0.6
Urban hospitals	2,481	854	864	1.2
0-99 beds	622	716	712	-0.5
100-199 beds	762	738	745	0.9
200-299 beds	464	786	795	1.2
300-499 beds	418	870	882	1.3
500 or more beds	215	1,016	1,031	1.5
Rural hospitals	923	564	568	0.6
0-49 beds	339	457	458	0.0
50-99 beds	328	517	521	0.7
100-149 beds	151	559	562	0.5
150-199 beds	59	628	633	0.7
200 or more beds	46	675	682	0.9
By Region:				
Urban by Region	2,481	854	864	1.2
New England	120	928	949	2.3
Middle Atlantic	318	900	920	2.2
South Atlantic	375	786	792	0.7
East North Central	395	818	825	0.9
East South Central	149	745	752	1.0
West North Central	165	851	860	1.0
West South Central	371	789	797	1.0
Mountain	156	890	896	0.6
Pacific	381	1,064	1,077	1.2
Puerto Rico	51	380	388	2.1
Rural by Region	923	564	568	0.6
New England	23	765	778	1.7
Middle Atlantic	69	581	585	0.6
South Atlantic	165	544	547	0.5
East North Central	119	586	590	0.7
East South Central	171	517	519	0.4
West North Central	100	596	602	0.9
West South Central	181	504	507	0.4
Mountain	65	617	617	-0.1
Pacific	29	723	733	1.4

TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE
[FY 2013 PAYMENTS COMPARED TO FY 2014 PAYMENTS]

	Number of hospitals	Average FY 2013 payments/case	Average FY 2014 payments/case	Change
Puerto Rico.....	1	198	210	6.2
By Payment Classification:				
All hospitals.....	3,404	816	826	1.1
Large urban areas (populations over 1 million).....	1,377	902	913	1.2
Other urban areas (populations of 1 million of fewer).....	1,118	794	803	1.2
Rural areas.....	909	571	574	0.5
Teaching Status:				
Non-teaching.....	2,378	699	704	0.7
Fewer than 100 Residents.....	782	803	814	1.3
100 or more Residents.....	244	1,148	1,166	1.6
Urban DSH:				
100 or more beds.....	1,562	874	886	1.3
Less than 100 beds.....	330	615	622	1.1
Rural DSH:				
Sole Community (SCH/EACH).....	260	530	530	-0.2
Referral Center (RRC/EACH).....	223	625	630	0.7
Other Rural:				
100 or more beds.....	29	523	521	-0.4
Less than 100 beds.....	294	460	461	0.3
Urban teaching and DSH:				
Both teaching and DSH.....	826	944	958	1.5
Teaching and no DSH.....	135	837	849	1.4
No teaching and DSH.....	1,066	737	745	1.0
No teaching and no DSH.....	468	770	771	0.1
Rural Hospital Types:				
Non special status hospitals.....	2,367	859	869	1.2
RRC/EACH.....	76	770	791	2.7
SCH/EACH.....	37	758	765	0.9
SCH, RRC and EACH.....	17	779	800	2.7
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY2014 Reclassifications:				
All Urban Reclassified.....	451	849	862	1.6
All Urban Non-Reclassified.....	1,990	858	867	1.1
All Rural Reclassified.....	311	601	607	1.1
All Rural Non-Reclassified.....	552	513	511	-0.2
Other Reclassified Hospitals (Section 1886(d)(8)(B)).....	53	553	560	1.3
Type of Ownership:				
Voluntary.....	1,944	828	839	1.3
Proprietary.....	895	741	748	1.0
Government.....	546	853	861	1.0
Medicare Utilization as a Percent of Inpatient Days:				
0-25.....	368	1,038	1,053	1.5
25-50.....	1,807	857	867	1.2
50-65.....	967	685	692	1.1
Over 65.....	171	601	606	0.8

L. Effects of Proposed Payment Rate Changes and Policy Changes under the LTCH PPS

1. Introduction and General Considerations

In section VIII. 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 2014. 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 423 LTCHs included in this impacts analysis, which includes data for 78 nonprofit (voluntary ownership control) LTCHs, 327 proprietary LTCHs, and 18 LTCHs that are government-owned and operated. (We note that although there are currently approximately 440 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 2014 MS-LTC-DRG relative weights (discussed in section VIII.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 1.8 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 second year phase 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 and labor-related share, and the best available claims and CCR data to estimate the change in payments for FY 2014. (As discussed in section IX.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 beginning in FY 2014.)

The standard Federal rate for FY 2013 is \$40,397.96. However, consistent with the statute, the payment for FY 2013 discharges occurring on or before December 28, 2012 does not reflect the one-time prospective adjustment under § 412.523(d)(3) of the regulations, and such discharges are paid based on a standard Federal rate of \$40,915.95 (77 FR 53710). For FY 2014, we are proposing to establish a standard Federal rate of \$40,622.06, which reflects the proposed 1.8 percent annual update to the standard Federal rate, and the proposed area wage budget neutrality factor of 1.000433 to ensure that the proposed changes in the wage indexes and labor-related share do not influence aggregate payments, and the proposed second year of the phase-in of the one-time prospective adjustment factor of 0.98734. We note that the proposed factors described above to determine the proposed FY 2014 standard Federal rate are

applied to the FY 2013 Federal standard rate set forth under section § 412.523(c)(3)(ix)(A) (that is, \$40,397.96).

Based on the best available data for the 423 LTCHs in our database, we estimate that the proposed annual update to the standard Federal rate for FY 2014 (discussed in section V.A.2. of the Addendum to this proposed rule) and the proposed changes to the area wage adjustment for FY 2014 (discussed in section V.B. of the Addendum to this proposed rule), in addition to an estimated increase in HCO payments would result in an increase in estimated payments from FY 2013 of approximately \$62 million. Based on the 423 LTCHs in our database, we estimate that the FY 2014 LTCH PPS payments would be approximately \$5.599 billion, as compared to estimated FY 2013 LTCH PPS payments of approximately \$5.537 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 \$62 million for the projected increase in estimated aggregate proposed LTCH PPS payments from FY 2013 to FY 2014 does not reflect changes in LTCH admissions or case-mix intensity in estimated LTCH PPS payments, which also will affect overall payment changes. (We note that this impact does not include an estimate effect of the 2.0 percentage points reduction to the proposed annual update to the LTCH PPS standard Federal rate for LTCHs that fail to submit quality data, as required by section 1886(m)(5)(C) of the Act, because we have not determined at this time which, if any, LTCHs failed to submit the requisite quality data for FY 2014 under the LTCH Quality Reporting Program.)

