

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Parts 405, 412, 413, and 485

[CMS-1655-P]

RIN 0938-AS77

#### Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; and Technical Changes Relating to Costs to Organizations and Medicare Cost Reports

**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 for FY 2017. Some of the proposed changes would implement certain statutory provisions contained in the Pathway for Sustainable Growth (SGR) Reform Act of 2013, the Improving Medicare Post-Acute Care Transformation Act of 2014, the Notice of Observation Treatment and Implications for Care Eligibility Act of 2015, and other legislation. We also are providing the estimated market basket update to apply to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits for FY 2017.

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) for FY 2017.

In addition, we are proposing to make changes relating to direct graduate medical education (GME) and indirect medical education (IME) payments to hospitals with rural track training programs. We are proposing to establish new requirements or revise requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs,

and inpatient psychiatric facilities) that are participating in Medicare, including related provisions for eligible hospitals and critical care hospitals (CAHs) participating in the Electronic Health Record (EHR) Incentive Program. We are proposing to update policies relating to the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program. We also are proposing to: Implement statutory provisions that require hospitals and CAHs to furnish notification to Medicare beneficiaries, including Medicare Advantage enrollees, when the beneficiaries receive outpatient observation services for more than 24 hours; announce the implementation of the Frontier Community Health Integration Project Demonstration; and make technical corrections and changes to regulations relating to costs to organizations and Medicare cost reports.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided in the **ADDRESSES** section, no later than 5 p.m. EDT on June 17, 2016.

**ADDRESSES:** In commenting, please refer to file code CMS-1655-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1655-P, P.O. Box 8011, Baltimore, MD 21244-1850.

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

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1655-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

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

a. For delivery in Washington, DC—Centers for Medicare & Medicaid

Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

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

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

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

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

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

**FOR FURTHER INFORMATION CONTACT:** Ing Jye Cheng, (410) 786-4548, and Donald Thompson, (410) 786-4487, Operating Prospective Payment, MS-DRGs, 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) Issues, Medicare-Dependent Small Rural Hospital (MDH) Program, and Low-Volume Hospital Payment Adjustment Issues.

Michele Hudson, (410) 786-4487, and Emily Lipkin, (410) 786-3633, 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, Rebasing and Revising the LTCH Market Basket Issues.

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

Jason Pteroski, (410) 786-4681, and Siddhartha Mazumdar, (410) 786-6673, Frontier Community Health Integration Project Demonstration Issues.

Kathryn McCann Smith, (410) 786-7623, Hospital Notification Procedures for Beneficiaries Receiving Outpatient Observation Services Issues; or

Stephanie Simons, (206) 615-2420, only for Related Medicare Health Plans Issues.

Lein Han, (617) 879-0129, Hospital Readmissions Reduction Program—Readmission Measures for Hospitals Issues.

Delia Houseal, (410) 786-2724, Hospital-Acquired Condition Reduction Program and Hospital Readmissions Reduction Program—Program Administration Issues.

Joseph Clift, (410) 786-4165, Hospital-Acquired Condition Reduction Program—Measures Issues.

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

Cindy Tourison, (410) 786-1093, Hospital Inpatient Quality Reporting—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues; and Readmission Measures for Hospitals Issues.

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

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

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

Mary Pratt, (410) 786-6867, Long-Term Care Hospital Quality Data Reporting Issues.

Jeffrey Buck, (410) 786-0407 and Cindy Tourison (410) 786-1093, Inpatient Psychiatric Facilities Quality Data Reporting Issues.

Deborah Krauss, (410) 786-5264, and Lisa Marie Gomez, (410) 786-1175, EHR Incentive Program Clinical Quality Measure Related Issues.

Elizabeth Myers, (410) 786-4751, EHR Incentive Program Nonclinical Quality Measure Related Issues.

Lauren Wu, (202) 690-7151, Certified EHR Technology Related Issues.

Kellie Shannon, (410) 786-0416, Technical Changes Relating to Costs to Organizations and Medicare Cost Reports Issues.

#### SUPPLEMENTARY INFORMATION:

##### Electronic Access

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

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

##### 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 the proposed rule and the final rule were published in the **Federal Register** as part of the annual proposed and final rules. However, beginning in FY 2012, some of the IPPS tables and LTCH PPS tables are no longer published in the **Federal Register**. Instead, these tables generally will be available only through the Internet. The IPPS tables for this proposed rule are available 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 2017 IPPS Proposed Rule Home Page” or “Acute Inpatient—Files for Download”. The LTCHy PPS tables for this FY 2017 proposed rule are available through the Internyent 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-1655-P. For further details on the contents of the tables referenced in this proposed rule, we refer readers to section VI. of the Addendum to this proposed rule.

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

##### Acronyms

3M 3M Health Information System  
 AAMC Association of American Medical Colleges  
 ACGME Accreditation Council for Graduate Medical Education  
 ACoS American College of Surgeons  
 AHA American Hospital Association  
 AHIC American Health Information Community  
 AHIMA American Health Information Management Association  
 AHRQ Agency for Healthcare Research and Quality  
 AJCC American Joint Committee on Cancer

ALOS Average length of stay  
 ALTHA Acute Long-Term Hospital Association  
 AMA American Medical Association  
 AMGA American Medical Group Association  
 AMI Acute myocardial infarction  
 AOA American Osteopathic Association  
 APR DRG All Patient Refined Diagnosis Related Group System  
 APRN Advanced practice registered nurse  
 ARRA American Recovery and Reinvestment Act of 2009, Public Law 111-5  
 ASCA Administrative Simplification Compliance Act of 2002, Public Law 107-105  
 ASITN American Society of Interventional and Therapeutic Neuroradiology  
 ASPE Assistant Secretary for Planning and Evaluation (DHHS)  
 ATRA American Taxpayer Relief Act of 2012, Public Law 112-240  
 BBA Balanced Budget Act of 1997, Public Law 105-33  
 BBRA Medicare, Medicaid, and SCHIP [State Children’s Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106-113  
 BIPA Medicare, Medicaid, and SCHIP [State Children’s Health Insurance Program] Benefits Improvement and Protection Act of 2000, Public Law 106-554  
 BLS Bureau of Labor Statistics  
 CABG Coronary artery bypass graft [surgery]  
 CAH Critical access hospital  
 CARE [Medicare] Continuity Assessment Record & Evaluation [Instrument]  
 CART CMS Abstraction & Reporting Tool  
 CAUTI Catheter-associated urinary tract infection  
 CBSAs Core-based statistical areas  
 CC Complication or comorbidity  
 CCN CMS Certification Number  
 CCR Cost-to-charge ratio  
 CDAC [Medicare] Clinical Data Abstraction Center  
 CDAD *Clostridium difficile*-associated disease  
 CDC Centers for Disease Control and Prevention  
 CERT Comprehensive error rate testing  
 CDI *Clostridium difficile* [C. difficile] infection  
 CFR Code of Federal Regulations  
 CLABSI Central line-associated bloodstream infection  
 CPI Capital input price index  
 CMI Case-mix index  
 CMS Centers for Medicare & Medicaid Services  
 CMSA Consolidated Metropolitan Statistical Area  
 COBRA Consolidated Omnibus Reconciliation Act of 1985, Public Law 99-272  
 COLA Cost-of-living adjustment  
 CoP [Hospital] condition of participation  
 COPD Chronic obstructive pulmonary disease  
 CPI Consumer price index  
 CQL Clinical quality language  
 CQM Clinical quality measure  
 CY Calendar year  
 DACA Data Accuracy and Completeness Acknowledgement

DPP Disproportionate patient percentage	I-O Input-Output	NHSN National Healthcare Safety Network
DRA Deficit Reduction Act of 2005, Public Law 109-171	IOM Institute of Medicine	NOP Notice of Participation
DRG Diagnosis-related group	IPF Inpatient psychiatric facility	NOTICE Act Notice of Observation Treatment and Implication for Care Eligibility Act, Public Law 114-42
DSH Disproportionate share hospital	IPFQR Inpatient Psychiatric Facility Quality Reporting [Program]	NQF National Quality Forum
EBRT External beam radiotherapy	IPPS [Acute care hospital] inpatient prospective payment system	NQS National Quality Strategy
ECE Extraordinary circumstances exemption	IRF Inpatient rehabilitation facility	NTIS National Technical Information Service
ECI Employment cost index	IQR [Hospital] Inpatient Quality Reporting	NTTAA National Technology Transfer and Advancement Act of 1991, Public Law 104-113
eCQM Electronic clinical quality measure	LAMCs Large area metropolitan counties	NUBC National Uniform Billing Code
EDB [Medicare] Enrollment Database	LEP Limited English proficiency	NVHRI National Voluntary Hospital Reporting Initiative
EHR Electronic health record	LOC Limitation on charges	OACT [CMS] Office of the Actuary
EMR Electronic medical record	LOS Length of stay	OBRA 86 Omnibus Budget Reconciliation Act of 1986, Public Law 99-509
EMTALA Emergency Medical Treatment and Labor Act of 1986, Public Law 99-272	LTC-DRG Long-term care diagnosis-related group	OES Occupational employment statistics
EP Eligible professional	LTCH Long-term care hospital	OIG Office of the Inspector General
FAH Federation of American Hospitals	LTCH QRP Long-Term Care Hospital Quality Reporting Program	OMB [Executive] Office of Management and Budget
FAA Food and Drug Administration	MA Medicare Advantage	ONC Office of the National Coordinator for Health Information Technology
FFY Federal fiscal year	MAC Medicare Administrative Contractor	OPM [U.S.] Office of Personnel Management
FPL Federal poverty line	MACRA Medicare Access and CHIP Reauthorization Act of 2015, Public Law 114-10	OQR [Hospital] Outpatient Quality Reporting
FQHC Federally qualified health center	MAP Measure Application Partnership	O.R. Operating room
FR Federal Register	MCC Major complication or comorbidity	OSCAR Online Survey Certification and Reporting [System]
FTE Full-time equivalent	MCE Medicare Code Editor	PAC Post-acute care
FY Fiscal year	MCO Managed care organization	PAMA Protecting Access to Medicare Act of 2014, Public Law 113-93
GAF Geographic Adjustment Factor	MDC Major diagnostic category	PCH PPS-exempt cancer hospital
GME Graduate medical education	MDH Medicare-dependent, small rural hospital	PCHQR PPS-exempt cancer hospital quality reporting
HAC Hospital-acquired condition	MedPAC Medicare Payment Advisory Commission	PMSAs Primary metropolitan statistical areas
HAI Healthcare-associated infection	MedPAR Medicare Provider Analysis and Review File	POA Present on admission
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems	MEI Medicare Economic Index	PPI Producer price index
HCFA Health Care Financing Administration	MGCRB Medicare Geographic Classification Review Board	PPR Potentially Preventable Readmissions
HCO High-cost outlier	MIEA-TRHCA Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006, Public Law 109-432	PPS Prospective payment system
HCP Healthcare personnel	MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110-275	PRM Provider Reimbursement Manual
HCRIS Hospital Cost Report Information System	MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173	ProPAC Prospective Payment Assessment Commission
HF Heart failure	MMEA Medicare and Medicaid Extenders Act of 2010, Public Law 111-309	PRRB Provider Reimbursement Review Board
HHA Home health agency	MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110-173	PRTFs Psychiatric residential treatment facilities
HHS Department of Health and Human Services	MOON Medicare Outpatient Observation Notice	PSF Provider-Specific File
HICAN Health Insurance Claims Account Number	MRHFP Medicare Rural Hospital Flexibility Program	PSI Patient safety indicator
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104-191	MRSA Methicillin-resistant <i>Staphylococcus aureus</i>	PS&R Provider Statistical and Reimbursement [System]
HIPC Health Information Policy Council	MSA Metropolitan Statistical Area	PQRS Physician Quality Reporting System
HIS Health information system	MS-DRG Medicare severity diagnosis-related group	PUF Public use file
HIT Health information technology	MS-LTC-DRG Medicare severity long-term care diagnosis-related group	QDM Quality data model
HMO Health maintenance organization	MU Meaningful Use [EHR Incentive Program]	QIES ASAP Quality Improvement Evaluation System Assessment Submission and Processing
HPMP Hospital Payment Monitoring Program	MUC Measure under consideration	QIG Quality Improvement Group [CMS]
HSA Health savings account	NAICS North American Industrial Classification System	QIO Quality Improvement Organization
HSCRC [Maryland] Health Services Cost Review Commission	NALTH National Association of Long Term Hospitals	QM Quality measure
HSRV Hospital-specific relative value	NCD National coverage determination	QRDA Quality Reporting Document Architecture
HSRVcc Hospital-specific relative value cost center	NCHS National Center for Health Statistics	RFA Regulatory Flexibility Act, Public Law 96-354
HQA Hospital Quality Alliance	NCQA National Committee for Quality Assurance	RHC Rural health clinic
HQI Hospital Quality Initiative	NCVHS National Committee on Vital and Health Statistics	RHQDAPU Reporting hospital quality data for annual payment update
HwH Hospital-within-hospital	NECMA New England County Metropolitan Areas	RIM Reference information model
ICD-9-CM International Classification of Diseases, Ninth Revision, Clinical Modification		RNHCI Religious nonmedical health care institution
ICD-10-CM International Classification of Diseases, Tenth Revision, Clinical Modification		RPL Rehabilitation psychiatric long-term care (hospital)
ICD-10-PCS International Classification of Diseases, Tenth Revision, Procedure Coding System		RRC Rural referral center
ICR Information collection requirement		
ICU Intensive care unit		
IGI IHS Global Insight, Inc.		
IHS Indian Health Service		
IME Indirect medical education		
IMPACT Act Improving Medicare Post-Acute Care Transformation Act of 2014, Public Law 113-185		

RSMR Risk-standard mortality rate  
 RSP Risk-standardized payment  
 RSSR Risk-standard readmission rate  
 RTI Research Triangle Institute, International  
 RUCAs Rural-urban commuting area codes  
 RY Rate year  
 SAF Standard Analytic File  
 SCH Sole community hospital  
 SCHIP State Child Health Insurance Program  
 SCIP Surgical Care Improvement Project  
 SFY State fiscal year  
 SGR Sustainable Growth Rate  
 SIC Standard Industrial Classification  
 SIR Standardized infection ratio  
 SNF Skilled nursing facility  
 SNF QRP Skilled Nursing Facility Quality Reporting Program  
 SNF VBP Skilled Nursing Facility Value-Based Purchasing  
 SOCs Standard occupational classifications  
 SOM State Operations Manual  
 SRR Standardized risk ratio  
 SSI Surgical site infection  
 SSI Supplemental Security Income  
 SSO Short-stay outlier  
 SUD Substance use disorder  
 TEFRA Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97-248  
 TEP Technical expert panel  
 THA/TKA Total hip arthroplasty/total knee arthroplasty  
 TMA TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007, Public Law 110-90  
 TPS Total Performance Score  
 UHDDS Uniform hospital discharge data set  
 UR Utilization review  
 VBP [Hospital] Value Based Purchasing [Program]  
 VTE Venous thromboembolism

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## I. Executive Summary and Background

### A. Executive Summary

#### 1. Purpose and Legal Authority

This proposed rule would make payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it would make payment and policy changes for 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.

We are proposing to establish new requirements or revise requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities) that are participating in Medicare, including related provisions for eligible hospitals and critical access hospitals (CAHs) participating in the Electronic Health Record (EHR) Incentive Program. We are proposing to update policies relating to the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program. We also are proposing to: Implement statutory provisions that require hospitals and CAHs to furnish notification to Medicare beneficiaries, including Medicare Advantage enrollees, when the beneficiaries receive outpatient observation services for more than 24 hours; announce the implementation of the Frontier Community Health Integration Project Demonstration; make technical corrections and changes to regulations relating to costs to organizations and Medicare cost reports.

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 2017 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 Public Law 106–113 and section 307(b)(1) of Public Law 106–554 (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of long-term care hospitals (LTCHs) described in section 1886(d)(1)(B)(iv) of the Act.

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

- Section 1866(k) of the Act, as added by section 3005 of the Affordable Care Act, which establishes a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as “PPS-exempt cancer hospitals.”

- Section 1886(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 a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.

- Section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act and amended by section 10309 of the Affordable Care Act, which establishes the “Hospital Readmissions Reduction Program” effective for discharges from an “applicable hospital” beginning on or after October 1, 2012, under which payments to those hospitals under section 1886(d) of the Act will be reduced to account for certain excess readmissions.

- Section 1886(r) of the Act, as added by section 3133 of the Affordable Care Act, which provides for a reduction to disproportionate share hospital (DSH) 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 requires that, for fiscal year 2014 and each subsequent fiscal year, subsection (d) hospitals that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act will receive two separate payments: (1) 25 percent of the amount they previously would have received under section 1886(d)(5)(F) of the Act 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 section 1886(d)(5)(F) of the Act; (2) 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured (minus 0.1 percentage points for FY 2014, and minus 0.2 percentage points for FY 2015 through FY 2017); and (3) a hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.

- Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), which provided for the establishment of site neutral payment rate criteria under the LTCH PPS with implementation beginning in FY 2016.

- Section 1886(m)(5)(D)(iv) of the Act, as added by section 1206 (c) of the Pathway for SGR Reform Act of 2013, which provides for the establishment of a functional status quality measure under the LTCH QRP for change in

mobility among inpatients requiring ventilator support.

- Section 1899B of the Act, as added by the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act), which imposes data reporting requirements for certain post-acute care providers, including LTCHs.

- Section 1886(d)(12) of the Act, as amended by section 204 of the Medicare Access and CHIP Reauthorization Act of 2015, which extended, through FY 2017, changes to the inpatient hospital payment adjustment for certain low-volume hospitals; and section 1886(d)(5)(G) of the Act, as amended by section 205 of the Medicare Access and CHIP Reauthorization Act of 2015, which extended, through FY 2017, the Medicare-dependent, small rural hospital (MDH) program.

## 2. Summary of the Major Provisions

### a. MS–DRG Documentation and Coding Adjustment

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

While our actuaries estimated that a –9.3 percent adjustment to the standardized amount would be necessary if CMS were to fully recover the \$11 billion recoupment required by section 631 of the ATRA in one year, it is often our practice to delay or phase in rate adjustments over more than one year, in order to moderate the effects on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, we made a –0.8 percent recoupment adjustment to the standardized amount in FY 2014, FY 2015, and FY 2016. For FY 2017, we are proposing to make an additional –1.5 percent recoupment adjustment to the standardized amount.

### b. Adjustment to IPPS Rates Resulting From 2-Midnight Policy

In this proposed rule, we are proposing a permanent adjustment of

(1/0.998) to the standardized amount, the hospital-specific payment rates, and the national capital Federal rate using our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to prospectively remove the 0.2 percent reduction to the rate put in place in FY 2014 to offset the estimated increase in IPPS expenditures as a result of the 2-midnight policy. In addition, we are proposing a temporary one-time prospective increase to the FY 2017 standardized amount, the hospital-specific payment rates, and the national capital Federal rate of 0.6 percent by including a temporary one-time factor of 1.006 in the calculation of the standardized amount, the hospital-specific payment rates, and the national capital Federal rate using our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act, to address the effects of the 0.2 percent reduction to the rate for the 2-midnight policy in effect for FYs 2014, 2015, and 2016.

### c. Reduction of Hospital Payments for Excess Readmissions

We are proposing to make changes to policies for the Hospital Readmissions Reduction Program, which is established under section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act, as amended by section 10309 of the Affordable Care Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. For FY 2017 and subsequent years, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG). In this proposed rule, to align with other quality reporting programs and allow us to post data as soon as possible, we are clarifying our public reporting policy so that excess readmission rates will be posted to the *Hospital Compare* Web site as soon as feasible following the preview period, and we are proposing the methodology to include the addition of the CABG applicable condition in the calculation of the readmissions payment adjustment for FY 2017.

### d. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal

year to hospitals based on their performance on measures established for a performance period for such fiscal year.

In this proposed rule, we are proposing to refine two previously adopted measures beginning with the FY 2019 program year, to update one previously adopted measure beginning with the FY 2021 program year, to adopt two new measures beginning with the FY 2021 program year, and to adopt one new measure beginning with the FY 2022 program year. We also are proposing to change the performance period for one previously adopted measure for the FY 2018 program year and to change the name of the Patient and Caregiver-Centered Experience of Care/Care Coordination domain to the Person and Community Engagement domain beginning with the FY 2019 program year. In addition, we are proposing changes to the immediate jeopardy citation policy.

### e. Hospital-Acquired Condition (HAC) Reduction Program

Section 1886(p) of the Act, as added under section 3008(a) of the Affordable Care Act, establishes an incentive to hospitals to reduce the incidence of hospital-acquired conditions by requiring the Secretary to make an adjustment to payments to applicable hospitals effective for discharges beginning on October 1, 2014. This 1-percent payment reduction applies to a hospital whose ranking is in the top quartile (25 percent) of all applicable hospitals, relative to the national average, of conditions acquired during the applicable period and on all of the hospital's discharges for the specified fiscal year. In this proposed rule, we are proposing the following HAC Reduction Program policies: (1) Establishing NHSN CDC HAI data submission requirements for newly opened hospitals; (2) a clarification of data requirements for Domain 1 scoring; (3) establishing performance periods for the FY 2018 and FY 2019 HAC Reduction Programs, including revising our regulations to accommodate variable timeframes; (4) adopting the refined PSI 90: Patient Safety and Adverse Events Composite (NQF #0531); and (5) changing the program scoring methodology from the current decile-based scoring to a continuous scoring methodology.

### f. DSH Payment Adjustment and Additional Payment for Uncompensated Care

Section 3133 of the Affordable Care Act modified the Medicare disproportionate share hospital (DSH) payment methodology beginning in FY

2014. Under section 1886(r) of the Act, which was added by section 3133 of the Affordable Care Act, starting in FY 2014, DSHs will receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. 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 an additional payment based on its share of the total amount of uncompensated care for all Medicare DSHs for a given time period.

In this proposed rule, we are proposing to update our estimates of the three factors used to determine uncompensated care payments for FY 2017 and proposing to continue our methodology of using a hospital's share of insured low-income days for purposes of determining Factor 3. For Puerto Rico hospitals, we are proposing to use 14 percent of Medicaid days as a proxy for SSI days in the calculation of Factor 3. We are proposing to continue to use the methodology we established in FY 2015 to calculate the uncompensated care payment amounts for merged hospitals such that we combine uncompensated care data for the hospitals that have undergone a merger in order to calculate their relative share of uncompensated care. We are proposing to expand the time period of the data used to calculate the uncompensated care payment amounts to be distributed, from one cost reporting period to three cost reporting periods. We also are proposing a future transition to using Worksheet S-10 data to determine the amounts and distribution of uncompensated care payments. Specifically, we are proposing a 3-year transition beginning in FY 2018 where we use a combination of Worksheet S-10 and proxy data until FY 2020 when all data used in computing the uncompensated care payment amounts to be distributed would come from Worksheet S-10.

**g. Payments for Capital-Related Costs for Hospitals Located in Puerto Rico**

Capital IPPS payments to hospitals located in Puerto Rico are currently computed based on a blend of 25 percent of the capital IPPS Puerto Rico rate and 75 percent of the capital IPPS Federal rate. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114-113) increased the applicable Federal percentage of the operating IPPS payment for hospitals

located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. In this proposed rule, we are proposing to revise the calculation of capital IPPS payments to hospitals located in Puerto Rico to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, beginning in FY 2017.

**h. Proposed Changes to the LTCH PPS**

In this proposed rule, we are proposing to revise and rebase the market basket used under the LTCH PPS (currently the 2009-based LTCH-specific market basket) to reflect a 2013 base year. In addition, in this proposed rule, we are proposing to change our 25-percent threshold policy by proposing to sunset our existing regulations at 42 CFR 412.534 and 412.536 and replace them with a single consolidated 25-percent threshold policy at proposed § 412.538. We also are proposing to change our existing regulations limiting allowable charges to beneficiaries for Subclause (II) LTCHs and proposing to make technical corrections to § 412.503.

**i. 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 payments. In past years, we have established measures for reporting data and the process for submittal and validation of the data.

In this proposed rule, we are making several proposals. First, we are proposing to remove 15 measures for the FY 2019 payment determination and subsequent years. Thirteen of these measures are electronic clinical quality measures (eCQMs), two of which we are proposing also to remove in their chart-abstracted form, because they are "topped-out," and two others are structural measures.

Second, we are proposing to refine two previously adopted measures beginning with the FY 2018 payment determination: (1) The Hospital-level, Risk-standardized Payment Associated with a 30-day Episode-of-Care for Pneumonia (NQF #2579); and (2) the Patient Safety and Adverse Events Composite (NQF #0531).

Third, we are proposing to add four new claims-based measures: (1) Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure; (2)

Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure; (3) Spinal Fusion Clinical Episode-Based Payment Measure; and (4) Excess Days in Acute Care after Hospitalization for Pneumonia for the FY 2019 payment determination and subsequent years.

Fourth, we are inviting public comment on potential new quality measures under consideration for future inclusion in the Hospital IQR Program: (1) A refined version of the NIH Stroke Scale for the Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Measure beginning as early as the FY 2022 payment determination; (2) the National Healthcare Safety Network (NHSN) Antimicrobial Use Measure (NQF #2720); and (3) one or more measures of behavioral health for the inpatient hospital setting, including measures previously adopted for the IPFQR Program (80 FR 46417). Also, we are seeking public comment on the possibility of future stratification of Hospital IQR Program data by race, ethnicity, sex, and disability on *Hospital Compare*, as well as on potential future hospital quality measures that incorporate health equity.

Fifth, we are proposing to require hospitals to submit all available eCQMs included in the Hospital IQR Program measure set for four quarters of data, on an annual basis, beginning with the CY 2017 reporting period/FY 2019 payment determination, in order to align the Hospital IQR Program with the Medicare and Medicaid EHR Incentive Programs. Also, we are proposing related eCQM submission requirements beginning with the FY 2019 payment determination.

Sixth, we are proposing to modify the existing validation process for Hospital IQR Program data to include validation of eCQMs beginning with the FY 2020 payment determination.

Seventh, we are proposing to update our Extraordinary Circumstances Extensions or Exemptions (ECE) policy by: (1) Extending the ECE request deadline for non-eCQM circumstances from 30 to 90 calendar days following an extraordinary circumstance, beginning in FY 2017 as related to extraordinary circumstance events that occur on or after October 1, 2016; and (2) establishing a separate submission deadline of April 1 following the end of the reporting calendar year for ECEs related to eCQMs beginning with an April 1, 2017 deadline and applying for subsequent eCQM reporting years.

j. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

Section 3004(a) of the Affordable Care Act amended section 1886(m)(5) of the Act to require the Secretary to establish the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). This program applies to all hospitals certified by Medicare as LTCHs. Beginning with the FY 2014 payment determination and subsequent years, the Secretary is required to reduce any annual update to the LTCH PPS standard Federal rate for discharges occurring during such fiscal year by 2 percentage points for any LTCH that does not comply with the requirements established by the Secretary.

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) amended the Act in ways that affect the LTCH QRP. Specifically, section 2(a) of the IMPACT Act amended title XVIII of the Act by adding section 1899B, titled Standardized Post-Acute Care (PAC) Assessment Data for Quality, Payment, and Discharge Planning. The Act requires that each LTCH submit, for FYs beginning on or after the specified application date (as defined in section 1899B(a)(2)(E) of the Act), data on quality measures specified under section 1899B(c)(1) of the Act and data on resource use and other measures specified under section 1899B(d)(1) of the Act in a manner and within the timeframes specified by the Secretary. In addition, each LTCH is required to submit standardized patient assessment data required under section 1899B(b)(1) of the Act in a manner and within the timeframes specified by the Secretary. Sections 1899B(c)(1) and 1899B(d)(1) of the Act require the Secretary to specify quality measures and resource use and other measures with respect to certain domains no later than the specified application date in section 1899B(a)(2)(E) of the Act that applies to each measure domain and PAC provider setting.

In this proposed rule, we are proposing three new measures for the FY 2018 payment determination and subsequent years to meet the requirements as set forth by the IMPACT Act. These proposed measures are: (1) MSPB-PAC LTCH QRP; (2) Discharge to Community-PAC LTCH QRP; and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for the PAC LTCH QRP. We also are proposing one new quality measure to meet the requirements of the IMPACT Act for the FY 2020 determination and subsequent years. The proposed measure, Drug Regimen Review Conducted with Follow-Up for

Identified Issues-PAC LTCH QRP, addresses the IMPACT Act domain of Medication Reconciliation.

In addition, we will publicly report LTCH quality data beginning in fall 2016, on a CMS Web site, such as *Hospital Compare*. We will initially publicly report quality data on four quality measures. In this proposed rule, we are proposing to publicly report data in 2017 on four additional measures. We are proposing additional details regarding procedures that would allow individual LTCHs to review and correct their data and information on measures that are to be made public before those measure data are made public. We also are proposing to provide confidential feedback reports to LTCHs on their performance on the specified measures, beginning 1 year after the specified application date that applies to such measures and LTCHs.

Finally, we are proposing to change the timing for submission of exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an LTCH from submitting their quality data for the LTCH QRP.

k. Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

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)(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 must submit to the Secretary data on quality measures as specified by the Secretary. The data must be submitted in a form and manner and at a time specified by the Secretary. In this proposed rule, for the IPFQR Program, we are making several proposals. We are proposing two new measures beginning with the FY 2019 payment determination:

- SUB-3 Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge (NQF #1664); and
- Thirty-day all-cause unplanned readmission following psychiatric hospitalization in an IPF.

We also are proposing a technical update to the previously finalized measure, "Screening for Metabolic Disorder." In addition, we are proposing to no longer specify in rulemaking the date of the public display of the program's data or that the preview

period will be approximately 12 weeks before the public display date.

3. Summary of Costs and Benefits

- Adjustment for MS-DRG Documentation and Coding Changes. We are proposing to make a -1.5 percent recoupment adjustment to the standardized amount for FY 2017 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 Public Law 110-90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Public Law 110-90.

While our actuaries estimated that a -9.3 percent recoupment adjustment to the standardized amount would be necessary if CMS were to fully recover the \$11 billion recoupment required by section 631 of the ATRA in FY 2014, it is often our practice to delay or phase in rate adjustments over more than one year, in order to moderate the effects on rates in any one year. Taking into account the cumulative effects of this proposed adjustment and the adjustments made in FYs 2014, 2015, and 2016, we estimate that we would recover the full \$11 billion required under section 631 of the ATRA by the end of FY 2017. We note that section 414 of the MACRA (Pub. L. 114-10), enacted on April 16, 2015, requires us to not make the single positive adjustment we intended to make in FY 2018, but instead make a 0.5 percent positive adjustment for each of FYs 2018 through 2023. The provision under section 414 of the MACRA does not impact our proposed FY 2017 recoupment adjustment, and we will address this MACRA provision in future rulemaking.

- Proposed Adjustment to IPPS Payment Rates as a Result of the 2-Midnight Policy. The proposed adjustment to IPPS rates resulting from the 2-midnight policy would increase IPPS payment rates by  $(1/0.998) * 1.006$  for FY 2017. The 1.006 is a one-time factor that would be applied to the standardized amount, the hospital-specific rates, and the national capital Federal rate for FY 2017 only. Therefore, for FY 2018, we would apply a one-time factor of  $(1/1.006)$  in the calculation of the rates to remove this one-time prospective increase.

- Proposed Changes to the Hospital Readmissions Reduction Program. For FY 2017 and subsequent years, the

reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG). Overall, in this proposed rule, we estimate that 2,603 hospitals will have their base operating DRG payments reduced by their proposed proxy FY 2017 hospital-specific readmission adjustment. As a result, we estimate that the Hospital Readmissions Reduction Program will save approximately \$532 million in FY 2017, an increase of approximately \$100 million over the estimated FY 2016 savings. This increase in the estimated savings for the Hospital Readmissions Reduction Program in FY 2017 as compared to FY 2016 is primarily due to the inclusion of the refinement of the pneumonia readmissions measure, which expanded the measure cohort, along with the addition of the CABG readmission measure, in the calculation of the payment adjustment.

- Value-Based Incentive Payments under the Hospital VBP Program. We estimate that there will be no net financial impact to the Hospital VBP Program for the FY 2017 program year in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given year must be equal to the total amount of base operating MS-DRG payment amount reductions for that year, as estimated by the Secretary. The estimated amount of base operating MS-DRG payment amount reductions for the FY 2017 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2017 discharges is approximately \$1.7 billion.

- Proposed Changes to the HAC Reduction Program. In regard to the five proposed changes to existing HAC Reduction Program policies described earlier, because a hospital's Total HAC score and its ranking in comparison to other hospitals in any given year depends on several different factors, any significant impact due to the HAC Reduction Program proposed changes for FY 2017, including which hospitals receive the adjustment, would depend on actual experience.

- Medicare DSH Payment Adjustment and Additional Payment for Uncompensated Care. Under section 1886(r) of the Act (as added by section 3133 of the Affordable Care Act), DSH payments to hospitals under section 1886(d)(5)(F) of the Act are reduced and an additional payment for

uncompensated care is made to eligible hospitals 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 in section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, will be the basis for determining the additional payments for uncompensated care 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 for uncompensated care based on its share of the total uncompensated care amount reported by Medicare DSHs. The reduction to Medicare DSH payments is not budget neutral.

For FY 2017, we are providing that the 75 percent of what otherwise would have been paid for Medicare DSH is adjusted to approximately 56.74 percent of the amount to reflect changes in the percentage of individuals that are uninsured and additional statutory adjustments. In other words, approximately 42.56 percent (the product of 75 percent and 56.74 percent) of our estimate of Medicare DSH payments, prior to the application of section 3133 of the Affordable Care Act, is available to make additional payments to hospitals for their relative share of the total amount of uncompensated care. We project that estimated Medicare DSH payments, and additional payments for uncompensated care made for FY 2017, would reduce payments overall by approximately 0.3 percent as compared to the estimate of Medicare DSH payments and uncompensated care payments that will be distributed in FY 2016. The additional payments 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 proposed payment amount is not directly tied to a hospital's number of discharges.

- Proposed Update to the LTCH PPS Payment Rates and Other Payment Factors. Based on the best available data for the 419 LTCHs in our data base, we estimate that the proposed changes to the payment rates and factors that we are presenting in the preamble and Addendum of this proposed rule, which includes the second year under the transition of the statutory application of the new site neutral payment rate

required by section 1886(m)(6)(A) of the Act, the proposed update to the LTCH PPS standard payment rate for FY 2017, the proposed update to the LTCH PPS adjustment for differences in area wage levels (which includes the proposed update to the labor-related share based on the proposed revised and rebased LTCH PPS market basket) and estimated changes to the site neutral payment rate and short-stay outlier (SSO) and high-cost outlier (HCO) payments would result in an estimated decrease in payments from FY 2016 of approximately \$355 million.

- Hospital Inpatient Quality Reporting (IQR) Program. In this proposed rule, we are proposing to remove 15 measures for the FY 2019 payment determination and subsequent years. We are proposing to add four new claims-based measures to the Hospital IQR Program for the FY 2019 payment determination and subsequent years. We also are proposing to require hospitals to report on all Hospital IQR Program electronic clinical quality measures that align with the Medicare EHR Incentive Program for four quarters of data on an annual basis for the FY 2019 payment determination and subsequent years. In addition, we are proposing to modify the existing validation process for the Hospital IQR Program data to include a random sample of up to 200 hospitals for validation of eCQMs. We estimate that our policies for the adoption and removal of measures will result in total hospital costs of \$30 million across 3,300 IPPS hospitals.

- Proposed Changes Related to the LTCH QRP. In this proposed rule, we are proposing four quality measures for the LTCH QRP. We estimate that the total cost related to one of these proposed measures, the Drug Regimen Review Conducted with Follow-up for Identified Issues-PAC measure, would be \$3,080 per LTCH annually, or \$1,330,721 for all LTCHs annually. We also estimate that while there will be some additional burden associated with our proposal to expand data collection for the measure NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (77 FR 53624 through 53627), this burden has been previously accounted for in PRA submissions approved under OMB control number 0938-1163. For a detailed explanation, we refer readers to section I.M. of Appendix A (Economic Analyses) of this proposed rule. There is no additional burden for the three other claims-based measures proposed for adoption. Overall, we estimate the total cost for the 13 previously adopted measures and the four proposed new

measures would be \$27,905 per LTCH annually or \$12,054,724 for all LTCHs annually. These estimates were based on 432 LTCHs that are currently certified by Medicare. This is an average increase of 14 percent over the burden for FY 2016. This increase includes all quality measures that LTCHs are required to report, with the exception of the four proposed measures for FY 2017. Section VIII.C. of this proposed rule includes a detailed discussion of the policies.

- Proposed Changes to the IPFQR Program. In this proposed rule, we are proposing to add two new measures beginning with the FY 2019 payment determination and for subsequent years. One of these measures, the 30-Day All-Cause Unplanned Readmissions following Psychiatric Hospitalization in an Inpatient Psychiatric Facility measure, is calculated from administrative claims data. For the second measure, we estimate that our proposed policies would result in total costs of \$11,834,748 for 1,684 IPFs nationwide.

#### B. Summary

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

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

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

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for

a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations. The Affordable Care Act revised the Medicare DSH payment methodology and provides for a new additional Medicare payment that considers the amount of uncompensated care beginning on October 1, 2013.

If the hospital is training residents in an approved residency program(s), 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. SCHs are the sole source of care 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.

Under current law, the Medicare-dependent, small rural hospital (MDH) program is effective through FY 2017. Through and including FY 2006, an MDH received the higher of the Federal rate or the Federal rate plus 50 percent of the amount by which the Federal rate was exceeded by the higher of its FY 1982 or FY 1987 hospital-specific rate. For discharges occurring on or after October 1, 2007, but before October 1, 2017, an MDH receives 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. MDHs are a major source of care for Medicare beneficiaries in their areas. 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).

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: Inpatient rehabilitation facility (IRF) 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 IRF hospitals and units, 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. Section 1206(a) of Public Law 113–67 established the site neutral payment rate under the LTCH PPS, which made the LTCH PPS a dual rate payment system beginning in FY 2016. Under this statute, based on a rolling effective date that is linked to the date on which a given LTCH’s Federal FY 2016 cost reporting period begins, LTCHs are paid for LTCH discharges at the site neutral payment rate unless the discharge meets the patient criteria for payment at the LTCH PPS standard Federal payment 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. Summary of Provisions of Recent Legislation Proposed To Be Implemented in This Proposed Rule

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

The American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240), enacted on January 2, 2013, made a number of changes that affect the IPPS. In this proposed rule, we are proposing to make policy changes to implement section 631 of the American Taxpayer Relief Act of 2012, which amended section 7(b)(1)(B) of Public Law 110–90 and requires a recoupment adjustment to the standardized amounts under section 1886(d) of the Act based upon the Secretary’s estimates for discharges occurring in FY 2014 through FY 2017 to fully offset \$11 billion (which represents the amount of the increase in aggregate payments from FYs 2008 through 2013 for which an adjustment was not previously applied).

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

The Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) introduced new payment rules in the LTCH PPS. Under section 1206 of this law, discharges in cost reporting periods beginning on or after October 1, 2015 under the LTCH PPS will receive payment under a site neutral rate unless the discharge meets

certain patient-specific criteria. In this proposed rule, we are providing clarifications to prior policy changes that implemented provisions under section 1206 of the Pathway for SGR Reform Act.

#### 3. Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185)

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act (Pub. L. 113–185), enacted on October 6, 2014, made a number of changes that affect the Long-Term Care Quality Reporting Program (LTCH QRP). In this proposed rule, we are continuing to implement portions of section 1899B of the Act, as added by section 2 of the IMPACT Act, which, in part, requires LTCHs, among other postacute care providers, to report standardized patient assessment data, data on quality measures, and data on resource use and other measures.

#### 4. The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10)

The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) extended the MDH program and changes to the payment adjustment for low-volume hospitals through FY 2017. In this proposed rule, we are proposing to update the low-volume hospital payment adjustment for FY 2017 under the extension of the temporary changes to the low-volume hospital payment adjustment provided for by section 204 of Public Law 114–10. We also state our intention to finalize in the FY 2017 IPPS/LTCH PPS final rule the provisions of the FY 2016 IPPS/LTCH PPS interim final rule with comment period (80 FR 49594 through 49597) that implemented sections 204 and 205 of Public Law 114–10.

#### 5. The Consolidated Appropriations Act, 2016 (Pub. L. 114–113)

The Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015, made changes that affect the IPPS and the LTCH PPS. Section 231 of Public Law 114–113 provides for a temporary exception for certain wound care discharges from the application of the site neutral payment rate under the LTCH PPS for certain LTCHs, which is being implemented in an interim final rule with comment period. Section 601 of Public Law 114–113 made changes to the payment calculation for operating IPPS payments for hospitals located in Puerto Rico. Section 602 of Public Law 114–113 specifies that Puerto Rico hospitals are eligible for incentive payments for the



meaningful use of certified EHR technology, effective beginning FY 2016, and also applies the adjustments to the applicable percentage increase under the statute for Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. In this proposed rule, we are proposing conforming changes to our regulations to reflect the provisions of section 601 of Public Law 114–113, which increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016.

#### 6. The Notice of Observation Treatment and Implication for Care Eligibility Act (the NOTICE Act) (Pub. L. 114–42)

The Notice of Observation Treatment and Implication for Care Eligibility Act (the NOTICE Act) (Pub. L. 114–42) enacted on August 6, 2015, amended section 1866(a)(1) of the Act by adding new subparagraph (Y) that requires hospitals and CAHs to provide written notification and an oral explanation of such notification to individuals receiving observation services as outpatients for more than 24 hours at the hospitals or CAHs. In this proposed rule, we are proposing to implement the provisions of Public Law 114–42.

#### *D. Summary of the Provisions of This Proposed Rule*

In this proposed rule, we are setting forth proposed payment and policy changes to the Medicare IPPS for FY 2017 operating costs and for capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS, including proposed changes relating to payments for IME and direct GME 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 and policy-related changes to programs associated with payment rate policies under the LTCH PPS for FY 2017.

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

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

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

- Proposed changes to MS–DRG classifications based on our yearly review for FY 2017.
- Proposed application of the documentation and coding adjustment for FY 2017 resulting from implementation of the MS–DRG system.
- Proposed recalibrations of the MS–DRG relative weights.
- A discussion of the FY 2017 status of new technologies approved for add-on payments for FY 2016 and a presentation of our evaluation and analysis of the FY 2017 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Public Law 108–173, obtained in a town hall meeting).

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

In section III. of the preamble to this proposed rule, we are proposing revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include, but not limited to, the following:

- The proposed FY 2017 wage index update using wage data from cost reporting periods beginning in FY 2013.
- Calculation of the proposed occupational mix adjustment for FY 2017 based on the 2013 Occupational Mix Survey.
- Analysis and implementation of the proposed FY 2017 occupational mix adjustment to the wage index for acute care hospitals.
- Proposed application of the rural floor, the proposed imputed floor, and the proposed frontier State floor.
- Transitional wage indexes relating to the continued use of the revised OMB labor market area delineations based on 2010 Decennial Census data.
- Proposed revisions to the wage index for acute care hospitals based on hospital redesignations and reclassifications under sections 1886(d)(8)(B), (d)(8)(E), and (d)(10) of the Act.
- Notification regarding proposed CMS “lock-in” date for urban to rural reclassifications under § 412.103.
- The proposed adjustment to the wage index for acute care hospitals for FY 2017 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.
- Determination of the labor-related share for the proposed FY 2017 wage index.
- Solicitation of Comments on Treatment of Overhead and Home Office Costs in the Wage Index Calculation

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

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

- Proposed conforming changes to our regulations to reflect the changes to operating payments for subsection (d) Puerto Rico hospitals in accordance with the provisions of section 601 of Public Law 114–113.
- Proposed changes to the inpatient hospital update for FY 2017.
- 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 2017.
- The statutorily required IME adjustment factor for FY 2017.
- Proposed changes to the methodologies for determining Medicare DSH payments and the additional payments for uncompensated care.
- 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 for FY 2017.
- Proposed changes to the requirements and provision of value-based incentive payments under the Hospital Value-Based Purchasing Program for FY 2017.
- Proposed requirements for payment adjustments to hospitals under the HAC Reduction Program for FY 2017.
- Proposed changes relating to direct GME and IME payments to urban hospitals with rural track training programs.
- Discussion of the Rural Community Hospital Demonstration Program and a proposal for making a budget neutrality adjustment for the demonstration program.
- Proposed implementation of the Notice of Observation Treatment and Implications for Care Eligibility Act (the NOTICE Act) for hospitals and CAHs.
- Proposed technical changes and corrections to regulations relating to cost to related organizations and Medicare cost reports.

#### 4. Proposed FY 2017 Policy Governing the IPPS for Capital-Related Costs

In section V. of the preamble to this proposed rule, we discuss the proposed payment policy requirements for capital-related costs and capital

payments to hospitals for FY 2017. In addition, we discuss proposed changes to the calculation of capital IPPS payments to hospitals located in Puerto Rico to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, beginning in FY 2017.

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

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

- Proposed changes to payments to certain excluded hospitals for FY 2017.
- Proposed implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration.

#### 6. Proposed Changes to the LTCH PPS

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

- Proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2017.
- Proposals to sunset our existing 25-percent threshold policy regulations, and replace them with single consolidated 25 percent threshold policy regulation.
- Proposed changes to the limitation on charges (LOC) to beneficiaries and related billing requirements for “subclause (II)” LTCHs to align those LTCH PPS payment adjustment policies with the LOC policies applied in the TEFRA payment context.
- Proposed technical corrections to certain definitions to correct and clarify their use under the application of the site neutral payment rate and proposed additional definitions in accordance with our proposed modifications to the 25-percent policy.
- Proposed rebasing and revising of the LTCH market basket to update the LTCH PPS, effective for FY 2017.

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

In section VIII. of the preamble of the 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 Program (LTCH QRP).
- Proposed changes to the requirements under the Inpatient

Psychiatric Facility Quality Reporting (IPFQR) Program.

- Proposed changes relating to clinical quality measures for the Medicare Electronic Health Record (EHR) Incentive Program and eligible hospitals and CAHs.

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

In the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2017 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 update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2017 for certain hospitals excluded from the IPPS.

#### 9. Determining Prospective Payment Rates for LTCHs

In the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2017 LTCH PPS standard Federal payment rate and other factors used to determine LTCH PPS payments under both the LTCH PPS standard Federal payment rate and the site neutral payment rate in FY 2017. 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 applicable fixed-loss amounts and the LTCH cost-to-charge ratios (CCRs) for both payment rates. We also are providing the estimated market basket update to apply to the ceiling used to determine payments under the existing payment adjustment for “subclause (II)” LTCHs for cost reporting periods beginning in FY 2017.

#### 10. Impact Analysis

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

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

In Appendix B of this proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provided our recommendations of the appropriate percentage changes for FY 2017 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS

for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs and MDHs).

- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
- The LTCH PPS standard Federal payment rate and the site neutral payment rate for hospital inpatient services provided for LTCH PPS discharges.

#### 12. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC’s March 2016 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We addressed these recommendations in Appendix B of this proposed rule. For further information relating specifically to the MedPAC March 2016 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/R/ 2010 LTCH PPS final rule (74 FR 43764 through 43766), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50053 through 50055), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51485 through 51487), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53273), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50512), the FY 2015 IPPS/LTCH PPS final rule (79 FR 49871), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49342).

#### *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 2017 MS-DRG Documentation and Coding Adjustment*

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

In the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189), we adopted the MS-DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS-DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. (Currently, for FY 2016, there are 756 MS-DRGs.) By increasing the number of MS-DRGs and more fully taking into account patient severity of illness in Medicare payment rates for acute care hospitals, MS-DRGs encourage hospitals to improve their documentation and coding of patient diagnoses.

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we indicated that the adoption of the MS-DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for additional documentation and coding. In that final rule with comment period, we exercised

our authority under section 1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case-mix. Our actuaries estimated that maintaining budget neutrality required an adjustment of -4.8 percent to the national standardized amount. We provided for phasing in this -4.8 percent adjustment over 3 years. Specifically, we established prospective documentation and coding adjustments of -1.2 percent for FY 2008, -1.8 percent for FY 2009, and -1.8 percent for FY 2010.

On September 29, 2007, Congress enacted the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007 (Pub. L. 110-90). Section 7(a) of Public Law 110-90 reduced the documentation and coding adjustment made as a result of the MS-DRG system that we adopted in the FY 2008 IPPS final rule with comment period to -0.6 percent for FY 2008 and -0.9 percent for FY 2009, and we finalized the FY 2008 adjustment through rulemaking, effective October 1, 2007 (72 FR 66886).

For FY 2009, section 7(a) of Public Law 110-90 required a documentation and coding adjustment of -0.9 percent, and we finalized that adjustment through rulemaking effective October 1, 2008 (73 FR 48447). The documentation and coding adjustments established in the FY 2008 IPPS final rule with comment period, which reflected the amendments made by section 7(a) of Public Law 110-90, are cumulative. As a result, the -0.9 percent documentation and coding adjustment for FY 2009 was in addition to the -0.6 percent adjustment for FY 2008, yielding a combined effect of -1.5 percent.

##### 2. Adjustment to the Average Standardized Amounts Required by Public Law 110-90

###### a. Prospective Adjustment Required by Section 7(b)(1)(A) of Public Law 110-90

Section 7(b)(1)(A) of Public Law 110-90 requires that, if the Secretary determines that implementation of the MS-DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different than the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110-90, the Secretary shall make an appropriate adjustment

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

Section 1886(d)(3)(A)(vi) of the Act authorizes adjustments to the average standardized amounts for subsequent fiscal years in order to eliminate the effect of such coding or classification changes. These adjustments are intended to ensure that future annual aggregate IPPS payments are the same as the payments that otherwise would have been made had the prospective adjustments for documentation and coding applied in FY 2008 and FY 2009 reflected the change that occurred in those years.

###### b. Recoupment or Repayment Adjustments in FYs 2010 Through 2012 Required by Section 7(b)(1)(B) Public Law 110-90

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

###### 3. Retrospective Evaluation of FY 2008 and FY 2009 Claims Data

In order to implement the requirements of section 7 of Public Law 110-90, we performed a retrospective

evaluation of the FY 2008 data for claims paid through December 2008 using the methodology first described in the FY 2009 IPPS/LTCH PPS final rule (73 FR 43768 and 43775) and later discussed in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43768 through 43772). We performed the same analysis for FY 2009 claims data using the same methodology as we did for FY 2008 claims (75 FR 50057 through 50068). The results of the analysis for the FY 2011 IPPS/LTCH PPS proposed and final rules, and subsequent evaluations in FY 2012, supported that the 5.4 percent estimate accurately reflected the FY 2009 increases in documentation and coding under the MS-DRG system. We were persuaded by both MedPAC's analysis (as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50064 through 50065)) and our own review of the methodologies proposed by various commenters that the methodology we employed to determine the required documentation and coding adjustments was sound.

As in prior years, the FY 2008, FY 2009, and FY 2010 MedPAR files are available to the public to allow independent analysis of the FY 2008 and FY 2009 documentation and coding effects. Interested individuals may still order these files through the CMS Web site at: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/> by clicking on MedPAR Limited Data Set (LDS)—Hospital (National). This CMS Web page describes the file and provides directions and further detailed instructions for how to order.

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

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

Centers for Medicare & Medicaid Services, RDDC Account, Accounting Division, P.O. Box 7520, Baltimore, MD 21207-0520.