The projected 1.1 percent increase in estimated proposed payments per discharge from FY 2013 to FY 2014 is attributable to several factors, including the proposed 1.8 percent annual update to the standard Federal rate, the proposed one-time prospective adjustment factor for FY 2014 of 0.98734 (approximately –1.3 percent), and projected increases in estimated HCO payments. As Table IV shows, the change attributable solely to the proposed annual update to the standard Federal rate (1.8 percent), including the proposed one-time prospective adjustment factor for FY 2014 under the second year of the phase-in (approximately –1.3 percent), is projected to result in an increase of 0.5 percent in payments per discharge from FY 2013 to FY 2014, on average, for all LTCHs. We note, the estimated change in payments solely attributable to the proposed annual update to the standard Federal rate does not take into account that the one-time prospective adjustment to the standard Federal rate for FY 2013 under § 412.523(d)(3) is not applied to payments for discharges occurring before December 29, 2012, consistent with the statute (and, therefore, are paid based on a relatively higher rate). The change in payments solely attributable to the proposed annual update to the standard Federal rate for FY 2014 would be a smaller increase in payments relative to the pre-December 29, 2012 LTCH payment rates (approximately 0.2 percent instead of 0.5 percent). In addition to the proposed 1.8 percent annual update for FY 2014 and the proposed -1.3 percent one-time prospective adjustment factor for FY 2014, this estimated increase in aggregate LTCH PPS payments of 0.5 percent 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 less than the proposed 0.5 percent annual update for FY 2014.

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 and labor-related share does not impact the increase in aggregate payments. In addition, we note that the updates to the standard Federal rate to determine the estimated effects described above were applied to the FY 2013 standard Federal rate set forth under section § 412.523(c)(3)(ix)(A) (that is, \$40,397.96).

As discussed in section V.B. of the Addendum to this proposed rule, we are proposing to update the wage index values for FY 2014 based on the most recent available data. In addition, we are proposing to decrease the labor-related share from 63.096 percent to 62.717 percent under the LTCH PPS for FY 2014, 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 1.000433, which increases the proposed standard Federal rate by approximately 0.04 percent. Therefore, the proposed changes to the wage data and labor-related share do not result in a change in estimated aggregate LTCH PPS payments.

Table IV below shows the impact of the proposed payment rate and the proposed policy changes on LTCH PPS payments for FY 2014 presented in this proposed rule by comparing estimated FY 2013 payments to estimated FY 2014 payments. The projected increase in payments per discharge from FY 2013 to FY 2014 is 1.1 percent (shown in

Column 9). This projected increase in payments is attributable to the impacts of the proposed change to the standard Federal rate (0.5 percent in Column 6) and the effect of the estimated increase in proposed payments for HCO cases and SSO cases (0.8 percent and 0.2 percent, respectively). That is, estimated total HCO payments are projected to increase from FY 2013 to FY 2014 in order to ensure that the estimated HCO payments would be 8 percent of the total estimated LTCH PPS payments in FY 2014. An analysis of the most recent available LTCH PPS claims data (that is, FY 2012 claims data from the December 2012 update of the MedPAR file) indicates that the FY 2013 HCO threshold of \$15,408 (as established in the FY 2013 IPPS/LTCH PPS final rule) may result in HCO payments in FY 2014 that fall below the estimated 8 percent. Specifically, we currently estimate that HCO payments would be approximately 7.2 percent of the estimated total LTCH PPS payments in FY 2013. We estimate that the impact of the increase in HCO payments would result in approximately a 0.8 percent increase in estimated payments from FY 2013 to FY 2014, on average, for all LTCHs. Furthermore, in calculating the estimated increase in payments from FY 2013 to FY 2014 for HCOs, we increased estimated costs by the applicable market basket percentage increase as projected by our actuaries. This increase in estimated costs also results in a projected increase in SSO payments of approximately 0.2 percent relative to last year. The net result of these projected changes in HCO and SSO payments in FY 2014 is an estimated change in aggregate payments of 1.0 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 2014 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 57 percent) are based on the estimated cost of the case.

As we discuss in detail throughout this proposed rule, based on the most recent available data, we believe that the provisions of this proposed rule relating to the LTCH PPS would result in an increase in estimated aggregate LTCH PPS payments and that the resulting LTCH PPS payment amounts would result in appropriate Medicare payments.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 0.7 percent increase in estimated payments per discharge for FY 2014 as compared to FY 2013 for rural LTCHs that would result from the proposed changes presented in this proposed rule, as well as the effect of estimated changes to HCO and SSO payments. This estimated impact is based on the data for the 27 rural LTCHs in our database (out of 423 LTCHs) for which complete data were available.

The estimated increase in LTCH PPS payments from FY 2013 to FY 2014 for rural LTCHs (0.7 percent) is less than the national average increase (1.1 percent). The estimated increase in LTCH PPS payments from FY 2013 to FY 2014 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 2014 compared to FY 2013.

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.L.1. of this Appendix, we project an increase in aggregate LTCH PPS payments in FY 2014 relative to FY 2013 of approximately \$62 million based on the 423 LTCHs in our database.

b. Expiration of Statutory Delay of Full Implementation of the “25-Percent Threshold” Payment Adjustment Policy and 1-Year Extension

As discussed in section VIII.D. of the preamble of this proposed rule, the statutory delay of the full application of the “25-percent threshold” payment adjustment for LTCHs under § 412.534 and § 412.536 expired for cost reporting periods beginning on or after July 1, 2012, or October 1, 2012, as applicable. We established a 1-year extension of the moratorium on the application of the “25-percent threshold” payment adjustment policy

as provided by section 114(c) of the MMSEA, as amended by section 4302(a) of the ARRA and sections 3106(a) and 10312(a) of the Affordable Care Act, for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013 (and for discharges occurring on or after October 1, 2012, through the end of the cost reporting period of LTCHs with cost reporting periods beginning on or after July 1, 2012, and before September 30, 2012, as explained in section VIII.D. of the preamble of this proposed rule). The regulatory moratorium on the full application of the “25-percent threshold” payment adjustment will expire for certain LTCHs for cost reporting periods beginning on or after October 1, 2013, and as discussed in section VIII.D. of the preamble of this proposed rule, we do not anticipate extending the regulatory moratorium of the full application of the 25-percent payment adjustment threshold further. We estimate that the expiration of this moratorium will result in a payment reduction of approximately \$190 million to LTCHs.

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, the 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 2014, it is

necessary to estimate payments per discharge for FY 2013 using the rates, factors (including the FY 2013 GROUPER (Version 30.0), and relative weights and the policies established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53458 through 53502 and 53708 through 53716). It is also necessary to estimate the payments per discharge that would be made under the proposed LTCH PPS rates, factors, policies, and GROUPER (proposed Version 31.0) for FY 2014 (as discussed in section VIII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule). These estimates of FY 2013 and FY 2014 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 2013 payments to estimated FY 2014 payments (on a per discharge basis) for each category of LTCHs. We are proposing to establish a standard Federal rate for FY 2014 of \$40,622.06 that includes the proposed 1.8 percent annual update, the proposed area wage budget neutrality factor of 1.000433, and the proposed one-time prospective adjustment to the standard Federal rate for FY 2014 of 0.98734 (approximately -1.3 percent).

Hospital groups were based on characteristics provided in the OSCAR data, FY 2009 through FY 2011 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 2012 MedPAR file to estimate payments for FY 2013 and to estimate payments for FY 2014 for 423 LTCHs. We believe that the discharges based on the FY 2012 MedPAR data for the 423 LTCHs in our database, which includes 327 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 2012 MedPAR files. For modeling estimated LTCH PPS payments for FY 2013, we used the FY 2013 standard Federal rate (that is, \$40,915.95 used to make payments for LTCH discharges occurring on or after October 1, 2012 through December 28, 2012, and \$40,397.96 for discharges occurring on or after December 29, 2012 through September 30, 2013).

For modeling estimated LTCH PPS payments for FY 2014, we used the proposed FY 2014 standard Federal rate of \$40,622.06, which includes the proposed one-time prospective adjustment of 0.98734 for FY 2014 for the second year of the 3-year phase-in. The proposed FY 2014 standard Federal rate of \$40,622.06 includes the proposed application of an area wage level budget neutrality factor of 1.000433 (as

discussed in section V.B.5. of the Addendum to this proposed rule). Furthermore, in modeling estimated LTCH PPS payments for both FY 2013 and FY 2014 in this impact analysis, we applied the FY 2013 and the proposed FY 2014 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 2013 payments using the current LTCH PPS labor-related share of 63.096 percent (77 FR 53711) and the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2013 IPPS/LTCH PPS final rule (which are available via the Internet (77 FR 53717)). We also applied the FY 2013 COLA factors shown in the table in section V.C. of the Addendum to that final rule (77 FR 53713) to adjust the FY 2013 nonlabor-related share (36.904 percent) for LTCHs located in Alaska and Hawaii. Similarly, we adjusted for differences in area wage levels in determining the estimated FY 2014 payments using the proposed FY 2014 LTCH PPS labor-related share of 62.717 percent and the proposed FY 2014 wage index values presented in Tables 12A and 12B listed in section VI. of the Addendum to this proposed rule (and available via the Internet). We also applied the proposed FY 2014 COLA factors shown in the table in section V.C. of the Addendum to this proposed rule to the proposed FY 2014 nonlabor-related share (37.283 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 2014, we applied an inflation factor of 4.8 percent

(determined by OACT) to estimate the costs of each case using the charges reported on the claims in the FY 2012 MedPAR files and the best available CCRs from the December 2012 update of the PSF. Furthermore, in modeling estimated LTCH PPS payments for FY 2014 in this impact analysis, we used the proposed FY 2014 fixed-loss amount of \$14,139 (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 2013 to FY 2014 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 2013 (as described above).
- The fifth column shows the estimated payment per discharge for FY 2014 (as described above).
- The sixth column shows the percentage change in estimated payments per discharge from FY 2013 to FY 2014 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 second year of the phase-in of the one-time prospective adjustment factor for FY 2014. (As noted previously, the estimate payment changes shown in this column do not take into account that the one-time prospective adjustment to the standard Federal

rate for FY 2013 under § 412.523(d)(3) is not applied to payments for discharges occurring before December 29, 2012, consistent with the statute.)

- The seventh column shows the percentage change in estimated payments per discharge from FY 2013 to FY 2014 for proposed changes to the area wage level adjustment (that is, the proposed wage indexes and proposed labor-related share), including the proposed application of an area wage level budget neutrality factor (as discussed in section V.B.5. of the Addendum to this proposed rule).

- The eighth column shows the percentage change in estimated payments per discharge from FY 2013 (Column 4) to FY 2014 (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 2014 (ESTIMATED FY 2013 PAYMENTS COMPARED TO ESTIMATED FY 2014 PAYMENTS*)

LTCH Classification (1)	Number of LTCHs (2)	Number of LTCH PPS Cases (3)	Average FY 2013 LTCH PPS Payment Per Case (4)	Average FY 2014 LTCH PPS Payment Per Case ¹ (5)	Percent Change in Estimated Payments Per Discharge from FY 2013 to Proposed FY 2014 for the Proposed Annual Update to the Federal Rate ² (6)	Percent Change in Estimated Payments Per Discharge from FY 2013 to FY 2014 for Proposed Changes to the Area Wage Level Adjustment with Proposed Budget Neutrality ³ (7)	Percent Change in Payments Per Discharge from FY 2013 to FY 2014 for All Proposed Changes ⁴ (8)
ALL PROVIDERS	423	140,490	\$39,417	\$39,856	0.5	0.0	1.1
BY LOCATION:							
RURAL	27	6,504	\$35,149	\$35,382	0.5	-0.2	0.7
URBAN	396	133,986	\$39,624	\$40,073	0.5	0.0	1.1
LARGE	197	77,541	\$41,615	\$42,133	0.4	0.1	1.2
OTHER	199	56,445	\$36,889	\$37,244	0.5	-0.1	1.0
BY PARTICIPATION DATE:							
BEFORE OCT. 1983	16	5,621	\$34,969	\$35,400	0.4	0.1	1.2
OCT. 1983 - SEPT. 1993	44	17,271	\$42,088	\$42,592	0.4	0.1	1.2
OCT. 1993 - SEPT. 2002	182	64,138	\$38,720	\$39,097	0.5	-0.1	1.0
AFTER OCTOBER 2002	181	53,460	\$39,858	\$40,351	0.5	0.1	1.2
BY OWNERSHIP TYPE:							
VOLUNTARY	78	19,042	\$39,558	\$40,137	0.4	0.0	1.5
PROPRIETARY	327	118,366	\$39,259	\$39,677	0.5	0.0	1.1
GOVERNMENT	18	3,082	\$44,603	\$45,012	0.4	-0.6	0.9
BY REGION:							
NEW ENGLAND	14	7,266	\$34,984	\$35,448	0.4	0.2	1.3
MIDDLE ATLANTIC	30	8,374	\$41,646	\$42,311	0.5	0.5	1.6
SOUTH ATLANTIC	60	18,053	\$41,634	\$42,024	0.4	-0.2	0.9
EAST NORTH CENTRAL	70	20,431	\$40,664	\$41,119	0.5	-0.1	1.1
EAST SOUTH CENTRAL	31	8,792	\$39,386	\$39,843	0.5	-0.1	1.2
WEST NORTH CENTRAL	26	6,492	\$39,461	\$39,921	0.5	-0.2	1.2
WEST SOUTH CENTRAL	135	50,268	\$35,416	\$35,733	0.5	-0.1	0.9
MOUNTAIN	32	7,034	\$42,722	\$43,279	0.5	-0.1	1.3