Mailing address if using express mail:

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

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

In the FY 2010 IPPS/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/LTCH PPS final rule for a detailed description of our proposal, responses to comments, and finalized policy. After analysis of the FY 2009 claims data for the FY 2011 IPPS/LTCH PPS final rule (75 FR 50057 through 50073), we found a total prospective documentation and coding effect of 5.4 percent. After accounting for the -0.6 percent and the -0.9 percent documentation and coding adjustments in FYs 2008 and 2009, we found a remaining documentation and coding effect of 3.9 percent. As we have discussed, an additional cumulative adjustment of -3.9 percent would be necessary to meet the requirements of section 7(b)(1)(A) of Public Law 110-90 to make an adjustment to the average standardized amounts in order to eliminate the full effect of the documentation and coding changes that do not reflect real changes in case-mix on future payments. Unlike section 7(b)(1)(B) of Public Law 110-90, section 7(b)(1)(A) does not specify when we must apply the prospective adjustment, but merely requires us to make an "appropriate" adjustment. Therefore, as we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50061), we believed the law provided some discretion as to the manner in which we applied the prospective adjustment of -3.9 percent. As we discussed extensively in the FY 2011 IPPS/LTCH PPS final rule, it has been our practice to moderate payment adjustments when necessary to mitigate the effects of significant downward adjustments on hospitals, to avoid what could be widespread, disruptive effects of such adjustments on hospitals. Therefore, we stated that we believed it was appropriate to not implement the -3.9 percent prospective adjustment in FY 2011 because we finalized a -2.9 percent recoupment adjustment for that fiscal year. Accordingly, we did not propose a prospective adjustment under section 7(b)(1)(A) of Public Law 110-90 for FY 2011 (75 FR 23868 through 23870). We noted that, as a result, payments in FY 2011 (and in each future fiscal year until we implemented the requisite adjustment) would be higher than they would have been if we had implemented an adjustment under section 7(b)(1)(A) of Public Law 110-90.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51489 and 51497), we indicated that, because further delay of this prospective adjustment would

result in a continued accrual of unrecoverable overpayments, it was imperative that we implement a prospective adjustment for FY 2012, while recognizing CMS' continued desire to mitigate the effects of any significant downward adjustments to hospitals. Therefore, we implemented a -2.0 percent prospective adjustment to the standardized amount instead of the full -3.9 percent.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53274 through 53276), we completed the prospective portion of the adjustment required under section 7(b)(1)(A) of Public Law 110-90 by finalizing a -1.9 percent adjustment to the standardized amount for FY 2013. We stated that this adjustment would remove the remaining effect of the documentation and coding changes that do not reflect real changes in case-mix that occurred in FY 2008 and FY 2009. We believed that it was imperative to implement the full remaining adjustment, as any further delay would result in an overstated standardized amount in FY 2013 and any future fiscal years until a full adjustment was made.

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

#### 5. Recoupment or Repayment Adjustment Authorized by Section 7(b)(1)(B) of Public Law 110-90

Section 7(b)(1)(B) of Public Law 110-90 requires the Secretary to make an adjustment to the standardized amounts under section 1886(d) of the Act to offset the estimated increase or decrease in aggregate payments for FY 2008 and FY 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustments applied under section 7(a) of Public Law 110-90. This determination must be based on a retrospective evaluation of claims data. Our actuaries estimated that there was a 5.8 percentage point difference resulting in an increase in aggregate payments of approximately \$6.9 billion. Therefore, as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50062 through 50067), we determined that an aggregate adjustment of -5.8 percent in FYs 2011 and 2012 would be necessary in order to meet the requirements of section 7(b)(1)(B) of Public Law 110-90

to adjust the standardized amounts for discharges occurring in FYs 2010, 2011, and/or 2012 to offset the estimated amount of the increase in aggregate payments (including interest) in FYs 2008 and 2009.

It is often our practice to phase in payment rate adjustments over more than one year in order to moderate the effect on payment rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, in the FY 2011 IPPS/LTCH PPS final rule, we made an adjustment to the standardized amount of -2.9 percent, representing approximately half of the aggregate adjustment required under section 7(b)(1)(B) of Public Law 110-90, for FY 2011. An adjustment of this magnitude allowed us to moderate the effects on hospitals in one year while simultaneously making it possible to implement the entire adjustment within the timeframe required under section 7(b)(1)(B) of Public Law 110-90 (that is, no later than FY 2012). For FY 2012, in accordance with the timeframes set forth by section 7(b)(1)(B) of Public Law 110-90, and consistent with the discussion in the FY 2011 IPPS/LTCH PPS final rule, we completed the recoupment adjustment by implementing the remaining -2.9 percent adjustment, in addition to removing the effect of the -2.9 percent adjustment to the standardized amount finalized for FY 2011 (76 FR 51489 and 51498). Because these adjustments, in effect, balanced out, there was no year-to-year change in the standardized amount due to this recoupment adjustment for FY 2012. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53276), we made a final +2.9 percent adjustment to the standardized amount, completing the recoupment portion of section 7(b)(1)(B) of Public Law 110-90. We note that with this positive adjustment, according to our estimates, all overpayments made in FY 2008 and FY 2009 have been fully recaptured with appropriate interest, and the standardized amount has been returned to the appropriate baseline.

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

Section 631 of the ATRA amended section 7(b)(1)(B) of Public Law 110-90

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

Similar to the adjustments authorized under section 7(b)(1)(B) of Public Law 110-90, the adjustment required under section 631 of the ATRA is a one-time recoupment of a prior overpayment, not a permanent reduction to payment rates. Therefore, we anticipated that any adjustment made to reduce payment rates in one year would eventually be offset by a positive adjustment in 2018, once the necessary amount of overpayment was recovered. However, section 414 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, Public Law 114-10, enacted on April 16, 2015, replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment for each of FYs 2018 through 2023. We stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49345) that we will address this MACRA provision in future rulemaking.

As we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515 through 50517), our actuaries estimate that a -9.3 percent adjustment to the standardized amount would be necessary if CMS were to fully recover the \$11 billion recoupment required by section 631 of the ATRA in FY 2014. It is often our practice to phase in payment rate adjustments over more than one year, in order to moderate the effect on payment rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, and after consideration of the public comments we received, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515 through 50517), we implemented a -0.8 percent recoupment adjustment to the standardized amount in FY 2014. We stated that if adjustments of approximately -0.8 percent are implemented in FYs 2014, 2015, 2016, and 2017, using standard inflation

factors, we estimate that the entire \$11 billion will be accounted for by the end of the statutory 4-year timeline. As estimates of any future adjustments are subject to slight variations in total savings, we did not provide for specific adjustments for FYs 2015, 2016, or 2017 at that time. We stated that we believed that this level of adjustment for FY 2014 was a reasonable and fair approach that satisfies the requirements of the statute while mitigating extreme annual fluctuations in payment rates.

Consistent with the approach discussed in the FY 2014 rulemaking for recouping the \$11 billion required by section 631 of the ATRA, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49874) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49345), we implemented additional -0.8 percent recoupment adjustments to the standardized amount in FY 2015 and FY 2016, respectively. We estimated that these adjustments, combined with leaving the prior -0.8 percent adjustments in place, would recover up to \$2 billion in FY 2015 and another \$3 billion in FY 2016. When combined with the approximately \$1 billion adjustment made in FY 2014, we estimated that approximately \$5 to \$6 billion would be left to recover under section 631 of the ATRA by the end of FY 2016.

However, due to lower than previously estimated inpatient spending, an adjustment of -0.8 percent in FY 2017 would not recoup the \$11 billion under section 631 of the ATRA. Based on the FY 2017 President's Budget, our actuaries currently estimate that FY 2014 through FY 2016 spending subject to the documentation and coding recoupment adjustment in the absence of the -0.8 percent adjustments made in FYs 2014 through 2016 would have been \$123.783 billion in FY 2014, \$124.361 billion in FY 2015, and \$127.060 billion in FY 2016. As shown in the following table, the amount recouped in each of those fiscal years is therefore calculated as the difference between those amounts and the amounts determined to have been spent in those years with the -0.8 percent adjustment applied, namely \$122.801 billion in FY 2014, \$122.395 billion in FY 2015, and \$124.059 billion in FY 2016. This yields an estimated total recoupment through the end of FY 2016 of \$5.950 billion.

RECOUPMENT MADE UNDER SECTION 631 OF THE AMERICAN TAXPAYER RELIEF ACT OF 2012 (ATRA)

	IPPS Spending * (billions)	Cumulative adjustment factor	Adjusted IPPS spending (billions)	Recoupment amount (billions)
FY 2014 .....	\$122.801	1.00800	\$123.783	\$0.98

## RECOUPMENT MADE UNDER SECTION 631 OF THE AMERICAN TAXPAYER RELIEF ACT OF 2012 (ATRA)—Continued

	IPPS Spending * (billions)	Cumulative adjustment factor	Adjusted IPPS spending (billions)	Recoupment amount (billions)
FY 2015 .....	122.395	1.01606	124.361	1.97
FY 2016 .....	124.059	1.02419	127.060	3.00
Total .....				5.95

\* Based on FY 2017 President's Budget, including capital, IME, and DSH payments.

These estimates and the estimate of FY 2017 spending subject to the documentation and coding recoupment adjustment also will be contained in a memorandum from the Office of the Actuary that we will make publicly available on the CMS Web site. A description of the President's Budget for FY 2017 is currently available on the OMB Web site at: <https://www.whitehouse.gov/omb/budget>.

Our actuaries currently estimate that the FY 2017 spending subject to the documentation and coding recoupment adjustment (including capital, IME, and DSH payment) would be \$129.625 billion in the absence of any documentation and recoupment adjustments from FY 2014 through FY 2017. Therefore, our actuaries currently estimate that, to the nearest tenth of a percent, the FY 2017 documentation and coding adjustment factor that will recoup as closely as possible \$11 billion from FY 2014 through FY 2017 without exceeding this amount is  $-1.5$  percent. This adjustment factor yields an estimated spending amount in FY 2017 of \$124.693 billion, calculated as  $\$129.625 / (1.008 * 1.008 * 1.008 * 1.015)$ . This estimated  $-1.5$  percent adjustment factor will be updated for the final rule based on the FY 2017 President's Budget Midsession Review. It is possible that, based on updated estimates, the necessary adjustment factor to the nearest tenth of a percent could be different than our actuaries' current estimate of  $-1.5$  percent. The proposed  $-1.5$  percent adjustment would be the final adjustment required under section 631 of the ATRA, and when combined with the effects of previous adjustments made in FY 2014, FY 2015, and FY 2016, we estimate will satisfy the section 631 of the ATRA recoupment. As stated earlier, once the recoupment was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the \$11 billion under section 631 of the ATRA. However, as stated earlier, section 414 of the MACRA requires that we not make the single positive adjustment we intended to make in FY 2018, but

instead make a 0.5 percent positive adjustment for each of FYs 2018 through 2023. The provision under section 414 of the MACRA does not impact our proposed FY 2017 adjustment, and we will address this MACRA provision in future rulemaking.

#### *E. Refinement of the MS-DRG Relative Weight Calculation*

##### 1. Background

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

As we implemented cost-based relative weights, some public commenters raised concerns about potential bias in the weights due to "charge compression," which is the practice of applying a higher percentage charge markup over costs to lower cost items and services, and a lower percentage charge markup over costs to higher cost items and services. As a result, the cost-based weights would undervalue high-cost items and overvalue low-cost items if a single cost-to-charge ratio (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 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://](http://www.rti.org/reports/cms/HHSM-500-2005-00291/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf)

[www.rti.org/reports/cms/HHSM-500-2005-00291/PDF/Refining\\_Cost\\_to\\_Charge\\_Ratios\\_200807\\_Final.pdf](http://www.rti.org/reports/cms/HHSM-500-2005-00291/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf)).

In the FY 2009 IPPS final rule (73 FR 48458 through 48467), in response to the RTI's recommendations concerning cost report refinements, we discussed our decision to pursue changes to the cost report to split the cost center for Medical Supplies Charged to Patients into one line for "Medical Supplies Charged to Patients" and another line for "Implantable Devices Charged to Patients." We acknowledged, as RTI had found, that charge compression occurs in several cost centers that exist on the Medicare cost report. However, as we stated in the FY 2009 IPPS final rule, we focused on the CCR for Medical Supplies and Equipment because RTI found that the largest impact on the MS-DRG relative weights could result from correcting charge compression for devices and implants. In determining the items that should be reported in these respective cost centers, we adopted the commenters' recommendations that hospitals 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 subscribed line for "Implantable Devices Charged to Patients" was created in July 2009. This new subscribed cost center has been available for use for cost reporting periods beginning on or after May 1, 2009.

As we discussed in the FY 2009 IPPS final rule (73 FR 48458) and in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68519 through 68527), in addition to the findings regarding implantable devices, RTI found that the costs and charges of computed tomography (CT) scans, magnetic resonance imaging (MRI), and cardiac catheterization differ significantly from the costs and charges of other services included in the standard associated cost center. RTI also concluded that both the IPPS and the

OPPS relative weights would better estimate the costs of those services if CMS were to add standard cost centers for CT scans, MRIs, and cardiac catheterization in order for hospitals to report separately the costs and charges for those services and in order for CMS to calculate unique CCRs to estimate the costs from charges on claims data. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080), we finalized our proposal to create standard cost centers for CT scans, MRIs, and cardiac catheterization, and to require that hospitals report the costs and charges for these services under new cost centers on the revised Medicare cost report Form CMS-2552-10. (We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080) for a detailed discussion of the reasons for the creation of standard cost centers for CT scans, MRIs, and cardiac catheterization.) The new standard cost centers for CT scans, MRIs, and cardiac catheterization are effective for cost reporting periods beginning on or after May 1, 2010, on the revised cost report Form CMS-2552-10.

In the FY 2009 IPPS final rule (73 FR 48468), we stated that, due to what is typically a 3-year lag between the reporting of cost report data and the availability for use in ratesetting, we anticipated that we might be able to use data from the new “Implantable Devices Charged to Patients” cost center to develop a CCR for “Implantable Devices Charged to Patients” in the FY 2012 or FY 2013 IPPS rulemaking cycle. However, as noted in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43782), due to delays in the issuance of the revised cost report Form CMS 2552-10, we determined that a new CCR for “Implantable Devices Charged to Patients” might not be available before FY 2013. Similarly, when we finalized the decision in the FY 2011 IPPS/LTCH PPS final rule to add new cost centers for CT scans, MRIs, and cardiac catheterization, we explained that data from any new cost centers that may be created will not be available until at least 3 years after they are first used (75 FR 50077). In preparation for the FY 2012 IPPS/LTCH PPS rulemaking, we checked the availability of data in the “Implantable Devices Charged to Patients” cost center on the FY 2009 cost reports, but we did not believe that there was a sufficient amount of data from which to generate a meaningful analysis in this particular situation. Therefore, we did not propose to use data from the “Implantable Devices Charged to Patients” cost center to create a distinct CCR for “Implantable

Devices Charged to Patients” for use in calculating the MS-DRG relative weights for FY 2012. We indicated that we would reassess the availability of data for the “Implantable Devices Charged to Patients” cost center for the FY 2013 IPPS/LTCH PPS rulemaking cycle and, if appropriate, we would propose to create a distinct CCR at that time.

During the development of the FY 2013 IPPS/LTCH PPS proposed and final rules, hospitals were still in the process of transitioning from the previous cost report Form CMS-2552-96 to the new cost report Form CMS-2552-10. Therefore, we were able to access only those cost reports in the FY 2010 HCRIS with fiscal year begin dates on or after October 1, 2009, and before May 1, 2010; that is, those cost reports on Form CMS-2552-96. Data from the Form CMS-2552-10 cost reports were not available because cost reports filed on the Form CMS-2552-10 were not accessible in the HCRIS. Further complicating matters was that, due to additional unforeseen technical difficulties, the corresponding information regarding charges for implantable devices on hospital claims was not yet available to us in the MedPAR file. Without the breakout in the MedPAR file of charges associated with implantable devices to correspond to the costs of implantable devices on the cost report, we believed that we had no choice but to continue computing the relative weights with the current CCR that combines the costs and charges for supplies and implantable devices. We stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53281 through 53283) that when we do have the necessary data for supplies and implantable devices on the claims in the MedPAR file to create distinct CCRs for the respective cost centers for supplies and implantable devices, we hoped that we would also have data for an analysis of creating distinct CCRs for CT scans, MRIs, and cardiac catheterization, which could then be finalized through rulemaking. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53281), we stated that, prior to proposing to create these CCRs, we would first thoroughly analyze and determine the impacts of the data, and that distinct CCRs for these new cost centers would be used in the calculation of the relative weights only if they were first finalized through rulemaking.

At the time of the development of the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27506 through 27507), we had a substantial number of hospitals completing all, or some, of these new cost centers on the FY 2011 Medicare

cost reports, compared to prior years. We stated that we believed that the analytic findings described using the FY 2011 cost report data and FY 2012 claims data supported our original decision to break out and create new cost centers for implantable devices, MRIs, CT scans, and cardiac catheterization, and we saw no reason to further delay proposing to implement the CCRs of each of these cost centers. Therefore, beginning in FY 2014, we proposed a policy 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 refer readers to the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27507 through 27509) and final rule (78 FR 50518 through 50523) in which we presented data analyses using distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. The FY 2014 IPPS/LTCH PPS final rule also set forth our responses to public comments we received on our proposal to implement these CCRs. As explained in more detail in the FY 2014 IPPS/LTCH PPS final rule, we finalized our proposal to use 19 CCRs to calculate MS-DRG relative weights beginning in FY 2014—the then existing 15 cost centers and the 4 new CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. Therefore, beginning in FY 2014, we calculate the IPPS MS-DRG relative weights using 19 CCRs, creating distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization.

## 2. Discussion of Policy for FY 2017

Consistent with our established policy, we calculated the proposed MS-DRG relative weights for FY 2017 using two data sources: The MedPAR file as the claims data source and the HCRIS as the cost report data source. We adjusted the charges from the claims to costs by applying the 19 national average CCRs developed from the cost reports. The description of the calculation of the proposed 19 CCRs and the proposed MS-DRG relative weights for FY 2017 is included in section II.G. of the preamble of this proposed rule. As we did with the FY 2016 IPPS/LTCH PPS final rule, we are providing the version of the HCRIS from which we calculated these proposed 19 CCRs 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 2017 IPPS Proposed Rule Home Page” or “Acute Inpatient Files for Download.”

### F. Proposed Changes to Specific MS-DRG Classifications

#### 1. Discussion of Changes to Coding System and Basis for MS-DRG Updates

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

As of October 1, 2015, providers use the International Classification of Diseases, 10th Revision (ICD-10) coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS-DRG system instead of the ICD-9-CM coding system, which was used through September 30, 2015. The ICD-10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) for inpatient hospital procedure coding, as well as the Official ICD-10-CM and ICD-10-PCS Guidelines for Coding and Reporting. The ICD-10 coding system was initially adopted for transactions conducted on or after October 1, 2013, as described in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification: Modifications to Medical Data Code Set Standards to Adopt ICD-10-CM and ICD-10-PCS Final Rule published in the **Federal Register** on January 16, 2009 (74 FR 3328 through 3362) (hereinafter referred to as the "ICD-10-CM and ICD-10-PCS final rule"). However, the Secretary of Health and Human Services (the Secretary) issued a final rule that delayed the compliance date for ICD-10 from October 1, 2013, to October 1, 2014. That final rule, entitled "Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for ICD-10-CM and ICD-10-PCS Medical Data Code Sets," CMS-0040-F, was published in the **Federal Register** on September 5, 2012 (77 FR 54664) and is available for viewing on the Internet at: <http://www.gpo.gov/fdsys/pkg/FR-2012-09-05/pdf/2012-21238.pdf>. On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113-93) was enacted, which specified that the Secretary may not adopt ICD-10 prior to October 1, 2015. Accordingly, the U.S. Department of Health and Human Services released a final rule in the **Federal Register** on August 4, 2014 (79 FR 45128 through 45134) that included

a new compliance date that required the use of ICD-10 beginning October 1, 2015. The rule also required HIPAA-covered entities to continue to use ICD-9-CM through September 30, 2015.

The anticipated move to ICD-10 necessitated the development of an ICD-10-CM/ICD-10-PCS version of the MS-DRGs. CMS began a project to convert the ICD-9-CM-based MS-DRGs to ICD-10 MS-DRGs. In response to the FY 2011 IPPS/LTCH PPS proposed rule, we received public comments on the creation of the ICD-10 version of the MS-DRGs to be implemented at the same time as ICD-10 (75 FR 50127 and 50128). While we did not propose an ICD-10 version of the MS-DRGs in the FY 2011 IPPS/LTCH PPS proposed rule, we noted that we have been actively involved in converting current MS-DRGs from ICD-9-CM codes to ICD-10 codes and sharing this information through the ICD-10 (previously ICD-9-CM) Coordination and Maintenance Committee. We undertook this early conversion project to assist other payers and providers in understanding how to implement their own conversion projects. We posted ICD-10 MS-DRGs based on Version 26.0 (FY 2009) of the MS-DRGs. We also posted a paper that describes how CMS went about completing this project and suggestions for other payers and providers to follow. Information on the ICD-10 MS-DRG conversion project can be found on the ICD-10 MS-DRG Conversion Project Web site at: <http://cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html>. We have continued to keep the public updated on our maintenance efforts for ICD-10-CM and ICD-10-PCS coding systems, as well as the General Equivalence Mappings that assist in conversion through the ICD-10 (previously ICD-9-CM) Coordination and Maintenance Committee. Information on these committee meetings can be found on the CMS Web site at: <http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html>.

During FY 2011, we developed and posted Version 28.0 of the ICD-10 MS-DRGs based on the FY 2011 MS-DRGs (Version 28.0) that we finalized in the FY 2011 IPPS/LTCH PPS final rule on the CMS Web site. This ICD-10 MS-DRGs Version 28.0 also included the CC Exclusion List and the ICD-10 version of the hospital-acquired conditions (HACs), which was not posted with Version 26. 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 and made updates as a result of these comments. We called the updated version the ICD-10 MS-DRGs Version 28-R1. We posted a Definitions Manual of ICD-10 MS-DRGs Version 28-R1 on our ICD-10 MS-DRG Conversion Project Web site. To make the review of Version 28-R1 updates easier for the public, we also made available pilot software on a CD ROM that could be ordered through the National Technical Information Service (NTIS). A link to the NTIS ordering page was provided on the CMS ICD-10 MS-DRGs Web site. We stated that we believed that, by providing the ICD-10 MS-DRGs Version 28-R1 Pilot Software (distributed on CD ROM), the public would be able to more easily review and provide feedback on updates to the ICD-10 MS-DRGs. We discussed the updated ICD-10 MS-DRGs Version 28-R1 at the September 14, 2011 ICD-9-CM Coordination and Maintenance Committee meeting. We encouraged the public to continue to review and provide comments on the ICD-10 MS-DRGs so that CMS could continue to update the system.

In FY 2012, we prepared the ICD-10 MS-DRGs Version 29, 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 on our ICD-10 MS-DRG Conversion Project Web site. We also prepared a document that describes changes made from Version 28 to Version 29 to facilitate a review. The ICD-10 MS-DRGs Version 29 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 based on the FY 2013 MS-DRGs (Version 30) 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 on our ICD-10 MS-DRG Conversion Project Web site. We also prepared a document that describes changes made from Version 29 to Version 30 to facilitate a review. We produced mainframe and computer software for Version 30, which was made available to the public in February 2013. Information on ordering the mainframe and computer software through NTIS was posted on the ICD-10 MS-DRG Conversion Project



Web site. The ICD-10 MS-DRGs Version 30.0 computer software facilitated additional review of the ICD-10 MS-DRGs conversion.

We provided information on a study conducted on the impact of converting the MS-DRGs to ICD-10. Information on this study is summarized in a paper entitled "Impact of the Transition to ICD-10 on Medicare Inpatient Hospital Payments." This paper was posted on the CMS ICD-10 MS-DRGs Conversion Project Web site and was distributed and discussed at the September 15, 2010 ICD-9-CM Coordination and Maintenance Committee meeting. The paper described CMS' approach to the conversion of the MS-DRGs from ICD-9-CM codes to ICD-10 codes. The study was undertaken using the ICD-9-CM MS-DRGs Version 27.0 (FY 2010), which was converted to the ICD-10 MS-DRGs Version 27.0. The study estimated the impact on aggregate payment to hospitals and the distribution of payments across hospitals. The impact of the conversion from ICD-9-CM to ICD-10 on Medicare MS-DRG hospital payments was estimated using FY 2009 Medicare claims data. The study found a hospital payment increase of 0.05 percent using the ICD-10 MS-DRGs Version 27.

CMS provided an overview of this hospital payment impact study at the March 5, 2012 ICD-9-CM Coordination and Maintenance Committee meeting. This presentation followed presentations on the creation of ICD-10 MS-DRGs Version 29.0. A summary report of this meeting can be found on the CMS Web site at: <http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html>. At this March 2012 meeting, CMS announced that it would produce an update on this impact study based on an updated version of the ICD-10 MS-DRGs. This update of the impact study was presented at the March 5, 2013 ICD-9-CM Coordination and Maintenance Committee meeting. The study found that moving from an ICD-9-CM-based system to an ICD-10 MS-DRG replicated system would lead to DRG reassignments on only 1 percent of the 10 million MedPAR sample records used in the study. Ninety-nine percent of the records did not shift to another MS-DRG when using an ICD-10 MS-DRG system. For the 1 percent of the records that shifted, 45 percent of the shifts were to a higher-weighted MS-DRG, while 55 percent of the shifts were to lower-weighted MS-DRGs. The net impact across all MS-DRGs was a reduction by 4/10000 or minus 4 pennies per \$100. The updated paper is posted on the CMS Web site at: <http://>

[cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html](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 software provided additional information to the public who were evaluating the conversion of the MS-DRGs to ICD-10 MS-DRGs.

CMS prepared the ICD-10 MS-DRGs Version 31 based on the FY 2014 MS-DRGs (Version 31) that we finalized in the FY 2014 IPPS/LTCH PPS final rule. In November 2013, we posted a Definitions Manual of the ICD-10 MS-DRGs Version 31 on the ICD-10 MS-DRG Conversion Project Web site at: <http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html>. We also prepared a document that described changes made from Version 30 to Version 31 to facilitate a review. We produced mainframe and computer software for Version 31, which was made available to the public in December 2013. Information on ordering the mainframe and computer software through NTIS was posted on the CMS Web site at: <http://cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html> under the "Related Links" section. This ICD-10 MS-DRGs Version 31.0 computer software facilitated additional review of the ICD-10 MS-DRGs conversion. We encouraged the public to submit to CMS any comments on areas where they believed the ICD-10 MS-DRGs did not accurately reflect grouping logic found in the ICD-9-CM MS-DRGs Version 31.

We reviewed public comments received and developed an update of ICD-10 MS-DRGs Version 31, which we called ICD-10 MS-DRGs Version 31-R. We posted a Definitions Manual of the ICD-10 MS-DRGs Version 31-R on the ICD-10 MS-DRG Conversion Project Web site at: <http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html>. We also prepared a document that describes changes made from Version 31 to Version 31-R to facilitate a review. We continued to share ICD-10 MS-DRG conversion activities with the public through this Web site.

CMS prepared the ICD-10 MS-DRGs Version 32 based on the FY 2015 MS-DRGs (Version 32) that we finalized in the FY 2015 IPPS/LTCH PPS final rule. In November 2014, we made available a

Definitions Manual of the ICD-10 MS-DRGs Version 32 on the ICD-10 MS-DRG Conversion Project Web site at: <http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html>. We also prepared a document that described changes made from Version 31-R to Version 32 to facilitate a review. We produced mainframe and computer software for Version 32, which was made available to the public in January 2015. Information on ordering the mainframe and computer software through NTIS was made available on the CMS Web site at: <http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html> under the "Related Links" section. This ICD-10 MS-DRGs Version 32 computer software facilitated additional review of the ICD-10 MS-DRGs conversion. We encouraged the public to submit to CMS any comments on areas where they believed the ICD-10 MS-DRGs did not accurately reflect grouping logic found in the ICD-9-CM MS-DRGs Version 32. We discussed five requests from the public to update the ICD-10 MS-DRGs Version 32 to better replicate the ICD-9-CM MS-DRGs in section II.G.3., 4., and 5. of the preamble of the FY 2016 IPPS/LTCH PPS final rule. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24351), we proposed to implement the MS-DRG code logic in the ICD-10 MS-DRGs Version 32 along with any finalized updates to the ICD-10 MS-DRGs Version 32 for the final ICD-10 MS-DRGs Version 33. In the proposed rule, we proposed the ICD-10 MS-DRGs Version 33 as the replacement logic for the ICD-9-CM based MS-DRGs Version 32 as part of the proposed MS-DRG updates for FY 2016. We invited public comments on how well the ICD-10 MS-DRGs Version 32 replicated the logic of the MS-DRGs Version 32 based on ICD-9-CM codes.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49356 through 49357 and 49363 through 49407), we addressed the public comments we received on the replication in the ICD-10 MS-DRGs Version 32 of the logic of the MS-DRGs Version 32 based on ICD-9-CM codes. We refer readers to that final rule for a discussion of the changes we made in response to public comments.

#### b. Basis for Proposed FY 2017 MS-DRG Updates

CMS encourages input from our stakeholders concerning the annual IPPS updates when that input is made available to us by December 7 of the year prior to the next annual proposed rule update. For example, to be considered for any updates or changes

in FY 2017, comments and suggestions should have been submitted by December 7, 2015. The comments that were submitted in a timely manner for FY 2017 are discussed in this section of the proposed rule. Interested parties should submit any comments and suggestions for FY 2018 by December 7, 2016, via the new CMS MS-DRG Classification Change Requests Mailbox located at: [MSDRGClassificationChange@cms.hhs.gov](mailto:MSDRGClassificationChange@cms.hhs.gov).

Following are the changes we are proposing to the MS-DRGs for FY 2017. We are inviting public comment on each of the MS-DRG classification proposed changes described in this rule, as well as our proposals to maintain certain existing MS-DRG classifications, which are also discussed later in this section of the proposed rule. In some cases, we are proposing changes to the MS-DRG classifications based on our analysis of claims data. In other cases, we are proposing to maintain the existing MS-DRG classification based on our analysis of claims data. For this FY 2017 proposed rule, our MS-DRG analysis is based on claims data from the December 2015 update of the FY 2015 MedPAR file, which contains hospital bills received through September 30, 2015, for discharges occurring through September 30, 2015. In our discussion of the proposed MS-DRG reclassification changes that follows, we refer to our analysis of claims data from the "December 2015 update of the FY 2015 MedPAR file."

As explained in previous rulemaking (76 FR 51487), in deciding whether to propose to make further modification to the MS-DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients in the MS-DRG. We evaluate patient care costs using average costs and lengths of stay and rely on the judgment of our clinical advisors to decide whether patients are clinically distinct or similar to other patients in the MS-DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS-DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally

prefer not to create a new MS-DRG unless it would include a substantial number of cases.

In our examination of the claims data, we apply the following criteria established in FY 2008 (72 FR 47169) to determine if the creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS-DRG is warranted:

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

In order to warrant creation of a CC or MCC subgroup within a base MS-DRG, the subgroup must meet all five of the criteria.

We note that some of the issues being evaluated for the FY 2017 MS-DRGs update continue to relate to the need for the ICD-10 MS-DRGs to accurately replicate the logic of the ICD-9-CM based version of the MS-DRGs. Replication is important because both the logic for the proposed MS-DRGs and the data source used to calculate and develop proposed relative payment weights are based on the same MedPAR claims data. In other words, as the logic for the proposed FY 2017 ICD-10 MS-DRGs is based upon the FY 2015 ICD-9-CM MedPAR claims data, the data source used to calculate and develop the proposed FY 2017 relative payment weights is also based on the FY 2015 ICD-9-CM MedPAR claims data, including any proposed MS-DRG classification changes discussed in this proposed rule. This is consistent with how the current FY 2016 relative payment weights are based on the ICD-9-CM diagnosis and procedure codes from the FY 2014 MedPAR claims data that were grouped through the ICD-9-CM version of the FY 2016 GROUPER Version 33. We note that we made the MS-DRG GROUPER and Medicare Code Editor (MCE) ICD-9-CM Software Version 33 available to the public for use in analyzing ICD-9-CM data to create relative payment weights using ICD-9-CM data on our CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page.html?DLSort=0&DLEntries=10&DLPage=1&DLSortDir=ascending>. Therefore, as discussed in section II.G.

of the preamble of this proposed rule, ICD-9-CM data were used for computing the proposed FY 2017 MS-DRG relative payment weights. If the ICD-9 and ICD-10 versions of MS-DRGs cease to be replications of each other, the relative payment weights computed using the ICD-9 claims data and MS-DRGs would be inconsistent with the relative payment weights assigned for the ICD-10 MS-DRGs, causing unintended payment redistributions. Thus, if the findings of our data analyses and the recommendations of our clinical advisors supported modifications to the current ICD-10 MS-DRG structure, prior to proposing any changes, we first evaluated whether the requested change could be replicated in the ICD-9-CM MS-DRGs. If the answer was "yes," from a replication perspective, the change was considered feasible. If the answer was "no," we examined whether the change in the ICD-10 MS-DRGs was likely to cause a significant number of patient cases to change or "shift" ICD-10 MS-DRGs. If relatively few patient cases would be impacted, we evaluated if it would be feasible to propose the change even though it could not be replicated by the ICD-9 MS-DRGs because it would not cause a material payment redistribution. For the ICD-10 MS-DRG classification change requests that could not be replicated in ICD-9-CM and that would cause a significant number of patient cases to shift MS-DRG assignment, we considered other alternatives.

## 2. Pre-Major Diagnostic Category (Pre-MDC): Total Artificial Heart Replacement

An ICD-10 MS-DRG replication issue regarding the assignment of two ICD-10-PCS procedure codes was identified after the October 1, 2015 implementation of the Version 33 ICD-10 MS-DRGs. ICD-10-PCS procedure codes 02RK0JZ (Replacement of right ventricle with synthetic substitute, open approach) and 02RL0JZ (Replacement of left ventricle with synthetic substitute, open approach), when reported together, describe a biventricular heart replacement (artificial heart). Under the Version 32 ICD-9-CM based MS-DRGs, this procedure was described by ICD-9-CM procedure code 37.52 (Implantation of total internal biventricular heart replacement system) and grouped to MS-DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System with and without MCC, respectively).

As discussed in section II.F.1.a. of the preamble of this proposed rule, to assist in the conversion from the ICD-9-CM

based MS-DRGs to ICD-10, beginning in FY 2011, draft versions of the ICD-10 based MS-DRGs were developed and made available for public comment. The two ICD-10-PCS procedure codes (02RK0JZ and 02RL0JZ) were assigned as a “cluster” to the draft ICD-10 based MS-DRGs 001 and 002 in prior draft versions of the ICD-10 MS-DRGs. In ICD-10-PCS, a cluster is the term used to describe when a combination of ICD-10-PCS procedure codes are needed to fully satisfy the equivalent meaning of an ICD-9-CM procedure code for it to be considered a plausible translation. Upon review of prior draft versions of the ICD-10 MS-DRGs, it was determined that Version 30 was the last version to include ICD-10-PCS procedure codes 02RK0JZ and 02RL0JZ as a code cluster (from ICD-9-CM procedure code 37.52) that grouped to the draft ICD-10 based MS-DRGs 001 and 002. Subsequent draft versions of the ICD-10 MS-DRGs inadvertently omitted this code cluster from those MS-DRGs.

Therefore, for FY 2017, we are proposing to assign ICD-10-PCS procedure codes 02RK0JZ and 02RL0JZ as a code cluster to ICD-10 Version 34 MS-DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System with and without MCC,

respectively) to accurately replicate the Version 32 ICD-9-CM based MS-DRG logic of procedure code 37.52. We are inviting public comments on our proposal.

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

a. Endovascular Embolization (Coiling) or Occlusion of Head and Neck Procedures

We received a repeat request to change the MS-DRG assignment for procedure codes describing endovascular embolization (coiling) or occlusion of the head and neck. This topic was discussed in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28005 through 28007); the FY 2015 IPPS/LTCH PPS final rule (79 FR 49883 through 49886); the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24351 through 24356); and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49358 through 49363). For these 2 fiscal years, we did not change the MS-DRG assignment for procedure codes describing endovascular embolization (coiling) or occlusion of the head and neck for the reasons discussed in these proposed and final rules.

For FY 2017, the requestor again asked that CMS change the MS-DRG assignment for procedure codes

describing endovascular embolization or occlusion of the head and neck as well as several other codes describing endovascular procedures of the head and neck.

The ICD-10-PCS procedure codes listed in the following table capture endovascular embolization or occlusion of the head and neck procedures that are assigned to the following MS-DRGs in ICD-10 Version 33 MS-DRGs: MS-DRG 020 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage with MCC); MS-DRG 021 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage with CC); MS-DRG 022 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage without CC/MCC); MS-DRG 023 (Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis with MCC or Chemo Implant); MS-DRG 024 (Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis without MCC); MS-DRG 025 (Craniotomy and Endovascular Intracranial Procedures with MCC); MS-DRG 026 (Craniotomy and Endovascular Intracranial Procedures with CC); and MS-DRG 027 (Craniotomy and Endovascular Intracranial Procedures without CC/MCC):

ICD-10-PCS CODES FOR ENDOVASCULAR EMBOLIZATION OR OCCLUSION OF THE HEAD AND NECK PROCEDURES ASSIGNED TO MS-DRGS 020 THROUGH 027 IN ICD-10 MS-DRGS VERSION 33

ICD-10-PCS code	Code description
03LG3BZ .....	Occlusion of intracranial artery with bioactive intraluminal device, percutaneous approach.
03LG3DZ .....	Occlusion of intracranial artery with intraluminal device, percutaneous approach.
03LG4BZ .....	Occlusion of intracranial artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LG4DZ .....	Occlusion of intracranial artery with intraluminal device, percutaneous endoscopic approach.
03LH3BZ .....	Occlusion of right common carotid artery with bioactive intraluminal device, percutaneous approach.
03LH3DZ .....	Occlusion of right common carotid artery with intraluminal device, percutaneous approach.
03LH4BZ .....	Occlusion of right common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LH4DZ .....	Occlusion of right common carotid artery with intraluminal device, percutaneous endoscopic approach.
03LJ3BZ .....	Occlusion of left common carotid artery with bioactive intraluminal device, percutaneous approach.
03LJ3DZ .....	Occlusion of left common carotid artery with intraluminal device, percutaneous approach.
03LJ4BZ .....	Occlusion of left common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LJ4DZ .....	Occlusion of left common carotid artery with intraluminal device, percutaneous endoscopic approach.
03LK3BZ .....	Occlusion of right internal carotid artery with bioactive intraluminal device, percutaneous approach.
03LK3DZ .....	Occlusion of right internal carotid artery with intraluminal device, percutaneous approach.
03LK4BZ .....	Occlusion of right internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LK4DZ .....	Occlusion of right internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03LL3BZ .....	Occlusion of left internal carotid artery with bioactive intraluminal device, percutaneous approach.
03LL3DZ .....	Occlusion of left internal carotid artery with intraluminal device, percutaneous approach.
03LL4BZ .....	Occlusion of left internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LL4DZ .....	Occlusion of left internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03LM3BZ .....	Occlusion of right external carotid artery with bioactive intraluminal device, percutaneous approach.
03LM3DZ .....	Occlusion of right external carotid artery with intraluminal device, percutaneous approach.
03LM4BZ .....	Occlusion of right external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LM4DZ .....	Occlusion of right external carotid artery with intraluminal device, percutaneous endoscopic approach.
03LN3BZ .....	Occlusion of left external carotid artery with bioactive intraluminal device, percutaneous approach.
03LN3DZ .....	Occlusion of left external carotid artery with intraluminal device, percutaneous approach.
03LN4BZ .....	Occlusion of left external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LN4DZ .....	Occlusion of left external carotid artery with intraluminal device, percutaneous endoscopic approach.
03LP3BZ .....	Occlusion of right vertebral artery with bioactive intraluminal device, percutaneous approach.
03LP3DZ .....	Occlusion of right vertebral artery with intraluminal device, percutaneous approach.
03LP4BZ .....	Occlusion of right vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.

ICD-10-PCS CODES FOR ENDOVASCULAR EMBOLIZATION OR OCCLUSION OF THE HEAD AND NECK PROCEDURES  
ASSIGNED TO MS-DRGs 020 THROUGH 027 IN ICD-10 MS-DRGs VERSION 33—Continued

ICD-10-PCS code	Code description
03LP4DZ .....	Occlusion of right vertebral artery with intraluminal device, percutaneous endoscopic approach.
03LQ3BZ .....	Occlusion of left vertebral artery with bioactive intraluminal device, percutaneous approach.
03LQ3DZ .....	Occlusion of left vertebral artery with intraluminal device, percutaneous approach.
03LQ4BZ .....	Occlusion of left vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LQ4DZ .....	Occlusion of left vertebral artery with intraluminal device, percutaneous endoscopic approach.
03LR3DZ .....	Occlusion of face artery with intraluminal device, percutaneous approach.
03LR4DZ .....	Occlusion of face artery with intraluminal device, percutaneous endoscopic approach.
03LS3DZ .....	Occlusion of right temporal artery with intraluminal device, percutaneous approach.
03LS4DZ .....	Occlusion of right temporal artery with intraluminal device, percutaneous endoscopic approach.
03LT3DZ .....	Occlusion of left temporal artery with intraluminal device, percutaneous approach.
03LT4DZ .....	Occlusion of left temporal artery with intraluminal device, percutaneous endoscopic approach.
03VG3BZ .....	Restriction of intracranial artery with bioactive intraluminal device, percutaneous approach.
03VG3DZ .....	Restriction of intracranial artery with intraluminal device, percutaneous approach.
03VG4BZ .....	Restriction of intracranial artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VG4DZ .....	Restriction of intracranial artery with intraluminal device, percutaneous endoscopic approach.
03VH3BZ .....	Restriction of right common carotid artery with bioactive intraluminal device, percutaneous approach.
03VH3DZ .....	Restriction of right common carotid artery with intraluminal device, percutaneous approach.
03VH4BZ .....	Restriction of right common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VH4DZ .....	Restriction of right common carotid artery with intraluminal device, percutaneous endoscopic approach.
03VJ3BZ .....	Restriction of left common carotid artery with bioactive intraluminal device, percutaneous approach.
03VJ3DZ .....	Restriction of left common carotid artery with intraluminal device, percutaneous approach.
03VJ4BZ .....	Restriction of left common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VJ4DZ .....	Restriction of left common carotid artery with intraluminal device, percutaneous endoscopic approach.
03VK3BZ .....	Restriction of right internal carotid artery with bioactive intraluminal device, percutaneous approach.
03VK3DZ .....	Restriction of right internal carotid artery with intraluminal device, percutaneous approach.
03VK4BZ .....	Restriction of right internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VK4DZ .....	Restriction of right internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03VL3BZ .....	Restriction of left internal carotid artery with bioactive intraluminal device, percutaneous approach.
03VL3DZ .....	Restriction of left internal carotid artery with intraluminal device, percutaneous approach.
03VL4BZ .....	Restriction of left internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VL4DZ .....	Restriction of left internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03VM3BZ .....	Restriction of right external carotid artery with bioactive intraluminal device, percutaneous approach.
03VM3DZ .....	Restriction of right external carotid artery with intraluminal device, percutaneous approach.
03VM4BZ .....	Restriction of right external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VM4DZ .....	Restriction of right external carotid artery with intraluminal device, percutaneous endoscopic approach.
03VN3BZ .....	Restriction of left external carotid artery with bioactive intraluminal device, percutaneous approach.
03VN3DZ .....	Restriction of left external carotid artery with intraluminal device, percutaneous approach.
03VN4BZ .....	Restriction of left external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VN4DZ .....	Restriction of left external carotid artery with intraluminal device, percutaneous endoscopic approach.
03VP3BZ .....	Restriction of right vertebral artery with bioactive intraluminal device, percutaneous approach.
03VP3DZ .....	Restriction of right vertebral artery with intraluminal device, percutaneous approach.
03VP4BZ .....	Restriction of right vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VP4DZ .....	Restriction of right vertebral artery with intraluminal device, percutaneous endoscopic approach.
03VQ3BZ .....	Restriction of left vertebral artery with bioactive intraluminal device, percutaneous approach.
03VQ3DZ .....	Restriction of left vertebral artery with intraluminal device, percutaneous approach.
03VQ4BZ .....	Restriction of left vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VQ4DZ .....	Restriction of left vertebral artery with intraluminal device, percutaneous endoscopic approach.
03VR3DZ .....	Restriction of face artery with intraluminal device, percutaneous approach.
03VR4DZ .....	Restriction of face artery with intraluminal device, percutaneous endoscopic approach.
03VS3DZ .....	Restriction of right temporal artery with intraluminal device, percutaneous approach.
03VS4DZ .....	Restriction of right temporal artery with intraluminal device, percutaneous endoscopic approach.
03VT3DZ .....	Restriction of left temporal artery with intraluminal device, percutaneous approach.
03VT4DZ .....	Restriction of left temporal artery with intraluminal device, percutaneous endoscopic approach.
03VU3DZ .....	Restriction of right thyroid artery with intraluminal device, percutaneous approach.
03VU4DZ .....	Restriction of right thyroid artery with intraluminal device, percutaneous endoscopic approach.
03VV3DZ .....	Restriction of left thyroid artery with intraluminal device, percutaneous approach.
03VV4DZ .....	Restriction of left thyroid artery with intraluminal device, percutaneous endoscopic approach.

Cases reporting any of the ICD-10-PCS procedure codes listed in the table above that are assigned to MS-DRGs 020, 021, and 022 under MDC 1 require a principal diagnosis of hemorrhage. Cases reporting any of the ICD-10-PCS procedure codes listed in the table above that are assigned to MS-DRGs 023

and 024 require the insertion of a major implant or an acute complex central nervous system (CNS) principal diagnosis. Cases reporting any of the ICD-10-PCS procedure codes listed in the table above that are assigned to MS-DRGs 025, 026, and 027 do not have a principal diagnosis of hemorrhage, an

acute complex CNS principal diagnosis, or a major device implant.

The requestor expressed concerns about the appropriateness of the MS-DRG assignment for the endovascular embolization or occlusion of head and neck procedures. The requestor stated that past data demonstrated that the cost of cases involving endovascular coils

exceeds the average cost of all cases within each of the MS-DRGs to which these procedures are assigned. The requestor pointed out that these procedures were formerly captured by the following ICD-9-CM codes that were assigned to MS-DRGs 020 through 027:

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

The commenter also expressed concern about the appropriateness of the current ICD-10 MS-DRG assignment of the following ICD-9-CM codes that describe other endovascular procedures of head and neck that were previously assigned to MS-DRGs 023 through 027 in the ICD-9-CM MS-DRGs Version 32. The commenter stated that these procedures are more clinically complex than other procedures assigned to these MS-DRGs.

- 00.62 (Percutaneous angioplasty of intracranial vessels(s));
- 39.74 (Endovascular removal of obstruction from head and neck vessel(s)); and

- 39.79 (Other endovascular procedures on other vessels).

We examined claims data from the December 2015 update of the FY 2015 MedPAR file for the endovascular embolization or occlusion of the head and neck procedures or other endovascular procedures reported under ICD-9-CM procedure codes 00.62, 39.72, 39.74, 39.75, 39.76, and 39.79 in MS-DRGs 020 through 027. The table below shows our findings.

**ENDOASCULAR EMBOLIZATION OR OCCLUSION OF THE HEAD AND NECK PROCEDURES AND OTHER ENDOASCULAR PROCEDURES**

MS-DRG	Number of cases	Average length of stay	Average costs
MS-DRG 020—All cases .....	1,213	16.44	\$70,716
MS-DRG 020—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76, or 39.79 .....	895	16.15	72,357
MS-DRG 021—All cases .....	350	13.74	53,289
MS-DRG 021—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76, or 39.79 .....	272	13.21	53,478
MS-DRG 022—All cases .....	84	7.83	33,598
MS-DRG 022—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76, or 39.79 .....	63	7.27	33,606
MS-DRG 023—All cases .....	6,360	10.63	38,204
MS-DRG 023—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76, or 39.79 .....	2,183	8.57	38,935
MS-DRG 024—All cases .....	2,376	5.52	28,270
MS-DRG 024—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76, or 39.79 .....	1,402	5.46	28,543
MS-DRG 025—All cases .....	17,756	9.19	29,657
MS-DRG 025—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76 or 39.79 .....	671	9.20	47,579
MS-DRG 026—All cases .....	7,630	5.80	21,441
MS-DRG 026—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76, or 39.79 .....	825	3.11	27,429
MS-DRG 027—All cases .....	9,628	2.99	17,158
MS-DRG 027—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76 or 39.79 .....	1,847	1.62	22,845

As can be seen from the table, most of the cases of endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures reported with procedure codes 00.62, 39.72, 39.74, 39.75, 39.76, and 39.79 occur in MS-DRGs 023, 024, and 027. There were 2,183 of these procedure cases reported in MS-DRG 023 with an average length of stay of 8.57 days and average costs of \$38,935, compared to an average length of stay of 10.63 days and average costs of \$38,204 for all 6,360 cases reported in MS-DRG 023. There were 1,402 of these cases reported in MS-DRG 024 with an average length of stay of 5.46 days and average costs of \$28,543, compared to an average length of stay of 5.52 days and average costs of \$28,270 for all 2,376 cases reported in MS-DRG 024. There were 1,847 of these cases reported in MS-DRG 027 with an average length of stay of 1.62 days and average costs of \$22,845, compared to an average length of stay of 2.99 days and average costs of \$17,158 for all

9,628 cases reported in MS-DRG 027. The average costs for endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS-DRGs 023 and 024 are not significantly different from the average costs for all cases reported in MS-DRGs 023 and 024. The average costs for endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS-DRG 027 are higher (\$22,845) than the average costs of all cases reported in MS-DRG 027 (\$17,158). However, average costs are not significantly different for the endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS-DRG 020 (\$72,357) compared to the average costs for all cases (\$70,716) reported in MS-DRS 020; for the endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS-DRG

021 (\$53,478) compared to the average costs for all cases (\$53,289) reported in MS-DRG 021; and for the endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS-DRG 022 (\$33,606) compared to the average costs for all cases (\$33,598) reported in MS-DRG 022.

Average costs were higher for the 671 endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS-DRG 025 (\$47,579) compared to the average costs for all 17,756 cases (\$29,657) reported in MS-DRG 025. The average costs also were higher for the 825 endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS-DRG 26 (\$27,429) compared to the average costs for all 7,630 cases (\$21,441) reported in MS-DRG 26. Given that average costs are similar for most endovascular embolization or occlusion of the head and neck

procedures and other endovascular procedures cases reported in MS-DRGs 020, 021, 022, 023, 024, 025, 026, and 027, we do not believe that all endovascular embolization or occlusion of the head and neck procedures and

other endovascular procedures should be reassigned from these eight MS-DRGs.

We also examined the average costs for each specific ICD-9-CM code compared to the average costs of all

cases within each of the eight MS-DRGs. The following table shows our findings.