LTCH Classification (1)	Number of LTCHs (2)	Number of LTCH PPS Cases (3)	Average FY 2013 LTCH PPS Payment Per Case (4)	Average FY 2014 LTCH PPS Payment Per Case ¹ (5)	Percent Change in Estimated Payments Per Discharge from FY 2013 to Proposed FY 2014 for the Proposed Annual Update to the Federal Rate ² (6)	Percent Change in Estimated Payments Per Discharge from FY 2013 to FY 2014 for Proposed Changes to the Area Wage Level Adjustment with Proposed Budget Neutrality ³ (7)	Percent Change in Payments Per Discharge from FY 2013 to FY 2014 for All Proposed Changes ⁴ (8)
PACIFIC	25	13,780	\$48,552	\$49,246	0.4	0.3	1.4
BY BED SIZE:							
BEDS: 0-24	25	2,948	\$35,535	\$35,745	0.5	-0.3	0.6
BEDS: 25-49	202	47,094	\$38,578	\$38,960	0.5	0.0	1.0
BEDS: 50-74	116	38,180	\$40,303	\$40,834	0.5	0.1	1.3
BEDS: 75-124	43	20,917	\$41,248	\$41,725	0.5	0.0	1.2
BEDS: 125-199	24	17,017	\$38,624	\$38,991	0.5	-0.1	1.0
BEDS: 200 +	13	14,334	\$38,882	\$39,342	0.5	0.1	1.2

¹ Estimated FY 2014 LTCH PPS payments based on the proposed payment rate and policy changes presented in the preamble and the Addendum to this proposed rule.

² Percent change in estimated payments per discharge from FY 2013 to FY 2014 for the proposed annual update to the standard Federal rate and the proposed one-time prospective adjustment factor for FY 2014 as discussed in section V.A.2. of the Addendum to this proposed rule. Note, this column does not take into account that the one-time prospective adjustment to the standard Federal rate for FY 2013 under § 412.523(d)(3) is not applied to payments for discharges occurring before December 29, 2012, consistent with the statute (and therefore, are paid based on a relatively higher rate).

³ Percent change in estimated payments per discharge from FY 2013 to FY 2014 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 2013 LTCH PPS (shown in Column 4) to FY 2014 LTCH PPS (shown in Column 5), including all of the proposed changes presented in the preamble and the Addendum to this proposed rule. Note, this column, which shows the percent change in estimated payments per discharge for all proposed changes, does not equal the sum of the percent changes in estimated payments per discharge for the proposed annual update to the standard Federal rate (column 6) and the proposed changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in both estimated payments to SSO cases that are paid based on estimated costs and aggregate HCO payments (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

e. Results

Based on the most recent available data for 423 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 1.1 percent, on average, for all LTCHs from FY 2013 to FY 2014 as a result of the proposed payment rate and policy changes presented in this proposed rule, including an estimated increase in HCO payments. This estimated 1.1 percent increase in LTCH PPS payments per discharge from the FY 2013 to FY 2014 for all LTCHs (as shown in Table IV) was determined by comparing estimated FY 2014 LTCH PPS payments (using the proposed payment rate and policies discussed in this proposed rule) to estimated FY 2013 LTCH PPS payments (as described above in section I.L.1. of this Appendix).

We are proposing to establish a standard Federal rate of \$40,622.06 for FY 2014. Specifically, we are proposing to update the standard Federal rate for FY 2014 by 1.8 percent, which is based on the latest estimate of the proposed LTCH PPS market basket increase (2.5 percent), the proposed reduction of 0.4 percentage point for the MFP adjustment, and the 0.3 percentage point reduction consistent with sections 1886(m)(3) and (m)(4) of the Act. In addition, we are proposing to apply a one-time prospective adjustment factor for FY 2014 of 0.98734 (approximately -1.3 percent) to the standard Federal rate for the second year of the 3-year phase-in. We note that consistent with the statute, the one-time prospective adjustment to the standard Federal rate for FY 2013 is not applied to payments for discharges occurring before December 29, 2012. Therefore, payments for FY 2013 discharges occurring on or before December 28, 2012, are paid based on a standard Federal rate that does not reflect that adjustment (and, therefore, are paid based on a relatively higher rate).

We noted earlier in this section that, for most categories of LTCHs, as shown in Table IV (Column 6), the impact of the increase of 0.5 percent in the proposed annual

update to the standard Federal rate and the proposed application of the one-time prospective adjustment for FY 2014 of approximately -1.3 percent for the second year of the 3-year phase-in is projected to result in approximately a 0.5 percent increase in estimated payments per discharge for all LTCHs from FY 2013 to FY 2014. (As noted previously, the estimate payment changes shown in this column were determined based on the FY 2013 standard Federal rate of \$40,915.95, and do not take into account that the one-time prospective adjustment to the standard Federal rate for FY 2013 under §412.523(d)(3) is not applied to payments for discharges occurring before December 29, 2012, consistent with the statute.)

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 would increase by less than 0.5 percent for certain hospital categories due to the proposed annual update to the standard Federal rate and the proposed application of the second phase of the one-time prospective adjustment for FY 2014.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 6 percent of the LTCHs are identified as being located in a rural area, and approximately 5 percent of all LTCH cases are treated in these rural hospitals. The impact analysis presented in Table IV shows that the average percent increase in estimated payments per discharge from FY 2013 to FY 2014 for all hospitals

is 1.1 percent for all proposed changes. For rural LTCHs, the percent change for all proposed changes is estimated to be 0.7 percent, while for urban LTCHs, we estimate the increase would be 1.1 percent. Large urban LTCHs are projected to experience an increase of 1.2 percent in estimated payments per discharge from FY 2013 to FY 2014, while other urban LTCHs are projected to experience an increase of 1.0 percent in estimated payments per discharge from FY 2013 to FY 2014, as shown in Table IV.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) after October 2002. Based on the most recent available data, the categories of LTCHs with the largest percentage of LTCH cases (approximately 46 percent) are in hospitals that began participating in the Medicare program between October 1993 and September 2002, and hospitals that began participating in the Medicare program after October 2002, and they are projected to experience a 1.0 and 1.2 percent in estimated payments per discharge from FY 2013 to FY 2014, respectively, 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 slightly higher than average percent increase (1.2 percent) in estimated payments per discharge from FY 2013 to FY 2014, 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 also projected to experience a 1.2 percent increase in estimated payments from FY 2013 to FY 2014.

(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 18 percent of LTCHs are identified as voluntary (Table IV). We expect that LTCHs in the voluntary category will experience a higher than the average increase (1.5 percent) in estimated FY 2014 LTCH PPS payments per discharge as compared to estimated payments in FY 2013 primarily because we project the estimated increase in HCO payments to be higher than the average increase for these LTCHs. The majority (over 77 percent) of LTCHs are identified as proprietary and these LTCHs are projected to experience the national average increase (1.1 percent) in estimated payments per discharge from FY 2013 to FY 2014. Finally, government-owned and operated LTCHs are also expected to experience an increase in payments of 0.9 percent in estimated payments per discharge from FY 2013 to FY 2014.