MS-DRG	Number of cases	Average length of stay	Average costs
MS-DRG 020—All cases	1,213	16.44	\$70,716
MS-DRG 020—Cases with code 00.62	11	16.09	95,422
MS-DRG 020—Cases with code 39.72	422	16.31	74,951
MS-DRG 020—Cases with code 39.74	9	16.78	71,478
MS-DRG 020—Cases with code 39.75	424	15.79	69,081
MS-DRG 020—Cases with code 39.76	39	18.26	71,630
MS-DRG 020—Cases with code 39.79	25	16.64	73,043
MS-DRG 021—All cases	350	13.74	53,289
MS-DRG 021—Cases with code 00.62	1	11.00	75,492
MS-DRG 021—Cases with code 39.72	130	13.12	54,715
MS-DRG 021—Cases with code 39.74	1	11.00	75,492
MS-DRG 021—Cases with code 39.75	133	13.46	52,819
MS-DRG 021—Cases with code 39.76	7	10.57	48,749
MS-DRG 021—Cases with code 39.79	3	12.00	40,458
MS-DRG 022—All cases	84	7.83	33,598
MS-DRG 022—Cases with code 00.62	0	0	0
MS-DRG 022—Cases with code 39.72	40	6.43	32,598
MS-DRG 022—Cases with code 39.74	0	0	0
MS-DRG 022—Cases with code 39.75	21	8.81	32,690
MS-DRG 022—Cases with code 39.76	3	10.00	62,417
MS-DRG 022—Cases with code 39.79	0	0	0
MS-DRG 023—All cases	6,360	10.63	38,204
MS-DRG 023—Cases with code 00.62	67	9.30	43,741
MS-DRG 023—Cases with code 39.72	56	11.14	52,589
MS-DRG 023—Cases with code 39.74	2,016	8.30	38,047
MS-DRG 023—Cases with code 39.75	20	12.65	53,837
MS-DRG 023—Cases with code 39.76	3	23.00	84,947
MS-DRG 023—Cases with code 39.79	71	13.08	50,720
MS-DRG 024—All cases	2,376	5.52	28,270
MS-DRG 024—Cases with code 00.62	76	6.74	32,415
MS-DRG 024—Cases with code 39.72	31	6.35	29,977
MS-DRG 024—Cases with code 39.74	1,284	5.35	28,268
MS-DRG 024—Cases with code 39.75	8	6.50	50,333
MS-DRG 024—Cases with code 39.76	2	1.50	19,567
MS-DRG 024—Cases with code 39.79	27	6.74	28,019
MS-DRG 025—All cases	17,756	9.19	29,657
MS-DRG 025—Cases with code 00.62	17	5.88	29,036
MS-DRG 025—Cases with code 39.72	380	9.46	51,082
MS-DRG 025—Cases with code 39.74	55	9.87	45,895
MS-DRG 025—Cases with code 39.75	139	8.94	52,188
MS-DRG 025—Cases with code 39.76	25	5.84	38,654
MS-DRG 025—Cases with code 39.79	82	11.04	39,839
MS-DRG 026—All cases	7,630	5.80	21,441
MS-DRG 026—Cases with code 00.62	31	3.48	25,611
MS-DRG 026—Cases with code 39.72	481	3.00	27,180
MS-DRG 026—Cases with code 39.74	16	4.69	27,519
MS-DRG 026—Cases with code 39.75	253	2.77	26,863
MS-DRG 026—Cases with code 39.76	31	3.32	27,891
MS-DRG 026—Cases with code 39.79	45	5.42	37,410
MS-DRG 027—All cases	9,628	2.99	17,158
MS-DRG 027—Cases with code 00.62	61	2.23	21,337
MS-DRG 027—Cases with code 39.72	1,159	1.58	22,893
MS-DRG 027—Cases with code 39.74	13	1.62	69,081
MS-DRG 027—Cases with code 39.75	580	1.63	23,296
MS-DRG 027—Cases with code 39.76	61	1.74	27,403
MS-DRG 027—Cases with code 39.79	30	1.53	17,740

As can be seen from the table above, there are a large number of cases reporting procedure code 39.74 in MS-DRGs 023 and 024. There were 2,016 cases that reported procedure code

39.74 in MS-DRG 023 compared to 6,360 total cases reported in the MS-DRG. The cases that reported procedure code 39.74 in MS-DRG 023 had an average length of stay of 8.30 days and

average costs of \$38,047, compared to an average length of stay of 10.63 days and average costs of \$38,204 for all cases reported in MS-DRG 023. There were 1,284 cases that reported

procedure code 39.74 in MS-DRG 024 compared to 2,376 total cases reported in MS-DRG 024. The cases that reported procedure code 39.74 in MS-DRG 024 had an average length of stay of 5.35 days and average costs of \$28,268, compared to an average length of stay of 5.52 days and average costs of \$28,270 for all cases reported in MS-DRG 024. The average length of stay and average costs for cases that reported procedure code 39.74 are very similar to the average length of stay and average costs for all cases reported in MS-DRGs 023 and 024. The only other group of endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases that exceeded 1,000 in number was reported in MS-DRG 027. There were 1,159 cases that reported procedure code 39.72 in MS-DRG 027, compared to 9,628 total cases reported in MS-DRG 027. The cases that reported procedure code 39.72 in MS-DRG 027 had an average length of stay of 1.58 days and average costs of \$22,893, compared to an average length of stay of 2.99 days and average costs of \$17,158 for all cases reported in MS-DRG 027. In other words, the cases that reported procedure code 39.72 in MS-DRG 027 had a shorter average length of stay and average costs that were \$5,735 higher than the average costs for all cases reported in MS-DRG 027. The cases that reported procedure code 39.72 in MS-DRG 020 had a shorter average length of stay and average costs that were \$4,235 higher than the average costs for all cases reported in MS-DRG 020. However, the average costs for the cases that reported procedure code 39.72 in MS-DRGs 021, 022, and 024 were close to the average costs for all cases reported in the three MS-DRGs (\$54,715 compared to \$53,289 in MS-DRG 021; \$32,598 compared to \$33,598 in MS-DRG 022; and \$29,997 compared to \$28,270 in MS-DRG 024).

Our clinical advisors reviewed this issue and advised us that the endovascular embolization or occlusion of head and neck procedures and other endovascular procedures currently are appropriately assigned to MS-DRGs 020 through 027. They did not support reassigning these procedures from MS-DRGs 020 through 027 to another MS-DRG or creating a new MS-DRG for these procedures. Our clinical advisors stated that these procedures are all clinically similar to other procedures in these MS-DRGs. In addition, they stated that the surgical techniques are all designed to correct the same clinical problem and advised us against

reassigning the procedures from MS-DRGs 020 through 027.

Based on the findings from our data analyses and the recommendations from our clinical advisors, we are not proposing to reassign the cited endovascular embolization or occlusion of head and neck procedures and other endovascular procedures from MS-DRGs 020 through 027 to another MS-DRG or to create a new MS-DRG for these procedures for FY 2017. We are inviting public comments on our proposal to maintain the current MS-DRG assignments of these procedures in MS-DRGs 020 through 027.

#### b. Mechanical Complication Codes

We received a request to reassign the following four ICD-10-CM diagnosis codes from MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs) under MS-DRGs 919, 920, and 921 (Complications of Treatment with MCC, with CC, and without CC/MCC, respectively) to MDC 1 (Diseases and Disorders of the Nervous System) under MS-DRGs 091, 092, and 093 (Other Disorders of the Nervous System with MCC, with CC, and without CC/MCC, respectively):

- T85.610A (Breakdown (mechanical) of epidural and subdural infusion catheter, initial encounter);
- T85.620A (Displacement of epidural and subdural infusion catheter, initial encounter);
- T85.630A (Leakage of epidural and subdural infusion catheter, initial encounter); and
- T85.690A (Other mechanical complication of epidural and subdural infusion catheter, initial encounter).

The requestor stated that these ICD-10-CM diagnosis code titles clearly describe mechanical complications of nervous system devices, implants, or grafts and are unquestionably nervous system codes. Therefore, the requestor recommended that these diagnosis codes be reassigned to MDC 1 under MS-DRGs 091, 092, and 093.

We examined ICD-10-CM diagnosis codes T85.610A, T85.620A, T85.630A, and T85.690A that are currently assigned to MDC 21 under MS-DRGs 919, 920, and 921. We note that the predecessor ICD-9-CM diagnosis code for these four ICD-10-CM diagnosis codes was diagnosis code 996.59 (Mechanical complication due to other implant and internal device, not elsewhere classified), which also was assigned to MDC 21 under MS-DRGs 919, 920, and 921. ICD-9-CM diagnosis code 996.59 did not describe the location of the device. However, ICD-10-CM diagnosis codes T85.610A, T85.620A, T85.630A, and T85.690A

provide additional detail that describes the location of the mechanical complication as being within the nervous system.

Based on the results of our examination, we agree with the requestor that ICD-10-CM diagnosis codes T85.610A, T85.620A, T85.630A, and T85.690A describe conditions occurring within the nervous system. Within the ICD-9-CM MS-DRGs, codes describing nervous system disorders were assigned to MDC 1. The prior ICD-9-CM codes for mechanical complications did not indicate the type of complication and therefore could not be assigned to a specific MDC. Therefore, the nonspecific complication codes were assigned to MDC 21. These new ICD-10-CM diagnosis codes describe concepts not previously captured by the ICD-9-CM codes and capture nervous system conditions. Therefore, ICD-10-CM diagnosis codes T85.610A, T85.620A, T85.630A, and T85.690A should be reassigned from MDC 21 under MS-DRGs 919, 920, and 921 to MDC 1 under MS-DRGs 091, 092, and 093. Our clinical advisors reviewed this issue and also agree that the four ICD-10-CM diagnosis codes describe conditions occurring within the nervous system and therefore should be reassigned from MDC 21 to MDC 1. Based on the results of our analysis and the recommendations of our clinical advisors, we are proposing to reassign ICD-10-CM diagnosis codes T85.610A, T85.620A, T85.630A, and T85.690A from MDC 21 under MS-DRGs 919, 920, and 921 to MDC 1 under MS-DRGs 091, 092, and 093.

We are inviting public comments on our proposal.

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

##### a. Proposed Reassignment of Diagnosis Code R22.2 (Localized Swelling, Mass and Lump, Trunk)

We received a request to reassign ICD-10-CM diagnosis code R22.2 (Localized swelling, mass and lump, trunk) from MDC 4 (Diseases and Disorders of the Respiratory System) to MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast). The requestor stated that this code is used to capture a buttock mass. The requestor pointed out that the ICD-10-CM index for localized swelling and localized mass directs the coder to diagnosis code R22.2 for both the chest and the trunk as sites.

We reviewed this issue and note that diagnosis code R22.2 is included in a category of ICD-10-CM codes describing symptoms and signs

involving the skin and subcutaneous tissue (categories R20 through R23). Diagnosis code R22.2 is clearly designated within the ICD-10 coding system as a code that describes a condition of the skin and subcutaneous tissue. Therefore, we agree with the requester that ICD-10-CM diagnosis code R22.2 should be reassigned from MDC 4 to MDC 9. One of the predecessor ICD-9-CM codes for ICD-10-CM diagnosis code R22.2 was diagnosis code 782.2 (Localized superficial swelling, mass, or lump), which is assigned to MS-DRG 606 and 607 (Minor Skin Disorders with and without MCC, respectively). Our clinical advisors reviewed this issue and agree that ICD-10-CM diagnosis code R22.2 captures a skin diagnosis. Therefore, for

FY 2017, we are proposing to reassign ICD-10-CM diagnosis code R22.2 from MDC 4 to MDC 9 under MS-DRGs 606 and 607 (Minor Skin Disorders with and without MCC, respectively).

We are inviting public comments on our proposal to reassign ICD-10-CM diagnosis code R22.2 from MDC 4 to MDC 9 under MS-DRGs 606 and 607.

**b. Pulmonary Embolism With tPA or Other Thrombolytic Therapy**

We received a request to create a new MS-DRG or to reassign cases with a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy was administered from MS-DRGs 175 and 176 (Pulmonary Embolism with and without MCC, respectively) to a higher paying MS-

DRG. The requestor suggested that CMS review cases reporting the following ICD-9-CM diagnosis codes describing pulmonary embolism: 415.11 (Iatrogenic pulmonary embolism and infarction), 415.12 (Septic pulmonary embolism), 415.13 (Saddle embolus of pulmonary artery), and 415.19 (Other pulmonary embolism and infarction), when reported in combination with ICD-9-CM procedure code 99.10 (Injection or infusion of thrombolytic agent), to identify that thrombolytic therapy was administered.

The comparable ICD-10-CM diagnosis code translations for the ICD-9-CM pulmonary embolism diagnosis codes to which the requestor cited consist of the following:

ICD-10-CM diagnosis code	Description
I26.01 .....	Septic pulmonary embolism with acute cor pulmonale.
I26.02 .....	Saddle embolus of pulmonary artery with acute cor pulmonale.
I26.09 .....	Other pulmonary embolism with acute cor pulmonale.
I26.90 .....	Septic pulmonary embolism without acute cor pulmonale.
I26.92 .....	Saddle embolus of pulmonary artery without acute cor pulmonale.
I26.99 .....	Other pulmonary embolism without acute cor pulmonale.

Thrombolytic therapy is identified with the following ICD-10-PCS procedure codes:

ICD-10-PCS procedure code	Description
3E03017 .....	Introduction of other thrombolytic into peripheral vein, open approach.
3E03317 .....	Introduction of other thrombolytic into peripheral vein, percutaneous approach.
3E04017 .....	Introduction of other thrombolytic into central vein, open approach.
3E04317 .....	Introduction of other thrombolytic into central vein, percutaneous approach.
3E05017 .....	Introduction of other thrombolytic into peripheral artery, open approach.
3E05317 .....	Introduction of other thrombolytic into peripheral artery, percutaneous approach.
3E06017 .....	Introduction of other thrombolytic into central artery, open approach.
3E06317 .....	Introduction of other thrombolytic into central artery, percutaneous approach.

A pulmonary embolism is an obstruction of pulmonary vasculature most commonly caused by a venous thrombus, and less commonly by fat or tumor tissue or air bubbles or both. Risk factors for a pulmonary embolism include prolonged immobilization from any cause, obesity, cancer, fractured hip or leg, use of certain medications such as oral contraceptives, presence of certain medical conditions such as heart failure, sickle cell anemia, or certain

congenital heart defects. Common symptoms of pulmonary embolism include shortness of breath with or without chest pain, tachycardia, hemoptysis, low grade fever, pleural effusion, and depending on the etiology of the embolus, might include lower extremity pain or swelling, syncope, jugular venous distention, and finally a pulmonary embolus could be asymptomatic.

We examined the claims data from the December 2015 update of the FY 2015 MedPAR file for ICD-9-CM MS-DRGs 175 and 176 for cases with a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy (procedure code 99.10) was administered and cases of a principal diagnosis of pulmonary embolism where no tPA or other thrombolytic therapy was administered. Our findings are shown in the table below.

**PRINCIPAL DIAGNOSIS OF PULMONARY EMBOLISM WITH AND WITHOUT tPA OR OTHER THROMBOLYTIC THERAPY ADMINISTERED**

MS-DRG	Number of cases	Average length of stay	Average costs
MS-DRG 175—All MCC cases .....	19,274	5.76	\$10,479



PRINCIPAL DIAGNOSIS OF PULMONARY EMBOLISM WITH AND WITHOUT tPA OR OTHER THROMBOLYTIC THERAPY ADMINISTERED—Continued

MS-DRG	Number of cases	Average length of stay	Average costs
MS-DRG 175—MCC cases with principal diagnosis of pulmonary embolism with tPA or other thrombolytic therapy administered .....	630	6.31	19,419
MS-DRG 175—MCC cases with principal diagnosis of pulmonary embolism without tPA or other thrombolytic therapy administered .....	18,529	5.74	10,181
MS-DRG 176—All Without MCC cases .....	33,565	3.81	6,645
MS-DRG 176—Without MCC cases with principal diagnosis of pulmonary embolism with tPA or other thrombolytic therapy administered .....	544	5.07	16,345
MS-DRG 176—Without MCC cases with principal diagnosis of pulmonary embolism without tPA or other thrombolytic therapy administered .....	32,789	3.79	6,483

As shown in the table above, for MS-DRG 175, there were a total of 19,274 cases with an average length of stay of 5.76 days and average costs of \$10,479. Of the 19,274 cases in MS-DRG 175, there were 630 cases that reported a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy was also reported with an average length of stay of 6.31 days and average costs of \$19,419. For MS-DRG 176, there were a total of 33,565 cases with an average length of stay of 3.81 days and average costs of \$6,645. Of the 33,565 cases reported in MS-DRG 176, there were 544 cases that reported a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy also was reported with an average length of stay of 5.07 days and average costs of \$16,345.

To address the request we received to create a new MS-DRG, we reviewed the data for the 1,174 total cases (630 and 544, respectively) that reported a principal diagnosis of pulmonary embolism that received tPA or other

thrombolytic therapy in MS-DRGs 175 and 176. As shown in the table above, our data analysis demonstrates the average costs for these cases are higher (\$19,419 compared to \$10,479 for MS-DRG 175, and \$16,345 compared to \$6,645 for MS-DRG 176) and the length of stay is slightly longer (6.31 days compared to 5.76 days for MS-DRG 175, and 5.07 days compared to 3.81 days for MS-DRG 176) compared to all cases reported in MS-DRGs 175 and 176. Out of a total of 52,492 cases (630 + 18,529 + 544 + 32,789) in MS-DRGs 175 and 176 reporting a principal diagnosis of pulmonary embolism, 1,174 (2.24 percent) of these cases also received tPA or other thrombolytic therapy. While we recognize the differences in average costs and length of stay for these cases, the volume of these cases as well as the potential creation of a new MS-DRG for this subset of patients raised some concerns with our clinical advisors. We present our clinical advisors' concerns following the additional data analysis discussions below.

We then conducted additional data analyses to determine if reassignment of cases with a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy was administered to a higher paying MS-DRG was supported. As displayed in the data findings in the tables below, we explored reassigning cases with a principal diagnosis of pulmonary embolism that received tPA or other thrombolytic therapy from MS-DRG 176 to the higher severity level MS-DRG 175. The data do not adequately support this reassignment, as the cases with a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy is administered would continue to be underpaid.

As shown in the data findings in the table below, the initial data analysis for MS-DRG 175 found the average costs for cases that reported a principal diagnosis of pulmonary embolism that received tPA or other thrombolytic therapy were \$19,419, and for MS-DRG 176, the average costs for these cases were \$16,345.

PRINCIPAL DIAGNOSIS OF PULMONARY EMBOLISM WITH tPA OR OTHER THROMBOLYTIC THERAPY ADMINISTERED

MS-DRG	Number of cases	Average length of stay	Average costs
MS-DRG 175—All MCC cases .....	19,274	5.76	\$10,479
MS-DRG 175—MCC cases with principal diagnosis of pulmonary embolism with tPA or other thrombolytic therapy administered .....	630	6.31	19,419
MS-DRG 176—All without MCC cases .....	33,565	3.81	6,645
MS-DRG 176—Without MCC cases with principal diagnosis of pulmonary embolism with tPA or other thrombolytic therapy administered .....	544	5.07	16,345

As displayed in the table below, if we reassigned the 544 cases with a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy is administered from the “without MCC” level, MS-DRG 176, to the “with MCC” severity level, MS-DRG 175, the average costs

for all cases in MS-DRG 175 would be approximately \$10,640. This figure continues to result in a difference of approximately \$9,000 for the MCC cases and \$6,000 for the without MCC cases when compared to findings for the average costs of these cases from the initial data analysis (\$19,419 – \$10,640

= \$8,779 and \$16,345 – \$10,640 = \$5,705, respectively). In addition, our clinical advisors had concerns about the prospect of moving the subset of 544 patients from the “without MCC” level to the “with MCC” level. We present these concerns following the additional data analysis discussion below.

## OPTION OF REASSIGNMENT OF CASES OF PRINCIPAL DIAGNOSIS OF PULMONARY EMBOLISM WITH AND WITHOUT TPA

MS-DRG 175—Cases with pulmonary embolism with MCC or tPA or other thrombolytic therapy .....	19,818	5.74	\$10,640
MS-DRG 176—Cases with pulmonary embolism without MCC .....	33,021	3.79	6,486

We also reviewed claims data in considering the option of adding another severity level to the current structure of MS-DRGs 175 and 176 and assigning the cases with a principal diagnosis of pulmonary embolism that receive tPA or other thrombolytic therapy to the highest level. This option would involve modifying the current 2-way severity level split of “with MCC” and “without MCC” to a 3-way severity

level split of “with MCC or tPA, with CC, and without CC/MCC.” Therefore, it would include proposing new MS-DRGs if the data and our clinical advisors supported creation of new MS-DRGs. However, as displayed in the data findings in the table below, the data did not support this option. In addition to similar results from the previous option’s discussion regarding continued differences in average costs for these

cases, the data failed to meet the criterion that there be at least a \$2,000 difference between the “with CC” and “without CC/MCC” subgroups. Our data analysis shows the average costs in the hypothetical “with CC” subgroup of \$6,932 and the average costs in the hypothetical “without CC/MCC” subgroup of \$5,309. The difference only amounts to \$1,623 (\$6,932 minus \$5,309 = \$1,623).

## PRINCIPAL DIAGNOSIS OF PULMONARY EMBOLISM WITH AND WITHOUT TPA OR OTHER THROMBOLYTIC THERAPY

Optional new MS-DRG	Number of cases	Average length of stay	Average costs
MS-DRG XXX—Pulmonary embolism with MCC or tPA or other thrombolytic therapy .....	19,819	5.74	\$10,641
MS-DRG XXX—Pulmonary embolism with CC .....	23,929	4.04	6,932
MS-DRG XXX—Pulmonary embolism without CC/MCC .....	9,091	3.13	5,309

Lastly, we explored reassigning cases with a principal diagnosis of pulmonary embolism that receive tPA or other thrombolytic therapy to other MS-DRGs within MDC 4. However, our review did not support reassignment of these cases to any other medical MS-DRGs as these cases would not be clinically coherent with the cases assigned to those other MS-DRGs.

In addition to the results of the various data analyses we performed for creating a new MS-DRG or for reassignment of cases of pulmonary embolism with tPA or other thrombolytic therapy to another higher paying MS-DRG, our clinical advisors also expressed a number of concerns. They pointed out that all patients with a diagnosis of pulmonary embolism are considered high risk and the small subset of patients receiving thrombolytic therapy does not necessarily warrant a separate MS-DRG or reassignment at this time. Our clinical advisors noted that it is unclear if: (1) The higher costs associated with receiving tPA or other thrombolytic therapy are due to a different subset of patients or complications; (2) if those patients treated with tPA or other thrombolytic therapy for pulmonary embolism are indeed sicker patients; (3) if the cost of tPA or other thrombolytic therapy for patients with pulmonary embolism is the reason for the higher costs seen with these cases; or (4) if the increased average costs for cases of pulmonary embolism with tPA or other

thrombolytic therapy is a combination of numbers (1) through (3). They recommended maintaining the current structure of MS-DRGs 175 and 176 at this time.

As a result of the data analysis and the concerns expressed by our clinical advisors, we are not proposing to create a new MS-DRG or to reassign cases with a principal diagnosis of pulmonary embolism with tPA or other thrombolytic therapy for FY 2017. We are inviting public comment on our proposal.

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

## a. Implant of Loop Recorder

We received a request to examine a potential ICD-9 to ICD-10 replication issue for procedures describing implantation or revision of loop recorder that were reported using ICD-9-CM procedure code 37.79 (Revision or relocation of cardiac device pocket). A loop recorder is also known as an implantable cardiac monitor. It is indicated for patients who experience episodes of unexplained syncope (fainting), heart palpitations, or patients at risk for various types of cardiac arrhythmias, such as atrial fibrillation or ventricular tachyarrhythmia. Loop recorders function by detecting and monitoring potential episodes of these kinds of conditions. The requestor acknowledged that these implantation procedures are frequently performed in the outpatient setting. However, the

requestor also noted that the implantation procedures are often performed in the inpatient setting and suggested that they be recognized under the ICD-10 MS-DRGs as they had been under the ICD-9-CM based MS-DRG logic.

The requestor stated that, under the ICD-9-CM based MS-DRGs, procedure code 37.79 was designated as an operating room (O.R.) procedure in the Definitions Manual under Appendix E—Operating Room Procedures and Procedure Code/MS-DRG Index and grouped to MS-DRGs 040, 041, and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC or peripheral neurostimulator, and without CC/MCC, respectively); MS-DRGs 260, 261, and 262 (Cardiac Pacemaker Revision Except Device Replacement with MCC, with CC, and without CC/MCC, respectively); MS-DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC and without CC/MCC, respectively); MS-DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively); and MS-DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively).

Under the current Version 33 ICD-10 MS-DRGs, there are two comparable ICD-10-PCS code translations for ICD-9-CM code 37.79. They are procedure codes 0JWT0PZ (Revision of cardiac

rhythm related device in trunk subcutaneous tissue and fascia, open approach) and 0JW3PZ (Revision of cardiac rhythm related device in trunk subcutaneous tissue and fascia, percutaneous approach), which are

designated as O.R. procedures and group to the above listed MS-DRGs. According to the requestor, the following six ICD-10-PCS procedure codes identify the implantation or revision of a loop recorder and were not replicated appropriately because they are currently designated as

nonoperating room (non-O.R.) procedures under the ICD-10 MS-DRGs. The requestor suggested that these codes be designated as O.R. procedures and assigned to the same MS-DRGs as the former ICD-9-CM procedure code 37.79:

ICD-10-PCS procedure code	Description
0JH602Z .....	Insertion of monitoring device into chest subcutaneous tissue and fascia, open approach.
0JH632Z .....	Insertion of monitoring device into chest subcutaneous tissue and fascia, percutaneous approach.
0JH802Z .....	Insertion of monitoring device into abdomen subcutaneous tissue and fascia, open approach.
0JH832Z .....	Insertion of monitoring device into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JWT02Z .....	Revision of monitoring device in trunk subcutaneous tissue and fascia, open approach.
0JW32Z .....	Revision of monitoring device in trunk subcutaneous tissue and fascia, percutaneous approach.

We examined the six ICD-10-PCS procedure codes that the commenter recommended be designated as O.R. procedures and assigned to the same MS-DRGs as ICD-9-CM procedure code 37.79. As discussed in section II.F.1.b. of the preamble of this proposed rule, in evaluating requested MS-DRG changes, we determined if they could be replicated in the ICD-9-CM MS-DRGs so as not to affect the FY 2017 relative payment weights. If the answer was “no,” we examined whether the change in the ICD-10 MS-DRGs was likely to cause a significant number of patient cases to change or “shift” ICD-10 MS-DRGs. If relatively few patient cases would be impacted, we evaluated if it would be feasible to propose the change even though it could not be replicated by the ICD-9 MS-DRGs logic because it would not cause a material payment redistribution.

Under our review, we recognized that the six ICD-10-PCS procedure codes are currently identified as comparable translations of ICD-9-CM procedure code 86.09 (Other incision of skin and subcutaneous tissue), which was designated as a non-O.R. procedure code under the ICD-9-CM based MS-DRGs. Therefore, changing the designation of the six ICD-10-PCS procedure codes from non-O.R. to O.R. for the ICD-10 MS-DRGs cannot be replicated in the ICD-9-CM based MS-DRGs. In other words, we cannot designate ICD-9-CM procedure code 86.09 as an O.R. code. However, we believe that if we limit the change in designation to four of the six identified ICD-10-PCS procedure codes from non-O.R. to O.R., the change would not have any impact. We are not including the two ICD-10-PCS procedure codes that describe the insertion of a monitoring device into the abdomen in our proposal because a loop recorder is not inserted

into that location and it would not be clinically appropriate.

Therefore, for FY 2017, we are proposing to designate the following four ICD-10-PCS codes as O.R. procedures within Appendix E of the Version 34 ICD-10 MS-DRG Definitions Manual:

- 0JH602Z (Insertion of monitoring device into chest subcutaneous tissue and fascia, open approach);
- 0JH632Z (Insertion of monitoring device into chest subcutaneous tissue and fascia, percutaneous approach);
- 0JWT02Z (Revision of monitoring device in trunk subcutaneous tissue and fascia, open approach); and
- 0JW32Z (Revision of monitoring device in trunk subcutaneous tissue and fascia, percutaneous approach).

We also are proposing that the ICD-10 MS-DRG assignment for these four ICD-10-PCS codes replicate the ICD-9-CM based MS-DRG assignment for procedure code 37.79; that is, MS-DRGs 040, 041, 042, 260, 261, 262, 579, 580, 581, 907, 908, 909, 957, 958, and 959 as cited earlier in this section.

We are inviting public comments on our proposals.

**b. Endovascular Thrombectomy of the Lower Limbs**

We received a comment stating that the logic for ICD-10 MS-DRGs Version 33 is not compatible with the ICD-9-CM MS-DRGs Version 32 for the assignment of procedures describing endovascular thrombectomy of the lower limbs. The commenter asked CMS to reconfigure the MS-DRG structure within the ICD-10 MS-DRGs for endovascular thrombectomy of the lower limbs, specifically MS-DRGs 270, 271, and 272 (Endovascular Thrombectomy of the Lower Limbs with MCC, with CC, and without CC/MCC, respectively). The commenter believed that this requested restructuring would be consistent with the MS-DRG

assignments for the other procedures describing lower extremity thrombectomy, and would accurately replicate the logic of the ICD-9-CM MS-DRGs Version 32. Under the ICD-9-CM, endovascular thrombectomy of the lower limbs is described by procedure code 39.79 (Other endovascular procedures on other vessels). The commenter stated that, with deep vein thrombosis (DVT) or any other circulatory system disorders as the principal diagnosis, cases involving procedures described by procedure code 39.79 grouped to ICD-9-CM MS-DRGs 237 and 238 (Major Cardiovascular Procedures with and without MCC, respectively). However, the commenter pointed out that, for FY 2016, ICD-9-CM MS-DRGs 237 and 238 were deleted and replaced with ICD-10 Version 33 MS-DRGs 268 and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon with and without MCC, respectively), for the higher complexity procedures, and MS-DRGs 270, 271, and 272 (Other Major Cardiovascular Procedures with MCC, with CC, and without CC/MCC, respectively), for the lower complexity procedures (80 FR 49389). The commenter stated that ICD-9-CM procedure code 39.79 describes the lower complexity procedures assigned to ICD-10-PCS MS-DRGs 270, 271, and 272. The commenter believed that the comparable ICD-10-PCS procedure codes also should have been assigned to MS-DRGs 270, 271, and 272.

We agree with the requestor that procedures describing endovascular thrombectomy of the lower limbs should be assigned to ICD-10 MS-DRGs 270, 271, and 272. Therefore, for implementation October 1, 2016, we are proposing to restructure the ICD-10-PCS MS-DRG configuration and add the ICD-10-PCS code translations listed in the following chart (which would

capture procedures describing lower limbs) to ICD–10–PCS Version 34  
 endovascular thrombectomy of the MS–DRGs 270, 271, and 272.

ICD–10–PCS ENDOVASCULAR THROMBECTOMY PROCEDURE CODES PROPOSED TO BE ASSIGNED TO MS–DRGs 270,  
 271, AND 272 FOR FY 2017

03C53ZZ .....	Extirpation of matter from right axillary artery, percutaneous approach.
03C63ZZ .....	Extirpation of matter from left axillary artery, percutaneous approach.
03C73ZZ .....	Extirpation of matter from right brachial artery, percutaneous approach.
03C83ZZ .....	Extirpation of matter from left brachial artery, percutaneous approach.
03C93ZZ .....	Extirpation of matter from right ulnar artery, percutaneous approach.
03CA3ZZ .....	Extirpation of matter from left ulnar artery, percutaneous approach.
03CB3ZZ .....	Extirpation of matter from right radial artery, percutaneous approach.
03CC3ZZ .....	Extirpation of matter from left radial artery, percutaneous approach.
03CD3ZZ .....	Extirpation of matter from right hand artery, percutaneous approach.
03CF3ZZ .....	Extirpation of matter from left hand artery, percutaneous approach.
03CY3ZZ .....	Extirpation of matter from upper artery, percutaneous approach.
04CK3ZZ .....	Extirpation of matter from right femoral artery, percutaneous approach.
04CL3ZZ .....	Extirpation of matter from left femoral artery, percutaneous approach.
04CM3ZZ .....	Extirpation of matter from right popliteal artery, percutaneous approach.
04CN3ZZ .....	Extirpation of matter from left popliteal artery, percutaneous approach.
04CP3ZZ .....	Extirpation of matter from right anterior tibial artery, percutaneous approach.
04CQ3ZZ .....	Extirpation of matter from left anterior tibial artery, percutaneous approach.
04CR3ZZ .....	Extirpation of matter from right posterior tibial artery, percutaneous approach.
04CS3ZZ .....	Extirpation of matter from left posterior tibial artery, percutaneous approach.
04CT3ZZ .....	Extirpation of matter from right peroneal artery, percutaneous approach.
04CU3ZZ .....	Extirpation of matter from left peroneal artery, percutaneous approach.
04CV3ZZ .....	Extirpation of matter from right foot artery, percutaneous approach.
04CW3ZZ .....	Extirpation of matter from left foot artery, percutaneous approach.
04CY3ZZ .....	Extirpation of matter from lower artery, percutaneous approach.
05C73ZZ .....	Extirpation of matter from right axillary vein, percutaneous approach.
05C83ZZ .....	Extirpation of matter from left axillary vein, percutaneous approach.
05C93ZZ .....	Extirpation of matter from right brachial vein, percutaneous approach.
05CA3ZZ .....	Extirpation of matter from left brachial vein, percutaneous approach.
05CB3ZZ .....	Extirpation of matter from right basilic vein, percutaneous approach.
05CC3ZZ .....	Extirpation of matter from left basilic vein, percutaneous approach.
05CD3ZZ .....	Extirpation of matter from right cephalic vein, percutaneous approach.
05CF3ZZ .....	Extirpation of matter from left cephalic vein, percutaneous approach.
05CG3ZZ .....	Extirpation of matter from right hand vein, percutaneous approach.
05CH3ZZ .....	Extirpation of matter from left hand vein, percutaneous approach.
05CL3ZZ .....	Extirpation of matter from intracranial vein, percutaneous approach.
05CM3ZZ .....	Extirpation of matter from right internal jugular vein, percutaneous approach.
05CN3ZZ .....	Extirpation of matter from left internal jugular vein, percutaneous approach.
05CP3ZZ .....	Extirpation of matter from right external jugular vein, percutaneous approach.
05CQ3ZZ .....	Extirpation of matter from left external jugular vein, percutaneous approach.
05CR3ZZ .....	Extirpation of matter from right vertebral vein, percutaneous approach.
05CS3ZZ .....	Extirpation of matter from left vertebral vein, percutaneous approach.
05CT3ZZ .....	Extirpation of matter from right face vein, percutaneous approach.
05CV3ZZ .....	Extirpation of matter from left face vein, percutaneous approach.
05CY3ZZ .....	Extirpation of matter from upper vein, percutaneous approach.
06C33ZZ .....	Extirpation of matter from esophageal vein, percutaneous approach.
06CM3ZZ .....	Extirpation of matter from right femoral vein, percutaneous approach.
06CN3ZZ .....	Extirpation of matter from left femoral vein, percutaneous approach.
06CP3ZZ .....	Extirpation of matter from right greater saphenous vein, percutaneous approach.
06CQ3ZZ .....	Extirpation of matter from left greater saphenous vein, percutaneous approach.
06CR3ZZ .....	Extirpation of matter from right lesser saphenous vein, percutaneous approach.
06CS3ZZ .....	Extirpation of matter from left lesser saphenous vein, percutaneous approach.
06CT3ZZ .....	Extirpation of matter from right foot vein, percutaneous approach.

We are inviting public comments on our proposal to assign the ICD–10–PCS procedures describing the endovascular thrombectomy of the lower limbs listed in the table above to ICD–10 Version 34 MS–DRGs 270, 271, and 272 for FY 2017.

c. Pacemaker Procedures Code Combinations

We received a request that CMS examine the list of ICD–10–PCS procedure code combinations that

describe procedures involving pacemakers to determine if some procedure code combinations were excluded from the ICD–10 MS–DRG assignments for MS–DRGs 242, 243, and 244 (Permanent Cardiac Pacemaker Implant with MCC, with CC, and without CC/MCC). The requestor believed that some ICD–10–PCS procedure code combinations describing procedures involving pacemaker devices and leads are not included in the current list.

We reviewed the list of ICD–10–PCS procedure code combinations describing procedures involving pacemakers assigned to ICD–10 MS–DRGs 242, 243, and 244, and determined that our initial approach of using specified procedure code combinations to identify procedures involving pacemakers and leads was overly complex and may have led to inadvertent omissions of qualifying procedure code combinations. Under our initial approach, we developed a list of

possible ICD-10-PCS procedure code combinations that describe procedures involving pacemaker devices and leads as well as ICD-10-PCS procedure code combinations for procedures describing the removal and replacement of pacemaker devices. We now believe that a more appropriate approach would be to compile a list of all procedure codes describing procedures involving pacemaker devices and a list of all procedure codes describing procedures involving pacemaker leads. If a procedure code from the list of procedure codes describing procedures

involving pacemaker devices and a procedure code from the list of procedure codes describing procedures involving pacemaker leads are reported in combination with one another, the case would be assigned to ICD-10 MS-DRGs 242, 243, and 244. We believe that this more generic approach would capture a wider range of possible reported procedure codes describing procedures involving pacemaker devices and leads. Therefore, we are proposing to modify the ICD-10 MS-DRG logic so that if one of the ICD-10-PCS procedure codes describing

procedures involving pacemaker devices listed in column 1 of the table below is reported in combination with one of the ICD-10-PCS procedure codes describing procedures involving leads listed in column 3 of the table below, the case would be assigned to MS-DRGs 242, 243, and 244. We believe that this proposed simplified approach would capture all possible cases reporting procedure code combinations describing procedures involving pacemaker devices and leads to ensure that these cases would be assigned to MS-DRGs 242, 243, and 244.

ICD-10-PCS Procedure codes describing procedures involving cardiac pacemaker devices (any one code reported from this column list) (1)		In combination with (2)	ICD-10-PCS Procedure codes describing procedures involving cardiac pacemaker leads (any one code reported from this column list) (3)	
Procedure code	Code description		Procedure code	Code description
0JH604Z .....	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, open approach.	.....	02H40JZ	Insertion of pacemaker lead into coronary vein, open approach.
0JH605Z .....	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, open approach.	.....	02H40MZ	Insertion of cardiac lead into coronary vein, open approach.
0JH606Z .....	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, open approach.	.....	02H43JZ	Insertion of pacemaker lead into coronary vein, percutaneous approach.
0JH607Z .....	Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, open approach.	.....	02H43MZ	Insertion of cardiac lead into coronary vein, percutaneous approach.
0JH60PZ .....	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach.	.....	02H44JZ	Insertion of pacemaker lead into coronary vein, percutaneous endoscopic approach.
0JH634Z .....	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, percutaneous approach.	.....	02H44MZ	Insertion of cardiac lead into coronary vein, percutaneous endoscopic approach.
0JH635Z .....	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, percutaneous approach.	.....	02H60JZ	Insertion of pacemaker lead into right atrium, open approach.
0JH636Z .....	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, percutaneous approach.	.....	02H60MZ	Insertion of cardiac lead into right atrium, open approach.
0JH637Z .....	Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, percutaneous approach.	.....	02H63JZ	Insertion of pacemaker lead into right atrium, percutaneous approach.
0JH63PZ .....	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach.	.....	02H63MZ	Insertion of cardiac lead into right atrium, percutaneous approach.
0JH804Z .....	Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, open approach.	.....	02H64JZ	Insertion of pacemaker lead into right atrium, percutaneous endoscopic approach.
0JH805Z .....	Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, open approach.	.....	02H64MZ	Insertion of cardiac lead into right atrium, percutaneous endoscopic approach.
0JH806Z .....	Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, open approach.	.....	02H70JZ	Insertion of pacemaker lead into left atrium, open approach.
0JH807Z .....	Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, open approach.	.....	02H70MZ	Insertion of cardiac lead into left atrium, open approach.
0JH80PZ .....	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, open approach.	.....	02H73JZ	Insertion of pacemaker lead into left atrium, percutaneous approach.
0JH834Z .....	Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, percutaneous approach.	.....	02H73MZ	Insertion of cardiac lead into left atrium, percutaneous approach.

ICD-10-PCS Procedure codes describing procedures involving cardiac pacemaker devices (any one code reported from this column list) (1)		In combination with (2)	ICD-10-PCS Procedure codes describing procedures involving cardiac pacemaker leads (any one code reported from this column list) (3)	
Procedure code	Code description		Procedure code	Code description
OJH835Z .....	Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, percutaneous approach.	.....	02H74JZ	Insertion of pacemaker lead into left atrium, percutaneous endoscopic approach.
OJH836Z .....	Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, percutaneous approach.	.....	02H74MZ	Insertion of cardiac lead into left atrium, percutaneous endoscopic approach.
OJH837Z .....	Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, percutaneous approach.	.....	02HK0JZ	Insertion of pacemaker lead into right ventricle, open approach.
OJH83PZ .....	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, percutaneous approach.	.....	02HK0MZ	Insertion of cardiac lead into right ventricle, open approach.
			02HK3JZ	Insertion of pacemaker lead into right ventricle, percutaneous approach.
			02HK3MZ	Insertion of cardiac lead into right ventricle, percutaneous approach.
			02HK4JZ	Insertion of pacemaker lead into right ventricle, percutaneous endoscopic approach.
			02HK4MZ	Insertion of cardiac lead into right ventricle, percutaneous endoscopic approach.
			02HL0JZ	Insertion of pacemaker lead into left ventricle, open approach.
			02HL0MZ	Insertion of cardiac lead into left ventricle, open approach.
			02HL3JZ	Insertion of pacemaker lead into left ventricle, percutaneous approach.
			02HL3MZ	Insertion of cardiac lead into left ventricle, percutaneous approach.
			02HL4JZ	Insertion of pacemaker lead into left ventricle, percutaneous endoscopic approach.
			02HL4MZ	Insertion of cardiac lead into left ventricle, percutaneous endoscopic approach.
			02HN0JZ	Insertion of pacemaker lead into pericardium, open approach.
			02HN0MZ	Insertion of cardiac lead into pericardium, open approach.
			02HN3JZ	Insertion of pacemaker lead into pericardium, percutaneous approach.
			02HN3MZ	Insertion of cardiac lead into pericardium, percutaneous approach.
			02HN4JZ	Insertion of pacemaker lead into pericardium, percutaneous endoscopic approach.
			02HN4MZ	Insertion of cardiac lead into pericardium, percutaneous endoscopic approach.

We are inviting public comments on our proposal to modify the MS-DRG logic for MS-DRGs 242, 243, and 244 to establish that cases reporting one ICD-10-PCS code from the list of procedure codes describing procedures involving pacemaker devices and one ICD-10-PCS code from the list of procedure codes describing procedures involving pacemaker leads in combination with one another would qualify the case for assignment to MS-DRGs 242, 243, and 244.

We also examined our GROUPE logic for MS-DRGs 258 and 259

(Cardiac Pacemaker Device Replacement with and without MCC, respectively). Assignments of cases to these MS-DRGs also include qualifying ICD-10-PCS procedure code combinations describing procedures that involve the removal of pacemaker devices and the insertion of new devices. We believe that this logic may also be overly complex. Moreover, we believe that a more simplified approach would be to compile a list of all ICD-10-PCS procedure codes describing procedures involving cardiac pacemaker device insertions. Therefore, we are proposing this approach for FY

2017. Under the proposed approach, if one of the procedure codes describing procedures involving pacemaker device insertions is reported, and there are no other procedure codes describing procedures involving the insertion of a pacemaker lead reported in combination with one of these procedures, the case would be assigned to MS-DRG 258 and 259. Cases reporting any one of the following ICD-10-PCS procedure codes describing procedures involving pacemaker device insertions would be assigned to MS-DRG 258 and 259.

PROCEDURE CODES DESCRIBING PROCEDURES INVOLVING CARDIAC PACEMAKER DEVICE INSERTIONS REPORTED WITHOUT ANY OTHER PACEMAKER DEVICE PROCEDURE CODE PROPOSED TO BE ASSIGNED TO ICD-10 MS-DRGs 258 AND 259

Procedure code	Description
0JH604Z .....	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, open approach.
0JH605Z .....	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, open approach.
0JH606Z .....	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, open approach.
0JH607Z .....	Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, open approach.
0JH60PZ .....	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach.
0JH634Z .....	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, percutaneous approach.
0JH635Z .....	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, percutaneous approach.
0JH636Z .....	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, percutaneous approach.
0JH637Z .....	Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, percutaneous approach.
0JH63PZ .....	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach.
0JH804Z .....	Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, open approach.
0JH805Z .....	Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, open approach.
0JH806Z .....	Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, open approach.
0JH807Z .....	Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, open approach.
0JH80PZ .....	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, open approach.
0JH834Z .....	Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH835Z .....	Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH836Z .....	Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH837Z .....	Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH83PZ .....	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, percutaneous approach.

We are inviting public comments on our proposal to modify the GROUPER logic for MS-DRGs 258 and 259 to establish that a case reporting one procedure code from the above list of ICD-10-PCS procedure codes describing procedures involving pacemaker device insertions without any other procedure codes describing procedures involving pacemaker leads reported would be assigned to MS-DRGs 258 and 259.

We also examined our GROUPER logic for MS-DRGs 260, 261, and 262 (Cardiac Pacemaker Revision Except Device with MCC, with CC, and without CC/MCC, respectively). Cases assigned to MS-DRGs 260, 261, and 262 also

include lists of procedure code combinations describing procedures involving the removal of pacemaker leads and the insertion of new leads, in addition to lists of single procedure codes describing procedures involving the insertion of pacemaker leads, removal of devices, and revision of devices. We believe that this logic may also be overly complex. Moreover, we believe that a more simplified approach would be to provide a single list of procedure codes describing procedures involving cardiac pacemaker lead insertions and other related procedures involving device insertions that would be assigned to MS-DRGs 260, 261, and 262. If one of these procedure codes

describing procedures involving the insertion of pacemaker leads is reported, and there are no other procedure codes describing procedures involving the insertion of a device reported, the case would be assigned to MS-DRG 260, 261, and 262. We are proposing that the list of ICD-10-PCS procedure codes describing procedures involving pacemaker lead insertion, removal, or revisions and insertion of hemodynamic devices in the following table would be assigned to MS-DRGs 260, 261, and 262. We are simply proposing to use a single list of ICD-10-PCS procedure codes to determine the MS-DRG assignment.

LIST OF PROCEDURE CODES PROPOSED TO BE ASSIGNED TO MS-DRGs 260, 261, AND 262

Procedure code	Description
02H40JZ .....	Insertion of pacemaker lead into coronary vein, open approach.
02H40MZ .....	Insertion of cardiac lead into coronary vein, open approach.
02H43JZ .....	Insertion of pacemaker lead into coronary vein, percutaneous approach.
02H43MZ .....	Insertion of cardiac lead into coronary vein, percutaneous approach.
02H44JZ .....	Insertion of pacemaker lead into coronary vein, percutaneous endoscopic approach.
02H44MZ .....	Insertion of cardiac lead into coronary vein, percutaneous endoscopic approach.
02H60MZ .....	Insertion of pacemaker lead into right atrium, open approach.
02H63JZ .....	Insertion of cardiac lead into right atrium, open approach.
02H63MZ .....	Insertion of pacemaker lead into right atrium, percutaneous approach.
02H64JZ .....	Insertion of cardiac lead into right atrium, percutaneous approach.
02H64MZ .....	Insertion of pacemaker lead into right atrium, percutaneous endoscopic approach.
02H70JZ .....	Insertion of cardiac lead into right atrium, percutaneous endoscopic approach.
02H70MZ .....	Insertion of pacemaker lead into left atrium, open approach.
02H73JZ .....	Insertion of cardiac lead into left atrium, open approach.
02H73MZ .....	Insertion of pacemaker lead into left atrium, percutaneous approach.
02H74JZ .....	Insertion of cardiac lead into left atrium, percutaneous approach.
02H74MZ .....	Insertion of pacemaker lead into left atrium, percutaneous endoscopic approach.
02HK00Z .....	Insertion of cardiac lead into left atrium, percutaneous endoscopic approach.

## LIST OF PROCEDURE CODES PROPOSED TO BE ASSIGNED TO MS-DRGs 260, 261, AND 262—Continued

Procedure code	Description
02HK02Z .....	Insertion of pressure sensor monitoring device into right ventricle, open approach.
02HK0JZ .....	Insertion of monitoring device into right ventricle, open approach.
02HK0MZ .....	Insertion of pacemaker lead into right ventricle, open approach.
02HK30Z .....	Insertion of cardiac lead into right ventricle, open approach.
02HK32Z .....	Insertion of pressure sensor monitoring device into right ventricle, percutaneous approach.
02HK3JZ .....	Insertion of monitoring device into right ventricle, percutaneous approach.
02HK3MZ .....	Insertion of pacemaker lead into right ventricle, percutaneous approach.
02HK40Z .....	Insertion of cardiac lead into right ventricle, percutaneous approach.
02HK42Z .....	Insertion of pressure sensor monitoring device into right ventricle, percutaneous endoscopic approach.
02HK4JZ .....	Insertion of monitoring device into right ventricle, percutaneous endoscopic approach.
02HK4MZ .....	Insertion of pacemaker lead into right ventricle, percutaneous endoscopic approach.
02HLOJZ .....	Insertion of cardiac lead into right ventricle, percutaneous endoscopic approach.
02HLOMZ .....	Insertion of pacemaker lead into left ventricle, open approach.
02HL3JZ .....	Insertion of cardiac lead into left ventricle, open approach.
02HL3MZ .....	Insertion of pacemaker lead into left ventricle, percutaneous approach.
02HL4JZ .....	Insertion of cardiac lead into left ventricle, percutaneous approach.
02HL4MZ .....	Insertion of pacemaker lead into left ventricle, percutaneous endoscopic approach.
02HN0JZ .....	Insertion of cardiac lead into left ventricle, percutaneous endoscopic approach.
02HN0MZ .....	Insertion of pacemaker lead into pericardium, open approach.
02HN3JZ .....	Insertion of cardiac lead into pericardium, open approach.
02HN3MZ .....	Insertion of pacemaker lead into pericardium, percutaneous approach.
02HN4JZ .....	Insertion of cardiac lead into pericardium, percutaneous approach.
02HN4MZ .....	Insertion of pacemaker lead into pericardium, percutaneous endoscopic approach.
02PA0MZ .....	Insertion of cardiac lead into pericardium, percutaneous endoscopic approach.
02PA3MZ .....	Removal of cardiac lead from heart, open approach.
02PA4MZ .....	Removal of cardiac lead from heart, percutaneous approach.
02PAXMZ .....	Removal of cardiac lead from heart, percutaneous endoscopic approach.
02WA0MZ .....	Revision of cardiac lead in heart, open approach.
02WA3MZ .....	Revision of cardiac lead in heart, percutaneous approach.
02WA4MZ .....	Revision of cardiac lead in heart, percutaneous endoscopic approach.
0JH600Z .....	Insertion of hemodynamic monitoring device into chest subcutaneous tissue and fascia, open approach.
0JH630Z .....	Insertion of hemodynamic monitoring device into chest subcutaneous tissue and fascia, percutaneous approach.
0JH800Z .....	Insertion of hemodynamic monitoring device into abdomen subcutaneous tissue and fascia, open approach.
0JH830Z .....	Insertion of hemodynamic monitoring device into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JPT0PZ .....	Removal of cardiac rhythm related device from trunk subcutaneous tissue and fascia, open approach.
0JPT3PZ .....	Removal of cardiac rhythm related device from trunk subcutaneous tissue and fascia, percutaneous approach.
0JWT0PZ .....	Revision of cardiac rhythm related device in trunk subcutaneous tissue and fascia, open approach.
0JWT3PZ .....	Revision of cardiac rhythm related device in trunk subcutaneous tissue and fascia, percutaneous approach.

We are inviting public comments on our proposal to modify the GROUPER logic for MS-DRGs 260, 261, and 262 so that cases reporting any one of the ICD-10-PCS procedure codes describing procedures involving pacemakers and related procedures and associated devices listed in the table above would be assigned to MS-DRGs 260, 261, and 262.

#### d. Transcatheter Mitral Valve Repair With Implant

As we did for the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28008 through 28010), for FY 2017, we received a request to modify the MS-DRG assignment for transcatheter mitral valve repair with implant procedures. We refer readers to detailed discussions of the MitraClip® System (hereafter referred to as MitraClip®) for transcatheter mitral valve repair in previous rulemakings, including the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25822) and final rule (76 FR 51528 through 51529) and the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27902

through 27903) and final rule (77 FR 53308 through 53310), in response to requests for MS-DRG reclassification, as well as the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27547 through 27552), under the new technology add-on payment policy. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50575), the application for a new technology add-on payment for MitraClip® was unable to be considered further due to lack of FDA approval by the July 1, 2013 deadline.

In the FY 2015 IPPS/LTCH PPS final rule, we finalized our proposal to not create a new MS-DRG or to reassign cases reporting procedures involving the MitraClip® to another MS-DRG (79 FR 49890 through 49892). Under a separate process, the request for a new technology add-on payment for the MitraClip® System was approved (79 FR 49941 through 49946). As discussed in section II.I.4.e. of the preamble of this proposed rule, we are proposing to discontinue the new technology add-on payment for MitraClip® for FY 2017.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49371), we finalized a modification to the MS-DRGs to which the procedure involving the MitraClip® System was assigned. For the ICD-10 based MS-DRGs to fully replicate the ICD-9-CM based MS-DRGs, ICD-10-PCS code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach), which identifies the use of the MitraClip® technology and is the ICD-10-PCS code translation for ICD-9-CM procedure code 35.97 (Percutaneous mitral valve repair with implant), was assigned to new MS-DRGs 273 and 274 (Percutaneous Intracardiac Procedures with and without MCC, respectively) and continued to be assigned to MS-DRGs 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively). According to the requestor, there are substantial clinical and resource differences between the transcatheter mitral valve repair procedure and other procedures currently grouping to MS-DRGs 273 and 274, which are the focus of the request.



The requestor submitted three options for CMS to consider for FY 2017. The first option was to create a new MS-DRG for endovascular cardiac valve repair with implant; the second option was to reassign cases for the MitraClip® implant from MS-DRGs 273 and 274 to

MS-DRGs 266 and 267 (Endovascular Cardiac Valve Replacement with and without MCC, respectively); and the third option was to reassign cases involving the MitraClip® system to another higher paying MS-DRG.