(4) Census Region

Estimated payments per discharge for FY 2014 are projected to increase for LTCHs located in all regions in comparison to FY 2013. Of the 9 census regions, we project that the increase in estimated payments per discharge will have the largest positive impact on LTCHs in the Middle Atlantic and Pacific regions (1.6 percent and 1.4 percent, respectively as shown in Table IV). The estimated percent increase in payments per discharge from FY 2013 to FY 2014 for those regions is largely attributable to the

proposed changes in the area wage level adjustment or proposed updates to the MS-LTC-DRGs classifications and relative weights.

In contrast, LTCHs located in the South Atlantic and West South Central regions are projected to experience the smallest increase in estimated payments per discharge from FY 2013 to FY 2014. The lower than average estimated increase in payments of 0.9 percent for LTCHs in the South Atlantic and West South Central regions 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 2013 to FY 2014. 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 1.2 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 2013 to FY 2014 (1.2 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 2014 relative to FY 2013 of approximately \$62 million (or approximately 1.1 percent) for the 423 LTCHs

in our database. In addition, the effects of the expiration of the regulatory moratorium on the application of the “25-percent threshold” payment adjustment policy effective for cost reporting periods beginning or after October 1, 2013 (as discussed in section VIII.D. of the preamble of this proposed rule) would result in a payment reduction of approximately \$190 million to LTCHs.

5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries under the LTCH PPS, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program.

M. 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 2016 payment determination. 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 2016 payment determination. We now estimate that approximately 200 hospitals may not receive the full annual percentage increase in any fiscal year. Based on historical information, we believe that increased reporting requirements for several new measure topics may contribute to an increase in the number of providers subject to payment reduction. However, historical information also indicates that reporting improves in subsequent years following an initial increase in the number of providers subject to payment reduction. We believe that this reporting improvement will offset increased proposed reporting requirements from newly added measures. Based on our current successful participation rate, we anticipate an increase in the number of hospitals that may not receive the full annual percentage increase – from approximately 95 to approximately 200. At the time that the analysis was prepared, 66 hospitals did not receive the full annual percentage increase for the FY 2013 payment determination.

We estimate that the total burden associated with the voluntary electronic 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 that could be used to satisfy the requirements for both programs, each hospital that participates in the proposed voluntary electronic quality measure reporting option could realize a reduction in burden of approximately 800 hours. This estimate assumes an annual collection burden for chart abstracted Stroke, VTE and PC-01 to be a combined 816 hours annually per hospital and an estimated 2.66 hours to submit those measures electronically for one quarter. Since the ED measures are a subset of the global measure set that also includes the Immunization measures, which will continue to be collected via chart abstraction, we do not believe there will be a significant reduction in burden for electronic submission of the ED-1 and ED-2 measures.

If our proposals related to validation, including submission of and reimbursement for secure electronic versions of medical information for validation for the FY 2016 payment determination and subsequent years are finalized, as described in the ICRs for the Hospital IQR Program, it will result in a cost savings to CMS of approximately \$1.3 million.

The cost to the Federal Government associated with the collection and validation of the data are estimated at \$14,550,000.00 annually for the validation, and quality reporting support contracts. In addition, this program takes 3 CMS staff at a GS-13 level to operate. A GS-13 level approximate annual salary is \$92,001 for an additional cost of \$276,000.

N. Effects of Proposals for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program for FY 2014

In section IX.B. of the preamble of this proposed rule, we discuss our proposed policies for FYs 2015 and 2016 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. The quality reporting requirements affect all PCHs participating in Medicare. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561), we adopted five quality measures for the FY 2014 program and subsequent program years.

In this proposed rule, we are proposing that PCHs submit data on 1 additional measure beginning with the FY 2015 program and 13 additional measures beginning with the FY 2016 program, for a total of 19 measures. We are not proposing to make changes to the reporting requirements that we have previously finalized for the five measures we first adopted beginning with the FY 2014 program.

The anticipated burden to these PCHs consists of the following: training of appropriate staff members on how to use the NSHN for the reporting of the proposed SSI measure, CMS (QualityNet) for the reporting of the proposed SCIP measures, and the CMS Web Measures Tool for the reporting of the proposed clinical process/oncology care measures; the time required for collection and aggregation of data; and the time required for the reporting of data by the PCH's representative.

In addition, in order for a PCH to participate in the collection of HCAHPS data, a PCH must either: (1) contract with an approved HCAHPS survey vendor that will conduct the survey and submit data on the PCH's behalf to the QIO Clinical Warehouse; or (2) self-administer the survey without using a vendor, provided that the PCH attends HCAHPS training. Finally, all PCHS that do not already report data under the PCHQR Program will need to register with QualityNet, identify a QualityNet administrator, complete an online Notice of Participation form, and learn the CMS contractor's and the CDC's collection mechanism in order to submit data for those measures.

One of our priorities is to help achieve better health and better health care for individuals through collection of valid, reliable, and relevant measures of quality health care data. Such data can be displayed publicly and used to further the development of health care quality, which, in turn, helps to further our objectives and goals. Health care organizations can use their health care quality data for many purposes such as in their risk management programs, health care acquired infection prevention programs and research and development of medical programs, among others.

We will share the information collected under the PCHQR Program with the public as is required under the statute. These data will be displayed on the Hospital Compare Web site. The goals of making these data available to the public in a public user-friendly and relevant format, include, but are not limited to: (1) keeping the public informed of the quality of care that is being provided in PCHs as a whole; (2) keeping the public informed of the quality of care being provided in specific PCHs; (3) allowing the public to compare and contrast the data about specific PCHs, thus enabling the public to

make informed health care decisions regarding PCHs; and (4) providing information about current trends in health care. There are many other public uses for these quality data concerning PCHs. Further, keeping the public informed of quality of care provided in health care has always been of high priority to CMS.

We also seek to align the PCHQR Program measures and reporting requirements with current HHS high priority conditions and topics and to ultimately provide a comprehensive assessment of the quality of health care delivered in a variety of settings.

O. Effects of Proposals for FY 2014 Relating to the LTCH Quality Reporting (LTCHQR) Program

In section IX.C. of the preamble of this proposed rule, we discuss the implementation of section 3004(a) of the Affordable Care Act, which added section 1886(m)(5) to the Act. Section 1886(m)(5) of the Act 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 will receive a 2.0 percentage point reduction to the annual update to the standard Federal rate for discharges for the hospital during the applicable fiscal year. The initial requirements for this LTCHQR Program were finalized in section VII.C. of the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51756).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51839 through 51840), we estimated that only a few LTCHs would not receive the full payment update in any fiscal year because they did not submit data under the LTCHQR Program. Data collection for the LTCHQR Program did not begin until October 1, 2012. We believe that the

statements we made in the FY 2012 IPPS/LTCH PPS final rule regarding the number and types of LTCHs that may not receive the full payment update as a result of failing to submit data to the Secretary under the LTCHQR Program remain valid. We are now able to verify, following the first quarter (October 1, 2012-December 31, 2012) of data collection and submission for the LTCHQR Program, that a majority of CMS-certified LTCHs are submitting quality data to CMS. We believe this number will only increase between the date of publication of this proposed rule and the final deadline for the first quarter of data submission (October 1, 2012 – December 31, 2012) of May 15, 2013. We believe that a majority of LTCHs will continue to submit data for CY 2013 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.

As discussed in section VIII.D.3. of the preamble of the FY 2013 IPPS/LTCH PPS final rule, for FY 2015, we retained the three quality measures that were finalized for use in the LTCHQR Program in the FY 2012 IPPS/LTCH PPS final rule, with some modifications . These measures are: (1) NHSN Catheter-Associated Urinary Tract Infections (CAUTI) Outcome Measure (NQF #0138); (2) NHSN Central Line Catheter-Associated Blood Stream Infection Event (CLABSI) Outcome Measure (NQF #0139); and (3) an Application of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51780 through 51781), we estimated that the total yearly cost to all LTCHs that are paid under the LTCH PPS to report these data (including NHSN registration and training for the CAUTI and CLABSI quality measures, data submission for all three

measures, and monitoring data submission) will be approximately \$756,326. We adopted this same burden estimate in the FY 2013 IPPS/LTCH PPS final rule.

As part of its endorsement maintenance process under NQF's Patient Safety Measures Project (http://www.qualityforum.org/projects/patient_safety_measures.aspx), the NQF reviewed the CAUTI and CLABSI measures that we adopted in the FY 2012 IPPS/LTCH PPS final rule. As a result of this review, the NQF expanded the scope of endorsement of these measures to include additional care settings, including LTCHs. In the FY 2013 IPPS/LTCH PPS final rule, we specified that the CAUTI and CLABSI measures will be adopted in their expanded form for the FY 2014 payment update determination and all subsequent fiscal year payment determinations.

We did not believe that the total burden estimate of \$756,326 that we made in the FY 2012 IPPS/LTCH PPS final rule would be affected by the expansion of the CAUTI and CLABSI measures. We made this statement because these expanded measures are the same measures we adopted in the FY 2012 IPPS/LTCH PPS final rule, except that the measure names have been changed and the scope of endorsement expanded so as to be applicable to the LTCH setting. The expanded CAUTI and CLABSI measures make no changes to the way that data are to be collected and reported by LTCHs. Thus, the use of the expanded CAUTI and CLABSI measures will place no additional financial burden on LTCHs. In addition, we believe that this financial burden should remain relatively stable over the first several years of this LTCHQR Program, subject to normal inflationary increases, such as increased labor wage rates.

As discussed in section VIII.D.3.d. of the preamble of the FY 2013 IPPS/LTCH PPS final rule, for the FY 2016 LTCHQR Program, we added two additional quality measures to the LTCHQR Program. These quality measures are: (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). Data for the staff immunization measure will be reported by LTCHs to the CDC's NHSN. Details related to the use of NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure can be found at <http://www.cdc.gov/nhsn/LTACH/hcp-flu-vac/index.html>.

Data for the patient influenza vaccination measure will be collected using the LTCH CARE Data Set, and we anticipate the new data item set will consist of 3 additional items added to the LTCH CARE Data Set. These items are harmonized with data elements (O0250: Influenza Vaccination Status) from the Minimum Data Set (MDS) 3.0.¹⁹⁵ The LTCH CARE Data Set Version 2.01 is currently under review by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act (PRA).¹⁹⁶ The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938-1163. The

¹⁹⁵ Centers for Medicare & Medicaid Services. MDS 3.0 Item Subsets V1.10.4 for the April 1, 2012 Release. Retrieved from https://www.cms.gov/NursingHomeQualityInits/30_NHOIMDS30TechnicalInformation.asp.

¹⁹⁶ The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938-1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956 published April 12, 2013 solicits public comment on additions and updates to the LTCH CARE Data Set. <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html>.

specifications and data elements for this measure are available in the MDS 3.0 QM

User's Manual available on our Web site at:

<https://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf>.

Because the LTCHQR Program is nearing the end of the submission timeframe first quarter of reporting, we have become more familiar with the burden of this program. We have now received feedback from LTCH providers about the time burden associated with the completion of the LTCH CARE Data Set. We have considered feedback from LTCH providers in the form of public comments to the most recent LTCH proposed rule (FY 2013 IPPS/LTCH PPS proposed rule), questions during Open Door forums, and LTCH helpdesk inquiries. LTCH providers have stated that we had underestimated the amount of time that is required of the LTCH staff to complete the LTCH CARE Data Set on each LTCH patient.

In response to the feedback received, we have significantly revised our burden estimates. For example, in our previous PRA package burden estimate we estimated burden based solely on LTCH yearly discharges of Medicare beneficiaries, while the revised burden estimate includes yearly LTCH discharges of both Medicare and non-Medicare patients. Additionally, the original burden calculation only took one assessment per patient (admission) into account, while the revised estimate includes two assessment records per patient (admission and discharge).

While the burden calculation for this PRA submission has increased significantly compared to our original calculation, we believe that the calculation now more accurately reflects the burden associated with implementing collection of the quality measures, as

mandated by section 1886(m)(5) of the Act. For a complete discussion on the current LTCH CARE Data Set version 2.01 burden estimate, we refer readers to the PRA package currently under review by OMB.¹⁹⁷

In section IX.C.8.b. and c. of the preamble to this proposed rule, we are proposing to adopt four new quality measures for inclusion in the LTCHQR Program: (1) NHSN Facility-Wide Inpatient Hospital-Onset *Methicillin-resistant Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); (2) NHSN Facility-Wide Inpatient Hospital-Onset *Clostridium Difficile* (*C. Difficile*) Outcome Measure (NQF #1717); (3) All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals; and (4) Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674) The first three proposed measures would apply to the FY 2017 payment update determination and subsequent payment determinations. The fourth proposed measure would apply to the FY 2018 payment update determination and subsequent payment determinations.

Of the measures listed above, we believe that the first two measures (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* (*C. Difficile*) Outcome Measure (NQF #1717)) will only minimally increase burden on LTCHs. These two measures are reported through the CDC's NHSN. LTCHs will be familiar with the submission of quality data using this

¹⁹⁷The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938-1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956 published April 12, 2013 solicits public comment on additions and updates to the LTCH CARE Data Set. <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html>.

system as they began submitting required quality data through NHSN beginning October 1, 2012 for CAUTI and CLABSI measures. The third measure (All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals) is a claims-based measure, and it will not increase the reporting burden of LTCHs since it is a Medicare FFS claims-based measure. Lastly, we believe the fourth measure (application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674) will also have a minimal impact on the reporting burden as calculated for the LTCH CARE Data Set version 2.01 currently under review by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act (PRA).¹⁹⁸ This measure will be collected using the LTCH CARE Data Set to which a total of two questions will be added in order to allow CMS to collect the data necessary to calculate this measure.