We analyzed claims data from the December 2015 update of the FY 2015 MedPAR file on reported cases of percutaneous mitral valve repair with implant (ICD-9-CM procedure code 35.97) in MS-DRGs 273 and 274. Our findings are shown in the table below.

PERCUTANEOUS MITRAL VALVE REPAIR WITH IMPLANT

MS-DRG	Number of cases	Average length of stay	Average costs
MS-DRG 273—All cases .....	6,620	8.01	\$27,625
MS-DRG 273—Cases with procedure code 35.97 .....	457	7.57	50,560
MS-DRG 274—All cases .....	14,220	3.46	19,316
MS-DRG 274—Cases with procedure code 35.97 .....	693	2.67	37,686

As shown in the table, the total number of cases reported in MS-DRG 273 was 6,620 and had an average length of stay of 8.01 days and average costs of \$27,625. The number of cases reporting the ICD-9-CM procedure code 35.97 in MS-DRG 273 totaled 457 and had an average length of stay of 7.57 days and average costs of \$50,560. For MS-DRG 274, there were a total of

14,220 cases with an average length of stay of 3.46 days and average costs of \$19,316. There were a total of 693 cases in MS-DRG 274 that reported procedure code 35.97; these cases had an average length of stay of 2.67 days and average costs of \$37,686. We recognize that the cases reporting procedure code 35.97 had a shorter length of stay and higher

average costs in comparison to all the cases within MS-DRGs 273 and 274.

As stated above, the first option of the requestor was that we create a new MS-DRG for endovascular cardiac valve repair with implant procedures for all cardiac valve repairs. We reviewed the following list of ICD-10-PCS procedure codes that the requestor submitted to comprise this proposed new MS-DRG.

ICD-10-PCS Code	Description
02UF37Z .....	Supplement aortic valve with autologous tissue substitute, percutaneous approach.
02UF38Z .....	Supplement aortic valve with zooplasic tissue, percutaneous approach.
02UF3JZ .....	Supplement aortic valve with synthetic substitute, percutaneous approach.
02UF3KZ .....	Supplement aortic valve with nonautologous tissue substitute, percutaneous approach.
02UG37Z .....	Supplement mitral valve with autologous tissue substitute, percutaneous approach.
02UG38Z .....	Supplement mitral valve with zooplasic tissue, percutaneous approach.
02UG3JZ .....	Supplement mitral valve with synthetic substitute, percutaneous approach.
02UG3KZ .....	Supplement mitral valve with nonautologous tissue substitute, percutaneous approach.
02UH37Z .....	Supplement pulmonary valve with autologous tissue substitute, percutaneous approach.
02UH38Z .....	Supplement pulmonary valve with zooplasic tissue, percutaneous approach.
02UH3JZ .....	Supplement pulmonary valve with synthetic substitute, percutaneous approach.
02UH3KZ .....	Supplement pulmonary valve with nonautologous tissue substitute, percutaneous approach.
02UJ37Z .....	Supplement tricuspid valve with autologous tissue substitute, percutaneous approach.
02UJ38Z .....	Supplement tricuspid valve with zooplasic tissue, percutaneous approach.
02UJ3JZ .....	Supplement tricuspid valve with synthetic substitute, percutaneous approach.
02UJ3KZ .....	Supplement tricuspid valve with nonautologous tissue substitute, percutaneous approach.

The above list of ICD-10-PCS procedure codes are currently assigned to MS-DRGs 216 through 221 (Cardiac Valve and Other Major Cardiovascular Procedures with and without Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively), with the exception of procedure code 02UG3JZ, which is assigned to MS-DRGs 273 and 274, as noted earlier in this section.

All 16 of the ICD-10-PCS procedure codes submitted by the requestor are comparable translations of ICD-9-CM procedure code 35.33 (Annuloplasty), which also grouped to MS-DRGs 216 through 221. However, ICD-10-PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute,

percutaneous approach) is the comparable translation for both ICD-9-CM procedure code 35.33 and ICD-9-CM procedure code 35.97 (Percutaneous mitral valve repair with implant), which grouped to MS-DRGs 273 and 274 as mentioned previously.

Upon review of the 16 ICD-10-PCS procedure codes submitted for consideration by the requestor, we determined that we cannot propose the suggested change because the resulting ICD-10 MS-DRG logic would not be an accurate replication of the ICD-9-CM based MS-DRG logic. Specifically, it is not possible to replicate reassigning the percutaneous annuloplasty codes from ICD-9-CM based MS-DRGs 216 through 221 to a new MS-DRG because we

cannot isolate those cases from procedure code 35.33. Under ICD-9-CM, procedure code 35.33 does not differentiate the specific type of approach used to perform the procedure. This is in contrast to the 60 comparable ICD-10 code translations that do differentiate among various approaches (open, percutaneous, and percutaneous endoscopic).

As stated previously, if the ICD-9-CM and ICD-10 versions of the MS-DRGs cease to be replications of each other, the relative payment weights (computed using the ICD-9-CM based MS-DRGs) would be inconsistent with the ICD-10 MS-DRG assignment, which may cause unintended payment redistribution. Therefore, we are not proposing to

create a new MS-DRG for transcatheter mitral valve repair with implant procedures for FY 2017.

The second option in the request was to evaluate reassigning cases involving the MitraClip® to MS-DRGs 266 and 267. This option is not supported for the same reasons provided in previous rulemaking regarding differences between valve replacements and valve

repairs. Our clinical advisors do not believe that these procedures are clinically coherent or similar in terms of resource consumption because the MitraClip® technology is utilized for a percutaneous mitral valve repair, while the other technologies assigned to MS-DRGs 266 and 267 are utilized for transcatheter/endovascular cardiac valve replacements. In addition, if cases

involving the MitraClip® were reassigned to MS-DRGs 266 and 267, they would be overpaid by approximately \$10,000 as shown in the table below. Our clinical advisors agree that we should not propose to reassign endovascular cardiac valve repair procedures to the endovascular cardiac valve replacement MS-DRGs.

ENDOVASCULAR CARDIAC VALVE REPLACEMENT WITH AND WITHOUT MCC

MS-DRG 266—All cases .....	7,436	8.54	\$59,675
MS-DRG 267—All cases .....	8,480	4.45	47,013

Next, we analyzed claims data from the December 2015 update of the FY 2015 MedPAR file relating to the possible reassignment of cases involving the MitraClip® (identified by ICD-9-CM procedure code 35.97) to MS-DRGs 228, 229, and 230 (Other Cardiothoracic Procedures with MCC, with CC, and

without CC/MCC, respectively). However, as shown in the findings in the table below, the claims data did not support this option under the current 3-way severity level split. That is, the data findings based on reassignment of MitraClip® cases (ICD-9-CM procedure code 35.97) to MS-DRGs 228, 229, and

230 did not support the required criterion that there be at least a \$2,000 difference between subgroups. A reassignment would not meet the requirement for the “with CC” and “without CC/MCC” subgroups (\$34,461 – \$33,216 = \$1,245).

OTHER CARDIOTHORACIC PROCEDURES (WITH PROCEDURE CODE 35.97)

MS-DRG	Number of cases	Average length of stay	Average costs
MS-DRG 228—with MCC .....	1,966	11.53	\$51,634
MS-DRG 229—with CC .....	2,318	6.28	34,461
MS-DRG 230—without CC/MCC .....	709	3.76	33,216

We then performed additional analysis consisting of the base DRG report for MS-DRGs 228, 229 and 230. As shown in the table below, the average costs between the “with CC” and the “without CC/MCC” subgroups

no longer meet the criterion that there be at least a 20-percent difference in average costs between subgroups. These data findings support collapsing MS-DRGs 228, 229, and 230 from a 3-way severity level split into a 2-way severity

level split (with MCC and without MCC) based on 2 years (FY 2014 and FY 2015) of MedPAR data. This option would involve the deletion of an MS-DRG.

OTHER CARDIOTHORACIC PROCEDURES

MS-DRG	Number of cases FY 2015	Average length of stay FY 2015	Average costs FY 2015	Number of cases FY 2014	Average length of stay FY 2014	Average costs FY 2014
MS-DRG 228—with MCC .....	1,509	12.73	\$51,960	1,486	12.75	\$50,688
MS-DRG 229—with CC .....	1,835	7.16	33,786	1,900	7.46	33,277
MS-DRG 230—without CC/MCC .....	499	4.52	30,697	443	4.84	31,053

In the additional analysis, we evaluated if reassignment of cases reporting ICD-9-CM procedure code 35.97 to this proposed 2-way severity split was supported. We confirmed that the reassignment of ICD-9-CM procedure code 35.97 could be replicated under the ICD-9 MS-DRGs. We believe that deleting MS-DRG 230, revising MS-DRG 229, and reassigning

cases with procedure code 35.97 from MS-DRGs 273 and 274 to this new structure would reflect these procedures more accurately in the ICD-10 MS-DRGs. Our clinical advisors agreed with a proposal to delete MS-DRG 230 and reassign cases involving percutaneous mitral valve repair with implant (MitraClip®) to MS-DRG 228 and revised MS-DRG 229. We believe that

this approach would maintain clinical coherence for these MS-DRGs and reflect more appropriate payment for procedures involving percutaneous mitral valve repair. The proposed revisions to the MS-DRGs, which include the MitraClip® cases, are shown in the table below.

OTHER CARDIOTHORACIC PROCEDURES

Proposed revised MS-DRGs	Number of cases	Average length of stay	Average costs
MS-DRG 228—with MCC .....	1,966	11.53	\$51,634
MS-DRG 229—without MCC .....	3,027	5.69	34,169

For FY 2017, we are proposing to collapse MS-DRGs 228, 229, and 230 from three severity levels to two severity levels by deleting MS-DRG 230 and revising MS-DRG 229. We also are proposing to reassign ICD-9-CM procedure code 35.97 and the cases reporting ICD-10-PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) from MS-DRGs 273 and 274 to MS-DRG 228 and proposed revised MS-DRG 229. The title of MS-DRG 229 would be modified as follows to reflect the “without MCC” designation. The title of proposed revised MS-DRG 229 would be “Other Cardiothoracic Procedures without MCC”. The title for MS-DRG 228 would remain the same: MS-DRG 228 (Other Cardiothoracic Procedures with MCC). We are inviting public comments on our proposals.

We also note that, as discussed earlier in this section, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49371), ICD-10-PCS code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) was assigned to MS-DRGs 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively), in addition to new MS-DRGs 273 and 274,

to fully replicate the ICD-9-CM based MS-DRG logic for ICD-9-CM procedure code 35.97. If our proposal in this FY 2017 proposed rule to reassign ICD-10-PCS code 02UG3JZ to MS-DRGs 228 and proposed revised MS-DRG 229 is finalized in the FY 2017 IPPS/LTCH PPS final rule, it will eliminate the need to continue having ICD-10-PCS code 02UG3JZ and ICD-9-CM code 35.97 group to MS-DRGs 231 and 232. This is due to the fact that, currently, MS-DRGs 228, 229, and 230 are listed higher than MS-DRGs 231 through 236 in the surgical hierarchy, as shown in the ICD-9 and ICD-10 MS-DRGs Definitions Manual Files in Appendix D—MS-DRG Surgical Hierarchy by MDC and MS-DRG, which is available via the Internet on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending>. Therefore, if the proposal is finalized for FY 2017, cases reporting ICD-10-PCS procedure code 02UG3JZ will group to MS-DRGs 228 and revised MS-DRG 229 versus MS-DRGs 231 and 232 because

of the surgical hierarchy GROUPER logic.

As a result, we are proposing to remove ICD-10-PCS procedure code 02UG3JZ and ICD-9-CM procedure code 35.97 from the PTCA list in MS-DRGs 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively) for FY 2017 if the proposal to reassign ICD-9-CM procedure code 35.97 and the cases reporting ICD-10-PCS procedure codes 02UG3JZ from MS-DRGs 273 and 274 to MS-DRGs 228 and proposed revised MS-DRG 229 is finalized. We are inviting public comments on our proposals.

e. MS-DRG 245 (AICD Generator Procedures)

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49369), we stated that we would continue to monitor MS-DRG 245 (AICD Generator Procedures) to determine if the data supported subdividing this base MS-DRG into severity levels. As displayed in the table below, the results of the FY 2015 data analysis showed there were a total of 1,464 cases, with an average length of stay of 5.5 days and average costs of \$34,564 for MS-DRG 245.

AICD GENERATOR PROCEDURES

MS-DRG	Number of cases	Average length of stay	Average costs
MS-DRG 245 .....	1,464	5.5	\$34,564

We applied the five criteria established in the FY 2008 IPPS final rule (72 FR 47169), as described in

section II.F.1.b. of the preamble of this proposed rule to determine if it was appropriate to subdivide MS-DRG 245

into severity levels. The table below illustrates our findings.

AICD GENERATOR PROCEDURES

MS-DRG by suggested severity level	Number of cases	Average length of stay	Average costs
MS-DRG 245—with MCC .....	449	8.37	\$40,175
MS-DRG 245—with CC .....	861	4.59	32,518
MS-DRG 245—without CC/MCC .....	154	2.86	29,646

Based on our analysis of claims data from the December 2015 update of the FY 2015 MedPAR file, the data findings

do not support creating new severity levels. The findings show that the data do not meet the criteria for a 3-way

severity level split as the criterion that there be at least a 20-percent difference in average costs between subgroups is

not met for the “with CC” and “without CC/MCC” severity levels. We also looked at the prospect of a 2-way severity level split.

AICD GENERATOR PROCEDURES

MS-DRG by suggested severity level	Number of cases	Average length of stay	Average costs
MS-DRG 245—with MCC .....	449	8.37	\$40,175
MS-DRG 245—without MCC .....	1,015	4.33	32,081

The findings do show that the data are close to meeting the criteria for a 2-way severity level split of “with MCC and without MCC.” However, the required criterion that there must be at least 500 cases in the MCC group is not met.

Therefore, for FY 2017, we are not proposing to subdivide MS-DRG 245 into severity levels. We are inviting public comments on our proposal to maintain the current structure for MS-DRG 245.

6. MDC 6 (Diseases and Disorders of the Digestive System): Excision of Ileum

We received a request to analyze an MS-DRG replication issue from the ICD-9-CM based MS-DRGs to the ICD-10 based MS-DRGs for excision procedures performed on the ileum. Under ICD-9-CM, procedure code 45.62 (Other partial resection of small intestine) was assigned to MS-DRGs 329, 330 and 331 (Major Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively). Under the current ICD-10 MS-DRGs Version 33, ICD-10-PCS procedure code 0DBB0ZZ (Excision of ileum, open approach) is assigned to MS-DRGs 347, 348, and 349 (Anal and Stomal Procedures with MCC, with CC, and without CC/MCC, respectively). The requestor indicated that, despite the variation in terms for “excision” and “resection” between the two code sets, the surgical procedure to remove a portion of the small intestine, whether it is the ileum, duodenum, or jejunum, has not changed and should not result in different MS-DRG assignments when translated from ICD-9-CM to ICD-10.

We agree that this is a replication error. In addition to ICD-10-PCS code 0DBB0ZZ, we also reviewed the MS-DRG assignments for ICD-10-PCS code 0DBA0ZZ (Excision of jejunum, open approach) and determined the MS-DRG assignment for this code resulted in the same replication error. Therefore, we are proposing to reassign ICD-10-PCS codes 0DBB0ZZ and 0DBA0ZZ from MS-DRGs 347, 348, and 349 to MS-DRGs 329, 330, and 331, effective with

the ICD-10 MS-DRGs Version 34 on October 1, 2016.

We are inviting public comments on our proposal.

7. MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas): Bypass Procedures of the Veins

We received a request to assign ICD-10-PCS code 06183DY (Bypass portal vein to lower vein with intraluminal device, percutaneous approach) to MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas) under MS-DRGs 405, 406, and 407 (Pancreas Liver and Shunt Procedures with MCC, with CC, and without CC/MCC, respectively). The requestor described this code as capturing a transjugular intrahepatic portosystem shunt procedure. The requestor stated that, under ICD-9-CM, when a procedure for cirrhosis of the liver was performed, the procedure was assigned to ICD-9-CM code 39.1 (Intra-abdominal venous shunt). The requestor noted that when ICD-9-CM procedure code 39.1 is reported with a principal diagnosis of cirrhosis of the liver, the procedure was assigned to MS-DRG 405, 406, or 407 in the ICD-9-CM MS-DRGs.

Currently, ICD-10-PCS procedure code 06183DY is assigned to only MDC 5 (Diseases and Disorders of the Circulatory System) and MS-DRGs 270, 271, and 272 (Other Major Cardiovascular Procedures with MCC, with CC, and without CC/MCC, respectively) under ICD-10 MS-DRGs Version 33. The requestor stated that ICD-10-PCS procedure code 06183DY code should also be assigned to MDC 7 and MS-DRGs 405, 406, and 407 to be consistent with the ICD-9-CM MS-DRGs Version 32.

We analyzed this issue and agree that the ICD-10 MS-DRGs do not fully replicate the ICD-9-CM MS-DRGs. We agree that ICD-10-PCS procedure code 06183DY should be assigned to MDC 7 and MS-DRGs 405, 406, and 407 to replicate the ICD-9-CM MS-DRGs. Our clinical advisors reviewed this issue and

also agree that ICD-10-PCS procedure code 06183DY should be assigned to MDC 7 and MS-DRGs 405, 406, and 407. Therefore, we are proposing to assign ICD-10-PCS procedure code 06183DY to MDC 7 and MS-DRGs 405, 406, and 407 for FY 2017.

We are inviting public comments on our proposal.

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

a. Proposed Updates to MS-DRGs 469 and 470 (Major Joint Replacement or Reattachment of Lower Extremity With and Without MCC, respectively)

(1) Total Ankle Replacement (TAR) Procedures

We received a request to create a new MS-DRG for total ankle replacement (TAR) procedures, which are currently assigned to MS-DRGs 469 and 470 (Major Joint Replacement or Reattachment of Lower Extremity with and without MCC, respectively). We previously discussed requested changes to the MS-DRG assignment for TAR procedures in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28013 through 28015) and in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49896 through 49899). For FY 2015, we did not change the MS-DRG assignment for total ankle replacements. The requestor stated that reassigning total ankle replacement procedures from MS-DRGs 469 and 470 to a new MS-DRG would have an important benefit for the new Medicare Comprehensive Care for Joint Replacement (CJR) model. The commenter noted that because total ankle replacement cases currently are assigned to MS-DRGs 469 and 470, they are included in the model.

Ankle replacement procedures were captured by ICD-9-CM code 81.56 (Total ankle replacement). We examined claims data for total ankle procedures using the December 2015 update of the FY 2015 MedPAR file. Our findings are displayed in the table below.

TOTAL ANKLE REPLACEMENT CASES REPORTED IN MS-DRGs 469 AND 470

MS-DRG	Number of cases	Average length of stay	Average costs
MS-DRG 469—All cases .....	25,729	6.92	\$22,358
MS-DRG 469—Total ankle replacement cases .....	30	5.40	34,889
MS-DRG 470—All cases .....	421,149	2.92	14,834
MS-DRG 470—Total ankle replacement cases .....	1,626	1.94	20,019

As the total ankle replacement claims data analysis showed, these procedures represent a small fraction of the total number of cases reported in MS-DRGs 469 and 470. There were 30 total ankle replacement cases reported in MS-DRG 469 and 1,626 total ankle replacement cases in MS-DRG 470, compared to 25,729 total cases reported in MS-DRG 469 and 421,149 total cases reported in MS-DRG 470. The average length of stay for total ankle replacement cases was 5.40 days and average costs for total ankle replacement cases were \$34,889 reported in MS-DRG 469, compared to average length of stay of 6.92 days and average costs of \$22,358 for all cases reported in MS-DRG 469. The average length of stay for total ankle replacement cases was 1.94 days and average costs of total ankle replacement cases were \$20,019 reported in MS-DRG 470, compared to an average length of stay of 2.92 days and average costs of \$14,834 for all cases reported in MS-DRG 470.

Given the low volume of cases, we believe that these cost data may not be a complete measure of actual differences in inpatient resource utilization for beneficiaries receiving total ankle replacements. In addition, these total ankle replacement cases may have been impacted by other factors such as complication or comorbidities. Several expensive cases could impact the average costs for a very small number of patients. The average cost of total ankle replacement cases reported in MS-DRG 469 was \$12,531 higher than all cases reported in MS-DRG 469 (\$34,889 compared to \$22,358 for all reported cases), but there were only 30 cases compared to a total of 25,729 cases reported in MS-DRG 469. The average cost of total ankle replacement cases reported in MS-DRG 470 was \$5,185 higher than all cases reported in MS-DRG 470. There were 1,626 total ankle replacement cases out of a total of 421,149 cases reported in MS-DRG 470. The average costs of the total ankle replacement cases were higher than those for all cases reported in MS-DRG 469 and 470. However, some cases have higher and some cases have lower average costs within any MS-DRG. MS-DRGs are groups of clinically similar

cases that have similar overall costs. Within a group of cases, one would expect that some cases have costs that are higher than the overall average and some cases have costs that are lower than the overall average.

The data do not support creating a new total ankle replacement MS-DRG for this small number of cases. Also, our clinical advisors pointed out that creating a new MS-DRG for total ankle replacements would result in combining cases reporting an MCC with an average length of stay of 5.40 days and cases not reporting an MCC with an average length of stay of 1.94 days. Our clinical advisors did not recommend the creation of a new MS-DRG for this single procedure with such a small number of cases. They also stated that patients undergoing total ankle replacement have similar clinical features compared to other patients undergoing procedures included in MS-DRGs 469 and 470. Furthermore, we believe that the volume of total ankle replacement procedures performed relative to hip and knee replacement procedures minimizes the benefit that a new MS-DRG would have on the Medicare CJR model. Our clinical advisors determined that the cases involving total ankle replacements are more appropriately assigned to MS-DRGs 469 and 470 with the two severity levels.

Based on the findings from our data analysis and the recommendations from our clinical advisors, we are not proposing to create a new MS-DRG for total ankle replacement procedures. We are proposing to maintain the current MS-DRG structure for MS-DRGs 469 and 470.

We are inviting public comments on this proposal.

(2) Hip Replacement Procedures With Principal Diagnosis of Hip Fracture

We received several requests to remove hip replacement procedures with a principal diagnosis of hip fracture from MS-DRGs 469 and 470 (Major Joint Replacement or Reattachment of Lower Extremity with and without MCC, respectively) and to create a new MS-DRG for assignment of these hip replacement procedures. One

requestor suggested that if such a new MS-DRG could not be created, CMS consider reassigning all hip replacement procedures with a principal diagnosis of hip fracture only to MS-DRG 469, even if there were no reported MCC.

The requestors stated that hip replacement procedures performed on patients with hip fractures involve a more fragile population of patients than the typical patient population who undergo elective hip or knee replacement and that these more fragile patient cases also are assigned to MS-DRGs 469 and 470. The requestors stated that cases of patients who have hip replacements with hip fractures may have significant comorbidities not present in patients who undergo elective hip replacements. One requestor stated that the absolute number of hospitalizations for hip fractures in the United States is currently more than 350,000 and the number is rising. The requestor stated that 90 percent of hip fractures result from a simple fall, and that hip fracture rates increase with age. According to the requestor, the 1-year mortality rate for patients who undergo hip replacement procedures after a hip fracture was approximately 20 percent, and the 3-year mortality rate was up to 50 percent. The requestor also stated that one out of three adults who lived independently before their hip fracture remains in a nursing home for at least a year after the hip fracture. In contrast, the requestor noted that patients under elective hip replacement procedures for arthritis have fewer comorbidities, improved health after the procedure, low rates of readmission, and less postacute needs. The requestor believed that there are many factors that impact the outcome of hip replacements for hip fractures, including patient factors, fracture type, surgeon and hospital factors, treatment decisions, complication rates, and rehabilitation factors/access. The requestor added that, despite the commitment to standardization, the use of protocol-driven care, early surgery (<24 hours) after surgical optimization, prevention of recurrent fractures, and comanagement with medical/surgical teams, many patients who undergo hip replacement procedures for hip

fractures have serious renal, cardiovascular, and liver disease, as well as multiple medical comorbidities. The rates of postoperative infections, readmissions, and postacute care for the patients who undergo hip replacements for hip fractures are higher than for patients who undergo elective hip replacement. Some requestors referenced the Bundled Payments for Care Improvement Initiative (BPCI) and believed that their requested changes to MS-DRGs 469 and 470 would support

this effort. The requestors stated that the MS-DRG assignment for the hip replacement procedures with hip fractures has tremendous implications for successful participation in the BPCI because the BPCI's clinical episodes track to MS-DRG assignment, and the Major Joint Replacement of the Lower Extremity Clinical Episode encompasses procedures assigned to MS-DRGs 469 and 470. Alternatively, the requestors suggested that CMS reassign all cases of hip replacement procedures with a

principal diagnosis of hip fracture to MS-DRG 469 to recognize the more significant adverse health profile of these types of cases.

We examined claims data for cases reporting hip replacement procedures for patients admitted with hip fractures under MS-DRGs 469 and 470 in the December 2015 update of the FY 2015 MedPAR file. We used the following list of ICD-9-CM diagnosis codes to identify cases representing hip replacements for hip fractures:

ICD-9-CM DIAGNOSIS CODES REVIEWED FOR CASES REPRESENTING HIP REPLACEMENT FOR HIP FRACTURES

ICD-9-CM diagnosis code	Descriptions
733.14 .....	Pathological fracture of neck of femur.
733.15 .....	Pathological fracture of other specified part of femur.
733.81 .....	Malunion of fracture.
733.82 .....	Nonunion of fracture.
733.96 .....	Stress fracture of femoral neck.
808.0 .....	Closed fracture of acetabulum.
808.1 .....	Open fracture of acetabulum.
820.8 .....	Fracture of unspecified part of neck of femur closed.
820.9 .....	Fracture of unspecified part of neck of femur open.
820.00 .....	Fracture of unspecified intracapsular section of neck of femur closed.
820.01 .....	Fracture of epiphysis (separation) (upper) of neck of femur closed.
820.02 .....	Fracture of midcervical section of femur closed.
820.03 .....	Fracture of base of neck of femur closed.
820.09 .....	Other transcervical fracture of femur closed.
820.10 .....	Fracture of unspecified intracapsular section of neck of femur open.
820.11 .....	Fracture of epiphysis (separation) (upper) of neck of femur open.
820.12 .....	Fracture of midcervical section of femur open.
820.13 .....	Fracture of base of neck of femur open.
820.19 .....	Other transcervical fracture of femur open.
820.20 .....	Fracture of unspecified trochanteric section of femur closed.
820.21 .....	Fracture of intertrochanteric section of femur closed.
820.22 .....	Fracture of subtrochanteric section of femur closed.
820.30 .....	Fracture of unspecified trochanteric section of femur open.
820.31 .....	Fracture of intertrochanteric section of femur open.
820.32 .....	Fracture of subtrochanteric section of femur open.

Our findings from our examination of the data are shown in the table below.

CASES OF HIP REPLACEMENTS WITH AND WITHOUT PRINCIPAL DIAGNOSIS OF HIP FRACTURE

MS-DRG	Number of cases	Average length of stay	Average costs
MS-DRG 469—All cases .....	25,729	6.9	\$22,358
MS-DRG 469—Hip replacement cases with hip fractures .....	14,459	7.9	22,852
MS-DRG 469—Hip replacement cases without hip fractures .....	4,714	5.7	22,430
MS-DRG 470—All cases .....	421,149	2.9	14,834
MS-DRG 470—Hip replacement cases with hip fractures .....	49,703	4.7	15,795
MS-DRG 470—Hip replacement cases without hip fractures .....	125,607	2.6	14,870

For MS-DRG 469, the average costs of all 25,729 reported cases were \$22,358 and the average length of stay was 6.9 days. Within MS-DRG 469, there were 14,459 cases of hip replacements with hip fractures reported, with average costs of \$22,852 and an average length of stay of 7.9 days. Within MS-DRG 469, there were 4,714 cases of hip

replacements without hip fractures reported, with average costs of \$22,430 and an average length of stay of 5.7 days. The average costs of reported cases of hip replacements with hip fractures are similar to the average costs of all cases reported within MS-DRG 469 (\$22,852 compared to \$22,358), and to the average costs of reported cases of

hip replacements without hip fractures (\$22,852 compared to \$22,430). However, the average length of stay for cases of hip replacements with hip fractures reported in MS-DRG 469 is higher than the average length of stay for all cases reported in MS-DRG 469 and for cases of hip replacements without hip fractures reported in MS-

DRG 469 (7.9 days compared to 6.9 days and 5.7 days, respectively.)

For MS-DRG 470, the average costs of all 421,149 cases reported were \$14,834 and the average length of stay was 2.9 days. Within MS-DRG 470, there were 49,703 reported cases of hip replacements with hip fractures, with average costs \$15,795 and an average length of stay of 4.7 days. Within MS-DRG 470, there were 125,607 cases of hip replacements without hip fractures reported, with average costs of \$14,870 and an average length of stay of 2.6 days. However, the average length of stay for cases of hip replacements with hip fractures reported in MS-DRG 470 was higher than the average length of stay for all cases and for cases of hip replacements without hip fractures reported in MS-DRG 470 (4.7 days compared to 2.9 days and 2.6 days, respectively). Therefore, the average costs of cases of hip replacements with hip fractures were similar for both MS-DRG 469 and MS-DRG 470 (\$22,852 compared to \$22,358 and \$15,795 compared to \$14,834, respectively). However, the average lengths of stay are longer for cases of hip replacements with hip fractures compared to all cases reported in both MS-DRGs 469 and 470 (7.9 days compared to 6.9 days and 4.7 days compared to 2.9 days, respectively).

The claims data do not support creating a new MS-DRG for the assignment of cases of hip replacements with hip fractures. As discussed earlier, the average costs for cases of hip replacements with hip fractures reported in MS-DRG 469 and MS-DRG 470 are similar to the average costs for all cases reported in MS-DRG 469 and MS-DRG 470. While the average length of stay is longer for cases of hip replacements with hip fractures than for cases of hip replacements without hip fractures reported within MS-DRGs 469 and 470, the increased length of stay did not impact the average costs of reported cases in either MS-DRG 469 or 470. The data showed that cases of hip replacement procedures are clearly influenced by the presence of an MCC. The average costs of all cases reported in MS-DRG 469, which identifies an MCC, were \$22,358, compared to average costs of \$14,834 for all cases reported in MS-DRG 470, which did not identify an MCC. The data showed that the presence of a principal diagnosis of

a hip fracture did not impact the average costs of cases reported in either MS-DRG 469 or MS-DRG 470.

We also examined the data in relation to the request to reassign all procedures of hip replacement with hip fractures from MS-DRG 470 to MS-DRG 469, even if there is no MCC present. The data showed that the 49,703 cases of hip replacements with hip fractures reported in MS-DRG 470 have average costs of \$15,795 and an average length of stay of 4.7 days. The 25,729 total cases of hip replacements reported in MS-DRG 469 have average costs of \$22,358 and an average length of stay of 6.9 days. Therefore, the data for average costs and average length of stay for all cases involving hip replacement procedures with hip fractures reported in MS-DRG 470 do not support reassigning all cases of hip replacement procedures with hip fractures to MS-DRG 469, even if there is no MCC present.

Our clinical advisors reviewed this issue and agree that the hip replacement procedures performed for patients with hip fractures are appropriately assigned to MS-DRGs 469 and 470. They did not support reassigning these procedures from MS-DRGs 469 and 470 to a new MS-DRG or reassigning all cases of hip replacement procedures with hip fractures to MS-DRG 469, even if the case does not have an MCC. Our clinical advisors stated that the surgical techniques used for hip replacements are similar for all patients. They advised that the fact that some patients also had a hip fracture would not justify creating a new MS-DRG or reassigning all cases of hip replacement procedures with hip fractures to MS-DRG 469. Our clinical advisors noted that the costs of cases of hip replacements are more directly impacted by the presence or absence of an MCC than the presence or absence of a hip fracture.

Based on the findings from our data analyses and the recommendations from our clinical advisors, we are not proposing to create a new MS-DRG for the assignment of procedures involving hip replacement in patients who have hip fractures or to reassign all procedures involving hip replacements with hip fractures to MS-DRG 469 even if there is no MCC present. We are proposing to maintain the current MS-DRG structure for MS-DRGs 469 and 470.

We are inviting public comments on our proposals.

b. Revision of Total Ankle Replacement Procedures

(1) Revision of Total Ankle Replacement Procedures

We received a request to modify the MS-DRG assignment for revision of total ankle replacement procedures. Currently, these procedures are assigned to MS-DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC and without CC/MCC, respectively). This topic was discussed in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28013 through 28015) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 49896 through 49899). However, at that time, we did not change the MS-DRG assignment for revisions of total ankle replacement procedures.

The requestor presented two options for consideration for modifying the MS-DRG assignment for the revisions of total ankle replacement procedures. The requestor's first option was to create a new MS-DRG for the assignment of revision of total ankle replacement procedures. The requestor believed that a new MS-DRG would be justified based on the distinct costs, resources, and utilization associated with ankle joint revision cases. The requestor's second option was to reassign revision of total ankle replacement procedures to MS-DRGs 466, 467, and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively) and rename MS-DRGs 466, 467, and 468 as "Revision of Hip, Knee, or Ankle with MCC, with CC, and without CC/MCC", respectively. The requestor believed that this second option would be justified because it is a reasonable, temporary approach until CMS has sufficient utilization and cost data for revision of total ankle replacement procedures based on the reporting of the new and more specific ICD-10-PCS procedure codes. The requestor pointed out that the following more specific ICD-10-PCS procedure codes were implemented effective October 1, 2015, with the implementation of ICD-10. The requestor stated that these new codes will provide improved data on these procedures that can be analyzed for future MS-DRG updates.

ICD-10-PCS procedure code	Description
OSWF0JZ .....	Revision of synthetic substitute in right ankle joint, open approach.
OSWF3JZ .....	Revision of synthetic substitute in right ankle joint, percutaneous approach.
OSWF4JZ .....	Revision of synthetic substitute in right ankle joint, percutaneous endoscopic approach.

ICD-10-PCS procedure code	Description
OSWFXJZ .....	Revision of synthetic substitute in right ankle joint, external approach.
OSWG0JZ .....	Revision of synthetic substitute in left ankle joint, open approach.
OSWG3JZ .....	Revision of synthetic substitute in left ankle joint, percutaneous approach.
OSWG4JZ .....	Revision of synthetic substitute in left ankle joint, percutaneous endoscopic approach.
OSWGXJZ .....	Revision of synthetic substitute in left ankle joint, external approach.

We agree with the requestor that the previous code used to identify revisions of total ankle replacement procedures, ICD-9-CM procedure code 81.59 (Revision of joint replacement of lower extremity, not elsewhere classified), is not as precise as the new ICD-10-PCS procedure codes that were implemented on October 1, 2015. As discussed in the FY 2015 IPPS/LTCH PPS proposed rule

and final rule, ICD-9-CM procedure code 81.59 included procedures involving revisions of joint replacements of a variety of lower extremity joints, including the ankle, foot, and toe. Therefore, the ICD-9-CM procedure code does not provide precise information on the number of revisions of total ankle replacement procedures as do the ICD-10-PCS procedure codes

listed above. We also agree that the ICD-10-PCS procedure codes will provide more precise data on revisions of ankle replacements.

We examined claims data from the December 2015 update of the FY 2015 MedPAR file on cases reporting procedure code 81.59 in MS-DRGs 515, 516, and 517. The table below shows our findings.

REVISIONS OF JOINT REPLACEMENTS PROCEDURES

MS-DRG	Number of cases	Average length of stay	Average costs
MS-DRG 515—All cases .....	3,852	8.54	\$21,900
MS-DRG 515—Cases reporting procedure code 81.59 .....	2	7.00	36,983
MS-DRG 516—All cases .....	8,567	5.24	14,839
MS-DRG 516—Cases reporting procedure code 81.59 .....	19	3.74	14,957
MS-DRG 517—All cases .....	5,664	3.20	12,979
MS-DRG 517—Cases reporting procedure code 81.59 .....	47	1.89	16,524

As can be seen from the data in the above table, there were only 68 total cases reported with procedure code 81.59 among MS-DRGs 515, 516, and 517: 2 Cases in MS-DRG 515; 19 cases in MS-DRG 516; and 47 in MS-DRG 517. We point out that while there were 68 total cases reported with procedure code 81.59 in MS-DRGs 515, 516, and 517, we are unable to determine how many of these cases were actually revisions of ankle replacements versus other revisions of joint replacement of lower extremities such as those of the foot or toe. This small number of cases does not justify creating a new MS-DRG as suggested by the requestor in its first option.

While the average costs of cases reporting procedure code 81.59 in MS-DRG 515 were \$36,983, compared to \$21,900 for all cases reported in MS-DRG 515, there were only 2 cases reporting procedure code 81.59 in MS-DRG 515, of the 3,852 total cases reported in MS-DRG 515. In MS-DRG 516, the average costs of the 19 cases reporting procedure code 81.59 cases were \$14,957, which is very close to the average costs of \$14,839 for all 8,567 cases reported in MS-DRG 516. The average costs for cases reporting procedure code 81.59 in MS-DRG 517 were higher than the average costs for all cases reported in MS-DRG 517

(\$16,524 for cases reporting procedure code 81.59 cases compared to \$12,979 for all cases reported in MS-DRG 517). While the average costs for cases reporting procedure code 81.59 were \$3,545 higher than all cases reported in MS-DRG 517, we point out that there were only 47 cases that reported procedure code 81.59 out of the 5,664 total cases reported in MS-DRG 517. The relatively small number of cases may have been impacted by other factors. Several expensive cases could impact the average costs for a very small number of patients.

As stated by the requestor, we do not yet have data using the more precise ICD-10-PCS revisions of total ankle replacement procedure codes that were implemented on October 1, 2015. These new codes will more precisely identify the number of patients who had a revision of total ankle replacement procedure and the number of patients who had revisions of other lower joint replacement procedures such as the foot or toe. The available clinical data from the December 2015 update of the FY 2015 MedPAR file do not support the creation of a new MS-DRG for the assignment of revisions of total ankle replacement procedures or the reassignment of these cases to other MS-DRGs, such as MS-DRGs 466, 467, and 468, because there were so few

cases and because we could not determine how many of these cases were revisions of ankle replacements. Claims data on the ICD-10-PCS codes will not be available until 2 years after the implementation of the codes, which was October 1, 2015.

Our clinical advisors reviewed this issue and determined that the revision of total ankle replacement procedures are appropriately classified within MS-DRGs 515, 516, and 517 along with other orthopedic procedures captured by nonspecific codes. They do not support reassignment of the procedures to MS-DRGs 466, 467, and 468 until such time as detailed data for ICD-10-PCS claims are available to evaluate revision of total ankle replacement procedures. Therefore, based on the findings of our analysis of claims data and the advice of our clinical advisors, we are proposing to maintain the current MS-DRG assignment for revision of total ankle replacement procedures for FY 2017.

We are inviting public comments on our proposal.

(2) Combination Codes for Removal and Replacement of Knee Joints

We received several requests asking CMS to examine whether additional combinations of procedure codes for the removal and replacements of knee joints should be added to MS-DRGs 466, 467,



and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively). This topic was discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR

24379 through 24395) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49390 through 49406). One requestor stated that the procedure codes in the following table were not included in the

code pairs that group to MS-DRGs 466, 467, and 468 in the ICD-10 MS-DRGs Version 33.

ICD-10-PCS procedure code	Description
0SPD08Z .....	Removal of spacer from left knee joint, open approach.
0SPD38Z .....	Removal of spacer from left knee joint, percutaneous approach.
0SPD48Z .....	Removal of spacer from left knee joint, percutaneous endoscopic approach.
0SPC08Z .....	Removal of spacer from right knee joint, open approach.
0SPC38Z .....	Removal of spacer from right knee joint, percutaneous approach.
0SPC48Z .....	Removal of spacer from right knee joint, percutaneous approach.

Other requestors stated that the procedure codes in the following table are not included in the list of

combinations that group to MS-DRGs 466, 467, and 468 when reported in conjunction with an ICD-10-PCS code

for the removal of synthetic substitute from the joint in the ICD-10 MS-DRGs Version 33.

ICD-10-PCS procedure code	Description
0SRC0J9 .....	Replacement of right knee joint with synthetic substitute, cemented, open approach.
0SRC0JA .....	Replacement of right knee joint with synthetic substitute, uncemented, open approach.
0SRC0JZ .....	Replacement of right knee joint with synthetic substitute, open approach.
0SRC07Z .....	Replacement of right knee joint with autologous tissue substitute, open approach.
0SRC0KZ .....	Replacement of right knee joint with nonautologous tissue substitute, open approach.

We agree that the joint revision cases involving the removal of a spacer and subsequent insertion of a new knee joint prosthesis should be assigned to MS-DRGs 466, 467, and 468. We examined knee joint revision combination codes that are not currently assigned to MS-

DRGs 466, 467, and 468 in ICD-10 MS-DRGs Version 33 and identified 58 additional combinations that also should be included so that the same logic is used in the ICD-10 version of the MS-DRGs as is used in the ICD-9-CM version. We are proposing to add

the following 58 new code combinations that capture the joint revisions to the Version 34 MS DRG structure for MS-DRGs 466, 467, and 468, effective October 1, 2016.

**ICD-10-PCS CODE PAIRS PROPOSED TO BE ADDED TO VERSION 34 ICD-10 MS-DRGs 466, 467, AND 468:  
PROPOSED NEW KNEE REVISION ICD-10-PCS COMBINATIONS**

Code	Code description		Code	Code description
0SPC08Z .....	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRC0J9 .....	Replacement of Right Knee Joint with Synthetic Substitute, Cemented, Open Approach.
0SPC08Z .....	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRC0JA .....	Replacement of Right Knee Joint with Synthetic Substitute, Uncemented, Open Approach.
0SPC08Z .....	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRC0JZ .....	Replacement of Right Knee Joint with Synthetic Substitute, Open Approach.
0SPC08Z .....	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRT0J9 .....	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Cemented, Open Approach.
0SPC08Z .....	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRT0JA .....	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPC08Z .....	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRT0JZ .....	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPC08Z .....	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRV0J9 .....	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Cemented, Open Approach.
0SPC08Z .....	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRV0JA .....	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPC08Z .....	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRV0JZ .....	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPC38Z .....	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRC0J9 .....	Replacement of Right Knee Joint with Synthetic Substitute, Cemented, Open Approach.
0SPC38Z .....	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRC0JA .....	Replacement of Right Knee Joint with Synthetic Substitute, Uncemented, Open Approach.
0SPC38Z .....	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRC0JZ .....	Replacement of Right Knee Joint with Synthetic Substitute, Open Approach.

ICD-10-PCS CODE PAIRS PROPOSED TO BE ADDED TO VERSION 34 ICD-10 MS-DRGs 466, 467, AND 468:  
PROPOSED NEW KNEE REVISION ICD-10-PCS COMBINATIONS—Continued

Code	Code description		Code	Code description
0SPC38Z .....	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRT0J9 .....	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Cemented, Open Approach.
0SPC38Z .....	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRT0JA .....	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPC38Z .....	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRT0JZ .....	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPC38Z .....	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRV0J9 .....	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Cemented, Open Approach.
0SPC38Z .....	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRV0JA .....	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPC38Z .....	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRV0JZ .....	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPC48Z .....	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRC0J9 .....	Replacement of Right Knee Joint with Synthetic Substitute, Cemented, Open Approach.
0SPC48Z .....	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRC0JA .....	Replacement of Right Knee Joint with Synthetic Substitute, Uncemented, Open Approach.
0SPC48Z .....	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRC0JZ .....	Replacement of Right Knee Joint with Synthetic Substitute, Open Approach.
0SPC48Z .....	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRT0J9 .....	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Cemented, Open Approach.
0SPC48Z .....	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRT0JA .....	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPC48Z .....	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRT0JZ .....	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPC48Z .....	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRV0J9 .....	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Cemented, Open Approach.
0SPC48Z .....	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRV0JA .....	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPC48Z .....	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRV0JZ .....	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPC4JZ .....	Removal of Synthetic Substitute from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRT0JZ .....	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPC4JZ .....	Removal of Synthetic Substitute from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRV0JZ .....	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPD08Z .....	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRD0J9 .....	Replacement of Left Knee Joint with Synthetic Substitute, Cemented, Open Approach.
0SPD08Z .....	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRD0JA .....	Replacement of Left Knee Joint with Synthetic Substitute, Uncemented, Open Approach.
0SPD08Z .....	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRD0JZ .....	Replacement of Left Knee Joint with Synthetic Substitute, Open Approach.
0SPD08Z .....	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRU0JA .....	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Cemented, Open Approach.
0SPD08Z .....	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRU0JA .....	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPD08Z .....	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRU0JZ .....	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPD08Z .....	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRW0J9 .....	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Cemented, Open Approach.
0SPD08Z .....	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRW0JA .....	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPD08Z .....	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRW0JZ .....	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPD38Z .....	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRD0J9 .....	Replacement of Left Knee Joint with Synthetic Substitute, Cemented, Open Approach.
0SPD38Z .....	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRD0JA .....	Replacement of Left Knee Joint with Synthetic Substitute, Uncemented, Open Approach.
0SPD38Z .....	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRD0JZ .....	Replacement of Left Knee Joint with Synthetic Substitute, Open Approach.

ICD-10-PCS CODE PAIRS PROPOSED TO BE ADDED TO VERSION 34 ICD-10 MS-DRGs 466, 467, AND 468:  
PROPOSED NEW KNEE REVISION ICD-10-PCS COMBINATIONS—Continued

Code	Code description		Code	Code description
OSPD38Z .....	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	OSRU0JA ....	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Cemented, Open Approach.
OSPD38Z .....	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	OSRU0JA ....	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Uncemented, Open Approach.
OSPD38Z .....	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	OSRU0JZ .....	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
OSPD38Z .....	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	OSRW0J9 ....	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Cemented, Open Approach.
OSPD38Z .....	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	OSRW0JA ....	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Uncemented, Open Approach.
OSPD38Z .....	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	OSRW0JZ ....	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
OSPD48Z .....	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	OSRD0J9 .....	Replacement of Left Knee Joint with Synthetic Substitute, Cemented, Open Approach.
OSPD48Z .....	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	OSRD0JA ....	Replacement of Left Knee Joint with Synthetic Substitute, Uncemented, Open Approach.
OSPD48Z .....	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	OSRD0JZ .....	Replacement of Left Knee Joint with Synthetic Substitute, Open Approach.
OSPD48Z .....	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	OSRU0JA ....	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Cemented, Open Approach.
OSPD48Z .....	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	OSRU0JA ....	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Uncemented, Open Approach.
OSPD48Z .....	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	OSRU0JZ .....	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
OSPD48Z .....	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	OSRW0J9 ....	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Cemented, Open Approach.
OSPD48Z .....	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	OSRW0JA ....	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Uncemented, Open Approach.
OSPD48Z .....	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	OSRW0JZ ....	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
OSPD4JZ .....	Removal of Synthetic Substitute from Left Knee Joint, Percutaneous Endoscopic Approach.	and	OSRU0JZ .....	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.

We are inviting public comments on our proposal to add the joint revision code combinations listed above to the ICD-10 Version 34 MS-DRGs 466, 467, and 468.

c. Decompression Laminectomy

Currently, under ICD-10-PCS, the procedure describing a decompression laminectomy is coded for the “release” of a specified area of the spinal cord. These decompression codes are assigned to MS-DRGs 028, 029, and 030 (Spinal Procedures with MCC, with CC or Spinal Neurostimulators, or without CC/MCC, respectively) and to MS-DRGs 518, 519, and 520 (Back and Neck

Procedures Except Spinal Fusion with MCC or Disc Device or Neurostimulator, with CC, or without CC/MCC, respectively) in the ICD-10 MS-DRGs Version 33. A commenter brought to our attention that codes describing release of specific peripheral nerve are assigned to MS-DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). The commenter suggested that a subset of these codes also be assigned to MS-DRGs 028 through 030 and MS-DRGs 518 through 520 for clinical coherence purposes. The commenter stated, for

example, that ICD-10-PCS procedure code 00NY0ZZ (Release lumbar spinal cord, open approach) is assigned to MS-DRGs 028 through 030 and MS-DRGs 518 through 520. However, ICD-10-PCS procedure code 01NB0ZZ (Release lumbar nerve, open approach) is assigned to MS-DRGs 515 through 517.

We agree with the commenter’s suggestion. Therefore, for FY 2017, we are proposing to reassign the ICD-10-PCS procedure codes listed in the following table from MS-DRGs 515 through 517 to MS-DRGs 028 through 030 and MS-DRGs 518 through 520 under the ICD-10 MS-DRGs Version 34.

ICD-10-PCS procedure code	Description
01N00ZZ .....	Release cervical plexus, open approach.
01N03ZZ .....	Release cervical plexus, percutaneous approach.
01N04ZZ .....	Release cervical plexus, percutaneous endoscopic approach.
01N10ZZ .....	Release cervical nerve, open approach.
01N13ZZ .....	Release cervical nerve, percutaneous approach.

ICD-10-PCS procedure code	Description
01N14ZZ .....	Release cervical nerve, percutaneous endoscopic approach.
01N80ZZ .....	Release thoracic nerve, open approach.
01N83ZZ .....	Release thoracic nerve, percutaneous approach.
01N84ZZ .....	Release thoracic nerve, percutaneous endoscopic approach.
01N90ZZ .....	Release lumbar plexus, open approach.
01N93ZZ .....	Release lumbar plexus, percutaneous approach.
01N94ZZ .....	Release lumbar plexus, percutaneous endoscopic approach.
01NA0ZZ .....	Release lumbosacral plexus, open approach.
01NA3ZZ .....	Release lumbosacral plexus, percutaneous approach.
01NA4ZZ .....	Release lumbosacral plexus, percutaneous approach.
01NB0ZZ .....	Release lumbar nerve, open approach.
01NB3ZZ .....	Release lumbar nerve, percutaneous approach.
01NB4ZZ .....	Release lumbar nerve, percutaneous endoscopic approach.

We are inviting public comments on our proposal.

d. Lordosis

An ICD-10 replication issue involving four diagnosis codes related to lordosis (excessive curvature of the lower spine) was discovered in MS-DRGs 456, 457, and 458 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC, with CC, and without CC/MCC). These MS-DRGs contain specific logic that requires a principal diagnosis describing a spinal curvature, a malignancy, or infection or a secondary diagnosis that describes a spinal curvature disorder related to another condition.

Under the ICD-10 MS-DRGs Version 33, the following diagnosis codes were listed on the principal diagnosis list and the secondary diagnosis list for MS-DRGs 456, 457, and 458:

- M40.50 (Lordosis, unspecified, site unspecified);
- M40.55 (Lordosis, unspecified, thoracolumbar region);
- M40.56 (Lordosis, unspecified, lumbar region); and
- M40.57 (Lordosis, unspecified, lumbosacral region).

We are proposing to remove the above four diagnosis codes from the secondary diagnosis list. We also are proposing to maintain these same four codes in the logic for the principal diagnosis list. This proposed change for MS-DRGs 456, 457, and 458 would be effective October 1, 2016, in the ICD-10 MS-DRGs Version 34.

We are inviting public comments on our proposals.

9. MDC 13 (Diseases and Disorders of the Female Reproductive System): Pelvic Evisceration

In the ICD-10 MS-DRG Definitions Manual Version 33, the GROUPER logic

for ICD-10 MS-DRGs 332, 333, and 334 (Rectal Resection with MCC, with CC and without CC/MCC, respectively) under MDC 6 (Diseases and Disorders of the Digestive System) and the GROUPER logic for MS-DRGs 734 and 735 (Pelvic Evisceration, Radical Hysterectomy and Radical Vulvectomy with CC/MCC and without CC/MCC, respectively) under MDC 13 (Diseases and Disorders of the Female Reproductive System) include a “cluster” of ICD-10-PCS procedure codes that describe pelvic evisceration. A “cluster” is the term used to describe a circumstance when a combination of ICD-10-PCS procedure codes is needed to fully satisfy the equivalent meaning of an ICD-9-CM procedure code for it to be considered a plausible code translation. The code cluster in MS-DRGs 332, 333, and 334 and MS-DRGs 734 and 735 is shown in the table below.

ICD-10-PCS procedure code in cluster	Description
0TTB0ZZ .....	Resection of bladder, open approach.
0TTD0ZZ .....	Resection of urethra, open approach.
0UT20ZZ .....	Resection of bilateral ovaries, open approach.
0UT70ZZ .....	Resection of bilateral fallopian tubes, open approach.
0UT90ZZ .....	Resection of uterus, open approach.
0UTC0ZZ .....	Resection of cervix, open approach.
0UTG0ZZ .....	Resection of vagina, open approach.