¹⁹⁸The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938-1163. Expiration Date April 30, 2013. FRN 78 21955 through 21956 published April 12, 2013 solicits public comment on additions and updates to the LTCH CARE Data Set. <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1252160.html>.

P. Effects of Proposed Changes to the Requirements for the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53644), we finalized policies to implement the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program. One goal of the IPFQR Program is to implement the statutory requirements of section 1886(s)(4) of the Act, as added by sections 3401(f) and 10322(a) of the Affordable Care Act. In addition, one of our priorities is to help achieve better health and better health care for individuals through collection of valid, reliable, and relevant measures of quality health care data. Such data can be shared with appropriate health care related organizations and used to further the development of health care quality, which, in turn, helps to further our objectives and goals. Health care organizations can use such health care quality data for many purposes such as in their risk management programs, patient safety and quality improvement initiatives and research and development of mental health programs, among others.

In section IX.D. of the preamble of this proposed rule, we are proposing that, for the FY 2016 payment determination and subsequent years, IPFs must submit aggregate data on three additional measures, for a total of 9 measures. In addition, we are proposing a request for voluntary information. We are not proposing to make changes to the administrative, reporting or submission requirements for the existing six measures previously finalized in last year's rule (77 FR 53654 through 53657). However, there will be new reporting and submission requirements associated with the three proposed

additional measures and proposed request for voluntary information for the FY 2016 payment determination and subsequent years.

We have estimated the burden associated with IPFs complying with the requirements of the IPFQR Program. In our burden estimate calculation, we have included the time that would be spent for (1) the submission of the voluntary information, (2) chart abstractions, and (3) training personnel on the collection of chart-abstracted data, aggregation of the data, and protocols to submit aggregate-level data through QualityNet. We estimate that the annual hourly burden to each IPF for the collection, submission, and training of personnel for submitting all quality measures, including 30 minutes needed for the voluntary submission, is approximately 1,030 hours a year for each IPF. Thus, the average hourly burden to each IPF is approximately 86 hours per month. At this time, we have no way to estimate how many IPFs will participate in the program. Therefore, we cannot estimate the aggregate impact.

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 0.1 percent in operating payments. As discussed in section I.G. of this Appendix, we estimate that proposed operating payments will decrease by approximately \$110 million in FY 2014 relative to FY 2013. 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 proposal discussed in section V.E. of the preamble of this proposed rule, we estimate that proposed operating payments would increase by approximately \$217 million relative to FY 2013. In addition, we estimate a savings of \$26 million associated with the proposed HACs policies in FY 2014, which is an additional \$2 million in savings as compared to FY 2013. We estimate that the expiration of the expansion of low-volume hospital payments in FY 2014 under section 605 of the ATRA will result in a decrease in payments of approximately \$288 million. We estimate new technology payments will increase payments by \$45 million in FY 2014, which is \$1 million less than our estimate of new technology payments made in FY 2013. These estimates, combined with our proposed FY 2014 operating estimate of \$217 million, result in an estimated decrease of approximately \$74 million for FY 2014. We estimate that hospitals will experience a 1.1 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 \$101 million increase in capital payments in FY 2014 compared to FY 2013. The proposed cumulative operating and capital payments would result in a net increase of

approximately \$27 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 2014. In the impact analysis, we are using the proposed rates, factors, and policies presented in this proposed rule, including proposed updated wage index values and relative weights, and the best available claims and CCR data to estimate the proposed change in payments under the LTCH PPS for FY 2014. Accordingly, based on the best available data for the 423 LTCHs in our database, we estimate that FY 2014 LTCH PPS payments will increase approximately \$62 million relative to FY 2013 as a result of the proposed payment rates and factors presented in this proposed rule. In addition, we estimate that the expiration of the moratorium on the full application of the “25-percent threshold” payment adjustment policy under current law, beginning with cost reporting period beginning on or after October 1, 2013 as discussed in section VIII.D. of the preamble of this proposed rule, will result in a reduction in LTCH PPS payments of \$190 million.

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 proposed change in Medicare payments to providers as a result of the proposed changes to the IPPS presented in this proposed rule. All expenditures are classified as transfers to Medicare providers.

The cost to the Federal Government associated with the policies in this proposed rule are estimated at \$27 million.

Table V.—Accounting Statement: Classification of Proposed Estimated Expenditures under the IPPS from FY 2013 to FY 2014

Category	Transfers
Annualized Monetized Transfers	\$27 million
From Whom to Whom	Federal Government to IPPS Medicare Providers
Total	\$27 million

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, in conjunction with the estimated payment impact of the moratorium on the full application of the “25-percent threshold” payment adjustment policy under current law, is projected to result in a decrease in estimated aggregate LTCH PPS payments in FY 2014 relative to FY 2013 of approximately -\$128 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 decrease 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).

The savings to the Federal Government associated with the proposed policies for LTCHs in this proposed rule is estimated at \$128 million.

TABLE VI.—Accounting Statement: Classification of Proposed Estimated Expenditures from the FY 2013 LTCH PPS to the FY 2014 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	Negative transfer--Estimated decrease in expenditures: \$128 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 \$7.5 million to \$34.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 33 of the Table of Small Business Size Standards for NAIC 622 found on the SBA Web site

at:

<http://www.sba.gov/contractingopportunities/sizestandardtopics/tableofsize/index.html>.)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We believe that the provisions of this proposed rule relating to acute care hospitals would have a significant impact on small entities as explained in this Appendix. Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary LTCHs. Therefore, we are assuming that all LTCHs are considered small entities for the purpose of the analysis in section I.L. of this Appendix. Medicare fiscal intermediaries and MACs are not considered to be small entities. Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this proposed rule constitutes our regulatory flexibility analysis. In this proposed rule, we are soliciting public comments on our estimates and analysis of the impact of our proposals on those small entities. 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 2013, 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 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 2014, 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 2014

A. Proposed FY 2014 Inpatient Hospital Update

Section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, sets the applicable percentage increase under the IPPS for FY 2014 as 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 data under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act, and then subject to an adjustment based on changes in economy-wide productivity and an additional reduction of 0.3 percentage point. Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that the application of the multifactor productivity adjustment and the additional FY 2014 adjustment of 0.3 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 this proposed rule, we are proposing to replace the FY 2006-based IPPS operating and capital market baskets with revised and rebased FY 2010-based IPPS operating and capital market baskets for FY 2014. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section V.A.1. of the preamble of this proposed rule, we are proposing a multifactor productivity (MFP) adjustment (the 10-year moving average of MFP for the period ending FY 2014) of 0.4 percent. Therefore, based on IHS Global Insight Inc.'s (IGI's) first quarter 2013 forecast of the proposed FY 2010-based IPPS market basket, we are proposing an applicable percentage

increase to the FY 2013 operating standardized amount of 1.8 percent (that is, the proposed FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less an adjustment of 0.4 percentage point for economy-wide productivity and less 0.3 percentage point) for hospitals in all areas, provided the hospital submits quality data in accordance with section 1886(b)(3)(B)(viii) of the Act and our rules. For hospitals that fail to submit quality data, we are proposing an applicable percentage increase to the operating standardized amount of -0.2 percent (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less 2.0 percentage points for failure to submit quality data, less an adjustment of 0.4 percentage point for economy-wide productivity, and less an additional adjustment of 0.3 percentage point).