Pelvic evisceration (or exenteration) is a procedure performed to treat gynecologic cancers (cervical, uterine, vulvar, and vaginal, among others) and involves resection of pelvic structures such as the procedures described by the cluster of procedure codes listed above.

Under the ICD-9-CM MS-DRGs Version 32, procedure code 68.8 (Pelvic evisceration) was used to report pelvic evisceration. ICD-9-CM procedure code 68.8 also was assigned to ICD-9-CM MS-DRGs 332, 333, and 334 and MS-DRGs 734 and 735 in MDCs 6 and 13,

respectively. The inclusion term in the ICD-9-CM Tabular List of Diseases for pelvic evisceration (procedure code 68.8) was “Removal of ovaries, tubes, uterus, vagina, bladder, and urethra (with removal of sigmoid colon and rectum).” In the ICD-9-CM Tabular List, the terms shown in parentheses are called a “non-essential modifier”. A “non-essential modifier” is used in the classification to identify a supplementary word that may, or may not, be present in the statement of a disease or procedure. In other words,

the terms in parentheses do not have to be documented to report the code.

Because the removal of sigmoid colon and the removal of rectum were classified as non-essential modifiers under ICD-9-CM, documentation that identified that removal of those body sites occurred was not required to report the procedure code describing pelvic evisceration (procedure code 68.8). In other words, when a pelvic evisceration procedure was performed and included removal of other body sites (ovaries and tubes, among others) listed in the

inclusion term, *absent* the terms in parentheses, procedure code 68.8 could be reported and grouped appropriately to MDC 13 under MS-DRGs 734 and 735. When a pelvic evisceration procedure was performed and removal of the body sites listed in the inclusion term occurred, *including* the terms in parentheses, procedure code 68.8 could be reported and grouped appropriately to MDC 6 under MS-DRGs 332 through 334.

Under ICD-10-PCS, users are instructed to code separately the organs or structures that are actually removed and for which there is a distinctly defined body part. Therefore, the case of a patient who undergoes a pelvic evisceration (exenteration) that involves the removal of the sigmoid colon and rectum would have each of those procedure sites (sigmoid colon and rectum) coded and reported separately (in addition to the procedure codes displayed in the cluster). In this scenario, if the principal diagnosis is a condition from the MDC 6 diagnosis list, the case would group to MS-DRGs 332, 333, and 334, regardless of the code cluster. In other words, it would not be necessary to retain the code cluster describing procedures performed on female pelvic organs in MDC 6.

Therefore, for FY 2017, we are proposing to remove the procedure code cluster for pelvic evisceration procedures from MDC 6 under the ICD-10 MS-DRGs Version 34. The cluster would remain in ICD-10 MDC 13 under MS-DRGs 734 and 735 only. We are inviting public comments on our proposal.

#### 10. MDC 19 (Mental Diseases and Disorders): Proposed Modification of Title of MS-DRG 884 (Organic Disturbances and Mental Retardation)

We received a request to change the title of MS-DRG 884 (Organic Disturbances and Mental Retardation) under MDC 19 (Mental Diseases and Disorders) to “MS-DRG 884 (Organic Disturbances and Intellectual Disability)” to reflect more recent terminology used to appropriately describe the latter medical condition in the MDC.

We agree with the requestor that the reference to the phrase “Mental Retardation” should be changed to “Intellectual Disability”, to reflect the current terminology used to describe the condition. Therefore, we are proposing to change the title of MS-DRG 884 as requested by the requestor.

We are inviting public comments on our proposal to change the title of MS-DRG 884 from “Organic Disturbances and Mental Retardation” to “Organic

Disturbances and Intellectual Disability”, effective October 1, 2016, in the ICD-10 MS-DRGs Version 34.

#### 11. MDC 23 (Factors Influencing Health Status and Other Contacts With Health Services): Logic of MS-DRGs 945 and 946 (Rehabilitation With and Without CC/MCC, Respectively)

We received several requests to examine the MS-DRG logic for MS-DRGs 945 and 946 (Rehabilitation with CC/MCC and without CC/MCC, respectively). The requestors were concerned that ICD-9-CM codes that clearly identified an encounter for rehabilitation services such as procedure codes V57.89 (Care involving other specified rehabilitation procedure) and V57.9 (Care involving unspecified rehabilitation procedure) were not included in ICD-10-CM Version 33. In addition, the requestors pointed out that ICD-10-CM has significantly changed the guidelines for coding of admissions/encounters for rehabilitation. The requestors pointed out that under ICD-9-CM, Section I.B.15. of the Official Guidelines for Coding and Reporting indicates that “when the purpose for the admission/encounter is rehabilitation, sequence the appropriate V code from category V57, Care involving use of rehabilitation procedures, as the principal/first listed diagnosis.” The requestors stated that the concept of the ICD-9-CM category V57 codes is no longer valid in ICD-10-CM and the guidelines have been revised to provide greater specificity. Instead, the requestors added, the ICD-10-CM guidelines state in Section II.K., “When the purpose for the admission/encounter is rehabilitation, sequence first the code for the condition for which the service is being performed. For example, for an admission/encounter for rehabilitation for right-sided dominant hemiplegia following a cerebrovascular infarction, report code I69.351, Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side, as the first-listed or principal diagnosis.”

Given this lack of ICD-10-CM codes to indicate that the reason for the encounter was for rehabilitation, some requestors asked that CMS review ICD-10-CM codes for conditions requiring rehabilitation (such as codes from category I69) and add them to MS-DRGs 945 and 946 when rehabilitation services are provided in order to replicate the logic found in the ICD-9-CM MS-DRG GROUPER. The requestors did not suggest any specific ICD-10-CM codes to add to MS-DRGs 945 and 946.

One requestor made a specific recommendation for updating MS-DRGs

945 and 946. The requestor previously recommended that CMS review diagnosis codes in ICD-10-CM category I69 for possible addition to MS-DRGs 945 and 946. The requestor stated that, upon further review, they believe that a great number of diagnosis codes beyond sequelae of stroke (ICD-10-CM category I69) would need to be added in order to replicate the logic of the ICD-9-CM MS-DRGs. Therefore, they modified their recommendation as follows:

- Designate MS-DRGs 945 and 946 as pre-major diagnostic categories (Pre-MDC) MS-DRGs so that cases are grouped to these MS-DRGs on the basis of the procedure code rather than the principal diagnosis. The requestor stated that the ICD-10-PCS rehabilitation codes (Section F, Physical Rehabilitation and Diagnostic Audiology, Body system 0, Rehabilitation) should be used to group cases to MS-DRGs 945 and 946 similar to how the MS-DRG GROUPER logic currently treats lung transplants and tracheostomies. This would ensure that the rehabilitation procedure codes drive the MS-DRG assignment.

- Revise ICD-10-PCS Official Guidelines for Coding and Reporting and designate that the ICD-10-PCS rehabilitation codes be used only for admissions for rehabilitation therapy.

We acknowledge that ICD-10-CM does not have clear diagnosis codes that indicate the reason for the encounter was for rehabilitation services. For that reason, CMS had to modify the MS-DRG logic using ICD-10-PCS procedure codes to assign these cases to MS-DRGs 945 and 946. The logic used in MS-DRGs 945 and 946 is shown in the Definitions Manual Version 33, which is posted on the CMS Web site at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending>. We also posted a Frequently Asked Question section to explain how inpatient admissions are assigned to MS-DRGs 945 and 946, which is posted on the CMS Web site at: <https://questions.cms.gov/faq.php?id=5005&faqId=12548>. As indicated in the Frequently Asked Question section, the ICD-10-CM codes required a different approach to make sure the same cases captured with ICD-9-CM codes would be captured with ICD-10-CM codes. As stated earlier, ICD-10-CM does not contain specific codes for encounters for rehabilitation such as ICD-9-CM procedure codes V57.89 and V57.9. In order to replicate the ICD-9-CM MS-DRG logic using ICD-10-CM and ICD-

10-PCS codes, CMS developed the new logic included in the MS-DRG Version 33 Definitions Manual.

The Frequently Asked Question section explains that, in order to be assigned to ICD-10 MS-DRG 945 or 946, a case must first have a principal diagnosis from MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services), where MS-DRGs 945 and 946 are assigned. This is currently the logic with the ICD-9-CM MS-DRGs Version 33 where one would first have to have a MDC 23 principal diagnosis. A complete list of ICD-10-CM principal diagnoses for MDC 23 can be found in the ICD-10 MS-DRGs Version 33 Definitions Manual which is posted on the FY 2016 IPPS Final Rule Home Page under the link for the FY 2016 Final Rule Data Files at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html>. Look under the Related Links section and select the ICD-10-CM/PCS MS-DRG v33 Definitions Manual Table of Contents Full Titles HTML Version file. Open this file and the Table of Contents page will appear. Click on the link for MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services). On the next page that opens (MDC 23), click on the link titled "MDC 23 Assignment of Diagnosis Codes" on the upper left side of the screen. By using the navigation arrows at the top right hand side of the page, users can review the 24 pages listing all of the principal diagnosis codes assigned to MDC 23, including many injury codes for subsequent encounters.

Under the GROUPER Logic, cases are assigned to MS-DRGs 945 and 946 in one of two ways as described in the Definitions Manual as follows:

- The encounter has a principal diagnosis code Z44.8 (Encounter for fitting and adjustment of other external prosthetic devices) or Z44.9 (Encounter for fitting and adjustment of unspecified external prosthetic device). Both of these codes are included in the list of principal diagnosis codes assigned to MDC 23.

- The encounter has an MDC 23 principal diagnosis code and one of the rehabilitation procedure codes listed under MS-DRGs 945 and 946.

If the case does not have a principal diagnosis code from the MDC 23 list, but does have a procedure code from the list included under the Rehabilitation Procedures for MS-DRGs 945 and 946, the case will not be assigned to MS-DRGs 945 or 946. The case will instead be assigned to a MS-DRG within the

MDC where the principal diagnosis code is found.

*Example:* The encounter has a principal diagnosis code of S02119D (Unspecified fracture of occiput, subsequent encounter for fracture with routine healing). This code is included in MDC 8. Therefore, diagnosis code S02119D and a procedure code from the MS-DRG 945 and 946 Rehabilitation Procedure list, such as procedure code F0706GZ (Therapeutic Exercise Treatment of Neurological System—Head and Neck using Aerobic Endurance and Conditioning Equipment) would not lead to assignment of the case to MS-DRGs 945 and 946 because the principal diagnosis code is not included in MDC 23.

Diagnosis code S02119D is included in MDC 8 as was the ICD-9-CM predecessor code, V54.19 (Aftercare for healing traumatic fracture of other bone). Therefore, these cases would be assigned to MS-DRGs 559, 560, and 561 (Aftercare, Musculoskeletal System and Connective Tissue with MCC, with CC, and without MCC/CC, respectively) within MDC 8.

At this time, we do not have any claims data that indicate how well this MS-DRG logic is working. We are hesitant to simply add more codes from category I69 without evaluating the impact of doing so using claims data. We also do not have claims data to indicate whether or not there have been changes in the types or numbers of cases assigned to MS-DRGs 945 and 946. We welcome specific suggestions of codes to be added to MS-DRGs 945 and 946 based on hospitals' experience in coding these cases. We would evaluate these suggestions once we have claims data to study the impact.

We have major concerns about the recommendation to revise the ICD-10-PCS Official Guidelines for Coding and Reporting and designate that the ICD-10-PCS rehabilitation codes be assigned and reported only for admissions for rehabilitation therapy. This would be a major new precedent for developing coding and reporting guidelines based on one specific payer's payment policies, in this case Medicare inpatient acute care prospective payment system policies. Hospitals would need to know who the payer was prior to knowing whether or not they could assign a code for a rehabilitation service that they provided. If those payment policies change, the hospital coder would need to be aware of those changes in order to determine whether or not they could submit a code that captures the fact that a rehabilitation service was provided. CMS has worked with the Centers for Disease Control and Prevention (CDC), the American Hospital Association (AHA), and the American Health

Information Management Association (AHIMA) to make ICD-10-PCS guidelines generic and applicable to all types of inpatient facilities and for all payer types. The current ICD-10-PCS Guidelines for Coding and Reporting do not support this recommendation that rehabilitation services could only be coded and reported if the admission was specifically for rehabilitation therapy. The ICD-10-PCS codes were created to accurately capture services provided.

We also have concerns about designating MS-DRGs 945 and 946 as pre-MDCs so that cases are grouped to these MS-DRGs on the basis of a rehabilitation procedure code rather than a principal diagnosis. Pre-MDCs were an addition to Version 8 of the Diagnosis Related Groups. This was the first departure from the use of principal diagnosis as the initial variable in DRG and subsequently MS-DRG assignment. For Pre-MDC DRGs, the initial step in DRG assignment was not the principal diagnosis, but was instead certain surgical procedures with extremely high costs such as heart transplant, liver transplant, bone marrow transplant, and tracheostomies performed on patients on long-term ventilation. These types of services were viewed as being very resource intensive. Recognizing these resource intensive services and assigning them to one of the high-cost MS-DRGs assures appropriate payment even if the patient is admitted for a variety of principal diagnoses. We believe it is inappropriate to consider rehabilitation services in the same group as high-cost procedures such as heart transplants. There is the significant potential of patients being classified out of higher paying surgical MS-DRGs in other MDCs and into the lower paying MS-DRGs 945 and 946 based on the reporting of a rehabilitation procedure code if these MS-DRGs are moved to the Pre-MDCs. We examined claims data for cases reporting a rehabilitation therapy code and found cases assigned to a wide variety of both medical and surgical MS-DRGs. The current coding and reporting of rehabilitation procedure codes for services provided suggest the potential of significant payment problems if MS-DRGs 945 and 946 were assigned to the Pre-MDC section and the reporting of cases with a rehabilitation code led to an inappropriate reassignment to the lower paying medical MS-DRGs 945 and 946.

The following are only a few examples of current claims data that showed the hospital reported a rehabilitation therapy procedure code for services provided which did not impact the MS-DRG assignment. Under the suggested approach of making MS-

DRGs 945 and 946 a Pre-MDC, these cases would move from the appropriately assigned MS-DRGs which may have significantly higher average costs, to MS-DRGs 945 and 946, which have much lower average costs. Based on claims data from the December 2015 update of the FY 2015 MedPAR file, the average costs for cases reported in MS-DRGs 945 and 946 were \$8,531 and \$8,411, respectively.

Examples of cases reporting a rehabilitation therapy code that would move to MS-DRGs 945 and 946 based on the suggested logic change are as follows:

- An MS-DRG 460 (Spinal Fusion Except Cervical with MCC) case with average costs of \$42,390;
- An MS-DRG 464 (Wound Debridement and Skin Graft Excluding Hand, for Musculoskeletal Tissue Disease with CC) case with average costs of \$55,633;
- An MS-DRG 579 (Other Skin, Subcutaneous Tissue and Breast Procedure with MCC) case with average costs of \$63,834;
- An MS-DRG 854 (Infectious and Parasitic Diseases with O.R. procedure with MCC) case with average costs of \$62,455; and
- An MS-DRG 021 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage with CC) case with average costs of \$90,522.

Our clinical advisors reviewed this issue and agreed that we should wait for ICD-10 claims data to become available prior to proposing updates to MS-DRGs 945 and 946. They did not support adding MS-DRGs 945 and 946 to the Pre-MDCs because the rehabilitation services are not as resource intensive as are the other MS-DRGs in the Pre-MDC section.

Considering these ICD-10-PCS guideline concerns, the structure of the pre-MDC section, and the lack of any ICD-10 claims data for MS-DRGs 945 and 946, we are proposing to maintain the current structure of MS-DRGs 945 and 946 and reconsider the issue when ICD-10 claims data become available and prior to proposing any updates.

We are inviting public comments on our proposal to maintain the current structure of MS-DRGs 945 and 946.

## 12. 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.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49409 through 49412), we finalized the ICD-10 Definitions of Medicare Code Edits (ICD-10 MCE) Version 33. ICD-10 MCE Version 33 was based on the FY 2015 ICD-9-CM MCE Version 32 and the draft ICD-10 MCE Version 32 that had been made publicly available for comments in November 2014 on the ICD-10 MS-DRG Conversion Project Web site at: <https://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html>. In August 2015, we posted the finalized FY 2016 ICD-10 MCE Version 33 manual file and an ICD-9-CM MCE Version 33.0A manual file (for analysis purposes only). The links to these MCE manual files, along with the links to purchase the mainframe and computer software for the MCE Version 33 (and ICD-10 MS-DRGs) were posted on the CMS Web site through the FY 2016 IPPS Final Rule Home Page at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page.html?DLSort=0&DLEntries=10&DLPage=1&DLSortDir=ascending>.

After implementation of the ICD-10 MCE Version 33, we received several requests to examine specific code edit lists that the requestors believed were incorrect and that affected claims processing functions. We received requests to review the MCE relating specifically to the Age conflict edit, the Sex conflict edit, the Non-covered procedure edit, and the Unacceptable principal diagnosis code edit. We discuss these code edit issues below.

### a. Age Conflict Edit

In the MCE, the Age conflict edit exists to detect inconsistencies between a patient's age and any diagnosis on the patient's record; for example, a 5-year-old patient with benign prostatic hypertrophy or a 78-year-old patient coded with a delivery. In these cases, the diagnosis is clinically and virtually impossible for a patient of the stated age. Therefore, either the diagnosis or the age is presumed to be incorrect. Currently, in the MCE, the following four age diagnosis categories appear under the Age conflict edit and are listed in the manual and written in the software program:

- Newborn—Age of 0 years; a subset of diagnoses intended only for newborns and neonates (e.g., fetal distress, perinatal jaundice).

- Pediatric—Age is 0–17 years inclusive (e.g., Reye's syndrome, routine child health exam).

- Maternity—Age range is 12–55 years inclusive (e.g., diabetes in pregnancy, antepartum pulmonary complication).

- Adult—Age range is 15–124 years inclusive (e.g., senile delirium, mature cataract).

### (1) Newborn Diagnosis Category

Under the ICD-10-CM Official Guidelines for Coding and Reporting (available on the Web site at: <https://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-CM-and-GEMs.html>), there are general guidelines and chapter-specific coding guidelines. The chapter-specific guidelines state that diagnosis codes from Chapter 16 (Certain Conditions Originating in the Perinatal Period) may be reported throughout the life of the patient if the condition is still present. The requestors noted that several codes from this Chapter 16 appear on the ICD-10 MCE Version 33 Age conflict edit for the newborn diagnosis category. Codes from this chapter are included in the P00 through P96 code range. Therefore, the requestors believed that because the chapter-specific guidelines state that codes within this chapter may be reported throughout the life of a patient, all codes within this range (P00 through P96) should be removed from the newborn diagnosis category on the Age conflict edit code list.

We examined the newborn diagnosis category on the age conflict edit list in the ICD-9-CM MCE Version 32 in comparison to the ICD-9-CM chapter-specific guidelines. Under ICD-9-CM, Chapter 15 (Certain Conditions Originating in the Perinatal Period) includes codes within the 760 through 779 range. We found that the same chapter-specific guideline under ICD-10 exists under ICD-9-CM: Diagnosis codes from Chapter 15 may be reported throughout the life of the patient if the condition is still present. Similar to the ICD-10 MCE Version 33 newborn diagnosis category in the Age conflict edit code list, we noted that several codes from this Chapter 15 appear on the ICD-9-CM MCE Version 32 Age conflict edit for the newborn diagnosis category.

Because the full definition of the chapter-specific guideline for “Certain Conditions Originating in the Perinatal Period” clearly states the codes within the chapter may be reported throughout the life of the patient *if the condition is still present*, we believe that, historically, under ICD-9-CM, this was the rationale for inclusion of the

diagnosis codes that were finalized for the newborn diagnosis category under the Age conflict edit (in code range 760 through 779). For example, under ICD-9-CM, there are four diagnosis codes in the 760.6x series that specifically include the term “newborn” in the title. These diagnosis codes are:

- 760.61 (Newborn affected by amniocentesis);
- 760.62 (Newborn affected by other in utero procedure);
- 760.63 (Newborn affected by other surgical operations on mother during pregnancy); and
- 760.64 (Newborn affected by previous surgical procedure on mother not associated with pregnancy).

Under the ICD-9-CM classification, the chapter-specific guidelines in Chapter 15 (Certain Conditions Originating in the Perinatal Period) state that, for coding and reporting purposes, the perinatal period is defined as before birth through the 28th day following birth. As such, for coding and reporting purposes, a patient that is beyond the 28th day of life is no longer considered a newborn. Therefore, we believe that the diagnosis codes listed on the newborn diagnosis category in the Age conflict edit code list are, in fact, appropriate because they identify what the title of Chapter 15 describes (certain conditions specific to beginning in the perinatal period); that is, a newborn. The intent of the diagnosis codes included on the Age conflict edit code list is to identify claims where any one of the listed diagnoses is reported for a patient who is beyond the 28th day of life. If that definition is met according to the patient’s date of birth, the edit is correctly triggered in those cases.

Transitioning to the ICD-10 MCE was based on replication of the ICD-9-CM based MCE (in parallel with the transition to the ICD-10 MS-DRGs, which was based on replication of the ICD-9-CM MS-DRGs). Therefore, the diagnosis codes included in the newborn diagnosis category on the Age conflict edit code list in the ICD-10 MCE are a replication of the diagnosis code descriptions included on the newborn diagnosis category on the Age conflict edit code list under the ICD-9-CM MCE. However, the chapter-specific guideline in ICD-10-CM Chapter 16, section C.16.e. (Low birth weight and immaturity status), specifies that codes

within category P07 (Disorders of newborn related to short gestation and low birth weight, not elsewhere classified) are for use for a child or adult who was premature or had a low birth weight as a newborn and this condition is affecting the patient’s current health status. Therefore, we agree that codes within the range of P07.00 through P07.39 should not be listed under newborn diagnosis category on the Age conflict edit code list in the ICD-10 MCE. It is unclear why this range of codes within category P07 is distinguished separately when under the General Perinatal Rules for Chapter 16 (Certain Conditions Originating in the Perinatal Period), section I.C.16.a.1. states that diagnosis codes from Chapter 16 may be reported throughout the life of the patient if the condition is still present. In addition, the guideline at section I.C.16.a.4. states that “should a condition originate in the perinatal period, and continue throughout the life of the patient, the perinatal code should continue to be used regardless of the patient’s age.” According to these general guidelines, we could assume that potentially *all* codes within Chapter 16 in the code range of P00 through P96 should be considered for removal from the newborn diagnosis category on the Age conflict edit code list. However, a subsequent section of Chapter 16, section 1.C.16.c.2. (Codes for conditions specified as having implication for future health care needs), instructs users to assign codes for conditions that have been specified by the provider as having implications for future health care needs. Immediately below that instruction is a note which states: “This guideline should not be used for adult patients.”

The ICD-10-CM Official Guidelines for Coding and Reporting are updated separately from the IPPS rulemaking process. Due to the confusion with the chapter-specific guidelines for codes in Chapter 16 and how they impact the newborn diagnosis category on the Age conflict edit code list, we believe it would be beneficial to fully evaluate the intent of these guidelines with the Centers for Disease Control’s (CDC’s) National Center for Health Statistics (NCHS) because NCHS has the lead responsibility for the ICD-10-CM diagnosis codes.

In the meantime, to address claims processing concerns related to the newborn diagnosis category on the Age conflict edit code list, we are proposing to remove all the ICD-10-CM diagnoses in the code range of P00 through P96 from the newborn diagnosis category in the Age conflict code edit list for the ICD-10 MCE for FY 2017. We are inviting public comments on our proposal. We also are soliciting public comments on the appropriateness of the other diagnosis codes currently listed under the newborn diagnosis category in the Age conflict edit in the ICD-10 MCE Version 33. We refer readers to Table 6P.1a. associated with this proposed rule (which is available via the Internet on the CMs Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>) for review of the diagnosis codes we are proposing to remove. In addition, for FY 2017, we are examining the need to revise the description for the newborn diagnosis category in the Age conflict edit under the MCE. The current description as written, Newborn—Age of 0 years; a subset of diagnoses intended only for newborns and neonates (e.g., fetal distress, perinatal jaundice), is not consistent with the instructions for reporting the diagnosis codes in Chapter 16. We are inviting public comments on our proposal to revise the description of the newborn diagnosis category in the Age conflict edit under the MCE.

(2) Pediatric Diagnosis Category

Under the ICD-10 MCE Version 33, the pediatric diagnosis category for the Age conflict edit considers the age range of 0 to 17 years inclusive. For that reason, the diagnosis codes on this Age conflict edit list would be expected to apply to conditions or disorders specific to that age group only. The code list for the pediatric diagnosis category in the Age conflict edit currently includes 12 diagnosis codes that fall within the F90 through F98 code range. These codes were included as a result of replication from the ICD-9-CM MCE Version 32 and the draft ICD-10 MCE Version 32.

We received a request to review the 12 ICD-10-CM diagnosis codes listed in the following table because they appear to conflict with guidance in the ICD-10-CM classification:

ICD-10-CM diagnosis code	Description
F93.0 .....	Separation anxiety disorder of childhood.
F93.8 .....	Other childhood emotional disorders.
F93.9 .....	Childhood emotional disorder, unspecified.



ICD-10-CM diagnosis code	Description
F94.1 .....	Reactive attachment disorder of childhood.
F94.2 .....	Disinhibited attachment disorder of childhood.
F94.8 .....	Other childhood disorders of social functioning.
F94.9 .....	Childhood disorder of social functioning, unspecified.
F98.21 .....	Rumination disorder of infancy.
F98.29 .....	Other feeding disorders of infancy and early childhood.
F98.3 .....	Pica of infancy and childhood.
F98.8 .....	Other specified behavioral and emotional disorders with onset usually occurring in childhood and adolescence.
F98.9 .....	Unspecified behavioral and emotional disorders with onset usually occurring in childhood and adolescence.

Under the ICD-10-CM Tabular List of Diseases and Injuries, Chapter 5 (Mental, Behavioral and Neurodevelopmental Disorders) contains a section titled “Behavioral and emotional disorders with onset usually occurring in childhood and adolescence” which includes codes for the F90 to F98 code range. At the beginning of this tabular section is an instructional “note” that states: “Codes within categories F90–F98 may be used regardless of the age of a patient. These disorders generally have onset within the childhood or adolescent years, but may continue throughout life or not be diagnosed until adulthood.”

Because the note specifically states that these codes may be used regardless of the age of a patient, we believe they should not be included on the pediatric diagnosis category on the Age conflict edit code list. Therefore, we are proposing to remove the 12 codes that fall within the F90 through F98 code range currently listed for the pediatric diagnosis category on the ICD-10 MCE age conflict edit code list, effective October 1, 2016, for FY 2017. We are inviting public comments on our proposal.

We also received a request to review whether another group of diagnosis codes is clinically incorrect for the ICD-

10 MCE Version 33 pediatric diagnosis category in the Age conflict edit. The requestor stated that ICD-10-CM diagnosis codes describing infantile and juvenile cataracts, by their titles, appear to merit inclusion on the pediatric diagnosis category on the Age conflict edit code list. However, according to the requestor, the diagnosis is not constrained to a patient’s age, but rather the “infantile” versus “juvenile” reference is specific to the type of cataract the patient has. These diagnosis codes that are currently listed for the pediatric diagnosis category in the ICD-10 MCE Age conflict edit code list are as follows:

ICD-10-CM diagnosis code	Description
H26.001 .....	Unspecified infantile and juvenile cataract, right eye.
H26.002 .....	Unspecified infantile and juvenile cataract, left eye.
H26.003 .....	Unspecified infantile and juvenile cataract, bilateral.
H26.009 .....	Unspecified infantile and juvenile cataract, unspecified eye.
H26.011 .....	Infantile and juvenile cortical, lamellar, or zonular cataract, right eye.
H26.012 .....	Infantile and juvenile cortical, lamellar, or zonular cataract, left eye.
H26.013 .....	Infantile and juvenile cortical, lamellar, or zonular cataract, bilateral.
H26.019 .....	Infantile and juvenile cortical, lamellar, or zonular cataract, unspecified eye.
H26.031 .....	Infantile and juvenile nuclear cataract, right eye.
H26.032 .....	Infantile and juvenile nuclear cataract, left eye.
H26.033 .....	Infantile and juvenile nuclear cataract, bilateral.
H26.039 .....	Infantile and juvenile nuclear cataract, unspecified eye.
H26.041 .....	Anterior subcapsular polar infantile and juvenile cataract, right eye.
H26.042 .....	Anterior subcapsular polar infantile and juvenile cataract, left eye.
H26.043 .....	Anterior subcapsular polar infantile and juvenile cataract, bilateral.
H26.049 .....	Anterior subcapsular polar infantile and juvenile cataract, unspecified eye.
H26.051 .....	Posterior subcapsular polar infantile and juvenile cataract, right eye.
H26.052 .....	Posterior subcapsular polar infantile and juvenile cataract, left eye.
H26.053 .....	Posterior subcapsular polar infantile and juvenile cataract, bilateral.
H26.059 .....	Posterior subcapsular polar infantile and juvenile cataract, unspecified eye.
H26.061 .....	Combined forms of infantile and juvenile cataract, right eye.
H26.062 .....	Combined forms of infantile and juvenile cataract, left eye.
H26.063 .....	Combined forms of infantile and juvenile cataract, bilateral.
H26.069 .....	Combined forms of infantile and juvenile cataract, unspecified eye.
H26.09 .....	Other infantile and juvenile cataract.

Our clinical advisors reviewed the list of diagnoses presented above and confirmed that these diagnosis codes are appropriate to include in the ICD-10 MCE for the pediatric diagnosis category in the Age conflict edit because the diseases described by these codes are typically diagnosed in early childhood

and treated very rapidly to prevent amblyopia. Therefore, for FY 2017, we are not proposing to remove these codes under the pediatric diagnosis category in the Age conflict edit. We are proposing to maintain this list in the ICD-10 MCE Version 34, effective

October 1, 2016. We are inviting public comments on our proposal.

As stated earlier, for the pediatric diagnosis category in the Age conflict edit, the MCE considers the age range of 0 through 17 years inclusive. In the ICD-10 MCE Version 33, there are four diagnosis codes describing the body

mass index (BMI) for pediatric patients in the pediatric diagnosis category on

the Age conflict edit code list. The four ICD–10–CM diagnosis codes describing

the BMI percentiles for pediatric patients are as follows:

ICD–10–CM diagnosis code	Description
Z68.51 .....	Body mass index (BMI) pediatric, less than 5th percentile for age.
Z68.52 .....	Body mass index (BMI) pediatric, 5th percentile to less than 85th percentile for age.
Z68.53 .....	Body mass index (BMI) pediatric, 85th percentile to less than 95th percentile for age.
Z68.54 .....	Body mass index (BMI) pediatric, greater than or equal to 95th percentile for age.

Under the ICD–10–CM Tabular List of Diseases and Injuries, the BMI pediatric diagnosis codes are designated for use in persons 2 through 20 years of age. The percentiles are based on the growth charts published by the CDC. As a result of the age discrepancy between the MCE pediatric diagnosis category in the Age conflict edit (ages 0 through 17) and the Tabular reference for the BMI pediatric codes (ages 2 through 20), we are proposing to remove ICD–10 diagnosis codes Z68.51, Z68.52, Z68.53, and Z68.54 from the ICD–10 MCE pediatric diagnosis category on the Age conflict edit code list for Version 34, effective FY 2017. We are inviting public comments on our proposal.

One requestor also asked that CMS review the ICD–10–CM diagnosis codes currently included in ICD–10–CM category R62 (Lack of expected normal physiological development in childhood and adults) series. Specifically, the requestor noted that there are adult patients diagnosed with the conditions in subcategory R62.5 (Other and unspecified lack of expected normal physiological development in childhood) and that three of these conditions also were listed in the ICD–10 MCE Version 33 pediatric diagnosis category on the Age conflict edit code list. These three diagnosis codes are:

- R62.50 (Unspecified lack of expected normal physiological development in childhood);
- R62.52 (Short stature (child)); and
- R62.59 (Other lack of expected normal physiological development in childhood).

We acknowledge that subcategory R62.5 can be confusing with regard to how to appropriately report a condition diagnosed for an adult when the titles reference the terms “child” or “childhood”. Therefore, we consulted with the ICD–10–CM classification staff at the NCHS to determine the intended use and reporting of the diagnosis codes R62.50, R62.52, and R62.59. The NCHS staff agreed that the three diagnosis codes should not be restricted to the pediatric ages as defined by the MCE. The NCHS staff stated the codes are

appropriate to report for adult patients, noting that if a patient is diagnosed with short stature as a child, the patient could very well carry over that diagnosis into adulthood.

During our review of the issue relating to the subcategory R62.5 pediatric diagnosis category on the Age conflict edit code list, we identified another diagnosis code that also appeared appropriate to report for an adult patient. ICD–10–CM diagnosis code Y93.6A (Activity, physical games generally associated with school recess, summer camp and children) is one of several activity codes included in ICD–10–CM Chapter 20 (External Causes of Morbidity). This diagnosis code includes games such as dodge ball and captures the flag, which one can reasonably expect an adult to be engaged in for physical activity.

We discussed this diagnosis code with the NCHS staff to receive their input on the intent for coding and reporting the code. They agreed that ICD–10–CM diagnosis code Y93.6A is applicable for adults as well as children. Therefore, for FY 2017, we are proposing to remove ICD–10–CM diagnosis codes R62.50, R62.52, and R62.59 in subcategory R62.5 and ICD–10–CM diagnosis code Y93.6A from the ICD–10 MCE pediatric diagnosis category on the Age conflict edit code list. We are inviting public comment on our proposal.

#### b. Sex Conflict Edit

In the MCE, the Sex conflict edit detects inconsistencies between a patient’s sex and any diagnosis or procedure on the patient’s record; for example, a male patient with cervical cancer (diagnosis) or a female patient with a prostatectomy (procedure). In both instances, the indicated diagnosis or the procedure conflicts with the stated sex of the patient. Therefore, the patient’s diagnosis, procedure, or sex is presumed to be incorrect.

We received a request to review ICD–10–CM diagnosis code Z79.890 (Hormone replacement therapy (postmenopausal)). This code is listed

on the Diagnoses for females only edit code list. Therefore, when the diagnosis is reported for a male patient, the edit will be triggered. However, the requester noted that the term “postmenopausal” is enclosed in parentheses and is a “non-essential modifier.” A “non-essential modifier” is used in the ICD–10–CM classification to identify a supplementary word that may, or may not be present in the statement of a disease or procedure. In other words, the term in parentheses does not have to be documented to report the code. If the medical record documentation states a female patient is undergoing hormone replacement therapy, the documentation supports assignment of the case to ICD–10–CM diagnosis code Z79.890 (Hormone replacement therapy (postmenopausal)). There does not need to be a diagnostic statement that the patient is postmenopausal to assign the code. The requester asked that CMS review why this diagnosis code is being classified as applicable to females only because, in the absence of the non-essential modifier (postmenopausal), the code could also apply to males.

We note that the ICD–9–CM equivalent code, V07.4 Hormone replacement therapy (postmenopausal) has been on the female only edit since October 1, 1992 in the ICD–9–CM MCE. We consulted with the ICD–10–CM classification staff at the NCHS to determine the intended use and reporting of this diagnosis code. The staff at NCHS acknowledged that, historically, the intent of the ICD–9–CM diagnosis code was for females only. However, they agreed that, under ICD–10–CM, the diagnosis code Z79.890 can be reported for both men and women. Therefore, we are proposing to remove this diagnosis code from the Diagnoses for females only edit code list effective October 1, 2016. We are inviting public comments on our proposal.

We also considered the ICD–10–CM diagnosis codes listed in the table below that are included on the Diagnoses for females only edit code list.

ICD-10-CM diagnosis code	Description
Z44.30 .....	Encounter for fitting and adjustment of external breast prosthesis, unspecified breast.
Z44.31 .....	Encounter for fitting and adjustment of external right breast prosthesis.
Z44.32 .....	Encounter for fitting and adjustment of external left breast prosthesis).
Z45.811 .....	Encounter for adjustment or removal of right breast implant.
Z45.812 .....	Encounter for adjustment or removal of left breast implant.
Z45.819 .....	Encounter for adjustment or removal of unspecified breast implant).

These codes describe encounters for breast implants or prostheses. Our clinical advisors and the NCHS staff agree that diagnosis codes Z44.30, Z44.31, Z44.32, Z45.811, Z45.812, and Z45.819 are clinically appropriate to report for male patients and should not be restricted to females. Therefore, we are proposing to remove these diagnosis codes from the Diagnoses for females only edit code list in the ICD-10 MCE, effective October 1, 2016. We are inviting public comments on our proposal.

c. Non-Covered Procedure Edit

In the MCE, the Non-covered procedure edit identifies procedures for which Medicare does not provide payment. Payment is not provided due to specific criteria that are established in the National Coverage Determination (NCD) process. We refer readers to the Web site at: <https://www.cms.gov/Medicare/Coverage/DeterminationProcess/>

*howtorequestanNCD.html* for additional information on this process. In addition, there are procedures that would normally not be paid by Medicare but, due to the presence of certain diagnoses, are paid.

(1) Endovascular Mechanical Thrombectomy

We received several requests to review ICD-10-PCS procedure code 03CG3ZZ (Extirpation of matter from intracranial artery, percutaneous approach) which is currently listed as a non-covered procedure in the ICD-10 MCE Non-covered procedure edit code list. The comparable ICD-9-CM code translations for ICD-10-PCS code 03CG3ZZ are ICD-9-CM codes 17.54 (Percutaneous atherectomy of intracranial vessel(s)) and 39.74 (Endovascular removal of obstruction from head and neck vessel(s)).

The requestors noted that, under ICD-9-CM, endovascular mechanical thrombectomy of a cerebral artery to

remove a clot that is causing an ischemic stroke was reported with procedure code 39.74 (Endovascular removal of obstruction from head and neck vessel(s)) and is a well-recognized procedure that has been covered by Medicare. After implementation of ICD-10 on October 1, 2015, claims that were correctly submitted for endovascular mechanical thrombectomy procedures with ICD-10-PCS procedure code 03CG3ZZ were triggering the Non-covered procedure edit. The requestors sought clarification as to whether there was a change in coverage or if there was a replication issue.

Under the ICD-9-CM MCE Version 32, procedure code 00.62 is listed on the Non-covered procedure edit code list. Percutaneous angioplasty of an intracranial vessel procedure (with and without stent) may be reported under ICD-10 with the ICD-10-PCS procedure codes listed in the following table:

ICD-10-PCS procedure code	Description
037G34Z .....	Dilation of intracranial artery with drug-eluting intraluminal device, percutaneous approach.
037G3DZ .....	Dilation of intracranial artery with intraluminal device, percutaneous approach.
037G3ZZ .....	Dilation of intracranial artery, percutaneous approach.
037G44Z .....	Dilation of intracranial artery with drug-eluting intraluminal device, percutaneous endoscopic approach.
037G4DZ .....	Dilation of intracranial artery with intraluminal device, percutaneous endoscopic approach.
037G4ZZ .....	Dilation of intracranial artery, percutaneous endoscopic approach.
057L3DZ .....	Dilation of intracranial vein with intraluminal device, percutaneous approach.
057L4DZ .....	Dilation of intracranial vein with intraluminal device, percutaneous endoscopic approach.

We discovered that a replication error occurred due to an outdated ICD-9-CM entry for procedure code 00.62. This error led to ICD-10-PCS procedure codes 03CG3ZZ (Extirpation of matter from intracranial artery, percutaneous approach) and 05CL3ZZ (Extirpation of

matter from intracranial vein, percutaneous approach) being listed as comparable translations for ICD-9-CM code 00.62. As a result, ICD-10-PCS procedure code 03CG3ZZ was included on the ICD-10 MCE Version 33 Non-covered procedure edit code list.

For FY 2017, we are proposing to remove the ICD-10-PCS procedure codes listed in the following table from the ICD-10 MCE Version 34.0 Non-covered procedure edit code list.

ICD-10-PCS procedure code	Description
03CG3ZZ .....	Extirpation of matter from intracranial artery, percutaneous approach.
03CG4ZZ .....	Extirpation of matter from intracranial artery, percutaneous endoscopic approach.
05CL3ZZ .....	Extirpation of matter from intracranial vein, percutaneous approach.
05CL4ZZ .....	Extirpation of matter from intracranial vein, percutaneous endoscopic approach.

We are inviting public comments on our proposal.

(2) Radical Prostatectomy

We received a request to review ICD-10-PCS procedure codes related to a radical prostatectomy. Specifically, the requestor noted that when coding cases where the removal of the vas deferens is also performed, a Non-covered procedure edit is triggered. The requestor suggested that the edit for this procedure may be intended for cases where the removal of the vas deferens is being performed for sterilization (vasectomy) purposes. According to the requester, removal of the vas deferens also may be involved with removing the prostate in the radical prostatectomy procedure. The requestor suggested that CMS address this issue by revising the ICD-10 MCE Non-covered procedure edit code list to reflect non-coverage of the procedure codes when the removal of vas deferens procedure is being performed solely for sterilization (vasectomy) purposes.

Because radical procedures can have different meanings, depending on the procedure, the term “radical” is not always reliable information for coding and reporting the procedure. Under ICD-10-PCS, users are instructed to code separately the organs or structures that were actually removed and for which there is a distinctly defined body part. A radical prostatectomy is coded as a “cluster” under ICD-10-PCS. A “cluster” is the term used to describe the circumstance when a combination of ICD-10-PCS procedure codes are needed to fully satisfy the equivalent meaning of an ICD-9-CM procedure code for it to be considered a plausible translation.

The cluster definition for a radical prostatectomy in ICD-10-PCS currently consists of the one of the following codes:

- 0VT00ZZ (Resection of prostate, open approach);
- 0VT04ZZ (Resection of prostate, percutaneous endoscopic approach);

- 0VT07ZZ (Resection of prostate, via natural or artificial opening); or
- 0VT08ZZ Resection of prostate, via natural or artificial opening endoscopic; in combination with one of the following codes:
  - 0VT30ZZ (Resection of bilateral seminal vesicles, open approach); or
  - 0VT34ZZ (Resection of bilateral seminal vesicles, percutaneous endoscopic approach).

As stated earlier, under ICD-10-PCS, users are instructed to code separately the organs or structures that were actually removed and for which there is a distinctly defined body part. Therefore, a patient who undergoes a radical prostatectomy that involves removal of the vas deferens would have this procedure reported separately, in addition to the options displayed in the “cluster.”

The ICD-10-PCS procedure codes that may be reported for sterilization and involve the bilateral vas deferens include the following:

ICD-10-PCS procedure code	Description
0V5Q0ZZ .....	Destruction of bilateral vas deferens, open approach.
0V5Q3ZZ .....	Destruction of bilateral vas deferens, percutaneous approach.
0V5Q4ZZ .....	Destruction of bilateral vas deferens, percutaneous endoscopic approach.
0VBQ0ZZ .....	Excision of bilateral vas deferens, open approach.
0VBQ3ZZ .....	Excision of bilateral vas deferens, percutaneous approach.
0VBQ4ZZ .....	Excision of bilateral vas deferens, percutaneous endoscopic approach.
0VTQ0ZZ .....	Resection of bilateral vas deferens, open approach.
0VTQ4ZZ .....	Resection of bilateral vas deferens, percutaneous endoscopic approach.

The eight procedure codes listed above describing various methods to remove the bilateral vas deferens are currently listed on the ICD-10 MCE Version 33 Non-covered procedure edit code list.

The requester is correct in stating that the codes related to removal of the bilateral vas deferens are included on the ICD-10 MCE Version 33 Non-covered procedure edit code list to reflect a sterilization procedure. While the vast majority of sterilization procedures will involve reporting the bilateral procedure codes, there are instances where one vas deferens may have been previously removed for other reasons and the remaining vas deferens requires sterilization. Therefore, the procedure codes describing removal of a unilateral vas deferens are also included on the ICD-10 MCE Version 33 Non-covered procedure edit code list to reflect a sterilization procedure. We agree that revising the language in the edit will resolve the issue of covered procedures being inappropriately subject to the edit.

In addition, while reviewing the Non-covered procedure edit list of codes that may be reported to identify sterilization procedures for males, we considered the procedure codes that may be reported to identify sterilization procedures for females. We examined the list of ICD-10-PCS procedure codes included on the ICD-10 MCE Version 33 Non-covered procedure edit code list that could reflect female sterilization (removal of fallopian tubes) and determined those codes also could be reported for other conditions and could be inappropriately subject to the current edit as well.

Therefore, for FY 2017, we are proposing to create a new ICD-10 MCE Version 34 Non-covered procedure edit to reflect that procedures performed on males involving the unilateral or bilateral vas deferens and procedures performed on females involving the fallopian tubes are not covered procedures for sterilization purposes. The proposed new ICD-10 MCE Version 34 Non-covered procedure edit would be displayed as follows: “G. Non-

covered procedure. The procedure codes shown below are identified as non-covered procedures *only* when ICD-10-CM diagnosis code Z30.2 (Encounter for sterilization) is listed as the principal diagnosis.”

We refer readers to Table 6P.1b. associated with this proposed rule (which are available via the Internet on the CMS Web site at: [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ AcuteInpatientPPS/index.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html)) to review the proposed list of non-covered procedure codes describing sterilization procedures for males and females for this proposed Non-covered procedure edit. We are inviting public comments on our proposal to create this new Non-covered procedure edit and also invite public comments on the proposed list of codes to describe sterilization procedures for the proposed edit.

d. Unacceptable Principal Diagnosis Edit

In the MCE, there are select codes that describe a circumstance which influences an individual’s health status

but does not actually describe a current illness or injury. There also are codes that are not specific manifestations but may be due to an underlying cause. These codes are considered unacceptable as a principal diagnosis. In limited situations, there are a few codes on the MCE Unacceptable principal diagnosis edit code list that are considered “acceptable” when a specified secondary diagnosis is also coded and reported on the claim.

(1) Liveborn Infant

We received a request to examine ICD–10–CM diagnosis codes Z38.1 (Single liveborn infant, born outside hospital), Z38.4 (Twin liveborn infant, born outside hospital), and Z38.7 (Other multiple liveborn infant, born outside hospital), all of which are currently listed on the Unacceptable principal diagnosis edit code list for the ICD–10 MCE Version 33. The requestor believed that these codes are listed in error and suggested their removal.

The ICD–10–CM diagnosis code descriptions for liveborn infants differ from the ICD–9–CM diagnosis code descriptions for liveborn infants. The ICD–9–CM codes differentiate between a liveborn infant that was born prior to admission and hospitalized versus a liveborn infant that was born prior to admission and *not* hospitalized. The following codes in the ICD–9–CM MCE Version 32 included on the Unacceptable principal diagnosis edit code list are those that describe a liveborn infant that was born outside the hospital and not hospitalized:

ICD–9–CM diagnosis code	Description
V30.2 .....	Single liveborn, born outside hospital and not hospitalized.
V31.2 .....	Twin birth, mate liveborn, born outside hospital and not hospitalized.
V32.2 .....	Twin birth, mate stillborn, born outside hospital and not hospitalized.
V33.2 .....	Twin birth, unspecified whether mate liveborn or stillborn, born outside hospital and not hospitalized.
V34.2 .....	Other multiple birth (three or more), mates all liveborn, born outside hospital and not hospitalized.
V35.2 .....	Other multiple birth (three or more), mates all stillborn, born outside of hospital and not hospitalized.
V36.2 .....	Other multiple birth (three or more), mates liveborn and stillborn, born outside hospital and not hospitalized.
V37.2 .....	Other multiple birth (three or more), unspecified whether mates liveborn or stillborn, born outside of hospital.
V39.1 .....	Liveborn, unspecified whether single, twin or multiple, born before admission to hospital.
V39.2 .....	Liveborn, unspecified whether single, twin or multiple, born outside hospital and not hospitalized.

For replication purposes, the comparable ICD–10–CM diagnosis codes for the above listed codes are: Z38.1 (Single liveborn infant, born outside hospital); Z38.4 (Twin liveborn infant, born outside hospital); and Z38.7 (Other multiple liveborn infant, born outside hospital). There are no other ICD–10–CM diagnosis codes that describe a liveborn infant born outside a hospital.

The liveborn infant codes are an example of where a particular concept involving the place of birth is not the same between the ICD–9–CM and ICD–10–CM classification systems. Because the ICD–10–CM diagnosis codes do not include the same concept as the ICD–9–CM diagnosis codes regarding whether the liveborn infant was hospitalized or

not, we agree it would not be appropriate to continue to include the ICD–10–CM diagnosis codes on the Unacceptable principal diagnosis list.

For FY 2017, we are proposing to remove ICD–10–CM diagnosis codes Z38.1, Z38.4, and Z38.7 from the Unacceptable principal diagnosis edit in the ICD–10 MCE Version 34. We are inviting public comments on our proposal.

(2) Multiple Gestation

We received a request to review the ICD–10–CM diagnosis codes related to multiple gestation that are currently listed on the ICD–10 MCE Version 33 Unacceptable principal diagnosis edit code list. The requestor expressed concern that these codes were included

in the edit and suggested that CMS evaluate further to determine if they were appropriate.

In the ICD–10–CM classification, a single diagnosis code describes a multiple gestation and contains information pertaining to the placenta. This differs from the ICD–9–CM classification, where two diagnosis codes are required to separately report (1) multiple gestation with a delivery or complication and (2) multiple gestation with the status of the placenta.

In the ICD–9–CM MCE Version 32, only the ICD–9–CM diagnosis codes describing the status of the placenta are listed on the Unacceptable principal diagnosis edit code list. These ICD–9–CM diagnosis codes are:

ICD–9–CM diagnosis code	Description
V91.00 .....	Twin gestation, unspecified number of placenta, unspecified number of amniotic sacs.
V91.01 .....	Twin gestation, monochorionic/monoamniotic (one placenta, one amniotic sac).
V91.02 .....	Twin gestation, monochorionic/diamniotic (one placenta, two amniotic sacs).
V91.03 .....	Twin gestation, dichorionic/diamniotic (two placentae, two amniotic sacs).
V91.09 .....	Twin gestation, unable to determine number of placenta and number of amniotic sacs.
V91.10 .....	Triplet gestation, unspecified number of placenta and unspecified number of amniotic sacs.
V91.11 .....	Triplet gestation, with two or more monochorionic fetuses.
V91.12 .....	Triplet gestation, with two or more monoamniotic fetuses.
V91.19 .....	Triplet gestation, unable to determine number of placenta and number of amniotic sacs.
V91.20 .....	(Quadruplet gestation, unspecified number of placenta and unspecified number of amniotic sacs).
V91.21 .....	Quadruplet gestation, with two or more monochorionic fetuses.
V91.22 .....	Quadruplet gestation, with two or more monoamniotic fetuses.
V91.29 .....	Quadruplet gestation, unable to determine number of placenta and number of amniotic sacs.
V91.90 .....	Other specified multiple gestation, unspecified number of placenta and unspecified number of amniotic sacs.
V91.91 .....	Other specified multiple gestation, with two or more monochorionic fetuses.
V91.92 .....	Other specified multiple gestation, with two or more monoamniotic fetuses.

ICD-9-CM diagnosis code	Description
V91.99 .....	Other specified multiple gestation, unable to determine number of placenta and number of amniotic sacs.

There are 68 ICD-10-CM diagnosis codes included on the ICD-10 MCE Version 33 Unacceptable principal diagnosis edit code list as comparable translations that describe multiple gestation and status of the placenta. The list of these codes is included in Table 6P.1c. associated with this proposed rule (which is available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>).

Because only one, and not both, concepts from the ICD-9-CM classification was considered to be an unacceptable principal diagnosis (status of placenta) in the ICD-9-CM MCE, we agree this was a replication error that incorrectly included the ICD-10-CM diagnosis codes that identify both concepts (multiple gestation and status of placenta) in a single code on the ICD-10 MCE. The edit cannot isolate the status of placenta for the ICD-10 MCE because it is reported in combination with the multiple gestation as a single code. Therefore, it is inappropriate to include these codes on the Unacceptable principal diagnosis edit code list.

For FY 2017, we are proposing to remove the ICD-10-CM diagnosis codes listed in Table 6P.1c. associated with this proposed rule (which is available via Internet on the CMS Web site at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>) from the ICD-10 MCE Version 34 Unacceptable principal diagnosis list. We are inviting public comments on our proposal.

(3) Supervision of High Risk Pregnancy

We received a request to review the ICD-10-CM diagnosis codes related to supervision of high risk pregnancy (elderly primigravida and multigravida) that are currently listed on the ICD-10 MCE Version 33 Unacceptable principal diagnosis edit code list. The requestor stated that these codes were not included in the edit under the ICD-9-CM MCE. According to the requester, the codes describing these conditions should be allowed for reporting as a principal diagnosis based on the ICD-10-CM Tabular List of Diseases instructions for Chapter 15 (Certain Conditions Originating in the Perinatal Period). The chapter-specific guidelines for ICD-10-CM state that “diagnosis code O80 (Encounter for full-term uncomplicated delivery) should be assigned when a woman is admitted for a full-term normal delivery and delivers a single, healthy infant without any complications antepartum, during the delivery, or postpartum during the delivery episode. Code O80 is always a principal diagnosis. It is not to be used if any other code from Chapter 15 is

needed to describe a current complication of the antenatal, delivery, or perinatal period.” The requestor stated that obstetric patients admitted as inpatients often meet the definition of an elderly primigravida or elderly multigravida,<sup>1</sup> which is the appropriate condition to be reported as the principal diagnosis. However, because the codes describing this condition are listed on the Unacceptable principal diagnosis edit code list, they are unable to be reported.

The diagnosis codes describing high-risk patients admitted for delivery differ between the ICD-10-CM and ICD-9-CM classifications. Under ICD-9-CM, two diagnosis codes are required to separately report concept 1 of elderly primigravida or elderly multigravida and whether a delivery occurred and concept 2 of supervision of high-risk pregnancy with elderly primigravida or elderly multigravida. We display the codes that correspond to these concepts below and titled them as Code List 1 and Code List 2. A code from each list would be reported to fully describe the circumstances of the admission and the patient.

Code List 1—We note that the following codes are listed on the ICD-9-CM MCE Version 32 Unacceptable principal diagnosis edit code list:

ICD-9-CM diagnosis code	Description
V23.81 .....	Supervision of high-risk pregnancy with elderly primigravida
V23.82 .....	Supervision of high-risk pregnancy with elderly multigravida

Code List 2—We note that the following codes are *not* listed on the ICD-9-CM MCE Version 32

Unacceptable principal diagnosis edit code list. However, we display them

here for the benefit of the reader in the discussion that follows.

ICD-9-CM diagnosis code	Description
659.50 .....	Elderly primigravida, unspecified as to episode of care or not applicable
659.51 .....	Elderly primigravida, delivered, with or without mention of antepartum condition
659.53 .....	Elderly primigravida, antepartum condition or complication
659.60 .....	Elderly multigravida, unspecified as to episode of care or not applicable
659.61 .....	Elderly multigravida, delivered with or without mention of antepartum condition
659.63 .....	Elderly multigravida, antepartum condition or complication

As noted above, in the ICD-9-CM MCE Version 32, only the ICD-9-CM

diagnosis codes describing the supervision of high-risk pregnancy are

listed on the Unacceptable principal diagnosis edit code list.

<sup>1</sup> The ICD-10-CM classification defines an elderly primigravida or elderly multigravida as a

complication of the pregnancy since the

management and care of the expectant mother is affected by the fact they are an older patient.

There are eight ICD–10–CM diagnosis codes included on the ICD–10 MCE Version 33 Unacceptable principal diagnosis edit code list that describe the

concept of elderly primigravida or elderly multigravida and supervision of high-risk pregnancy, in a *single* code. As shown below, the concept of whether a

delivery occurred is not included in the code description for the eight codes.

ICD–10–CM diagnosis code	Description
O09.511 .....	Supervision of elderly primigravida, first trimester
O09.512 .....	Supervision of elderly primigravida, second trimester
O09.513 .....	Supervision of elderly primigravida, third trimester
O09.519 .....	Supervision of elderly primigravida, unspecified trimester
O09.521 .....	Supervision of elderly multigravida, first trimester
O09.522 .....	Supervision of elderly multigravida, second trimester
O09.523 .....	Supervision of elderly multigravida, third trimester
O09.529 .....	Supervision of elderly multigravida, unspecified trimester

Because the concepts and coding guidelines between the ICD–9–CM and ICD–10–CM classifications differ greatly in how they define this subset of patients, we acknowledge that the eight ICD–10–CM diagnosis codes listed above should be removed from the ICD–10 MCE Unacceptable principal diagnosis edit code list to permit the reporting of these codes as principal diagnosis when the documentation supports such assignment.

We also note that during our analysis of the eight diagnosis codes describing elderly primigravida and elderly multigravida high risk pregnancy patients, we found additional codes on the ICD–10 MCE Version 33 Unacceptable principal diagnosis edit code list related to high-risk pregnancy that we believe should also be removed so as to permit the reporting of these codes as principal diagnosis when the documentation supports such assignment.

For FY 2017, we are proposing to remove all the ICD–10–CM diagnosis codes related to high-risk pregnancy currently listed in Table 6P.1d, associated with this proposed rule (which is available via Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>) from the ICD–10 MCE Version 34 Unacceptable principal diagnosis edit code list. We are inviting public comment on our proposal.

e. Other MCE Issues

The following MCE discussion and proposals are the result of internal review of other MCE issues.

(1) Procedure Inconsistent With Length of Stay Edit

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49411), we finalized a revision for the language of the ICD–10 MCE Version 33 edit for “Procedure inconsistent with length of stay” with regard to ICD–10–PCS procedure code

5A1955Z (Respiratory ventilation, greater than 96 consecutive hours). The current description of the code edit reads as follows: “The following procedure code should only be coded on claims with a length of stay greater than four days.”

As we strive to assist providers with correct coding and reporting of this service, we are proposing to further revise the description of this code edit. For FY 2017, we are proposing to modify the edit description to read as follows: “The following procedure code should only be coded on claims when the respiratory ventilation is provided for greater than four consecutive days during the length of stay.”

We believe this modification will further clarify the appropriate circumstances in which ICD–10–PCS code 5A1955Z may be reported. We are inviting public comments on our proposal.

Also, consistent with the discussion in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49411 through 49412), we believe it would be beneficial to revise the title for ICD–10 MS–DRG 208 (Respiratory System Diagnosis with Ventilator Support <96 Hours). Currently, this ICD–10 MS–DRG title references terminology for mechanical ventilation “< 96 hours” based on the GROUPER logic for MS–DRG 208, which includes ICD–10–PCS codes 5A1935Z (Respiratory ventilation, less than 24 consecutive hours) and 5A1945Z (Respiratory ventilation, 24–96 consecutive hours). Because ICD–10–PCS code 5A1945Z includes mechanical ventilation up to and including 96 hours, we are proposing to modify the title of MS–DRG 208 by adding an “equal” sign (=) after the “less than” (<) sign to better reflect the GROUPER logic. We are proposing to revise the title of ICD–10 MS–DRG 208 as follows, effective October 1, 2016: MS–DRG 208 (Respiratory System Diagnosis with Ventilator Support <=96 Hours). We are

inviting public comments on our proposal.

(2) Maternity Diagnoses

We identified three ICD–10–CM diagnosis codes that describe conditions related to pregnancy or the puerperium that are not currently listed on the ICD–10 MCE Version 33 Age conflict edit code list for maternity diagnoses. The diagnosis codes include:

- C58 (Malignant neoplasm of placenta);
- D39.2 (Neoplasm of uncertain behavior of placenta); and
- F53 (Puerperal psychosis).

To be consistent with other related conditions currently included on the Age conflict edit code list for maternity diagnoses, we are proposing to add ICD–10–CM diagnosis codes C58, D39.2, and F53 to the Age conflict edit code list for maternity diagnoses.

We are inviting public comments on our proposals for changes to the FY 2017 ICD–10 MCE Version 34.

(3) Manifestation Codes Not Allowed as Principal Diagnosis Edit

Section I.A.13. of the FY 2016 ICD–10–CM Official Guidelines for Coding and Reporting states that certain conditions have both an underlying etiology and multiple body system manifestations due to the underlying etiology. For such conditions, the classification has a coding convention that requires the underlying condition be sequenced first followed by the manifestation. Wherever such a combination exists, there is a “use additional code” note at the etiology code, and a “code first” note at the manifestation code. These instructional notes indicate proper sequencing order of the codes, etiology followed by manifestation.

We found that in the ICD–10–CM Tabular List of Diseases at category M02- (Postinfective and reactive arthropathies), a “Code first underlying disease” note exists. This would

indicate that there are codes in that category that are manifestations of an underlying etiology. We then examined the ICD-10 MCE Version 33 to determine if diagnosis codes from that category were included on the Manifestation codes not allowed as principal diagnosis edit code list. Only three ICD-10-CM diagnosis codes from that category were listed:

- M02.88 (Other reactive arthropathies, vertebrae);
- M02.89 (Other reactive arthropathies, multiple sites); and
- M02.9 (Reactive arthropathy, unspecified).

Based on the instructional note at the M02- category level, the title at subcategory M02.8 (Other reactive arthropathies), and the three diagnosis codes listed above on the current ICD-10 MCE Version 33 Manifestation codes

not allowed as principal diagnosis edit code list, it seems appropriate that all of the diagnosis codes in subcategory M02.8 should be identified as manifestation codes.

We are proposing to add the ICD-10-CM diagnosis codes listed in the following table to the ICD-10 MCE Version 34 Manifestation codes not allowed as principal diagnosis edit code list.

ICD-10-CM diagnosis code	Description
M02.80 .....	Other reactive arthropathies, unspecified site.
M02.811 .....	Other reactive arthropathies, right shoulder.
M02.812 .....	Other reactive arthropathies, left shoulder.
M02.819 .....	Other reactive arthropathies, unspecified shoulder.
M02.821 .....	Other reactive arthropathies, right elbow.
M02.822 .....	Other reactive arthropathies, left elbow.
M02.829 .....	Other reactive arthropathies, unspecified elbow.
M02.831 .....	Other reactive arthropathies, right wrist.
M02.832 .....	Other reactive arthropathies, left wrist.
M02.839 .....	Other reactive arthropathies, unspecified wrist.
M02.841 .....	Other reactive arthropathies, right hand.
M02.842 .....	Other reactive arthropathies, left hand.
M02.849 .....	Other reactive arthropathies, unspecified hand.
M02.851 .....	Other reactive arthropathies, right hip.
M02.852 .....	Other reactive arthropathies, left hip.
M02.859 .....	Other reactive arthropathies, unspecified hip.
M02.861 .....	Other reactive arthropathies, right knee.
M02.862 .....	Other reactive arthropathies, left knee.
M02.869 .....	Other reactive arthropathies, unspecified knee.
M02.871 .....	Other reactive arthropathies, right ankle and foot.
M02.872 .....	Other reactive arthropathies, left ankle and foot.
M02.879 .....	Other reactive arthropathies, unspecified ankle and foot.

We are inviting public comments on our proposal.

(4) Questionable Admission Edit

In the MCE, some diagnoses are not usually sufficient justification for admission to an acute care hospital. For example, if a patient is assigned ICD-10-CM diagnosis code R03.0 (Elevated blood pressure reading, without diagnosis of hypertension), the patient would have a questionable admission because an elevated blood pressure reading is not normally sufficient justification for admission to a hospital.

Upon review of the ICD-10-CM diagnosis codes listed under the ICD-10 MCE Version 33 Questionable Admission edit, our clinical advisors determined that certain diagnoses clinically warrant hospital admission. Therefore, we are proposing to remove the following diagnosis codes from the ICD-10 MCE Version 34.0 Questionable admission edit.

- T81.81XA (Complication of inhalation therapy, initial encounter);
- T88.4XXA (Failed or difficult intubation, initial encounter);

- T88.7XXA (Unspecified adverse effect of drug or medicament, initial encounter);
- T88.8XXA (Other specified complications of surgical and medical care, not elsewhere classified, initial encounter); and
- T88.9XXA (Complication of surgical and medical care, unspecified, initial encounter).

We are inviting public comments on our proposal.

(5) Removal of Edits and Future Enhancement

With the implementation of ICD-10, it is clear that there are several concepts that differ from the ICD-9-CM classification. These differences are evident in the MCE as discussed earlier in this section. Looking ahead to the needs and uses of coded data as the data continue to evolve from the reporting, collection, processing, coverage, payment and analysis aspect, we believe the need to ensure the accuracy of the coded data becomes increasingly significant.

The purpose of the MCE is to ensure that errors and inconsistencies in the coded data are recognized during

Medicare claims processing. As shown in the FY 2016 ICD-10 MCE Version 33 manual file and an ICD-9-CM MCE Version 33.0A manual file (developed for analysis only), an edit code list exists according to the definition or criteria set forth for each specified type of edit. Over time, certain edits under the ICD-9-CM MCE became discontinued as they were no longer needed. However, the MCE manual has continued to make reference to these discontinued edits, including through the replication process with transitioning to ICD-10.

Currently, the FY 2016 ICD-10 MCE Version 33 manual file displays the following edits:

- 12. Open biopsy check. Effective October 1, 2010, the Open biopsy check edit was discontinued and will appear for claims processed using MCE Version 2.0-26.0 only.
- 13. Bilateral procedure. Effective with the ICD-10 implementation, the bilateral procedure edit will be discontinued.

Because these edits are no longer valid, we are proposing to remove the reference to them, effective with the ICD-10 MCE manual and software



Version 34.0, for FY 2017. We are inviting public comments on our proposal.

As we continue to evaluate the purpose and function of the MCE with respect to the transition to ICD-10, we encourage public input for future discussion. For instance, we recognize a need to further examine the current list of edits and the definitions of those edits. We encourage public comments on whether there are additional concerns with the current edits, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to assist in detecting errors or inaccuracies in the coded data.

### 13. Proposed Changes to Surgical Hierarchies

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

Because the relative resource intensity of surgical classes can shift as a function of MS-DRG reclassification and recalibrations, for FY 2017, 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 in this rule.

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

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the “other O.R. procedures” surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS-DRG or MS-DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The “other O.R. procedures” class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

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

Based on the changes that we are proposing to make for FY 2017, as discussed in section II.F.4.c. of the preamble of this FY 2017 IPPS/LTCH PPS proposed rule, we are proposing to

maintain the existing surgical hierarchy in MDC 5 for proposed revised MS-DRGs 228 and 229 (Other Cardiothoracic Procedures with MCC and without MCC, respectively).

We are inviting public comments on our proposals.

### 14. Proposed Changes to the MS-DRG Diagnosis Codes for FY 2017

The tables identifying the proposed additions and deletions to the MCC severity levels list and the proposed additions and deletions to the CC severity levels list for FY 2017 are available via the Internet on the CMS Web site at: <http://cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html> as follows:

- Table 6I.1—Proposed Additions to the MCC List—FY 2017;
- Table 6I.2—Proposed Deletions to the MCC List—FY 2017;
- Table 6J.1—Proposed Additions to the CC List—FY 2017; and
- Table 6J.2—Proposed Deletions to the CC List—FY 2017.

### 15. Proposed 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 2017

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 previously indicated, 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 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. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50541) for detailed information regarding revisions that were made to the CC Exclusion Lists under the ICD-9-CM MS-DRGs.

For FY 2017, we are proposing changes to the ICD-10 MS-DRGs Version 34 CC Exclusion List. Therefore,

we have developed Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2017; Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2017; Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2017; and Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2017. Each of these principal diagnosis codes for which there is a CC exclusion is shown in Table 6G.2. with an asterisk and the conditions that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. Beginning with discharges on or after October 1 of each year, the indented diagnoses are not recognized by the GROUPER as valid CCs for the asterisked principal diagnoses. Tables 6G and 6H associated with this proposed rule are available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>.

To capture new and deleted diagnosis and procedure codes, for FY 2017, we have developed Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, and Table 6C.—Invalid Diagnosis Codes to this proposed rule. However, they are not published in the Addendum to this proposed rule but are available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>, as described in section VI. of the Addendum to this proposed rule. We note that while we did not specifically develop a Table 6E.—Revised Diagnosis Code Titles for this proposed rule, a document containing the FY 2017 revised diagnosis code titles, as well as new diagnosis codes that have been finalized to date since implementation of the partial code freeze, was made available in advance in response to requests from the health care industry. During the March 9–10, 2016 ICD-10 Coordination and Maintenance Committee meeting, a discussion regarding this document was presented. Participants were informed that the document titled “FY 2017 New Released ICD-10-CM Codes” would contain the information that would otherwise be included for this table. This document has been posted along with the other March 9–10, 2016 ICD-10 Coordination and Maintenance Committee meeting materials on the CDC Web site at: [http://www.cdc.gov/nchs/icd/icd9cm\\_maintenance.htm](http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm).

In addition, we did not specifically develop a Table 6F.—Revised Procedure

Code Titles for this proposed rule. However, a document containing the FY 2017 revised procedure code titles, as well as new procedure codes that have been finalized to date since implementation of the partial code freeze, was made available in advance in response to requests from the health care industry. During the March 9–10, 2016 ICD-10 Coordination and Maintenance Committee meeting, a discussion regarding this document was presented. Participants were informed that the document titled “FY 2017 New Revised ICD-10-PCS Codes” would contain the information that would otherwise be included for this table. This document is posted on the CMS Web site at: <https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials-Items/2016-03-09-MeetingMaterials.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending>.

As mentioned in section II.F.14. of this proposed rule, we are proposing additions and deletions to the MS-DRG MCC and CC Lists for FY 2017 based on the creation of new ICD-10-CM codes. This information is available in Tables 6I.1 (Proposed Additions to the MCC List—FY 2017), 6I.2 (Proposed Deletions to the MCC List—FY 2017), 6J.1 (Proposed Additions to the CC List—FY 2017), and 6J.2 (Proposed Deletions to the CC List—FY 2017). However, they are not published in the Addendum to this proposed rule but are available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>, as described in section VI. of the Addendum to this proposed rule.

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

Each year, we review cases assigned to MS-DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively); MS-DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively); and MS-DRGs 987, 988, and 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to determine whether it would be appropriate to change the procedures assigned among these MS-DRGs. MS-DRGs 981 through 983, 984 through 986, and 987 through 989 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. Under ICD-9-CM, MS-DRGs 984 through 986 are assigned to those discharges in which one or more of the following prostatic procedures are performed and are unrelated to the principal diagnosis:

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

Under the ICD-10 MS-DRGs Version 33, the comparable ICD-10-PCS code translations for the above list of codes are available in Table 6P.2. associated with this proposed rule (which is available via the Internet on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>). 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.

We refer the reader to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50544 through 50545) for detailed information regarding modifications that were made to the former ICD-9-CM CMS DRG 468 (MS-DRGs 981 through 983), CMS DRG 476 (MS-DRGs 984 through 986), and CMS DRG 477 (MS-DRGs 987 through 989) with regard to the movement of procedure codes. We note that no

procedure codes were moved from these DRGs from FY 2008 through FY 2016.

Our review of MedPAR claims data showed that there are no cases that merited movement or should logically be reassigned from ICD-10 MS-DRGs 984 through 986 to any of the other MDCs. Therefore, for FY 2017, we are not proposing to change the procedures assigned among these MS-DRGs. We are inviting public comments on our proposal to maintain the current structure of these MS-DRGs.

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

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

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS-DRGs for the MDC in which the diagnosis falls. Upon review of the claims data from the December 2015 update of the FY 2015 MedPAR file, we did not find any cases that merited movement or that should logically be assigned to any of the other MDCs. Therefore, for FY 2017, 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. We are inviting public comments on our proposal to maintain the current structure of these MS-DRGs.

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

We also reviewed the list of ICD-10-PCS procedures that, when in combination with their principal diagnosis code, result in assignment to MS-DRGs 981 through 983, 984 through 986, or 987 through 989, to ascertain

whether any of those procedures should be reassigned from one of those three groups of MS-DRGs to another of the three groups of 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 are 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 2017, we are not proposing to move any procedure codes among these MS-DRGs. We are inviting public comments on our proposal.

#### c. Adding Diagnosis or Procedure Codes to MDCs

Based on the review of cases in the MDCs, we are proposing to add multiple diagnosis and procedure codes to MDCs for FY 2017 to address replication issues. We discuss each of these proposals below.

##### (1) Angioplasty of Extracranial Vessel

In the ICD-9-CM MS-DRGs Version 32, procedures describing angioplasty of an extracranial vessel were assigned to MDC 1 (Diseases and Disorders of the Nervous System) under MS-DRGs 037, 038, and 039 (Extracranial Procedures with MCC, with CC, or without CC/MCC, respectively). Under ICD-9-CM, more than one ICD-9-CM code could be reported for these procedures, depending on the approach that was documented. For example, ICD-9-CM procedure code 00.61 (Percutaneous angioplasty of extracranial vessel(s)) would have been appropriately reported if the percutaneous approach was documented, and procedure code 39.50 (Angioplasty of other non-coronary vessel(s)) would have been appropriately reported if a specified approach was not documented.

A replication issue for 41 ICD-10-PCS procedure codes describing angioplasty with the open approach was identified after implementation of the ICD-10 MS-DRGs Version 33. In the code translation, these 41 ICD-10-PCS procedure codes were grouped and assigned to ICD-10 MS-DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with

MCC, with CC, and without CC/MCC, respectively). However, these procedure codes should have been grouped to ICD-10 MS-DRGs 037 through 039

when a principal diagnosis was reported under MDC 1.

To resolve this replication issue, we are proposing to add the 41 ICD-10-PCS

procedure codes listed in the following table to ICD-10 MS-DRGs 037 through 039 under MDC 1.

ICD-10-PCS procedure code	Description
037H04Z .....	Dilation of right common carotid artery with drug-eluting intraluminal device, open approach.
037H0DZ .....	Dilation of right common carotid artery with intraluminal device, open approach.
037H0ZZ .....	Dilation of right common carotid artery, open approach.
037J04Z .....	Dilation of left common carotid artery with drug-eluting intraluminal device, open approach.
037J0DZ .....	Dilation of left common carotid artery with intraluminal device, open approach.
037J0ZZ .....	Dilation of left common carotid artery, open approach.
037K04Z .....	Dilation of right internal carotid artery with drug-eluting intraluminal device, open approach.
037K0DZ .....	Dilation of right internal carotid artery with intraluminal device, open approach.
037K0ZZ .....	Dilation of right internal carotid artery, open approach.
037L04Z .....	Dilation of left internal carotid artery with drug-eluting intraluminal device, open approach.
037L0DZ .....	Dilation of left internal carotid artery with intraluminal device, open approach.
037L0ZZ .....	Dilation of left internal carotid artery, open approach.
037M04Z .....	Dilation of right external carotid artery with drug-eluting intraluminal device, open approach.
037M0DZ .....	Dilation of right external carotid artery with intraluminal device, open approach.
037M0ZZ .....	Dilation of right external carotid artery, open approach.
037N04Z .....	Dilation of left external carotid artery with drug-eluting intraluminal device, open approach.
037N0DZ .....	Dilation of left external carotid artery with intraluminal device, open approach.
037N0ZZ .....	Dilation of left external carotid artery, open approach.
037P04Z .....	Dilation of right vertebral artery with drug-eluting intraluminal device, open approach.
037P0DZ .....	Dilation of right vertebral artery with intraluminal device, open approach.
037P0ZZ .....	Dilation of right vertebral artery, open approach.
037Q04Z .....	Dilation of left vertebral artery with drug-eluting intraluminal device, open approach.
037Q0DZ .....	Dilation of left vertebral artery with intraluminal device, open approach.
037Q0ZZ .....	Dilation of left vertebral artery, open approach.
037Y04Z .....	Dilation of upper artery with drug-eluting intraluminal device, open approach.
037Y0DZ .....	Dilation of upper artery with intraluminal device, open approach.
037Y0ZZ .....	Dilation of upper artery, open approach.
057M0DZ .....	Dilation of right internal jugular vein with intraluminal device, open approach.
057M0ZZ .....	Dilation of right internal jugular vein, open approach.
057N0DZ .....	Dilation of left internal jugular vein with intraluminal device, open approach.
057N0ZZ .....	Dilation of left internal jugular vein, open approach.
057P0DZ .....	Dilation of right external jugular vein with intraluminal device, open approach.
057P0ZZ .....	Dilation of right external jugular vein, open approach.
057Q0DZ .....	Dilation of left external jugular vein with intraluminal device, open approach.
057Q0ZZ .....	Dilation of left external jugular vein, open approach.
057R0DZ .....	Dilation of right vertebral vein with intraluminal device, open approach.
057R0ZZ .....	Dilation of right vertebral vein, open approach.
057S0DZ .....	Dilation of left vertebral vein with intraluminal device, open approach.
057S0ZZ .....	Dilation of left vertebral vein, open approach.
057T0DZ .....	Dilation of right face vein with intraluminal device, open approach.
057T0ZZ .....	Dilation of right face vein, open approach.

We are inviting public comments on our proposal to add the above listed codes to ICD-10 MS-DRGs 037, 038, and 039 (Extracranial Procedures with MCC, with CC, or without CC/MCC, respectively) under MDC 1, effective October 1, 2016, for the ICD-10 MS-DRGs Version 34.

#### (2) Excision of Abdominal Arteries

In the ICD-9-CM MS-DRGs Version 32, procedures involving excision of a vessel and anastomosis, such as those performed for the treatment of an abdominal artery aneurysm (aneurysmectomy), are identified with procedure code 38.36 (Resection of vessel with anastomosis, abdominal arteries) and are assigned to the following MDCs and MS-DRGs:

- MDC 5 (Diseases and Disorders of the Circulatory System): MS-DRGs 270 through 272 (Other Major Cardiovascular Procedures with MCC, with CC and without CC/MCC, respectively);

- MDC 6 (Diseases and Disorders of the Digestive System): MS-DRGs 356 through 358 (Other Digestive System O.R. Procedures with MCC, with CC and without CC/MCC, respectively);

- MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract): MS-DRGs 673 through 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC and without CC/MCC, respectively);

- MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs): MS-DRGs 907 through 909 (Other O.R. Procedures for

Injuries with MCC, with CC, and without CC/MCC, respectively); and

- MDC 24 (Multiple Significant Trauma): MS-DRG 957 through 959 (Other O.R. Procedures for Multiple Significant Trauma without CC/MCC).

A replication issue for 34 ICD-10-PCS procedure codes describing aneurysmectomy procedures with the open and percutaneous endoscopic approach was identified after implementation of the ICD-10 MS-DRGs Version 33. For example, cases with a principal diagnosis of I72.2 (Aneurysm of renal artery) and procedure code 04BA0ZZ (Excision of left renal artery, open approach) are resulting in assignment to ICD-10 MS-DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and

without CC/MCC, respectively) instead of to MDC 11 in MS-DRGs 673 through 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively).

To resolve this replication issue, we are proposing to add the 34 ICD-10-PCS procedure codes listed in the following table that are comparable translations of ICD-9-CM procedure code 38.36 to

ICD-10 MDCs 6, 11, 21, and 24. We note that there is no replication issue related to MDC 5 as the ICD-10-PCS procedure codes listed in the table below group there appropriately.

ICD-10-PCS procedure code	Description
04B10ZZ	Excision of celiac artery, open approach.
04B14ZZ	Excision of celiac artery, percutaneous endoscopic approach.
04B20ZZ	Excision of gastric artery, open approach.
04B24ZZ	Excision of gastric artery, percutaneous endoscopic approach.
04B30ZZ	Excision of hepatic artery, open approach.
04B34ZZ	Excision of hepatic artery, percutaneous endoscopic approach.
04B40ZZ	Excision of splenic artery, open approach.
04B44ZZ	Excision of splenic artery, percutaneous endoscopic approach.
04B50ZZ	Excision of superior mesenteric artery, open approach.
04B54ZZ	Excision of superior mesenteric artery, percutaneous endoscopic approach.
04B60ZZ	Excision of right colic artery, open approach.
04B64ZZ	Excision of right colic artery, percutaneous endoscopic approach.
04B70ZZ	Excision of left colic artery, open approach.
04B74ZZ	Excision of left colic artery, percutaneous endoscopic approach.
04B80ZZ	Excision of middle colic artery, open approach.
04B84ZZ	Excision of middle colic artery, percutaneous endoscopic approach.
04B90ZZ	Excision of right renal artery, open approach.
04B94ZZ	Excision of right renal artery, percutaneous endoscopic approach.
04BA0ZZ	Excision of left renal artery, open approach.
04BA4ZZ	Excision of left renal artery, percutaneous endoscopic approach.
04BB0ZZ	Excision of inferior mesenteric artery, open approach.
04BB4ZZ	Excision of inferior mesenteric artery, percutaneous endoscopic approach.
04BC0ZZ	Excision of right common iliac artery, open approach.
04BC4ZZ	Excision of right common iliac artery, percutaneous endoscopic approach.
04BD0ZZ	Excision of left common iliac artery, open approach.
04BD4ZZ	Excision of left common iliac artery, percutaneous endoscopic approach.
04BE0ZZ	Excision of right internal iliac artery, open approach.
04BE4ZZ	Excision of right internal iliac artery, percutaneous endoscopic approach.
04BF0ZZ	Excision of left internal iliac artery, open approach.
04BF4ZZ	Excision of left internal iliac artery, percutaneous endoscopic approach.
04BH0ZZ	Excision of right external iliac artery, open approach.
04BH4ZZ	Excision of right external iliac artery, percutaneous endoscopic approach.
04BJ0ZZ	Excision of left external iliac artery, open approach.
04BJ4ZZ	Excision of left external iliac artery, percutaneous endoscopic approach.

Adding these procedures to those MDCs in the ICD-10 MS-DRGs Version 34 will result in a more accurate replication for the same procedure under the ICD-9-CM MS-DRGs Version 32. We also are proposing that these procedure codes be assigned to the corresponding MS-DRGs in each respective MDC as listed above. The proposed changes would eliminate erroneous assignment to MS-DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for these procedures.

We are inviting public comments on our proposal to add the above listed codes to MDCs 6, 11, 21, and 24 in the corresponding MS-DRGs, effective October 1, 2016, in the ICD-10 MS-DRGs Version 34.

(3) Excision of Retroperitoneal Tissue

In the ICD-9-CM MS-DRGs Version 32, procedures involving excision of a retroperitoneal lesion (or tissue), such as those performed for the treatment of a

neoplasm, are identified with procedure code 54.4 (Excision or destruction of peritoneal tissue) and are assigned to a number of MDCs and MS-DRGs across a variety of body systems, some of which include the following:

- MDC 6 (Diseases and Disorders of the Digestive System): MS-DRGs 356 through 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively);
- MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas): MS-DRGs 423 through 425 (Other Hepatobiliary or Pancreas O.R. Procedures with MCC, with CC, and without CC/MCC, respectively); and
- MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders): MS-DRGs 628 through 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for the ICD-10-PCS procedure codes describing excision of retroperitoneum that involves MDC 6 was identified after

implementation of the ICD-10 MS-DRGs Version 33. These procedure codes are ICD-10-PCS codes 0WBH0ZZ (Excision of retroperitoneum, open approach), 0WBH3ZZ (Excision of retroperitoneum, percutaneous approach), and 0WBH4ZZ (Excision of retroperitoneum, percutaneous endoscopic approach). For example, when an ICD-10-CM diagnosis code such as D20.0 (Benign neoplasm of soft tissue of retroperitoneum) is reported with any one of these three ICD-10-PCS procedure codes, the case is assigned to MS-DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

To resolve this replication issue, we are proposing to add the three ICD-10-PCS procedure codes to MDC 6 in MS-DRGs 356 through 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). This would result in a more accurate replication of the comparable procedure under the ICD-9-CM MS-DRGs Version

32. The proposed changes also would eliminate erroneous assignment to MS-DRGs 981 through 983 for these procedures.

We are inviting public comments on our proposal to add the three ICD-10-PCS codes describing excision of retroperitoneum to MDC 6 in MS-DRGs 356 through 358, effective October 1, 2016, in the ICD-10 MS-DRGs Version 34.

#### (4) Occlusion of Vessels: Esophageal Varices

In the ICD-9-CM MS-DRGs Version 32, procedures including ligation or surgical occlusion of esophageal varices are identified with procedure code 42.91 (Ligation of esophageal varices) and are assigned to MDC 6 (Diseases and Disorders of the Digestive System) under MS-DRGs 326 through 328 (Stomach, Esophageal and Duodenal Procedures with MCC, with CC, and without CC/MCC, respectively) and MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas) under MS-DRGs 423 through 425 (Other Hepatobiliary or Pancreas O.R. procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for MDC 7 involving ICD-10-PCS procedure codes 06L30CZ (Occlusion of esophageal vein with extraluminal device, open approach) and 06L30DZ (Occlusion of esophageal vein with intraluminal device, open approach) was identified in the ICD-10 MS-DRGs Version 33 after implementation on October 1, 2015. For instance, when an ICD-10-CM diagnosis code such as K70.30 (Alcoholic cirrhosis of liver without ascites) is reported with either one of the ICD-10-PCS procedure codes, it results in assignment to MS-DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

To resolve this replication issue, we are proposing to add the two ICD-10-PCS procedure codes describing occlusion of esophageal vein to MDC 7 under MS-DRGs 423 through 425. This will result in a more accurate replication of the comparable procedure under the ICD-9-CM MS-DRGs Version 32. The proposed changes also would eliminate erroneous assignment to MS-DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for these procedures.

We are inviting public comments on our proposal to add ICD-10-PCS procedure codes 06L30CZ and 06L30DZ to MDC 7 under MS-DRGs 423 through

425, effective October 1, 2016, in the ICD-10 MS-DRGs Version 34.

#### (5) Excision of Vulva

In the ICD-9-CM MS-DRGs Version 32, procedures involving excision of the vulva are identified with procedure code 71.3 (Other local excision or destruction of vulva and perineum) and are assigned to the following MDCs and MS-DRGs:

- MDC 9 (Diseases & Disorders of the Skin, Subcutaneous Tissue and Breast): MS-DRGs 579 through 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC, and without CC/MCC, respectively); and
- MDC 13 (Diseases & Disorders of the Female Reproductive System): MS-DRG 746 (Vagina, cervix and vulva procedures with CC/MCC) and MS-DRG 747 (Vagina, Cervix and Vulva procedures without CC/MCC).

A replication issue involving ICD-10-PCS procedure code 0UBMXZZ (Excision of vulva, external approach) was identified after implementation of the ICD-10 MS-DRGs Version 33. For example, when cases with an ICD-10-CM principal diagnosis of code D07.1 (Carcinoma in situ of vulva) are reported with ICD-10-PCS procedure code 0UBMXZZ (Excision of vulva, external approach), they are resulting in assignment to MS-DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

To resolve this replication issue, we are proposing to add ICD-10-PCS procedure code 0UBMXZZ to MDC 13 under MS-DRGs 746 and 747. Adding procedure code 0UBMXZZ to MDC 13 in MS-DRGs 746 and 747 would result in a more accurate replication of the comparable procedure under the ICD-9-CM MS-DRGs Version 32. The proposed changes also would eliminate erroneous assignment to MS-DRGs 981 through 983 for these procedures. In addition, the proposed changes would be consistent with the assignment of other clinically similar procedures, such as ICD-10-PCS procedure code 0WBNXZZ (Excision of female perineum, external approach). Finally, we note that there is no replication issue for MDC 9 regarding this procedure code.

We are inviting public comment on our proposal to add ICD-10-PCS procedure code 0UBMXZZ to MDC 13 in MS-DRGs 746 and 747, effective October 1, 2016, in the ICD-10 MS-DRGs Version 34.

#### (6) Lymph Node Biopsy

In the ICD-9-CM MS-DRGs Version 32, procedures involving a lymph node

biopsy are identified with procedure code 40.11 (Biopsy of lymphatic structure), which may be assigned to several MDCs representing various body systems. Under the ICD-10 MS-DRGs Version 33, this procedure has 114 ICD-10-PCS procedure codes considered to be comparable translations that describe diagnostic drainage or excision of specified lymphatic structures and also warrant assignment to the same MDCs across various body systems.

A replication issue for the lymph node biopsy procedure involving MDC 4 (Diseases and Disorders of the Respiratory System) under the ICD-10 MS-DRGs Version 33 was identified after implementation on October 1, 2015. For example, when a respiratory system diagnosis is reported with the comparable ICD-10-PCS procedure code 07B74ZX (Excision of thorax lymphatic, percutaneous endoscopic approach, diagnostic), the case is assigned to MS-DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

To resolve this replication issue, we are proposing to add ICD-10-PCS procedure code 07B74ZX to MDC 4 under MS-DRGs 166 through 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) to more accurately replicate assignment of the comparable procedure code under the ICD-9-CM MS-DRGs Version 32.

While reviewing that specific example, we also identified two other comparable ICD-10-PCS procedure code translations of ICD-9-CM procedure code 40.11 (Biopsy of lymphatic structure) describing diagnostic excision of thoracic lymphatic structures that were not replicated consistent with the ICD-9-CM MS-DRGs Version 32. These are ICD-10-PCS procedure codes 07B70ZX (Excision of thorax lymphatic, open approach, diagnostic) and 07B73ZX (Excision of thorax lymphatic, percutaneous approach, diagnostic). Therefore, we are proposing to add these two ICD-10-PCS procedure codes to MDC 4 in MS-DRGs 166 through 168 as well.

Adding ICD-10-PCS procedure codes 07B74ZX, 07B70ZX, and 07B73ZX that describe diagnostic excision of thoracic lymphatic structures to MDC 4 under MS-DRGs 166 through 168 would result in a more accurate replication of the comparable procedure under ICD-9-CM MS-DRGs Version 32. The proposed changes would eliminate erroneous assignment to MS-DRGs 987 through 989 for these procedures.

We are inviting public comments on our proposal to add ICD-10-PCS procedure codes 07B74ZX, 07B70ZX, and 07B73ZX to the ICD-10 MS-DRGs

Version 34 for MS-DRGs 166 through 168 in MDC 4, effective October 1, 2016.  
(7) Obstetrical Laceration Repair  
A replication issue for eight ICD-10-PCS procedure codes describing

procedures that may be performed for the repair of obstetrical lacerations was identified after implementation of the ICD-10 MS-DRGs Version 33. These codes are:

ICD-10-PCS procedure code	Description
0DQQ0ZZ .....	Repair anus, open approach.
0DQQ3ZZ .....	Repair anus, percutaneous approach.
0DQQ4ZZ .....	Repair anus, percutaneous endoscopic approach.
0DQQ7ZZ .....	Repair anus, via natural or artificial opening.
0DQQ8ZZ .....	Repair anus, via natural or artificial opening endoscopic.
0DQR0ZZ .....	Repair anal sphincter, open approach.
0DQR3ZZ .....	Repair anal sphincter, percutaneous approach.
0DQR4ZZ .....	Repair anal sphincter, percutaneous endoscopic approach.

We discovered that the ICD-10 MDC and MS-DRG assignment are not consistent with other ICD-10-PCS procedure codes that identify and describe clinically similar procedures for the repair of obstetrical lacerations which are coded and reported based on the extent of the tear. For example, ICD-10-PCS procedure code 0DQP0ZZ (Repair rectum, open approach) is appropriately assigned to MDC 14 (Pregnancy, Childbirth and the Puerperium) under MS-DRG 774 (Vaginal Delivery with Complicating Diagnoses). This procedure may be performed in the treatment of a fourth-degree perineal laceration involving the rectal mucosa. In contrast, ICD-10-PCS procedure code 0DQR0ZZ (Repair anal sphincter, open approach), when reported for repair of a perineal laceration, currently results in assignment to MS-DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis).

To resolve this replication issue, we are proposing to add these eight ICD-10-PCS procedure codes to MDC 14 in MS-DRG 774. The proposed changes would eliminate erroneous assignment to MS-DRGs 987 through 989 for these procedures.

We are inviting public comments on our proposal to add the eight listed codes to MDC 14 under MS-DRG 774, effective October 1, 2016, in the ICD-10 MS-DRGs Version 34.

17. Proposed Changes to the ICD-10-CM and ICD-10-PCS Coding Systems

a. ICD-10 Coordination and Maintenance Committee

In September 1985, the ICD-9-CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS), the Centers for

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

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

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

The Committee encourages participation in the previously mentioned 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 2017 at a public meeting held on September 22-23, 2015, and finalized the coding changes after consideration of comments received at the meetings and in writing by November 13, 2015.

The Committee held its 2016 meeting on March 9-10, 2016. It was announced at this meeting that any new ICD-10-CM/PCS codes for which there was consensus of public support and for which complete tabular and indexing changes would be made by May 2016 would be included in the October 1, 2016 update to ICD-10-CM/ICD-10-PCS. As discussed in earlier sections of this preamble, there are new and deleted ICD-10-CM diagnosis codes and ICD-10-PCS procedure codes that are captured in Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, and Table 6C.—Invalid Diagnosis Codes for the proposed rule, which are available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>. Because of the length of these tables, they are not

published in the Addendum to this proposed rule. Rather, they are available via the Internet as discussed in section VI. of the Addendum to this proposed rule.

Live Webcast recordings of the discussions of procedure codes at the Committee's September 22–23, 2015 meeting and March 9–10, 2016 meeting can be obtained from the CMS Web site at: [http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/03\\_meetings.asp](http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/03_meetings.asp). The minutes of the discussions of diagnosis codes at the September 23–24, 2015 meeting and March 9–10, 2016 meeting are found at: [http://www.cdc.gov/nchs/icd/icd9cm\\_maintenance.html](http://www.cdc.gov/nchs/icd/icd9cm_maintenance.html). These Web sites also provide detailed information about the Committee, including information on requesting a new code, attending a Committee meeting, and timeline requirements and meeting dates.

We encourage commenters to address suggestions on coding issues involving diagnosis codes to: Donna Pickett, Co-Chairperson, ICD–10 Coordination and Maintenance Committee, NCHS, Room 2402, 3311 Toledo Road, Hyattsville, MD 20782. Comments may be sent by Email to: [nchc@cdc.gov](mailto:nchc@cdc.gov).

Questions and comments concerning the procedure codes should be addressed to: Patricia Brooks, Co-Chairperson, ICD–10 Coordination and Maintenance Committee, CMS, Center for Medicare Management, Hospital and Ambulatory Policy Group, Division of Acute Care, C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244–1850. Comments may be sent by Email to: [ICDProcedureCodeRequest@cms.hhs.gov](mailto:ICDProcedureCodeRequest@cms.hhs.gov).

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

Section 503(a) of Public Law 108–173 included a requirement for updating diagnosis and procedure codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or

diagnosis-related group classification) until the fiscal year that begins after such date. This requirement improves the recognition of new technologies under the IPPS system by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

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

The ICD–10 (previously the ICD–9–CM) Coordination and Maintenance Committee holds its meetings in the spring and fall in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the Committee meeting if the request is received at least 2 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS Web site. Final decisions on code title revisions are currently made by March 1 so that these titles can be included in the IPPS proposed rule. A complete addendum describing details of all diagnosis and procedure coding changes, both tabular and index, is published on the CMS and NCHS Web sites in May of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers. This 5-month time period has proved to be necessary for hospitals and other providers to update their systems.

A discussion of this timeline and the need for changes are included in the December 4–5, 2005 ICD–9–CM Coordination and Maintenance Committee Meeting minutes. The public agreed that there was a need to hold the fall meetings earlier, in September or October, in order to meet the new implementation dates. The public provided comment that additional time would be needed to update hospital

systems and obtain new code books and coding software. There was considerable concern expressed about the impact this new April update would have on providers.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the requester at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. The participants at the meeting and those reviewing the Committee meeting summary report are provided the opportunity to comment on this expedited request. All other topics are considered for the October 1 update. Participants at the Committee meeting are encouraged to comment on all such requests. There were no requests approved for an expedited April 1, 2016 implementation of a code at the September 22–23, 2015 Committee meeting. Therefore, there were no new codes implemented on April 1, 2016.

ICD–9–CM addendum and code title information is published on the CMS Web site at: <http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/01overview.asp#TopofPage>. ICD–10–CM and ICD–10–PCS addendum and code title information is published on the CMS Web site at: <http://www.cms.gov/Medicare/Coding/ICD10/index.html>. Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can also be found on the CDC Web site at: <http://www.cdc.gov/nchs/icd/icd10.htm>. Information on new, revised, and deleted ICD–10–CM/ICD–10–PCS codes is also provided to the AHA for publication in the *Coding Clinic for ICD–10*. AHA also distributes information to publishers and software vendors.

CMS also sends copies of all ICD–10–CM and ICD–10–PCS coding changes to its Medicare contractors for use in updating their systems and providing education to providers.



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

b. Code Freeze

In the January 16, 2009 ICD-10-CM and ICD-10-PCS final rule (74 FR 3340), there was a discussion of the need for a partial or total freeze in the annual updates to both ICD-9-CM and ICD-10-CM and ICD-10-PCS codes. The public comment addressed in that final rule stated that the annual code set updates should cease 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 Public Law 108-173. There were to be no updates to ICD-9-CM on October 1, 2014.
- On October 1, 2015, one year after the originally scheduled implementation of ICD-10, regular updates to ICD-10 were to begin.

On May 15, 2014, CMS posted an updated Partial Code Freeze schedule on the CMS Web site at: <http://www.cms.gov/Medicare/Coding/ICD10/ICD-9-CM-Coordination-and-Maintenance-Committee-Meetings.html>. This updated schedule provided information on the extension of the partial code freeze until 1 year after the implementation of ICD-10. As stated earlier, on April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113-93) was enacted, which specified that the Secretary may not adopt ICD-10 prior to October 1, 2015. On August 4, 2014, the Department published a final rule with a compliance date to require the use of ICD-10 beginning October 1, 2015. The final rule also required HIPAA-covered entities to continue to use ICD-9-CM through September 30, 2015.

Accordingly, the updated schedule for the partial code freeze was as follows:

- The last regular annual updates to both ICD-9-CM and ICD-10 code sets were made on October 1, 2011.
- On October 1, 2012, October 1, 2013, and October 1, 2014, there will be

only limited code updates to both the ICD-9-CM and ICD-10 code sets to capture new technologies and diseases as required by section 1886(d)(5)(K) of the Act.

- On October 1, 2015, there will be only limited code updates to ICD-10 code sets to capture new technologies and diagnoses as required by section 1886(d)(5)(K) of the Act. There will be no updates to ICD-9-CM, as it will no longer be used for reporting.
- On October 1, 2016 (1 year after implementation of ICD-10), regular updates to ICD-10 will begin.

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

Complete information on the partial code freeze and discussions of the issues at the Committee meetings can be found on the ICD-10 Coordination and Maintenance Committee Web site at: <http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html>. A summary of the September 19, 2012 Committee meeting, along with both written and audio transcripts of this meeting, is posted on the Web site at: <http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials-Items/2012-09-19-MeetingMaterials.html>.

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

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

ICD-9-CM Codes			ICD-10-CM and ICD-10-PCS Codes		
Fiscal year	Number	Change	Fiscal year	Number	Change
FY 2009 (October 1, 2008)			FY 2009		
Diagnoses .....	14,025	348	ICD-10-CM .....	68,069	+5
Procedures .....	3,824	56	ICD-10-PCS .....	72,589	-14,327
FY 2010 (October 1, 2009)			FY 2010		
Diagnoses .....	14,315	290	ICD-10-CM .....	69,099	+1,030
Procedures .....	3,838	14	ICD-10-PCS .....	71,957	-632
FY 2011 (October 1, 2010)			ICD-10-CM .....	69,368	+269
Diagnoses .....	14,432	117	ICD-10-PCS .....	72,081	+124
Procedures .....	3,859	21	FY 2012		
FY 2012 (October 1, 2011)			ICD-10-CM .....	69,833	+465
Diagnoses .....	14,567	135			

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

ICD-9-CM Codes			ICD-10-CM and ICD-10-PCS Codes		
Fiscal year	Number	Change	Fiscal year	Number	Change
Procedures .....	3,877	18	ICD-10-PCS .....	71,918	- 163
FY 2013 (October 1, 2012)			FY 2013		
Diagnoses .....	14,567	0	ICD-10-CM .....	69,832	- 1
Procedures .....	3,878	1	ICD-10-PCS .....	71,920	+2
FY 2014 (October 1, 2013)			FY 2014		
Diagnoses .....	14,567	0	ICD-10-CM .....	69,823	-9
Procedures .....	3,882	4	ICD-10-PCS .....	71,924	+4
FY 2015 (October 1, 2014)			FY 2015		
Diagnoses .....	14,567	0	ICD-10-CM .....	69,823	0
Procedures .....	3,882	0	ICD-10-PCS .....	71,924	0
FY 2016 (October 1, 2015)			FY 2016		
Diagnoses .....	14,567	0	ICD-10-CM .....	69,823	0
Procedures .....	3,882	0	ICD-10-PCS .....	71,924	0
Proposed FY 2017 (October 1, 2016)			Proposed FY 2017		
Diagnoses .....	14,567	0	ICD-10-CM .....	71,558	0
Procedures .....	3,882	0	ICD-10-PCS .....	75,625	0

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

At the September 22-23, 2015 and March 9-10, 2016 Committee meetings, we discussed any requests we had received for new ICD-10-CM diagnosis codes and ICD-10-PCS procedure codes that were to be implemented on October 1, 2016. We did not discuss ICD-9-CM codes. Because the partial code freeze will end on October 1, 2016, the public no longer had to comment on whether or not new ICD-10-CM and ICD-10-PCS codes should be created based on the partial code freeze criteria. We

invited public comments on any code requests discussed at the September 22-23, 2015 and March 9-10, 2016 Committee meetings for implementation as part of the October 1, 2016 update. The deadline for commenting on code proposals discussed at the September 22-23, 2015 Committee meeting was November 13, 2015. The deadline for commenting on code proposals discussed at the March 9-10, 2016 Committee meeting was April 8, 2016.

18. Replaced Devices Offered Without Cost or With a Credit

a. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS-DRGs where the

implantation of a device that has been recalled determined the base MS-DRG assignment. At that time, we specified that we will reduce a hospital's IPPS payment for those MS-DRGs where the hospital received a credit for a replaced device equal to 50 percent or more of the cost of the device.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 through 51557), we clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly.

b. Proposed Changes for FY 2017

For FY 2017 we are proposing not to add any MS-DRGs to the policy for replaced devices offered without cost or with a credit. We are proposing to continue to include the existing MS-DRGs currently subject to the policy as displayed in the table below.

MDC	MS-DRG	MS-DRG Title
Pre-MDC ...	001	Heart Transplant or Implant of Heart Assist System with MCC.
Pre-MDC ...	002	Heart Transplant or Implant of Heart Assist System without MCC.
1 .....	023	Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis with MCC or Chemo Implant.
1 .....	024	Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis without MCC.
1 .....	025	Craniotomy & Endovascular Intracranial Procedures with MCC.
1 .....	026	Craniotomy & Endovascular Intracranial Procedures with CC.
1 .....	027	Craniotomy & Endovascular Intracranial Procedures without CC/MCC.
1 .....	040	Peripheral/Cranial Nerve & Other Nervous System Procedure with MCC.
1 .....	041	Peripheral/Cranial Nerve & Other Nervous System Procedure with CC or Peripheral Neurostimulator.
1 .....	042	Peripheral/Cranial Nerve & Other Nervous System Procedure without CC/MCC.
3 .....	129	Major Head & Neck Procedures with CC/MCC or Major Device.
3 .....	130	Major Head & Neck Procedures without CC/MCC.
5 .....	215	Other Heart Assist System Implant.
5 .....	216	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheter with MCC.
5 .....	217	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheter with CC.
5 .....	218	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheter without CC/MCC.
5 .....	219	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheter with MCC.
5 .....	220	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheter with CC.