B. Proposed Update for SCHs for FY 2014

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2014 applicable percentage increase in the hospital-specific rate for SCHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital specific rate for SCHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, we are proposing an applicable percentage increase to the hospital-specific rate applicable to SCHs of 1.8 percent for hospitals that submit quality data or -0.2 percent for hospitals that fail to submit quality data.

C. Proposed FY 2014 Puerto Rico Hospital Update

Section 401(c) of Pub. L. 108-173 amended section 1886(d)(9)(C)(i) of the Act and states that, for discharges occurring in a fiscal year (beginning with FY 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for FY 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved. Therefore, the update to the Puerto Rico-specific operating standardized amount is subject to the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act as amended by sections 3401(a) and 10319(a) of the Affordable Care Act (that is, the same update factor as for all other hospitals subject to the IPPS). Accordingly, we are proposing an applicable percentage increase to the Puerto Rico-specific standardized amount of 1.8 percent.

D. Proposed Update for Hospitals Excluded from the IPPS

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's and cancer hospitals. Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under 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, and RNHCIs are among the remaining three types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. We are proposing that, for FY 2014 and subsequent fiscal years, the rate-of-increase percentage applicable to the target amount for children's hospitals, PPS-excluded cancer hospitals, and RNHCIs is the percentage increase in the proposed revised and rebased FY 2010-based IPPS operating market basket. Accordingly, the FY 2014 rate-of-increase percentage to be applied to the target amount for cancer hospitals, children's hospitals, and RNHCIs would be the FY 2014 percentage increase in the proposed revised and rebased FY 2010-based IPPS operating market basket. For this proposed rule, the current estimate of the FY 2014 IPPS operating market basket percentage increase is 2.5 percent.

E. Proposed Update for LTCHs for FY 2014

Section 123 of Pub. L. 106-113, as amended by section 307(b) of Pub. L. 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 2014 based on the full LTCH PPS market basket increase estimate (for this proposed rule, estimated to be 2.5 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)(D) of the Act, provided the LTCH submits quality data in accordance with section 1886(m)(5)(C) of the act and our rules. Beginning in FY 2014, 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 quality data. The productivity adjustment described in section 1886(b)(3)(B)(xi)(ii) of the Act is currently estimated to be 0.4 percent for FY 2014. In addition, section 1886(m)(3)(A)(ii) of the Act requires that any annual update for FY 2014 be reduced by the “other adjustment” at section 1886(m)(4)(D) of the Act, which is 0.3 percentage point. Therefore, based on IGI’s first quarter 2013 forecast of the FY 2014 market basket increase, we are proposing an annual update to the LTCH PPS standard Federal rate of 1.8 percent (that is, the current FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less a proposed adjustment of 0.4 percentage point for economy-wide productivity and less 0.3 percentage point), provided the LTCH submits quality data in accordance with the LTCHQR Program under section 1886(m)(5)(C) of the Act. Accordingly, we are proposing to apply an update factor of 1.018 in determining the LTCH PPS standard Federal rate for FY 2014 provided the LTCH submits quality data in accordance with section 1886(m)(5)(C) of the Act and our rules. For LTCHs that fail to submit quality data, we are proposing an annual update to the LTCH PPS standard Federal rate of -0.2 percent (that is, the FY 2014 estimate of the market basket rate-of increase of 2.5 percent less a proposed adjustment of 0.4 percentage point for economy-wide productivity, less an additional adjustment of 0.3 percentage point, and less 2.0 percentage points for failure to submit quality data) by applying an update factor of 0.998 in determining the LTCH PPS standard Federal rate for FY 2014. Furthermore, we are proposing to make an adjustment for the second 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 2014, consistent with current law.

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update equal to one percent for FY 2014. MedPAC's rationale for this update recommendation is described in more detail below. As mentioned above, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, we are recommending an applicable percentage increase to the standardized amount of 1.8 percent (that is, the FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less a proposed adjustment of 0.4 percentage point for economy-wide productivity and less 0.3 percentage point). We are recommending that the same applicable percentage increase apply to SCHs and the Puerto Rico-specific standardized amount.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update for children's hospitals, cancer hospitals, and RNHCIs of 2.5 percent.

For FY 2014, consistent with policy set forth in section VIII. of the preamble of this proposed rule, we are recommending an update of 1.8 percent (that is, the current FY 2014 estimate of the market basket rate-of-increase of 2.5 percent less a proposed adjustment of 0.4 percentage point for economy-wide productivity and less 0.3 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 2013 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 1.0 percent. MedPAC expects Medicare margins to remain low in 2013. At the same time, MedPAC's analysis finds that efficient hospitals have been able to maintain positive Medicare margins while maintaining a relatively high quality of care. MedPAC also recommended that Congress should require the Secretary to use the difference between the increase of the applicable percentage increase under the IPPS for FY 2014 and MedPAC's recommendation of a 1.0 percent update to gradually recover past overpayments due to documentation and coding changes.

Response: With regard to MedPAC's recommendation of an update to the hospital inpatient rates equal to 1 percent, for FY 2014, 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 2014 applicable percentage increase. Therefore, we are

proposing an applicable percentage increase for FY 2014 of 1.8 percent, provided the hospital submits quality data, consistent with these statutory requirements.

With regard to MedPAC's recommendation that Congress should require the Secretary to use the difference between the increase of the applicable percentage increase under the IPPS for FY 2014 and MedPAC's recommendation of a 1.0 percent update to gradually recover past overpayments due to documentation and coding changes, we refer readers to section II.D. of the preamble of this proposed rule for a complete discussion of the FY 2014 documentation and coding adjustment. We note that section 631 of the ATRA amended section 7(b)(1)(B) of Pub. L. 110-90 to require the Secretary to make a recoupment totaling \$11 billion by 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 Pub. L. 110-90 until FY 2013. Our actuaries estimate that if CMS were to fully account for the \$11 billion recoupment required by section 631 of the ATRA in FY 2014, a -9.3 percent adjustment to the standardized amount would be necessary. MedPAC estimates that a -2.4 percent adjustment made in FY 2014, and not removed until FY 2018, also would recover the required recoupment amount. It is often our practice to delay or phase in rate adjustments over more than 1 year, in order to moderate the effect on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, we are proposing a -0.8 percent adjustment to the standardized amount in FY 2014.

We also note that, because the operating and capital prospective payment systems remain separate, we are continuing to use separate updates for operating and capital

payments. The proposed update to the capital rate is discussed in section III. of the Addendum to this proposed rule.

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