MDC	MS-DRG	MS-DRG Title
5	221	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheter without CC/MCC.
5	222	Cardiac Defibrillator Implant with Cardiac Catheter with AMI/Heart Failure/Shock with MCC.
5	223	Cardiac Defibrillator Implant with Cardiac Catheter with AMI/Heart Failure/Shock without MCC.
5	224	Cardiac Defibrillator Implant with Cardiac Catheter without AMI/Heart Failure/Shock with MCC.
5	225	Cardiac Defibrillator Implant with Cardiac Catheter without AMI/Heart Failure/Shock without MCC.
5	226	Cardiac Defibrillator Implant without Cardiac Catheter with MCC.
5	227	Cardiac Defibrillator Implant without Cardiac Catheter without MCC.
5	242	Permanent Cardiac Pacemaker Implant with MCC.
5	243	Permanent Cardiac Pacemaker Implant with CC.
5	244	Permanent Cardiac Pacemaker Implant without CC/MCC.
5	245	AICD Generator Procedures.
5	258	Cardiac Pacemaker Device Replacement with MCC.
5	259	Cardiac Pacemaker Device Replacement without MCC.
5	260	Cardiac Pacemaker Revision Except Device Replacement with MCC.
5	261	Cardiac Pacemaker Revision Except Device Replacement with CC.
5	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC.
5	266	Endovascular Cardiac Valve Replacement with MCC.
5	267	Endovascular Cardiac Valve Replacement without MCC.
5	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC.
5	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC.
5	270	Other Major Cardiovascular Procedures with MCC.
5	271	Other Major Cardiovascular Procedures with CC.
5	272	Other Major Cardiovascular Procedures without CC/MCC.
8	461	Bilateral or Multiple Major Joint Procedures Of Lower Extremity with MCC.
8	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC.
8	466	Revision of Hip or Knee Replacement with MCC.
8	467	Revision of Hip or Knee Replacement with CC.
8	468	Revision of Hip or Knee Replacement without CC/MCC.
8	469	Major Joint Replacement or Reattachment of Lower Extremity with MCC.
8	470	Major Joint Replacement or Reattachment of Lower Extremity without MCC.

We are soliciting public comments on our proposal to continue to include the existing MS-DRGs currently subject to the policy and to not add any additional MS-DRGs to the policy. The final list of MS-DRGs subject to the policy for FY 2017 will be listed in the FY 2017 IPPS/LTCH PPS final rule, as well as issued to providers in the form of a Change Request (CR).

19. Other Proposed Policy Changes

a. MS-DRG GROUPER Logic  
(1) Operations on Products of Conception

In the ICD-9-CM MS-DRGs Version 32, intrauterine operations that may be performed in an attempt to correct a fetal abnormality are identified by ICD-9-CM procedure code 75.36 (Correction of fetal defect). This procedure code is designated as an O.R. procedure and is assigned to MDC 14 (Pregnancy, Childbirth and the Puerperium) in MS-DRG 768 (Vaginal Delivery with O.R. Procedure Except Sterilization and/or Dilation and Curettage).

A replication issue for 208 ICD-10-PCS comparable code translations that describe operations on the products of conception (fetus) to correct fetal defects was identified during an internal review. These 208 procedure codes were inadvertently omitted from the MDC 14 GROUPER logic for ICD-10 MS-DRG 768. To resolve this replication issue,

we are proposing to add the 208 ICD-10-PCS procedure codes shown in Table 6P.3a. associated with this proposed rule (which is available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index>) to MDC 14 in MS-DRG 768, effective October 1, 2016, in ICD-10 MS-DRGs Version 34. We are inviting public comments on our proposal.

Separate from the replication issue described above, during our internal review, we also concluded that the proposed MS-DRG logic for these intrauterine procedures under ICD-10 may not accurately represent a subset of the 208 ICD-10-PCS procedure codes (listed in Table 6P.3a.). For example, the GROUPER logic for MS-DRG 768 requires that a vaginal delivery occur during the same episode of care in which an intrauterine procedure is performed. However, this scenario may not be clinically consistent with all pregnant patients who undergo fetal surgery. For example, a pregnant patient whose fetus is diagnosed with a congenital diaphragmatic hernia (CDH) may undergo a fetoscopic endoluminal tracheal occlusion (FETO) procedure in which the pregnant patient does not subsequently deliver during the same hospital stay. The goal of this specific fetal surgery is to allow the fetus to remain in utero until its lungs have

developed to increase the chance of survival. Therefore, this scenario of a patient who has fetal surgery but does not have a delivery during the same hospital stay is not appropriately captured in the GROUPER logic. We believe that further analysis is warranted regarding a future proposal for a new MS-DRG to better recognize this subset of patients.

In past rulemaking (72 FR 24700 and 24705), we have acknowledged that CMS does not have the expertise or data to maintain the DRGs in clinical areas that have very low volume in the Medicare population, including for conditions associated with and/or occurring in the maternal-fetal patient population. Additional information is needed to fully and accurately evaluate all the possible fetal conditions that may fall under similar scenarios to the one described above before making a specific proposal. Therefore, we are soliciting public comments on two clinical concepts for consideration for a possible future proposal for the FY 2018 ICD-10 MS-DRGs Version 35: (1) The ICD-10-CM diagnosis codes and ICD-10-PCS procedure codes that describe fetal abnormalities for which fetal surgery may be performed in the absence of a delivery during the same hospital stay; and (2) the ICD-10-CM diagnosis codes and ICD-10-PCS procedure codes that describe fetal abnormalities for which fetal surgery

may be performed with a subsequent delivery during the same hospital stay. This second concept is the structure of current MS-DRG 768. Commenters should submit their code recommendations for these concepts to the following email address [MSDRGClassificationChange@cms.hhs.gov](mailto:MSDRGClassificationChange@cms.hhs.gov) by December 7, 2016. We encourage public comments as we consider these enhancements for the FY 2018 ICD-10 MS-DRGs Version 35.

(2) Other Heart Revascularization

In the ICD-9-CM MS-DRGs Version 32, revascularization procedures that are

performed to restore blood flow to the heart are identified with procedure code 36.39 (Other heart revascularization). This procedure code is designated as an O.R. procedure and is assigned to MDC 5 (Diseases and Disorders of the Circulatory System) in MS-DRGs 228 through 230 (Other Cardiothoracic Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for 16 ICD-10-PCS comparable code translations that describe revascularization procedures was identified after implementation of the ICD-10 MS-DRGs Version 33. These

16 procedure codes were inadvertently omitted from the MDC 5 GROUPER logic for ICD-10 MS-DRGs 228 through 230. We note that, as discussed in section II.F.5.d. of the preamble of this proposed rule, we are proposing to delete MS-DRG 230 and revise MS-DRG 229. Accordingly, to resolve this replication issue, we are proposing to add the 16 ICD-10-PCS procedure codes listed in the table below to MDC 5 in MS-DRG 228 and proposed revised MS-DRG 229.

ICD-10-PCS procedure code	Description
0210344 .....	Bypass coronary artery, one site from coronary vein with drug-eluting intraluminal device, percutaneous approach.
02103D4 .....	Bypass coronary artery, one site from coronary vein with intraluminal device, percutaneous approach.
0210444 .....	Bypass coronary artery, one site from coronary vein with drug-eluting intraluminal device, percutaneous endoscopic approach.
02104D4 .....	Bypass coronary artery, one site from coronary vein with intraluminal device, percutaneous endoscopic approach.
0211344 .....	Bypass coronary artery, two sites from coronary vein with drug-eluting intraluminal device, percutaneous approach.
02113D4 .....	Bypass coronary artery, two sites from coronary vein with intraluminal device, percutaneous approach.
0211444 .....	Bypass coronary artery, two sites from coronary vein with drug-eluting intraluminal device, percutaneous endoscopic approach.
02114D4 .....	Bypass coronary artery, two sites from coronary vein with intraluminal device, percutaneous endoscopic approach.
0212344 .....	Bypass coronary artery, three sites from coronary vein with drug-eluting intraluminal device, percutaneous approach.
02123D4 .....	Bypass coronary artery, three sites from coronary vein with intraluminal device, percutaneous approach.
0212444 .....	Bypass coronary artery, three sites from coronary vein with drug-eluting intraluminal device, percutaneous endoscopic approach.
02124D4 .....	Bypass coronary artery, three sites from coronary vein with intraluminal device, percutaneous endoscopic approach.
0213344 .....	Bypass coronary artery, four or more sites from coronary vein with drug-eluting intraluminal device, percutaneous approach.
02133D4 .....	Bypass coronary artery, four or more sites from coronary vein with intraluminal device, percutaneous approach.
0213444 .....	Bypass coronary artery, four or more sites from coronary vein with drug-eluting intraluminal device, percutaneous endoscopic approach.
02134D4 .....	Bypass coronary artery, four or more sites from coronary vein with intraluminal device, percutaneous endoscopic approach.

We are inviting public comments on our proposal to add the above listed ICD-10-PCS procedure codes to MDC 5 in MS-DRG 228 and proposed revised MS-DRG 229 (Other Cardiothoracic Procedures with and without MCC, respectively), effective October 1, 2016, in ICD-10 MS-DRGs Version 34.

(3) Procedures on Vascular Bodies: Chemoreceptors

In the ICD-9-CM MS-DRGs Version 32, procedures performed on the sensory receptors are identified with ICD-9-CM procedure code 39.89 (Other operations on carotid body, carotid sinus and other vascular bodies). This procedure code is designated as an O.R. procedure and is assigned to MDC 5 (Diseases and Disorders of the Circulatory System) in MS-DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for 234 ICD-10-PCS comparable code translations that describe these procedures was identified after implementation of the ICD-10 MS-DRGs Version 33. These 234 procedure codes were inadvertently

omitted from the MDC 5 GROUPER logic for ICD-10 MS-DRGs 252 through 254. To resolve this replication issue, we are proposing to add the 234 ICD-10-PCS procedure codes listed in Table 6P.3b. associated with this proposed rule (which is available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index>) to MDC 5 in MS-DRG 252, 253, and 254, effective October 1, 2016, in ICD-10 MS-DRGs Version 34. We are inviting public comments on our proposal.

(4) Repair of the Intestine

In the ICD-9-CM MS-DRGs Version 32, the procedure for a repair to the intestine may be identified with procedure code 46.79 (Other repair of intestine). This procedure code is designated as an O.R. procedure and is assigned to MDC 6 (Diseases and Disorders of the Digestive System) in MS-DRGs 329, 330, and 331 (Major Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for four ICD-10-PCS comparable code translations was identified after implementation of the ICD-10 MS-DRGs Version 33. These four procedure codes are:

- 0DQF0ZZ (Repair right large intestine, open approach);
- 0DQG0ZZ (Repair left large intestine, open approach);
- 0DQL0ZZ (Repair transverse colon, open approach); and
- 0DQM0ZZ (Repair descending colon, open approach).

These four ICD-10-PCS codes were inadvertently omitted from the MDC 6 GROUPER logic for ICD-10 MS-DRGs 329 through 331. To resolve this replication issue, we are proposing to add the four ICD-10-PCS procedure codes to MDC 6 in MS-DRG 329, 230, and 331, effective October 1, 2016, in ICD-10 MS-DRGs Version 34. We are inviting public comments on our proposal.

(5) Insertion of Infusion Pump

In the ICD-9-CM MS-DRGs Version 32, the procedure for insertion of an infusion pump is identified with procedure code 86.06 (Insertion of

totally implantable infusion pump), which is designated as an O.R. procedure and assigned to a number of MDCs and MS-DRGs across various body systems. We refer readers to the ICD-9-CM MS-DRG Definitions Manual Appendix E—Operating Room Procedures and Procedure Code/MS-

DRG Index, which is available on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Rule-Data-Files.html>, for the complete list of MDCs and MS-

DRGs to which procedure code 86.06 is assigned  
A replication issue for 16 ICD-10-PCS comparable code translations was identified after implementation of the ICD-10 MS-DRGs Version 33. These 16 procedure codes are listed in the table below:

ICD-10-PCS procedure code	Description
0JHD0VZ .....	Insertion of infusion pump into right upper arm subcutaneous tissue and fascia, open approach.
0JHD3VZ .....	Insertion of infusion pump into right upper arm subcutaneous tissue and fascia, percutaneous approach.
0JHF0VZ .....	Insertion of infusion pump into left upper arm subcutaneous tissue and fascia, open approach.
0JHF3VZ .....	Insertion of infusion pump into left upper arm subcutaneous tissue and fascia, percutaneous approach.
0JHG0VZ .....	Insertion of infusion pump into right lower arm subcutaneous tissue and fascia, open approach.
0JHG3VZ .....	Insertion of infusion pump into right lower arm subcutaneous tissue and fascia, percutaneous approach.
0JHH0VZ .....	Insertion of infusion pump into left lower arm subcutaneous tissue and fascia, open approach.
0JHH3VZ .....	Insertion of infusion pump into left lower arm subcutaneous tissue and fascia, percutaneous approach.
0JHL0VZ .....	Insertion of infusion pump into right upper leg subcutaneous tissue and fascia, open approach.
0JHL3VZ .....	Insertion of infusion pump into right upper leg subcutaneous tissue and fascia, percutaneous approach.
0JHM0VZ .....	Insertion of infusion pump into left upper leg subcutaneous tissue and fascia, open approach.
0JHM3VZ .....	Insertion of infusion pump into left upper leg subcutaneous tissue and fascia, percutaneous approach.
0JHN0VZ .....	Insertion of infusion pump into right lower leg subcutaneous tissue and fascia, open approach.
0JHN3VZ .....	Insertion of infusion pump into right lower leg subcutaneous tissue and fascia, percutaneous approach.
0JHPOVZ .....	Insertion of infusion pump into left lower leg subcutaneous tissue and fascia, open approach.
0JHP3VZ .....	Insertion of infusion pump into left lower leg subcutaneous tissue and fascia, percutaneous approach.

These codes were inadvertently omitted from the MDCs and MS-DRGs to which they should be assigned (consistent with the assignment of ICD-9-CM procedure code 86.06) to accurately replicate the ICD-9-CM MS-DRG logic. To resolve this replication issue, we are proposing to add the 16 ICD-10-PCS procedure codes listed above to the corresponding MDCs and MS-DRGs, as set forth in the ICD-9-CM MS-DRG Definitions Manual—Appendix E—Operating Room Procedures and Procedure Code/MS-DRG Index as described earlier, effective October 1, 2016, in ICD-10 MS-DRGs Version 34. We are inviting public comments on our proposal.

(6) Procedures on the Bursa

In the ICD-9-CM MS-DRGs Version 32, procedures that involve cutting into the bursa are identified with procedure code 83.03 (Bursotomy). This procedure code is designated as an O.R. procedure and is assigned to MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) in MS-DRGs 500, 501, and 502 (Soft Tissue Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for six ICD-10-PCS comparable code translations was identified after implementation of the ICD-10 MS-DRGs Version 33. These six procedure codes are:

- 0M850ZZ (Division of right wrist bursa and ligament, open approach);

- 0M853ZZ (Division of right wrist bursa and ligament, percutaneous approach);
- 0M854ZZ (Division of right wrist bursa and ligament, percutaneous endoscopic approach);
- 0M860ZZ (Division of left wrist bursa and ligament, open approach);
- 0M863ZZ (Division of left wrist bursa and ligament, percutaneous approach); and
- 0M864ZZ (Division of left wrist bursa and ligament, percutaneous endoscopic approach).

These codes were inadvertently omitted from the MDC 8 GROUPE logic for ICD-10 MS-DRGs 500, 501, and 502. To resolve this replication issue, we are proposing to add the six ICD-10-PCS procedure codes listed above to MDC 8 in MS-DRGs 500, 501, and 502, effective October 1, 2016, in ICD-10 MS-DRGs Version 34. We are inviting public comments on our proposal.

(7) Procedures on the Breast

In the ICD-9-CM MS-DRGs Version 32, procedures performed for a simple repair to the skin of the breast may be identified with procedure code 86.59 (Closure of skin and subcutaneous tissue of other sites). This procedure code is designated as a non-O.R. procedure. Therefore, this procedure code does not have an impact on MS-DRG assignment.

A replication issue for two ICD-10-PCS comparable code translations was identified after implementation of the

ICD-10 MS-DRGs Version 33. These two procedure codes are: 0HQVXZZ (Repair bilateral breast, external approach) and 0HQYXZZ (Repair supernumerary breast, external approach). These ICD-10-PCS procedures codes were inadvertently assigned to ICD-10 MS-DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC, respectively) in the ICD-10 MS-DRG GROUPE logic. To resolve this replication issue, we are proposing to remove these two ICD-10-PCS procedure codes from MS-DRG 981, 982, and 983, to designate them as non-O.R. procedures, effective October 1, 2016, in ICD-10 MS-DRGs Version 34. We are inviting public comments on our proposal.

(8) Excision of Subcutaneous Tissue and Fascia

In the ICD-9-CM MS-DRGs Version 32, procedures involving excision of the skin and subcutaneous tissue are identified with procedure code 86.3 (Other local excision of lesion or tissue of skin and subcutaneous tissue). This procedure code is designated as a non-O.R. procedure that affects MS-DRG assignment for MS-DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC and without CC/MCC, respectively) in MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast).

A replication issue for 19 ICD-10-PCS comparable code translations was

identified after implementation of the ICD-10 MS-DRGs Version 33. These 19 procedure codes are listed in the table below:

ICD-10-PCS code	Description
0JB03ZZ .....	Excision of scalp subcutaneous tissue and fascia, percutaneous approach.
0JB43ZZ .....	Excision of anterior neck subcutaneous tissue and fascia, percutaneous approach.
0JB53ZZ .....	Excision of posterior neck subcutaneous tissue and fascia, percutaneous approach.
0JB63ZZ .....	Excision of chest subcutaneous tissue and fascia, percutaneous approach.
0JB73ZZ .....	Excision of back subcutaneous tissue and fascia, percutaneous approach.
0JB83ZZ .....	Excision of abdomen subcutaneous tissue and fascia, percutaneous approach.
0JB93ZZ .....	Excision of buttock subcutaneous tissue and fascia, percutaneous approach.
0JBB3ZZ .....	Excision of perineum subcutaneous tissue and fascia, percutaneous approach.
0JBC3ZZ .....	Excision of pelvic region subcutaneous tissue and fascia, percutaneous approach.
0JBD3ZZ .....	Excision of right upper arm subcutaneous tissue and fascia, percutaneous approach.
0JBF3ZZ .....	Excision of left upper arm subcutaneous tissue and fascia, percutaneous approach.
0JBG3ZZ .....	Excision of right lower arm subcutaneous tissue and fascia, percutaneous approach.
0JBH3ZZ .....	Excision of left lower arm subcutaneous tissue and fascia, percutaneous approach.
0JBL3ZZ .....	Excision of right upper leg subcutaneous tissue and fascia, percutaneous approach.
0JBM3ZZ .....	Excision of left upper leg subcutaneous tissue and fascia, percutaneous approach.
0JBN3ZZ .....	Excision of right lower leg subcutaneous tissue and fascia, percutaneous approach.
0JBP3ZZ .....	Excision of left lower leg subcutaneous tissue and fascia, percutaneous approach.
0JBQ3ZZ .....	Excision of right foot subcutaneous tissue and fascia, percutaneous approach.
0JBR3ZZ .....	Excision of left foot subcutaneous tissue and fascia, percutaneous approach.

These codes were inadvertently omitted from the ICD-10 MS-DRG GROUPER logic for MDC 9 in MS-DRGs 579, 580, and 581. To resolve this replication issue, we are proposing to add the 19 ICD-10-PCS procedure codes listed in the table above to MDC 9 in MS-DRGs 579, 580, and 581, effective October 1, 2016, in ICD-10 MS-DRGs Version 34. We are inviting public comments on our proposal.

#### (9) Shoulder Replacement

In the ICD-9-CM MS-DRGs Version 32, procedures that involve replacing a component of bone from the upper arm are identified with procedure code 78.42 (Other repair or plastic operations on bone, humerus). This procedure code is designated as an O.R. procedure and is assigned to MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) in MS-DRGs 492, 493, and 494 (Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with MCC, with CC, and without CC/MCC, respectively).

A replication issue for two ICD-10-PCS comparable code translations was identified after implementation of the ICD-10 MS-DRGs Version 33. These two procedure codes are: 0PRC0JZ (Replacement of right humeral head with synthetic substitute, open approach) and 0PRD0JZ (Replacement of left humeral head with synthetic substitute, open approach). These two codes were inadvertently omitted from the ICD-10 MS-DRG GROUPER logic for MDC 8 in MS-DRGs 492, 493, and 494. To resolve this replication issue, we are proposing to add these two ICD-10-PCS procedure codes to MDC 8 in

MS-DRGs 492, 493, and 494, effective October 1, 2016, in ICD-10 MS-DRGs Version 34. We are inviting public comments on our proposal.

#### (10) Reposition

In the ICD-9-CM MS-DRGs Version 32, procedures that involve the percutaneous repositioning of an area in the vertebra are identified with procedure code 81.66 (Percutaneous vertebral augmentation). This procedure code is designated as an O.R. procedure and is assigned to MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) in MS-DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for four ICD-10-PCS comparable code translations was identified after implementation of the ICD-10 MS-DRGs Version 33. These four procedure codes are:

- 0PS33ZZ (Reposition cervical vertebra, percutaneous approach);
- 0PS43ZZ (Reposition thoracic vertebra, percutaneous approach);
- 0QS03ZZ (Reposition lumbar vertebra, percutaneous approach); and
- 0QS13ZZ (Reposition sacrum, percutaneous approach).

These four ICD-10-PCS procedure codes were inadvertently omitted from the ICD-10 MS-DRG GROUPER logic for MDC 8 and MS-DRGs 515, 516, and 517. To resolve this replication issue, we are proposing to add these four ICD-10-PCS procedure codes to MDC 8 in MS-DRGs 515, 516, and 517, effective October 1, 2016, in ICD-10 MS-DRGs Version 34. We are inviting public comments on our proposal.

#### (11) Insertion of Infusion Device

In the ICD-9-CM MS-DRGs Version 32, the procedure for insertion of an infusion pump is identified with procedure code 86.06 (Insertion of totally implantable infusion pump) which is designated as an O.R. procedure and assigned to a number of MDCs and MS-DRGs, one of which is MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) in MS-DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for 49 ICD-10-PCS comparable code translations that describe insertion of an infusion device into a joint or disc was identified after implementation of the ICD-10 MS-DRGs Version 33. These 49 procedure codes appear to describe procedures that utilize a specific type of infusion device known as an infusion pump and were inadvertently omitted from the ICD-10 MS-DRG GROUPER logic for MDC 8. To resolve this replication issue, we are proposing to add the 49 ICD-10-PCS procedure codes shown in Table 6P.3c. (which is available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index>) to MDC 8 in MS-DRGs 515, 516, and 517, effective October 1, 2016, in ICD-10 MS-DRGs Version 34. We are inviting public comments on our proposal.

#### (12) Bladder Neck Repair

In the ICD-9-CM MS-DRGs Version 32, a procedure involving a bladder

repair is identified with procedure code 57.89 (Other repair of bladder) which is designated as an O.R. procedure and assigned to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) in MS-DRGs 653, 654, and 655 (Major Bladder Procedures with MCC, with CC, and without CC/MCC, respectively) and MDC 13 (Diseases and Disorders of the Female Reproductive System) in MS-DRGs 749 and 750 (Other Female Reproductive System O.R. Procedures with CC/MCC and without CC/MCC, respectively).

A replication issue for five ICD-10-PCS comparable code translations that describe a bladder neck repair was identified after implementation of the ICD-10 MS-DRGs Version 33. These five procedure codes are:

- 0TQC0ZZ (Repair Bladder Neck, Open Approach);
- 0TQC3ZZ (Repair Bladder Neck, Percutaneous Approach);
- 0TQC4ZZ (Repair Bladder Neck, Percutaneous Endoscopic Approach);
- 0TQC7ZZ (Repair Bladder Neck, Via Natural or Artificial Opening); and
- 0TQC8ZZ (Repair Bladder Neck, Via Natural or Artificial Opening Endoscopic).

These five ICD-10-PCS procedure codes were inadvertently omitted from the ICD-10 MS-DRG GROUPER logic for MDC 11 in MS-DRGs 653, 654, and 655 and MDC 13 in MS-DRGs 749 and 750. To resolve this replication issue, we are proposing to add these five ICD-10-PCS procedure codes to MDC 11 in MS-DRGs 653, 654, and 655 and MDC 13 in MS-DRGs 749 and 750, effective October 1, 2016, in ICD-10 MS-DRGs Version 34. We are inviting public comments on our proposal.

### (13) Future Consideration

We note that commenters have suggested that there are a number of procedure codes that may not appear to be clinically feasible due to a specific approach or device value in relation to a unique body part in a given body system. These commenters have not identified a comprehensive list of codes to be deleted. However, they have suggested that CMS examine these codes further. Due to the multiaxial structure of ICD-10-PCS, the current system allows for multiple possibilities for a given procedure, some of which may not currently be used. As our focus to refine the ICD-10 MS-DRGs continues, for FY 2018, we will begin to conduct an analysis of where such ICD-10-PCS codes may exist. We welcome suggestions from the public of code refinements that could address the issue of current ICD-10-PCS codes that capture procedures that would not

reasonably be performed. Commenters should submit their recommendations for these code refinements to the following email address:

*MSDRGClassificationChanges@cms.hhs.gov* by December 7, 2016.

We also note that any suggestions that are received by December 7, 2016 to update ICD-10-PCS, including creating new codes or deleting existing codes, will be addressed by the ICD-10 Coordination and Maintenance Committee. Proposals to address the modification of any ICD-10-PCS codes are discussed at the ICD-10 Coordination and Maintenance Committee meetings held in March and September of each year. We refer the reader to section II.F.17. of the preamble of this proposed rule for information related to this process to request updates to ICD-10-PCS.

### b. Issues Relating to MS-DRG 999 (Ungroupable)

Under the ICD-9-CM MS-DRGs Version 32, a diagnosis of complications of an obstetric surgical wound after delivery is identified with diagnosis code 674.32 (Other complications of obstetrical surgical wounds, delivered, with mention of postpartum complication) and is assigned to MDC 14 (Pregnancy, Childbirth and the Puerperium) under MS-DRG 769 (Postpartum and Post Abortion Diagnoses with O.R. Procedure) or MS-DRG 776 (Postpartum and Post Abortion Diagnoses without O.R. Procedure). A replication issue under the ICD-10 MS-DRGs Version 33 for this condition was identified after implementation on October 1, 2015. Under ICD-10-CM, diagnosis code O90.2 (Hematoma of obstetric wound) is the comparable translation for ICD-9-CM diagnosis code 674.32. We discovered that cases where a patient has been readmitted to the hospital after a delivery and ICD-10-CM diagnosis code O90.2 is reported as the principal diagnosis are resulting in assignment to MS-DRG 999 (Ungroupable).

In the ICD-9-CM diagnosis code description, the concept of “delivery” is included in the code title. This concept is not present in the ICD-10-CM classification and has led to a replication issue for patients who delivered during a previous stay and are subsequently readmitted for the complication. To resolve this replication issue, we are proposing to add ICD-10-CM diagnosis code O90.2 to MDC 14 under MS-DRGs 769 and 776. This refinement would be consistent with the ICD-9-CM diagnosis code assignment and result in a more accurate replication of the ICD-9-CM MS-DRGs Version 32.

We are inviting public comments on our proposal to add ICD-10-CM diagnosis code O90.2 to MS-DRG 769 and MS-DRG 776 in MDC 14, effective October 1, 2016, in the ICD-10 MS-DRGs Version 34.

### c. Other Operating Room (O.R.) and Non-O.R. Issues

#### (1) O.R. Procedures to Non-O.R. Procedures

For this FY 2017 IPPS/LTCH PPS proposed rule, we continued our efforts to address the MS-DRG replication issues between ICD-9-CM logic and ICD-10 that were brought to our attention. As a result of analyzing those specific requests, we identified areas in the ICD-10-PCS classification where additional refinements could further support our replication efforts. We discuss these below.

We evaluated specific groups of ICD-10-PCS procedure codes with respect to their current operating room (O.R.) designation that were determined to be inconsistent with the ICD-9-CM procedure codes from which the designation was initially derived. Our review demonstrated that these ICD-10-PCS procedure codes should instead have the attributes of a more logical ICD-9-CM procedure code translation for MS-DRG replication purposes. As specified below, we are proposing to change the status of ICD-10-PCS procedure codes from being designated as O.R. to non-O.R. for the ICD-10 MS-DRGs Version 34. For each group summarized below, the detailed code lists are shown in Tables 6P.4a. through 6P.4k. (ICD-10-CM and ICD-10-PCS Codes for Proposed MCE and MS-DRG Changes—FY 2017) associated with this proposed rule, which are available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>.

#### (a) Endoscopic/Transorifice Insertion

We found 72 ICD-10-PCS procedure codes describing an endoscopic/transorifice (via natural or artificial opening) insertion of infusion and monitoring devices into various tubular body parts that, when coded under ICD-9-CM, would reasonably correlate to other noninvasive catheterization and monitoring types of procedure codes versus an “incision of [body part]” or “other operation on a [body part]” procedure code. We are proposing that the 72 ICD-10-PCS procedure codes in Table 6P.4a. associated with this proposed rule (which is available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/>

*Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be assigned the attributes of the ICD-9-CM procedure code specified in column C. The ICD-9-CM procedure codes and descriptions in column C would replace the ICD-9-CM procedure codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(b) Endoscopic/Transorifice Removal

We found 155 ICD-10-PCS procedure codes describing an endoscopic/transorifice (via natural or artificial opening) removal of common devices such as a drainage device, infusion device, intraluminal device, or monitoring device from various tubular body parts that, when coded under ICD-9-CM, would reasonably correlate to other nonoperative removal of a wide range of devices/appliances procedure codes versus an “incision of [body part]” or “other operation on a [body part]” procedure code. We are proposing that the 155 ICD-10-PCS procedure codes in Table 6P.4b. associated with this proposed rule (which is available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>) be assigned the attributes of the ICD-9-CM procedure code specified in column C. The ICD-9-CM procedure codes and descriptions in column C would replace the ICD-9-CM procedure codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(c) Tracheostomy Device Removal

We found five ICD-10-PCS procedure codes describing removal of a tracheostomy device with various approaches such that, when coded under ICD-9-CM, would reasonably correlate to the nonoperative removal of a tracheostomy device procedure code versus an “incision of [body part]” or “other operation on a [body part]” procedure code. We acknowledge that, under ICD-10-PCS, an “open” approach is defined as “cutting through.” However, this procedure was designated as non-O.R. under ICD-9-CM. For replication purposes, we are proposing that the five ICD-10-PCS procedure codes in Table 6P.4c. associated with this proposed rule (which is available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>) be assigned the attributes of the ICD-9-CM procedure code specified

in column C. The ICD-9-CM procedure codes and descriptions in column C would replace the ICD-9-CM procedure codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(d) Endoscopic/Percutaneous Insertion

We found 117 ICD-10-PCS procedure codes describing the endoscopic/percutaneous insertion of infusion and monitoring devices into vascular and musculoskeletal body parts that, when coded under ICD-9-CM, would reasonably correlate to other noninvasive catheterization and monitoring types of procedure codes versus an “incision of [body part]” or “other operation on a [body part]” procedure code. We are proposing that the 117 ICD-10-PCS procedure codes in Table 6P.4d. associated with this proposed rule (which is available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>) be assigned the attributes of the ICD-9-CM procedure code specified in column C. The ICD-9-CM procedure codes and descriptions in column C would replace the ICD-9-CM procedure codes and descriptions reflected in column D, which are less accurate correlations. We are inviting public comments on this proposal.

(e) Percutaneous Removal

We found 124 ICD-10-PCS procedure codes describing the percutaneous removal of drainage, infusion and monitoring devices from vascular and musculoskeletal body parts that, when coded under ICD-9-CM, would reasonably correlate to the nonoperative removal of a wide range of devices/appliances procedure codes versus an “incision of [body part]” or “other operation on a [body part]” procedure code. We are proposing that the 124 ICD-10-PCS procedure codes in Table 6P.4e. associated with this proposed rule (which is available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>) be assigned the attributes of the ICD-9-CM procedure code specified in column C. The ICD-9-CM procedure codes and descriptions in column C would replace the ICD-9-CM procedure codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(f) Percutaneous Drainage

We found 518 ICD-10-PCS procedure codes describing the percutaneous therapeutic drainage of all body sites that do not have specific percutaneous drainage codes. The list includes procedure codes for drainage with or without placement of a drainage device. Exceptions to this are cranial, intracranial and the eye where small incisions are the norm and appropriately classified as O.R. These 518 ICD-10-PCS procedure codes, when coded under ICD-9-CM, would reasonably correlate to the nonoperative puncture or drainage of various body sites and other miscellaneous procedures versus an “incision of [body part]” procedure code. We are proposing that the 518 ICD-10-PCS procedure codes in Table 6P.4f. associated with this proposed rule (which is available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>) be assigned the attributes of the ICD-9-CM procedure code specified in column C. The ICD-9-CM procedure codes and descriptions in column C would replace the ICD-9-CM procedure codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(g) Percutaneous Inspection

We found 131 ICD-10-PCS procedure codes describing the percutaneous inspection of body part sites, with the exception of the cranial cavity and brain, whose designation is not consistent with other percutaneous inspection codes. When coded under ICD-9-CM, these procedure codes would reasonably correlate to the “other nonoperative examinations” and “other diagnostic procedures on [body part]” codes where the approach is not specified and the codes are designated as non-O.R. We are proposing that the 131 ICD-10-PCS procedure codes in Table 6P.4g. associated with this proposed rule (which is available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>) be assigned the attributes of the ICD-9-CM procedure code specified in column C. The ICD-9-CM procedure codes and descriptions in column C would replace the ICD-9-CM procedure codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.



(h) Inspection Without Incision

We found 40 ICD-10-PCS procedure codes describing the inspection of various body sites with endoscopic/transorifice and external approaches. Under ICD-9-CM, these codes would reasonably correlate to “other diagnostic procedures on [body part]” codes where the approach is not specified and the codes are designated as non-O.R. We are proposing that the 40 ICD-10-PCS codes in Table 6P.4h. associated with this proposed rule (which is available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>) be assigned the attributes of the ICD-9-CM code specified in column C. The ICD-9-CM codes and descriptions in column C would replace the ICD-9-CM codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(i) Dilation of Stomach

We found six ICD-10-PCS procedure codes describing the dilation of stomach and pylorus body sites with various approaches whose designation is not consistent with all other gastrointestinal body parts dilation codes. Under ICD-9-CM, where a unique dilation code exists, the approach is not specified and these codes are designated as non-O.R. Therefore, we are proposing that the six ICD-10-PCS procedure codes in Table 6P.4i. (which is available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>) be assigned the attributes of the ICD-9-CM code specified in column C. The ICD-9-CM codes and descriptions in column C would replace the ICD-9-CM codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(j) Endoscopic/Percutaneous Occlusion

We found six ICD-10-PCS codes describing percutaneous occlusion of esophageal vein with and without a device that, when coded under ICD-9-CM would reasonably correlate to the endoscopic excision or destruction of the vessel versus an open surgical procedure. We are proposing that the six ICD-10-PCS procedure codes in Table

6P.4j. associated with this proposed rule (which is available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>) be assigned the attributes of the ICD-9-CM code specified in column C. The ICD-9-CM codes and descriptions in column C would replace the ICD-9-CM codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(k) Infusion Device

We found 82 ICD-10-PCS codes describing the insertion of an infusion device to various body parts that, when coded under ICD-9-CM, would reasonably correlate to the insertion of a common infusion catheter versus the insertion of a totally implantable infusion pump. We are proposing that the 82 ICD-10-PCS procedure codes in Table 6P.4k. associated with this proposed rule (which is available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>) be assigned the attributes of the ICD-9-CM code specified in column C. The ICD-9-CM codes and descriptions in column C would replace the ICD-9-CM codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(2) Non-O.R. Procedures to O.R. Procedures

(a) Drainage of Pleural Cavity

In the ICD-9-CM MS-DRGs Version 32 Definitions Manual under Appendix E—Operating Room Procedures and Procedure Code/MS-DRG Index, procedure code 34.06 (Thoracoscopic drainage of pleural cavity) is designated as an O.R. procedure code and is assigned to MS-DRGs 166 through 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 4 (Diseases and Disorders of the Respiratory System).

A replication issue regarding the procedure code designation and MS-DRG assignment for the comparable code translations under the ICD-10 MS-DRGs Version 33 was brought to our attention after implementation on

October 1, 2015. The replication issue involves the following four ICD-10-PCS procedure codes:

- 0W9940Z (Drainage of right pleural cavity with drainage device, percutaneous endoscopic approach);
- 0W994ZZ (Drainage of right pleural cavity, percutaneous endoscopic approach);
- 0W9B40Z (Drainage of left pleural cavity with drainage device, percutaneous endoscopic approach); and
- 0W9B4ZZ (Drainage of left pleural cavity, percutaneous endoscopic approach).

In the ICD-10 MS-DRGs Version 33, these four ICD-10-PCS procedure codes are not recognized as O.R. procedures for purposes of MS-DRG assignment. We agree that this was a replication error and the designation and MS-DRG assignment should be consistent with the designation and MS-DRG assignment of ICD-9-CM procedure code 34.06.

To resolve this replication issue, we are proposing to add ICD-10-PCS procedure codes 0W9940Z, 0W994ZZ, 0W9B40Z, and 0W9B4ZZ to the FY 2017 ICD-10 MS-DRGs Version 34 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS-DRG Index as O.R. procedures assigned to MS-DRGs 166 through 168 in MDC 4. We are inviting public comments on our proposal.

(b) Drainage of Cerebral Ventricle

In the ICD-9-CM MS-DRGs Version 32 Definitions Manual under Appendix E—Operating Room Procedures and Procedure Code/MS-DRG Index, procedure code 02.22 (Intracranial ventricular shunt or anastomosis) is designated as an O.R. procedure code and is assigned to MS-DRGs 023 through 027, collectively referred to as the “Craniotomy” MS-DRGs, in MDC 1 (Diseases and Disorders of the Nervous System).

A replication issue regarding the procedure code designation and MS-DRG assignment for the comparable code translations under the ICD-10 MS-DRGs Version 33 was brought to our attention after implementation on October 1, 2015. The replication issue involves the following ICD-10-PCS procedure codes:

ICD-10-PCS procedure code	Description
009130Z .....	Drainage of cerebral meninges with drainage device, percutaneous approach.
00913ZZ .....	Drainage of cerebral meninges, percutaneous approach.
009140Z .....	Drainage of cerebral meninges with drainage device, percutaneous endoscopic approach.

ICD-10-PCS procedure code	Description
00914ZZ .....	Drainage of cerebral meninges with drainage device, percutaneous endoscopic approach.
009230Z .....	Drainage of dura mater with drainage device, percutaneous approach.
00923ZZ .....	Drainage of dura mater, percutaneous approach.
009240Z .....	Drainage of dura mater with drainage device, percutaneous endoscopic approach.
00924ZZ .....	Drainage of dura mater, percutaneous endoscopic approach.
009430Z .....	Drainage of subdural space with drainage device, percutaneous approach.
00943ZZ .....	Drainage of subdural space, percutaneous approach.
009440Z .....	Drainage of subdural space with drainage device, percutaneous endoscopic approach.
00944ZZ .....	Drainage of subdural space, percutaneous endoscopic approach.
009530Z .....	Drainage of subarachnoid space with drainage device, percutaneous approach.
00953ZZ .....	Drainage of subarachnoid space, percutaneous approach.
009540Z .....	Drainage of subarachnoid space with drainage device, percutaneous endoscopic approach.
00954ZZ .....	Drainage of subarachnoid space, percutaneous endoscopic approach.
00963ZZ .....	Drainage of cerebral ventricle, percutaneous approach.
00964ZZ .....	Drainage of cerebral ventricle, percutaneous endoscopic approach.

In the ICD-10 MS-DRGs Version 33, these ICD-10-PCS procedure codes are not recognized as O.R. procedures for purposes of MS-DRG assignment. We agree that this was a replication error and their translation should be consistent with the designation and MS-DRG assignment of ICD-9-CM procedure 02.22.

To resolve this replication issue, we are proposing to add the ICD-10-PCS procedure codes listed above to the FY 2017 ICD-10 MS-DRGs Version 34 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS-DRG Index as O.R. procedures assigned to MS-DRGs 023 through 027 in MDC 1. We are inviting public comments on our proposal.

### G. Recalibration of the Proposed FY 2017 MS-DRG Relative Weights

#### 1. Data Sources for Developing the Relative Weights

In developing the proposed FY 2017 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 2015 MedPAR data used in this proposed rule include discharges occurring on October 1, 2014, through September 30, 2015, based on bills received by CMS through December 31, 2015, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS). The FY 2015 MedPAR file used in calculating the proposed relative weights includes data for approximately 9,706,869 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, 2015 update of the FY 2015 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 2017 also excludes claims with claim type values not equal to “60.” The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. We note that the proposed FY 2017 relative weights are based on the ICD-9-CM diagnoses and procedures codes from the FY 2015 MedPAR claims data, grouped through the ICD-9-CM version of the FY 2017 GROUPER (Version 34).

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, 2015 update of the FY 2014 HCRIS for calculating the proposed FY 2017 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 calculated the proposed FY 2017 relative weights based on 19 CCRs, as we did for FY 2016. The methodology we used to calculate the proposed FY 2017 MS-DRG cost-based relative weights based on claims data in the FY 2015 MedPAR file and data from the FY 2014 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2017 MS-DRG classifications discussed in sections II.B. and II.F. 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 2015 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 92.4 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.

- 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.

In addition, 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 Bundled Payments for Care Improvement (BPCI) initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process without regard to hospitals’ participation within these bundled payment models (that is, as if hospitals were not participating in those models under the BPCI initiative). The 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. For FY 2017, 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. 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).

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 2014 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 proposed 19 national cost center CCRs. If stakeholders have comments about the groupings in this table, we may consider those comments as we finalize our policy.

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

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				
Intensive Days .....	Semi-Private Room Charges. Ward Charges .... Intensive Care Charges. Coronary Care Charges.	012X, 013X and 016X-019X.	Intensive Care Unit.	C_1_C5_31 .....	C_1_C6_31 .....	D3_HOS_C2_31				
		015X.								
		020X .....								
		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
Drugs .....	Pharmacy Charges.	025X, 026X and 063X.	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				
			Intravenous Therapy.	C_1_C5_64 .....	C_1_C6_64 .....	D3_HOS_C2_64				
			Drugs Charged To Patient.	C_1_C5_73 .....	C_1_C6_73 .....	D3_HOS_C2_73				
			Medical Supplies Charged to Patients.	C_1_C5_71 .....	C_1_C6_71 .....	D3_HOS_C2_71				
Supplies and Equipment.	Medical/Surgical Supply Charges.	0270, 0271, 0272, 0273, 0274, 0277, 0279, and 0621, 0622, 0623.	DME-Rented .....	C_1_C5_96 .....	C_1_C6_96 .....	D3_HOS_C2_96				
			Used Durable Medical Charges.	0293 .....	DME-Sold .....	C_1_C5_97 .....	C_1_C6_97 .....	D3_HOS_C2_97		
Implantable Devices.	.....	0290, 0291, 0292 and 0294-0299.	Implantable Devices Charged to Patients.	C_1_C5_72 .....	C_1_C6_72 .....	D3_HOS_C2_72				
			0275, 0276, 0278, 0624.							
Therapy Services ...	Physical Therapy Charges. Occupational Therapy Charges. Speech Pathology Charges.	042X .....	Physical Therapy	C_1_C5_66 .....	C_1_C6_66 .....	D3_HOS_C2_66				
		043X .....	Occupational Therapy.	C_1_C5_67 .....	C_1_C6_67 .....	D3_HOS_C2_67				
		044X and 047X ....	Speech Pathology	C_1_C5_68 .....	C_1_C6_68 .....	D3_HOS_C2_68				
Inhalation Therapy	Inhalation Therapy Charges.	041X and 046X ....	Respiratory Therapy.	C_1_C5_65 .....	C_1_C6_65 .....	D3_HOS_C2_65				
Operating Room ....	Operating Room Charges.	036X .....	Operating Room	C_1_C5_50 .....	C_1_C6_50 .....	D3_HOS_C2_50				
		071X .....	Recovery Room ..	C_1_C5_51 .....	C_1_C6_51 .....	D3_HOS_C2_51				
Labor & Delivery ....	Operating Room Charges.	072X .....	Delivery Room and Labor Room.	C_1_C5_52 .....	C_1_C6_52 .....	D3_HOS_C2_52				
Anesthesia .....	Anesthesia Charges.	037X .....	Anesthesiology ...	C_1_C5_53 .....	C_1_C6_53 .....	D3_HOS_C2_53				
Cardiology .....	Cardiology Charges.	048X and 073X ....	Electro-cardiology	C_1_C5_69 .....	C_1_C6_69 .....	D3_HOS_C2_69				
		.....	Cardiac Catheterization.	C_1_C5_59 .....	C_1_C6_59 .....	D3_HOS_C2_59				
Cardiac Catheterization.	.....	0481 .....	Laboratory .....	C_1_C5_60 .....	C_1_C6_60 .....	D3_HOS_C2_60				
Laboratory .....	Laboratory Charges.	030X, 031X, and 075X.	PBP Clinic Laboratory Services.	C_1_C5_61 .....	C_1_C6_61 .....	D3_HOS_C2_61				
		074X, 086X .....	Electro-Encephalography.	C_1_C5_70 .....	C_1_C6_70 .....	D3_HOS_C2_70				
Radiology .....	Radiology Charges.	032X, 040X .....	Radiology—Diagnostic.	C_1_C5_54 .....	C_1_C6_54 .....	D3_HOS_C2_54				
		028x, 0331, 0332, 0333, 0335, 0339, 0342.	Radiology—Therapeutic.	C_1_C5_55 .....	C_1_C6_55 .....	D3_HOS_C2_55				
		0343 and 344 .....	Radioisotope .....	C_1_C5_56 .....	C_1_C6_56 .....	D3_HOS_C2_56				
Computed Tomography (CT) Scan.	CT Scan Charges	035X .....	Computed Tomography (CT) Scan.	C_1_C5_57 .....	C_1_C6_57 .....	D3_HOS_C2_57				

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

3. Development of National Average CCRs

We developed the national average CCRs as follows:

Using the FY 2014 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 2017 cost-based relative weights were then normalized by an adjustment factor of 1.690233 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 2017 are as follows:

Group	CCR
Routine Days .....	0.459
Intensive Days .....	0.378
Drugs .....	0.194
Supplies & Equipment .....	0.298
Implantable Devices .....	0.336
Therapy Services .....	0.322
Laboratory .....	0.120
Operating Room .....	0.192
Cardiology .....	0.113
Cardiac Catheterization .....	0.119
Radiology .....	0.154
MRIs .....	0.079
CT Scans .....	0.039
Emergency Room .....	0.172
Blood and Blood Products .....	0.325
Other Services .....	0.368
Labor & Delivery .....	0.411
Inhalation Therapy .....	0.170
Anesthesia .....	0.090

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. For FY 2017, we are proposing to use that same case threshold in recalibrating the MS-DRG relative weights for FY 2017. Using data from the FY 2015 MedPAR file, there were 8 MS-DRGs that contain fewer than 10 cases. Under the MS-DRGs, we have fewer low-volume DRGs than under the CMS DRGs because we no longer have separate DRGs for patients aged 0 to 17 years. With the exception of newborns, we previously separated some DRGs based on whether the patient was age 0 to 17 years or age 17 years and older. Other than the age split, cases grouping to these DRGs are identical. The DRGs for patients aged 0 to 17 years generally have very low volumes because children are typically ineligible for Medicare. In the past, we have found that the low volume of cases for the pediatric DRGs could lead to significant year-to-year instability in their relative weights. Although we have

always encouraged non-Medicare payers to develop weights applicable to their own patient populations, we have received frequent complaints from providers about the use of the Medicare relative weights in the pediatric population. We believe that eliminating this age split in the MS-DRGs will provide more stable payment for pediatric cases by determining their payment using adult cases that are much higher in total volume. Newborns are unique and require separate MS-DRGs that are not mirrored in the adult population. Therefore, it remains necessary to retain separate MS-DRGs for newborns. All of the low-volume MS-DRGs listed are for newborns. For FY 2017, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for these low-volume MS-DRGs, we are proposing to compute relative weights for the low-volume MS-DRGs by adjusting their final FY 2016 relative weights by the percentage change in the average weight of the cases in other MS-DRGs. The crosswalk table is shown:

Low-volume MS-DRG	MS-DRG title	Crosswalk to MS-DRG
768 .....	Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C.	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs).
789 .....	Neonates, Died or Transferred to Another Acute Care Facility.	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs).
790 .....	Extreme Immaturity or Respiratory Distress Syndrome, Neonate.	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs).
791 .....	Prematurity with Major Problems .....	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs).
792 .....	Prematurity without Major Problems .....	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs).
793 .....	Full-Term Neonate with Major Problems	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs).
794 .....	Neonate with Other Significant Problems	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs).
795 .....	Normal Newborn .....	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs).

We are inviting public comments on this proposal.

*H. Proposed Add-On Payments for New Services and Technologies for FY 2017*

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 2010 IPPS/RV 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically: (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS-DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered “new” for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352), and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

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, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, 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 2016 IPPS/LTCH PPS final rule contains the final thresholds that we used to evaluate applications for new medical service and new technology add-on payments for FY 2017. We refer readers to the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS->

*Final-Rule-Tables.html* to download and view Table 10.

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 medical service and 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 or medical service (if the estimated costs for the case including the new technology or medical service 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 or new medical service.

Section 503(d)(2) of Public Law 108-173 provides that there shall be no

reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of Public Law 108-173, add-on payments for new medical services or technologies for FY 2005 and later years have not been subjected to budget neutrality.

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We 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 and medical services between CMS and other entities. The CTI, composed of senior CMS staff and clinicians, was established under section 942(a) of Public Law 108-173. The Council is co-chaired by the Director of the Center for Clinical Standards and Quality (CCSQ) and the Director of the Center for Medicare (CM), who is also designated as the CTI's Executive Coordinator.

The specific processes for coverage, coding, and payment are implemented by CM, CCSQ, and the local claims-payment contractors (in the case of local coverage and payment decisions). The CTI supplements, rather than replaces, these processes by working to assure that all of these activities reflect the agency-wide priority to promote high-quality, innovative care. At the same time, the CTI also works to streamline, accelerate, and improve coordination of these processes to ensure that they remain up to date as new issues arise. To achieve its goals, the CTI works to streamline and create a more transparent coding and payment process, improve the quality of medical

decisions, and speed patient access to effective new treatments. It is also dedicated to supporting better decisions by patients and doctors in using Medicare-covered services through the promotion of better evidence development, which is critical for improving the quality of care for Medicare beneficiaries.

To improve the understanding of CMS' processes for coverage, coding, and payment and how to access them, the CTI has developed an "Innovator's Guide" to these processes. The intent is to consolidate this information, much of which is already available in a variety of CMS documents and in various places on the CMS Web site, in a user-friendly format. This guide was published in 2010 and is available on the CMS Web site at: [http://www.cms.gov/CouncilonTechInnov/Downloads/InnovatorsGuide5\\_10\\_10.pdf](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 services or 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](mailto:CTI@cms.hhs.gov).

We note that applicants for add-on payments for new medical services or technologies for FY 2018 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html>. To allow interested parties to identify the new medical services or technologies under review

before the publication of the proposed rule for FY 2018, the CMS Web site also will post the tracking forms completed by each applicant.

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

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

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries;

- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending;

- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement; and

- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2017 prior to publication of the FY 2017 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on November 30, 2015 (80 FR 74774), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on February 16, 2016. In the announcement notice for the meeting, we stated that the opinions and presentations 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 2017 new medical service and technology add-on payment applications before the publication of the FY 2017 IPPS/LTCH PPS proposed rule.

Approximately 76 individuals registered to attend the town hall meeting in person, while additional individuals listened over an open telephone line. We also live-streamed the town hall meeting and posted the town hall on the CMS YouTube Web page at: <https://www.youtube.com/watch?v=dn-R5KGQu-M>. 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, 2016, in our evaluation of the new technology add-on payment applications for FY 2017 in this proposed rule.

As indicated earlier in this section, CMS is required to 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 recent years, CMS has live-streamed the town hall meeting through the CMS YouTube Web page and later posted the recorded version of the town hall meeting, in addition to maintaining an open telephone line. We are proposing to conduct future town hall meetings entirely via teleconference and Webcast using the same technologies. Under this proposal, we would continue to publish a notice informing the public of the date of the meeting, as well as requirements for the submission of presentations. We also would continue to maintain an open telephone line, with an option for participation in the Webcast. The recording of the town hall meeting would continue to be available on the CMS YouTube Web page or other CMS Web site following the meeting. This recording would include closed captioning of all presentations and comments. In addition to submitting materials for discussion at the town hall meeting, individuals would continue to be able to submit other written comments after the town hall meeting on whether the service or technology represents a substantial clinical improvement. We are inviting public comments on this proposal.

In response to the published notice and the February 16, 2016 New Technology Town Hall meeting, we received written comments regarding the applications for FY 2017 new technology add-on payments. We summarize below a general comment that does not relate to a specific application for FY 2017 new technology



add-on payments. We also summarize comments regarding individual applications, or, if applicable, indicate that there were no comments received in section II.H.5. of the preamble of this proposed rule at the end of each discussion of the individual applications.

*Comment:* One commenter recommended that CMS broaden the criteria applied in making substantial clinical improvement determinations to require, in addition to existing criteria, consideration of whether the new technology or medical service meets one or more of the following additional suggested criteria: (1) Results in a reduction of the length of a hospital stay; (2) improves patient quality of life; (3) creates long-term clinical efficiencies in treatment; (3) addresses patient-centered objectives as defined by the Secretary; or (4) meets such other criteria as the Secretary may specify. The commenter also suggested that an entity that submits an application for new technology add-on payments be entitled to administrative review of an adverse determination made by the Secretary.

*Response:* We appreciate these recommendations and suggestions and will consider them in future rulemaking.

We note that the commenter also provided comments that were unrelated to the substantial clinical improvement criterion. As stated earlier, the purpose of the new technology town hall meeting is specifically to discuss the substantial clinical improvement criterion in regard to pending new technology add-on payment applications for FY 2017. Therefore, we are not summarizing these additional comments in this proposed rule. However, the commenter is welcome to resubmit its comments in response to proposals presented in this proposed rule.

### 3. ICD-10-PCS Section "X" Codes for Certain New Medical Services and Technologies

As discussed in the FY 2016 IPPS/LTCH final rule (80 FR 49434), the ICD-10-PCS includes a new section containing the new Section "X" codes, which began being used with discharges occurring on or after October 1, 2015. Decisions regarding changes to ICD-10-PCS Section "X" codes will be handled in the same manner as the decisions for all of the other ICD-10-PCS code changes. That is, proposals to create, delete, or revise Section "X" codes under the ICD-10-PCS structure will be referred to the ICD-10 Coordination and Maintenance Committee. In addition,

several of the new medical services and technologies that have been, or may be, approved for new technology add-on payments may now, and in the future, be assigned a Section "X" code within the structure of the ICD-10-PCS. We posted ICD-10-PCS Guidelines on the CMS Web site at: <http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html>, including guidelines for ICD-10-PCS "X" codes. We encourage providers to view the material provided on ICD-10-PCS Section "X" codes.

### 4. Proposed FY 2017 Status of Technologies Approved for FY 2016 Add-On Payments

#### 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.

Kcentra™ was approved by the FDA on April 29, 2013. Under the ICD-10 coding system, Kcentra™ is uniquely identified by ICD-10-CM procedure code 30283B1 (Transfusion of nonautologous 4-factor prothrombin complex concentrate into vein, percutaneous approach).

After evaluation of the newness, cost, and substantial clinical improvement criteria for new technology add-on payments for Kcentra™ and consideration of the public comments we received in response to the FY 2014 IPPS/LTCH PPS proposed rule, we approved Kcentra™ for new technology add-on payments for FY 2014 (78 FR 50575 through 50580). In the application, the applicant estimated that the average Medicare beneficiary would require an average dosage of 2500 International Units (IU). Vials contain 500 IU at a cost of \$635 per vial.

Therefore, cases of Kcentra™ would incur an average cost per case of \$3,175 (\$635 × 5). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS-DRG payment for the case. As a result, the maximum add-on payment for a case of Kcentra™ was \$1,587.50 for FY 2014. We refer the reader to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50579) for complete details on the new technology add-on payments for Kcentra™.

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 Kcentra™, we considered the beginning of the newness period to commence when Kcentra™ was approved by the FDA on April 29, 2013. Because the 3-year anniversary date for Kcentra™ will occur in the latter half of FY 2016 (April 29, 2016), in the FY 2016 IPPS/LTCH PPS final rule, we continued new technology add-on payments for this technology for FY 2016 (80 FR 49437). However, for FY 2017, the 3-year anniversary date of the entry of Kcentra™ on the U.S. market (April 29, 2016) will occur prior to the beginning of FY 2017. Therefore, we are proposing to discontinue new technology add-on payments for this technology for FY 2017. We are inviting public comments on this proposal.

#### 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.

With regard to the newness criterion, the applicant received a Humanitarian Device Exemption (HDE) approval from the FDA on February 14, 2013. However, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49924 through 49925), we discussed comments we had received informing CMS that the Argus® II System was not available on the U.S. market until December 20, 2013. The applicant explained that, as part of the lengthy approval process, it was required to submit a request to the Federal Communications Commission (FCC) for a waiver of section 15.209(a) of the FCC rules that would allow the applicant to apply for FCC authorization to utilize this specific RF band. The FCC approved the applicant's waiver request on November 30, 2011. After receiving the FCC waiver of the section 15.209(a) rules, the applicant requested and obtained a required Grant of Equipment Authorization to utilize the specific RF band, which the FCC issued on December 20, 2013. Therefore, the applicant stated that the date the Argus® II System first became available for commercial sale in the United States was December 20, 2013. We agreed with the applicant that, due to the delay, the date of newness for the Argus® II System was December 20, 2013, instead of February 14, 2013.

After evaluation of the new technology add-on payment application and consideration of public comments received, we concluded that the Argus® II System met all of the new technology add-on payment policy criteria. Therefore, we approved the Argus® II System for new technology add-on payments in FY 2014 (78 FR 50580 through 50583). Cases involving the Argus® II System that are eligible for new technology add-on payments currently are identified when one of the following ICD-10-PCS procedure codes is reported: 08H005Z (Insertion of epiretinal visual prosthesis into right eye, open approach); or 08H105Z (Insertion of epiretinal visual prosthesis into left eye, open approach). In the

application, the applicant provided a breakdown of the costs of the Argus® II System. The total operating cost of the Argus® II System is \$144,057.50. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS-DRG payment for the case. As a result, the maximum add-on payment for a case involving the Argus® II System for FY 2014 was \$72,028.75.

With regard to the newness criterion for the Argus® II System, we considered the beginning of the newness period to commence when the Argus® II System became available on the U.S. market on December 20, 2013. Because the 3-year anniversary date for the Argus® II System will occur after FY 2016 (December 20, 2016), in the FY 2016 IPPS/LTCH PPS final rule, we continued new technology add-on payments for this technology for FY 2016 (80 FR 49439). However, for FY 2017, the 3-year anniversary date of the entry of the Argus® II System on the U.S. market (December 20, 2016) will occur in the first half of FY 2017. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry on to the U.S. market occurs in the latter half of the fiscal year. Therefore, we are proposing to discontinue new technology add-on payments for this technology for FY 2017. We are inviting public comments on this proposal.

#### c. CardioMEMS™ HF (Heart Failure) Monitoring System

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

The CardioMEMS™ HF Monitoring System utilizes radiofrequency (RF) energy to power the sensor and to measure pulmonary artery (PA) pressure and consists of three components: An Implantable Sensor with Delivery Catheter, an External Electronics Unit, and a Pulmonary Artery Pressure Database. The system provides the physician with the patient's PA pressure

waveform (including systolic, diastolic, and mean pressures) as well as heart rate. The sensor is permanently implanted in the distal pulmonary artery using transcatheter techniques in the catheterization laboratory where it is calibrated using a Swan-Ganz catheter. PA pressures are transmitted by the patient at home in a supine position on a padded antenna, pushing one button which records an 18-second continuous waveform. The data also can be recorded from the hospital, physician's office or clinic.

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

The applicant received FDA approval on May 28, 2014.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the CardioMEMS™ HF Monitoring System and consideration of the public comments we received in response to the FY 2015 IPPS/LTCH PPS proposed rule, we approved the CardioMEMS™ HF Monitoring System for new technology add-on payments for FY 2015 (79 FR 49940). Cases involving the CardioMEMS™ HF Monitoring System that are eligible for new technology add-on payments are identified by either ICD-10-PCS procedure code 02HQ30Z (Insertion of pressure sensor monitoring device into right pulmonary artery, percutaneous approach) or ICD-10-PCS procedure code 02HR30Z (Insertion of pressure sensor monitoring device into left pulmonary artery, percutaneous approach). With the new technology add-on payment application, the applicant stated that the total operating cost of the CardioMEMS™ HF Monitoring System is \$17,750. Under § 412.88(a)(2), we limit new technology add-on payments 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 new technology add-on payment for a case involving the CardioMEMS™ HF Monitoring System is \$8,875.

With regard to the newness criterion for the CardioMEMS™ HF Monitoring System, we considered the beginning of the newness period to commence when the CardioMEMS™ HF Monitoring System was approved by the FDA on May 28, 2014. Because the 3-year

anniversary date of the entry of the CardioMEMS™ HF Monitoring System on the U.S. market will occur in the latter half of FY 2017 (May 28, 2017), we are proposing to continue new technology add-on payments for this technology for FY 2017. The maximum payment for a case involving the CardioMEMS™ HF Monitoring System would remain at \$8,875 for FY 2017. We are inviting public comments on our proposal.

#### d. MitraClip® System

Abbott Vascular submitted an application for new technology add-on payments for the MitraClip® System for FY 2015. The MitraClip® System is a transcatheter mitral valve repair system that includes a MitraClip® device implant, a Steerable Guide Catheter, and a Clip Delivery System. It is designed to perform reconstruction of the insufficient mitral valve for high-risk patients who are not candidates for conventional open mitral valve repair surgery.

With regard to the newness criterion, the MitraClip® System received a premarket approval from the FDA on October 24, 2013. The MitraClip® System is indicated “for the percutaneous reduction of significant symptomatic mitral regurgitation (MR  $\geq$  3+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.” The MitraClip® System became immediately available on the U.S. market following FDA approval. The MitraClip® System is a Class III device, and has an investigational device exemption (IDE) for the EVEREST study (Endovascular Valve Edge-to-Edge Repair Study)—IDE G030061, and for the COAPT study (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Health Failure Patients with Functional Mitral Regurgitation)—IDE G120024. Cases involving the MitraClip® System are identified using ICD-10-PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach).

On August 7, 2014, CMS issued a National Coverage Decision (NCD) concerning Transcatheter Mitral Valve Repair procedures. We refer readers to the CMS Web site at: <http://www.cms.gov/medicare-coverage-database/>

<details/nca-tracking-sheet.aspx?NCAId=273> for information related to this NCD.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the MitraClip® System and consideration of the public comments we received in response to the FY 2015 IPPS/LTCH PPS proposed rule, we approved the MitraClip® System for new technology add-on payments for FY 2015 (79 FR 49946). As discussed in the FY 2015 IPPS/LTCH PPS final rule, this approval is on the basis of using the MitraClip® consistent with the NCD. The average cost of the MitraClip® System is reported as \$30,000. Under section 412.88(a)(2), we limit new technology add-on payments 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 new technology add-on payment for a case involving the MitraClip® System is \$15,000 for FY 2015.

With regard to the newness criterion for the MitraClip® System, we considered the beginning of the newness period to commence when the MitraClip® System was approved by the FDA on October 24, 2013. Because the 3-year anniversary date of the entry of the MitraClip® System on the U.S. market (October 24, 2016) will occur after FY 2016, in the FY 2016 IPPS/LTCH PPS final rule, we continued new technology add-on payments for this technology for FY 2016 (80 FR 49442). However, for FY 2017, the 3-year anniversary date of the entry of MitraClip® System on the U.S. market (October 24, 2016) will occur in the first half of FY 2017. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry on to the U.S. market occurs in the latter half of the fiscal year. Therefore, we are proposing to discontinue new technology add-on payments for this technology for FY 2017. We are inviting public comments on this proposal.

#### e. Responsive Neurostimulator (RNS®) System

NeuroPace, Inc. submitted an application for new technology add-on payments for FY 2015 for the use of the RNS® System. (We note that the applicant submitted an application for new technology add-on payments for FY 2014, but failed to receive FDA approval prior to the July 1 deadline.) Seizures occur when brain function is disrupted by abnormal electrical activity. Epilepsy

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

With regard to the newness criterion, the applicant stated that some patients diagnosed with partial onset seizures that cannot be controlled with antiepileptic medications may be candidates for the vagus nerve stimulator (VNS) or for surgical removal of the seizure focus. According to the applicant, these treatments are not appropriate for, or helpful to, all patients. Therefore, the applicant believed that there is an unmet clinical need for additional therapies for partial onset seizures. The applicant further stated that the RNS® System addresses this unmet clinical need by providing a novel treatment option for treating persons diagnosed with medically intractable partial onset seizures. The applicant received FDA premarket approval on November 14, 2013.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the RNS® System and consideration of the public comments we received in response to the FY 2015 IPPS/LTCH PPS proposed rule, we approved the RNS® System for new technology add-on payments for FY 2015 (79 FR 49950). Cases involving the RNS® System that are eligible for new technology add-on payments are identified using the following ICD-10-PCS procedure code

combination: ONH00NZ (Insertion of neurostimulator generator into skull, open approach) in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach). According to the applicant, cases using the RNS<sup>®</sup> System would incur an anticipated cost per case of \$36,950. Under § 412.88(a)(2) of the regulations, we limit new technology add-on payments to the lesser of 50 percent of the average costs of the device or 50 percent of the costs in excess of the MS-DRG payment rate for the case. As a result, the maximum new technology add-on payment for cases involving the RNS<sup>®</sup> System is \$18,475.

With regard to the newness criterion for the RNS<sup>®</sup> System, we considered the beginning of the newness period to commence when the RNS<sup>®</sup> System was approved by the FDA on November 14, 2013. Because the 3-year anniversary date of the entry of the RNS<sup>®</sup> System on the U.S. market (November 14, 2016) will occur after FY 2016, in the FY 2016 IPPS/LTCH PPS final rule, we continued new technology add-on payments for this technology for FY 2016 (80 FR 49443). However, for FY 2017, the 3-year anniversary date of the entry of RNS<sup>®</sup> System on the U.S. market (November 14, 2016) will occur in the first half of FY 2017. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry on to the U.S. market occurs in the latter half of the fiscal year. Therefore, we are proposing to discontinue new technology add-on payments for this technology for FY 2017. We are inviting public comments on this proposal.

f. Blinatumomab (BLINCYTO<sup>™</sup> Trade Brand)

Amgen, Inc. submitted an application for new technology add-on payments for FY 2016 for Blinatumomab (BLINCYTO<sup>™</sup>), a bi-specific T-cell engager (BiTE) used for the treatment of Philadelphia chromosome-negative (Ph-) relapsed or refractory (R/R) B-cell precursor acute-lymphoblastic leukemia (ALL), which is a rare aggressive cancer of the blood and bone marrow. Approximately 6,050 individuals are diagnosed with Ph- R/R B-cell precursor ALL in the United States each year, and approximately 2,400 individuals, representing 30 percent of all new cases, are adults. Ph- R/R B-cell precursor ALL occurs when there are malignant transformations of B-cell or T-cell progenitor cells, causing an accumulation of lymphoblasts in the blood, bone marrow, and occasionally

throughout the body. As a bi-specific T-cell engager, the BLINCYTO<sup>™</sup> technology attaches to a molecule on the surface of the tumorous cell, as well as to a molecule on the surface of normal T-cells, bringing the two into closer proximity and allowing the normal T-cell to destroy the tumorous cell. Specifically, the BLINCYTO<sup>™</sup> technology attaches to a cell identified as CD19, which is present on all of the cells of the malignant transformations that cause Ph- R/R B-cell precursor ALL and helps attract the cell into close proximity of the T-cell CD3 with the intent of getting close enough to allow the T-cell to inject toxins that destroy the cancerous cell. According to the applicant, the BLINCYTO<sup>™</sup> technology is the first, and the only, bi-specific CD19-directed CD3 T-cell engager single-agent immunotherapy approved by the FDA.

BLINCYTO<sup>™</sup> is administered as a continuous IV infusion delivered at a constant flow rate using an infusion pump. A single cycle of treatment consists of 28 days of continuous infusion, and each treatment cycle followed by 2 weeks without treatment prior to administering any further treatments. A course of treatment would consist of two phases. Phase 1 consists of initial inductions or treatments intended to achieve remission followed by additional inductions and treatments to maintain consolidation; or treatments given after remission has been achieved to prolong the duration. During phase 1 of a single treatment course, up to two cycles of BLINCYTO<sup>™</sup> are administered, and up to three additional cycles are administered during consolidation. The recommended dosage of BLINCYTO<sup>™</sup> administered during the first cycle of treatment is 9 mcg per day for the first 7 days of treatment. The dosage is then increased to 28 mcg per day for 3 weeks until completion. During phase 2 of the treatment course, all subsequent doses are administered as 28 mcg per day throughout the entire duration of the 28-day treatment period.

With regard to the newness criterion, the BLINCYTO<sup>™</sup> technology received FDA approval on December 3, 2014, for the treatment of patients diagnosed with Ph- R/R B-cell precursor ALL, and the product gained entry onto the U.S. market on December 17, 2014.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for BLINCYTO<sup>™</sup> and consideration of the public comments we received in response to the FY 2016 IPPS/LTCH PPS proposed rule, we approved BLINCYTO<sup>™</sup> for new technology add-

on payments for FY 2016 (80 FR 49449). Cases involving BLINCYTO<sup>™</sup> that are eligible for new technology add-on payments are identified using one of the following ICD-10-PCS procedure codes: XW03351 (Introduction of Blinatumomab antineoplastic immunotherapy into peripheral vein, percutaneous approach, new technology group 1) or XW04351 (Introduction of Blinatumomab antineoplastic immunotherapy into central vein, percutaneous approach, new technology group1).

As discussed in the FY 2016 IPPS/LTCH final rule (80 FR 49449), the applicant recommended that CMS consider and use the cost of the full 28-day inpatient treatment cycle as the expected length of treatment when determining the maximum new technology add-on payment for cases involving the BLINCYTO<sup>™</sup> rather than the average cost of lesser number of days used as other variables. For the reasons discussed, we disagreed with the applicant and established the maximum new technology add-on payment amount for a case involving the BLINCYTO<sup>™</sup> technology for FY 2016 using the weighted average of the cycle 1 and cycle 2 observed treatment length. Specifically, in the Phase II trial, the most recent data available, 92 patients received cycle 1 for an average length of 21.2 days, and 52 patients received cycle 2 for an average length of 10.2 days. The weighted average of cycle 1 and 2 treatment length is 17 days. We noted that a small number of patients also received 3 to 5 treatment cycles. However, based on the data provided, these cases do not appear to be typical at this point and we excluded them from this calculation. We noted that, if we included all treatment cycles in this calculation, the weighted average number of days of treatment is much lower, 10 days. Using the clinical data provided by the applicant, we stated that we believe that setting the maximum new technology add-on payment amount for a case involving the BLINCYTO<sup>™</sup> technology for FY 2016 based on a 17-day length of treatment cycle is representative of historical and current practice. We also stated that, for FY 2017, if new data on length of treatment are available, we would consider any such data in evaluating the maximum new technology add-on payment amount. However, we did not receive any new data from the applicant to evaluate for FY 2017.

In the application, the applicant estimated that the average Medicare beneficiary would require a dosage of 9mcg/day for the first 7 days under the

first treatment cycle, followed by a dosage of 28mcg/day for the duration of the treatment cycle, as well as all days included in subsequent cycles. All vials contain 35mcg at a cost of \$3,178.57 per vial. The applicant noted that all vials are single-use. Therefore, we determined that cases involving the use of the BLINCYTO™ technology would incur an average cost per case of \$54,035.69 (1 vial/day × 17 days × \$3,178.57/vial). Under 42 CFR 412.88(a)(2), we limit new technology add-on payments 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 amount for a case involving the use of the BLINCYTO™ is \$27,017.85 for FY 2016.

With regard to the newness criterion for BLINCYTO™, we considered the beginning of the newness period to commence when the product gained entry onto the U.S. market on December 17, 2014. Because the 3-year anniversary date of the entry of the BLINCYTO™ on the U.S. market will occur after FY 2017 (December 17, 2017), we are proposing to continue new technology add-on payments for this technology for FY 2017. The maximum payment for a case involving BLINCYTO™ would remain at \$27,017.85 for FY 2017. We are inviting public comments on this proposal.

g. Lutonix® Drug Coated Balloon PTA Catheter and In.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter

Two manufacturers, CR Bard Inc. and Medtronic, submitted applications for new technology add-on payments for FY 2016 for LUTONIX® Drug-Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) Catheter (LUTONIX®) and IN.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter (IN.PACT™ Admiral™), respectively. Both of these technologies are drug-coated balloon angioplasty treatments for patients diagnosed with peripheral artery disease

(PAD). Typical treatments for patients with PAD include angioplasty, stenting, atherectomy and vascular bypass surgery. PAD most commonly occurs in the femoropopliteal segment of the peripheral arteries, is associated with significant levels of morbidity and impairment in quality of life, and requires treatment to reduce symptoms and prevent or treat ischemic events.<sup>2</sup> Treatment options for symptomatic PAD include noninvasive treatment such as medication and life-style modification (for example, exercise programs, diet, and smoking cessation) and invasive options which include endovascular treatment and surgical bypass. The 2013 American College of Cardiology and American Heart Association (ACC/AHA) guidelines for the management of PAD recommend endovascular therapy as the first-line treatment for femoropopliteal artery lesions in patients suffering from claudication (Class I, Level A recommendation).<sup>3</sup>

According to both applicants, LUTONIX® and IN.PACT™ Admiral™ are the first drug coated balloons that can be used for treatment of patients who are diagnosed with PAD. In the FY 2016 IPPS/LTCH final rule, we stated that because cases eligible for the two devices would group to the same MS-DRGs and we believe that these devices are substantially similar to each other (that is, they are intended to treat the same or similar disease in the same or similar patient population and are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action), we evaluated both technologies as one application for new technology add-on payment under the IPPS. The applicants submitted separate cost and clinical data, and we reviewed and discussed each set of data separately. However, we made one determination regarding new technology add-on payments that applied to both devices. We believe that this is consistent with our policy statements in the past regarding substantial similarity. Specifically, we have noted that approval of new technology add-on payments would extend to all technologies that are substantially similar (66 FR 46915), and

that we believe that continuing our current practice of extending a new technology add-on payment without a further application from the manufacturer of the competing product or a specific finding on cost and clinical improvement if we make a finding of substantial similarity among two products is the better policy because we avoid—

- Creating manufacturer-specific codes for substantially similar products;
- Requiring different manufacturers of substantially similar products from having to submit separate new technology applications;
- Having to compare the merits of competing technologies on the basis of substantial clinical improvement; and
- Bestowing an advantage to the first applicant representing a particular new technology to receive approval (70 FR 47351).

CR Bard, Inc. received FDA approval for LUTONIX® on October 9, 2014. Commercial sales in the U.S. market began on October 10, 2014. Medtronic received FDA approval for IN.PACT™ Admiral™ on December 30, 2014. Commercial sales in the U.S. market began on January 29, 2015.

In accordance with our policy, we stated in the FY 2016 IPPS/LTCH final rule (80 FR 49463) that we believe it is appropriate to use the earliest market availability date submitted as the beginning of the newness period. Accordingly, for both devices, we stated that the beginning of the newness period will be October 10, 2014.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the LUTONIX® and IN.PACT™ Admiral™ technologies and consideration of the public comments we received in response to the FY 2016 IPPS/LTCH PPS proposed rule, we approved the LUTONIX® and IN.PACT™ Admiral™ technologies for new technology add-on payments for FY 2016 (80 FR 49469). Cases involving the LUTONIX® and IN.PACT™ Admiral™ technologies that are eligible for new technology add-on payments are identified using one of the ICD-10-PCS procedure codes in the following table:

ICD-10-PCS Code	Code description
047K041 .....	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, open approach.

<sup>2</sup> Tepe G, Zeller T, Albrecht T, Heller S, Schwarzwald U, Beregi JP, Claussen CD, Oldenburg A, Scheller B, Speck U.: Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg. *N Engl J Med* 2008; 358: 689-99.

<sup>3</sup> Anderson JL, Halperin JL, Albert NM, Bozkurt B, Brindis RG, Curtis LH, DeMets D, Guyton RA, Hochman JS, Kovacs RJ, Ohman EM, Pressler SJ, Sellke FW, Shen WK.: Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/AHA guideline recommendations): a

report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol* 2013; 61:1555-70. Available at: <http://dx.doi.org/10.1016/j.jacc.2013.01.004>.

ICD-10-PCS Code	Code description
047K0D1 .....	Dilation of right femoral artery with intraluminal device using drug-coated balloon, open approach.
047K0Z1 .....	Dilation of right femoral artery using drug-coated balloon, open approach.
047K341 .....	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047K3D1 .....	Dilation of right femoral artery with intraluminal device using drug-coated balloon, percutaneous approach.
047K3Z1 .....	Dilation of right femoral artery using drug-coated balloon, percutaneous approach.
047K441 .....	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047K4D1 .....	Dilation of right femoral artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047K4Z1 .....	Dilation of right femoral artery using drug-coated balloon, percutaneous endoscopic approach.
047L041 .....	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047L0D1 .....	Dilation of left femoral artery with intraluminal device using drug-coated balloon, open approach.
047L0Z1 .....	Dilation of left femoral artery using drug-coated balloon, open approach.
047L341 .....	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047L3D1 .....	Dilation of left femoral artery with intraluminal device using drug-coated balloon, percutaneous approach.
047L3Z1 .....	Dilation of left femoral artery using drug-coated balloon, percutaneous approach.
047L441 .....	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047L4D1 .....	Dilation of left femoral artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047L4Z1 .....	Dilation of left femoral artery using drug-coated balloon, percutaneous endoscopic approach.
047M041 .....	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047M0D1 .....	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, open approach.
047M0Z1 .....	Dilation of right popliteal artery using drug-coated balloon, open approach.
047M341 .....	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047M3D1 .....	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, percutaneous approach.
047M3Z1 .....	Dilation of right popliteal artery using drug-coated balloon, percutaneous approach.
047M441 .....	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047M4D1 .....	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047M4Z1 .....	Dilation of right popliteal artery using drug-coated balloon, percutaneous endoscopic approach.
047N041 .....	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047N0D1 .....	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, open approach.
047N0Z1 .....	Dilation of left popliteal artery using drug-coated balloon, open approach.
047N341 .....	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047N3D1 .....	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, percutaneous approach.
047N3Z1 .....	Dilation of left popliteal artery using drug-coated balloon, percutaneous approach.
047N441 .....	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047N4D1 .....	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047N4Z1 .....	Dilation of left popliteal artery using drug-coated balloon, percutaneous endoscopic approach.

As discussed in the FY 2016 IPPS/LTCH final rule (80 FR 49469), each of the applicants submitted operating costs for its DCB. The manufacturer of the LUTONIX® stated that a mean of 1.37 drug-coated balloons was used during the LEVANT 2 clinical trial. The acquisition price for the hospital will be \$1,900 per drug-coated balloon, or \$2,603 per case (1.37 × \$1,900). The applicant projected that approximately 8,875 cases will involve use of the LUTONIX® for FY 2016. The manufacturer for the IN.PACT™ Admiral™ stated that a mean of 1.4 drug-coated balloons was used during the IN.PACT™ Admiral™ DCB arm. The acquisition price for the hospital will be \$1,350 per drug-coated balloon, or \$1,890 per case (1.4 × \$1,350). The applicant projected that approximately 26,000 cases will involve use of the IN.PACT™ Admiral™ for FY 2016.

For FY 2016, we based the new technology add-on payment for cases involving these technologies on the weighted average cost of the two DCBs described by the ICD-10-PCS procedure

codes listed above (which are not manufacturer specific). Because ICD-10 codes are not manufacturer specific, we cannot set one new technology add-on payment amount for IN.PACT™ Admiral™ and a different new technology add-on payment amount for LUTONIX®; both technologies will be captured by using the same ICD-10-PCS procedure code. As such, we stated that we believe that the use of a weighted average of the cost of the standard DCBs based on the projected number of cases involving each technology to determine the maximum new technology add-on payment would be most appropriate. To compute the weighted cost average, we summed the total number of projected cases for each of the applicants, which equaled 34,875 cases (26,000 plus 8,875). We then divided the number of projected cases for each of the applicants by the total number of cases, which resulted in the following case-weighted percentages: 25 Percent for the LUTONIX® and 75 percent for the IN.PACT™ Admiral™. We then multiplied the cost per case for the

manufacturer specific DCB by the case-weighted percentage (0.25 \* \$2,603=\$662.41 for LUTONIX® and 0.75 \* \$1,890=\$1,409.03 for the IN.PACT™ Admiral™). This resulted in a case-weighted average cost of \$2,071.45 for DCBs. Under § 412.88(a)(2), we limit new technology add-on payments 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 payment for a case involving the LUTONIX® or IN.PACT™ Admiral™ DCBs is \$1,035.72.

With regard to the newness criterion for LUTONIX® and IN.PACT™ Admiral™ technologies, we considered the beginning of the newness period to commence when LUTONIX® gained entry onto the U.S. market on October 10, 2014. Because the 3-year anniversary date of the entry of LUTONIX® on the U.S. market will occur after FY 2017 (October 10, 2017), we are proposing to continue new technology add-on payments for both the LUTONIX® and IN.PACT™ Admiral™ technologies for

FY 2017. The maximum add-on payment for a case involving LUTONIX® and IN.PACT™ Admiral™ would remain at \$1,035.72 for FY 2017. We are inviting public comments on this proposal.

#### 5. Proposed FY 2017 Applications for New Technology Add-On Payments

We are reviewing nine applications for new technology add-on payments for FY 2017. In accordance with the regulations under § 412.87(c), applicants for new technology add-on payments must have FDA approval by July 1 of each year prior to the beginning of the fiscal year that the application is being considered. One applicant withdrew its application prior to the issuance of this proposed rule.

##### a. MAGEC® Spinal Bracing and Distraction System (MAGEC® Spine)

Ellipse Technologies, Inc. submitted an application for new technology add-on payments for FY 2017 for the MAGEC® Spine. According to the applicant, the MAGEC® Spine has been developed for use in the treatment of children diagnosed with severe spinal deformities, such as scoliosis. The system can be used in the treatment of skeletally immature patients less than 10 years of age who have been diagnosed with severe progressive spinal deformities associated with or at risk of Thoracic Insufficiency Syndrome (TIS). The MAGEC® Spine consists of a (spinal growth) rod that can be lengthened through the use of magnets that are controlled by an external remote controller (ERC). The rod(s) can be implanted into children as young as 2 years of age. According to the applicant, use of the MAGEC® Spine has proven to be successfully used in the treatment of patients diagnosed with scoliosis who have not been responsive to other treatments.

The MAGEC® Spine initially received FDA approval for use of the predicate device, which used a Harrington Rod on February 27, 2014. Subsequent FDA approval was granted for use of the modified device, which uses a shorter 70 mm on September 18, 2014. After minor modification of the product, the MAGEC® Spine received its final FDA approvals on March 24, 2015, and May 29, 2015, respectively. Currently, there is no ICD-9-CM or ICD-10-PCS code to uniquely describe procedures involving the MAGEC® Spine.

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 substantially similar to an existing technology, specifically: (1) Whether a

product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS-DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered “new” for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352), and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

With regard to the first criterion, the applicant stated that the MAGEC® Spine’s mechanism of action is dependent upon growing rods used for the treatment of patients diagnosed with early onset scoliosis (EOS), and is unique because the technique uses magnetic distraction (lengthening), which does not require the patients to be subjected to the potential and adverse effects of additional surgeries.

The applicant explained that treatment of patients diagnosed with EOS involves the implantation of traditional growth rods (TGRs) followed by surgery every 6 months to distract the rods to accommodate the growing spine until the patient reaches a level of spinal maturity when the spine can then be fused. The average number of distraction surgeries per patient is 12 over the course of 6 years. Once spinal alignment and maturity is reached, the TGRs are surgically and permanently removed. The applicant stated that, while the most recent modification to the MAGEC® Spine’s rods accomplish the same goal as the predicate device, Harrington rods, MAGEC® Spine rods achieve the predetermined goal with minimally invasive techniques after implantation, which prevents the patients from being subjected to the potential and adverse effects of numerous lengthening surgeries. The applicant further noted that after the MAGEC® Spine’s rod has been implanted, the ERC is placed externally over the patient’s spine at the location of the magnet in the MAGEC® Spine’s rod. Periodic, noninvasive distraction of the rod is performed to lengthen the spine and to provide adequate bracing during growth. Routine X-ray or ultrasound procedures are used to confirm the position and amount of distraction. The frequency of distraction sessions is customized to the needs of

the individual patient by the treating surgeon.

With regard to the first criterion, we are concerned that the MAGEC® Spine uses the same mechanism of action, spinal rod distraction, to achieve the same therapeutic outcome of spinal alignment as other currently available technologies and treatment options for Medicare beneficiaries. Specifically, TGRs are implanted and affixed to the immature spine in order to correct spinal deformities. As a child grows, the TGRs must be distracted to accommodate spinal growth. The common denominator between TGRs and the MAGEC® Spine is that they both are devices (rods) that use the same mechanism of action to perform and achieve spinal distraction, the implantation of rods that are later lengthened. While we acknowledge the applicant noted that the MAGEC® Spine does not require the patient to endure the potential and adverse effects of additional surgeries, this assertion seems to be a component of substantial clinical improvement rather than a basis to distinguish the mechanism of action.

In consideration of the applicant’s statements that the mechanism of action of the MAGEC® Spine, which uses growing rods in the treatment of patients diagnosed with EOS, is unique because the technique of using magnetic distraction (lengthening) does not require patients to endure the potential and adverse effects of additional surgeries, we note that there are other technologies and products currently available that achieve spinal growth without the need to subject patients to potential and adverse effects of additional surgeries. For example, the Shilla growth guidance system, which received FDA approval in 2014, uses a non-locking set screw at the proximal and distal portions of the construct’s rods. This specific feature is designed to allow the rod to slide through the screw heads as a child’s spine grows, while still providing correction of the spinal deformity. The Shilla technique also eliminates the need for scheduled distraction surgeries, as the applicant pointed out are needed with the use of TGRs. Therefore, we believe that the MAGEC® Spine’s mechanism of action may be similar to the mechanism of action employed by the Shilla growth guidance system because both technologies achieve the same therapeutic outcome and do not require the patient to endure the potential and adverse effects of additional surgeries.

With regard to the second criterion, cases that may be eligible for treatment involving the MAGEC® Spine map to the following MS-DRGs: 456 (Spinal

Fusion Except Cervical With Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC); 457 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with CC); and 458 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions without CC/MCC). All cases involving procedures describing spinal distraction devices, including those that use TGRs and the Shilla growth guidance system, currently map to the same MS–DRGs.

With regard to the third criterion, we believe that the MAGEC® Spine technology involves the treatment of the same or similar type of disease and the same or similar patient population. Although the applicant stated that the MAGEC® Spine was developed for the use in the treatment of children diagnosed with severe spinal deformities, the MAGEC® Spine treats the same patient population as other currently available spinal distraction devices and technologies, including those that use TGRs and the Shilla growth guidance system. Because it appears that the MAGEC® Spine is substantially similar to these other currently available devices used to treat the same or similar types of diseases and the same or similar patient populations, we are concerned that the technology may not be considered “new” for the purposes of new technology add-on payments. We are inviting public comments on whether the MAGEC® Spine meets the newness criterion.

With regard to the cost criterion, the applicant maintained that there is an insufficient number of cases in the Medicare claims data to evaluate because of the small number of potential cases and cases reflecting patients who were actually diagnosed with or who experience early onset scoliosis (EOS) requiring the implantation of growing rods. Specifically, the majority of the Medicare population is 65 years of age and older, while patients who may be eligible for the MAGEC® Spine are typically less than 10 years of age. Therefore, the applicant estimated the number of EOS cases using internal estimates for de novo cases (<10 year of age), as well as cases that could potentially convert to using the MAGEC® Spine without searching the MedPAR data file or any other data source. The applicant estimated that a total of 2,500 EOS cases may be eligible for treatment using the MAGEC® Spine in FY 2016. According to the applicant, 580 cases would map to MS–DRG 456, 870 cases would map to MS–DRG 457, and 1,050 cases would map to MS–DRG

458. The applicant based the distribution of cases on data from its medical advisors, customers, and reimbursement support team.

The applicant used Medicare and non-Medicare data for six providers that used the MAGEC® Spine during CY 2016. This resulted in an average unstandardized case-weighted charge per case of \$243,999. The applicant then removed charges related to the predicate technology. Using the Impact File published with the FY 2016 IPPS/LTCH PPS final rule, the applicant standardized the charges and applied an inflation factor of 10 percent. The applicant computed an average CCR of the six hospitals based on the overall hospitals CCRs in the FY 2016 IPPS/LTCH final rule Impact File. The applicant then computed the charges for the device by dividing the costs of the device by the average CCR and added these charges to determine the inflated average standardized case-weighted charge per case. The applicant noted that the cost of the technology was proprietary information. Based on the FY 2016 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was \$105,909. The applicant computed an inflated average standardized case-weighted charge per case of \$248,037. Because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

We have the following concerns regarding the applicant’s cost analysis:

- The applicant did not specify how many cases were the basis for the average standardized case-weighted charges per case. Therefore, we cannot determine if the charges per case represent a statistical sample relative to the projected cases eligible for the MAGEC® Spine for the upcoming fiscal year.
- The applicant did not specify how many cases included in the analysis were Medicare and non-Medicare cases. We typically rely on Medicare data and understand the limitations of this patient population in the Medicare data (as the applicant explained above). However, CMS would still like the details regarding the numerical representation of Medicare and non-Medicare cases the applicant used in its analysis.

- The applicant did not explain the methodology it used to remove the charges for the predicate technology, as well as the type of technology that the charges replaced. Therefore, we are unable to validate the accuracy of the applicant’s methodology.

- The applicant did not explain the basis of using a 10-percent inflation factor. Specifically, the applicant used cases from CY 2016 and inflated the costs to FY 2017 using a 10-percent inflation factor. However, the 1-year inflation factor in the FY 2016 IPPS/LTCH final rule (80 FR 49784) is 3.7 percent. Therefore, we do not believe that a 10-percent inflation factor is appropriate.

The applicant used the average overall CCR of the six hospitals to convert the costs of the MAGEC® Spine to charges. However, rather than using an average CCR, to increase the precision of determining the charges of the MAGEC® Spine, the applicant could have instead used each hospital’s individual CCR or the implantable device CCR of 0.337 as reported in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49429).

We are inviting public comments on whether the MAGEC® Spine meets the cost criterion, particularly with regard to the concerns we have raised.

With regard to substantial clinical improvement, the applicant stated that use of the MAGEC® Spinal Bracing and Distraction System significantly improves clinical outcomes for the pediatric patient population with spinal deformities when compared to technologies and treatment options that employ TGRs by decreasing the number of subsequent surgeries and potential adverse effects following implantation. The applicant provided results from a study<sup>4</sup>, which demonstrated that patients receiving treatment using the magnetically controlled growth rods (MAGR) system had 57 fewer surgeries as a whole than those patients receiving treatment options using TGRs. According to the applicant, the results further projected decreased rates of infection and attendant costs because the need for additional distraction (lengthening) surgeries is eliminated. In addition, the applicant stated that 1,500 patients located around the world have been successfully treated with the use of this technology. The applicant indicated that the results from another study<sup>5</sup> cited the following qualitative outcomes: Minimal surgical scarring, decreased psychological distress and improved quality of life, improved

<sup>4</sup> Akbarnia BA, Cheung K, Noordeen H et al. Traditional rods versus magnetically controlled growing rods in early onset scoliosis: a case-matched two year study. 2013.

<sup>5</sup> Cheng, KMC, Cheung JPY, Damartzis, D, Mak, KC, Wong, WYC, Akbaria, BA, Luk KDK. Magnetically controlled growing rods for severe spinal curvature in young children. A prospective study. *Lancet* 379 (830) 26 May–1 June 2012, pp. 1967–1974.



pulmonary function tests (PFTs), and capabilities to continuously monitor neurological behaviors because the patient is not exposed to anesthesia during follow-up distractions.

We are concerned that the applicant's assertions that the MAGEC® Spine technology leads to significantly better clinical outcomes; specifically, decreased rates of infection, when compared to treatment options that use TGRs has not been shown by the results of the studies provided. The results of the studies provided did not compare rates of infection for patients receiving treatment using the MAGEC® Spine versus patients receiving treatment using TGRs or other spinal growth rods. Also, as previously mentioned, there are other currently available technologies and devices such as the Shilla growth guidance system that also achieve the same therapeutic outcome and do not require the patient to be subjected to the potential and adverse effects of additional surgery. Therefore, we are concerned that the MAGEC® Spine may not represent a substantial clinical improvement over existing technologies. We are inviting public comments on whether the MAGEC® Spine meets the substantial clinical improvement criterion.

We did not receive any written public comments in response to the February 2016 New Technology Town Hall meeting regarding this application for new technology add-on payments.

**b. MIRODERM Biologic Wound Matrix (MIRODERM)**

Miomatrix Medical, Inc. submitted an application for new technology add-on payments for FY 2017 for MIRODERM. MIRODERM is a non-crosslinked acellular wound matrix that is derived from the porcine liver and is processed and stored in a phosphate buffered aqueous solution. MIRODERM is clinically indicated for the management of wounds, including: Partial and full-thickness wounds, pressure ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds, drainage wounds, and surgical wounds. Typical decellularization where tissues are immersed in a decellularization solution is a diffusion-based process, and thereby limits the ability to fully decellularize thick, complex tissues such as the liver. MIRODERM uses a perfusion decellularization process that rapidly removes cellular material while maintaining the native architecture, vasculature and tissue structure. Following decellularization, MIRODERM is isolated from partial thickness liver sections following slight

compression of the liver. This allows for the retention of the native liver structure, including the vasculature, within MIRODERM. The applicant noted that the MIRODERM is the only acellular skin substitute product that is derived from the liver.

According to the applicant, MIRODERM is positioned to completely contact the entire surface of the wound bed and extend slightly beyond all wound margins. As required, it is securely anchored to the wound site with a physician's preferred fixation method. An appropriate, primary non-adherent wound dressing is then applied over the MIRODERM matrix. A secondary dressing (multi-layer compression bandage system), total contact cast, or other appropriate dressing that will manage the wound exudate should be applied in order to keep the MIRODERM matrix moist and keep all layers securely in place. Additional applications of MIRODERM are applied as needed until the wound closes.

MIRODERM received FDA approval for its use on January 27, 2015. Currently, there are no ICD-10-PCS procedure codes to uniquely identify the use of MIRODERM. The applicant submitted a request for a unique ICD-10-PCS procedure code that was presented at the March 2016 ICD-10 Coordination and Maintenance Committee meeting. If approved, the procedure codes would become effective on October 1, 2016 (FY 2017). More information on this request can be found on the CMS Web site located at: <http://www.cms.gov/Medicare/Coding/ICD10ProviderDiagnosticCodes/ICD-10-CM-C-and-M-Meeting-Materials.html>.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered "new" for purposes of new technology add-on payments.

With regard to the first substantial similarity criterion, whether the product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant stated that current wound healing therapies are provided in several different modalities, which include hyperbaric oxygen treatment, negative wound pressure therapy, and treatment with other bioengineered skin substitute products. The applicant noted that other products that have been commonly used for similar procedures are Oasis Wound Matrix, Primatrix Dermal Repair, and Theraskin. The applicant asserted that MIRODERM is different from these other products because it is the only

product sourced from porcine liver and undergoes a unique, patented process of perfusion decellularization that rapidly removes cellular material, while maintaining the native architecture, vasculature and tissue structure. The applicant explained that MIRODERM is isolated from partial thickness liver sections following slight compression of the liver, which allows for the retention of the native liver structure, including the vasculature, within MIRODERM. The applicant stated that partial thickness allows for one surface of MIRODERM to retain the native liver capsule (an epithelial basement membrane) and the other opposite surface to be comprised of open liver matrix. The applicant further stated that case studies of the MIRODERM demonstrated accelerated healing, which is likely the result of the unique perfusion decellularization technology that retains a 3-dimensional extracellular matrix that includes the vasculature.

With regard to the first criterion, similar to other current wound matrix treatments, the MIRODERM uses a collagen matrix for tissue repair and regeneration. Therefore, we are concerned that MIRODERM employs the same mechanism of action as other wound matrix treatments. Although the applicant has described how the MIRODERM differs from other wound matrix treatments due to the perfusion decellularization process, and is the first product that is derived from the porcine liver, we believe that the mechanism of action of MIRODERM may be substantially similar or the same as those employed by other wound treatment matrixes. With regard to the second criterion, whether a product is assigned to the same or a different MS-DRG, cases that may be eligible for treatment using MIRODERM map to the same MS-DRGs as other currently approved wound treatment matrixes. With regard to the third criterion, 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, MIRODERM is used to treat the same patient population as other currently approved wound treatment matrixes. Because it appears that the MIRODERM may be substantially similar to currently approved wound treatment matrixes, we are concerned that the technology may not be considered "new" for the purposes of new technology add-on payments. We are inviting public comments on whether MIRODERM meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following

analysis. The applicant began by researching the 2014 Medicare Inpatient Hospital Standard Analytical File (SAF) file for cases primarily associated with dermal regenerative grafts that may be eligible for treatment using MIRODERM. The applicant searched for claims that reported ICD-9-CM procedure code 86.67 (Dermal regenerative graft) that mapped to one of the following MS-DRGs: 463, 464, and 465 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal System and Connective Tissue Disorders with MCC, with CC, or without CC/MCC, respectively); 573, 574, and 575 (Skin Graft for Skin Ulcer or Cellulitis with MCC, with CC, or without CC/MCC, respectively); 576, 577, and 578 (Skin Graft Except for Skin Ulcer or Cellulitis with MCC, with CC, or without CC/MCC, respectively); 622, 623, and 624 (Skin Grafts and Wound Debridement for Endocrine, Nutritional and Metabolic Diseases with MCC, with CC or without CC/MCC, respectively); and 904 and 905 (Skin Grafts for Injuries with CC/MCC or without CC/MCC, respectively). As a result, the applicant identified 1,130 cases across the MS-DRGs listed, which resulted in an average case-weighted charge per case of \$83,059.

Included in the average case-weighted charge per case were charges for other previously used dermal regenerative grafts. According to the applicant, the MIRODERM would replace the need for other dermal regenerative grafts and, therefore, the applicant removed charges related to the use of other currently used dermal regenerative grafts from the average case-weighted charge per case. Specifically, using the January 2016 CMS Part B Drug Pricing File, the applicant first computed an average cost per square centimeter for currently used dermal regenerative grafts (Apligraf \$31.207/cm<sup>2</sup>, Oasis \$10.676/cm<sup>2</sup>, Integra DRT \$21.585/cm<sup>2</sup>, Dermagraft \$32.858/cm<sup>2</sup>, Integra skin substitute \$35.627/cm<sup>2</sup>, Primatrix \$37.590/cm<sup>2</sup>, and Theraskin \$38.474/cm<sup>2</sup>), which equaled \$29.72/cm<sup>2</sup>. To determine the average amount of square centimeters of the other dermal regenerative grafts used for each case within the MS-DRG, given the vast complexity and variation in wounds, the applicant used clinical judgment based on experience, observation and typical sizes and depths of wounds that would present on different parts of the body. For an example, wounds on the hand would typically be smaller than those located on the lower extremities. The applicant also assumed that other dermal regenerative grafts would require

three applications to close a wound as opposed to treatment using MIRODERM, which requires only two applications. Based on this assumption, the applicant noted that it assumed that the first application required 100 percent of the amount of skin substitute required to treat the original wound area, the second application required 70 percent, and the third application required 40 percent, totaling 210 percent. To compute the total amount of square centimeters used for each case within the MS-DRG, the applicant multiplied this percentage (210 percent) by the amount of square centimeters used for the first application for each case within the MS-DRG. The applicant then multiplied the average cost of the other previously used dermal regenerative grafts (\$29.72/cm<sup>2</sup>) by the average amount of centimeters used for each case within the MS-DRG to determine the average cost of the other previously used dermal regenerative grafts for each case within the MS-DRG. To convert the costs to charges, the applicant computed an average CCR for each MS-DRG using CCRs from the FY 2014 Standardizing File of the hospitals indicated on each of the claims for each case within the MS-DRG. The applicant then divided the average cost of the other previously used dermal regenerative grafts for each MS-DRG by the average CCR for each MS-DRG to determine the average charges of the other previously used dermal regenerative grafts for each MS-DRG. The applicant also reduced the charges for the number of days of hospitalization by 30 percent because the applicant believed that MIRODERM heals patients faster than the other currently used dermal regenerative grafts, resulting in a reduction in the average lengths of stay. The applicant then deducted the charges related to the other previously used dermal regenerative grafts and the charges for the reduction in the average lengths of stay from the average case-weighted charge per case and then standardized the charges, which resulted in an average standardized case-weighted charge per case of \$34,279. The applicant then inflated the average standardized case-weighted charge per case by 7.7 percent, the same inflation factor used by CMS to update the FY 2016 outlier threshold (80 FR 49784).

After inflating the charges it was necessary to add the associated charges for the use of MIRODERM. The applicant conducted a similar calculation to compute the charges for MIRODERM. Specifically, the applicant used clinical judgment based on

experience, observation, and typical sizes and depths of wounds that would be present on different parts of the body. The applicant stated that because MIRODERM has shown greater efficacy in wound closure based on their case series, the applicant modeled for only two applications with 50 percent closure of the wound after the first application and full closure of the wound after the second application. Based on this assumption, the applicant noted that it assumed that the first application required 100 percent of the amount of skin substitute required to treat the original wound area and the second application required 50 percent, totaling 150 percent. To compute the total amount of square centimeters used for each MS-DRG, the applicant multiplied this percentage (150 percent) by the amount of square centimeters used for the first application for each MS-DRG. The applicant then multiplied the cost per square centimeter for MIRODERM by the average amount of centimeters used for each case within the MS-DRG to determine the average cost of MIRODERM grafts used for each MS-DRG. Similar to above, to convert the costs to charges, the applicant used the same average CCRs for each MS-DRG and divided the average cost of MIRODERM for each MS-DRG by the average CCR for each MS-DRG to determine the average charges of MIRODERM for each MS-DRG. The applicant then added charges related to the use of MIRODERM to the inflated average standardized charges and determined a final inflated average standardized case-weighted charge per case of \$94,009. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was \$67,559 (all calculations above were performed using unrounded numbers). Because the final inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

We are inviting public comments on whether the MIRODERM technology meets the cost criterion.

With regard to substantial clinical improvement, the applicant believed that the technology represents a substantial clinical improvement over existing technologies because patients treated with the MIRODERM for complicated wounds heal quicker and avoid additional surgeries. To demonstrate that the technology meets the substantial clinical improvement criterion, the applicant submitted the results of two actual case studies of a complicated wound from necrotizing fasciitis that was treated with the

MIRODERM. According to the applicant, one case study involved a complicated wound that would typically be treated with a diverting colostomy. The applicant noted that the patient was discharged with intact anoplasty and good sphincter control after 35 days and four applications for MIRODERM. The applicant further stated that the use of MIRODERM demonstrated rapid healing and likely avoided at least two major debilitating surgeries, as well as the emotional and physical impact of a colostomy for 3 to 6 months. In the second case study, according to the applicant, the attending physician estimated the wound would likely take greater than 90 days to close using traditional wound care matrixes. The applicant stated that after 12 days and two applications of MIRODERM the patient was discharged and after 21 days the wound was sutured closed.

The applicant noted that additional patients have been treated with MIRODERM. According to the applicant, given the recent product launch, the case studies have not been completed, but similar results have been communicated to the applicant.

We are concerned that the clinical data the applicant submitted is from a very small sample with no comparisons to other currently approved wound treatment matrixes. Specifically, the applicant submitted data from only two case studies. Also, the applicant compared the use of MIRODERM to the use of other treatments, such as diverting colostomy. While MIRODERM may represent an improvement in treatment options compared to the other treatment options such as diverting colostomy, we are unable to determine if use of MIRODERM represents a substantial clinical improvement when compared to other wound treatment matrixes of other currently approved treatments. We are inviting public comments on whether MIRODERM meets the substantial clinical improvement criterion.

We did not receive any written public comments in response to the February 2016 New Technology Town Hall meeting regarding this application for new technology add-on payments.

#### c. Idarucizumab

Boehringer Ingelheim Pharmaceuticals, Inc. submitted an application for new technology add-on payments for FY 2017 for Idarucizumab; a product developed as an antidote to reverse the effects of PRADAXA® (Dabigatran), which is also manufactured by Boehringer Ingelheim Pharmaceuticals, Inc. (We note that the applicant submitted an application for

new technology add-on payments for FY 2016, but failed to obtain FDA approval prior to the July 1 deadline.) Dabigatran is an oral direct thrombin inhibitor currently indicated to: (1) Reduce the risk of stroke and systemic embolism in patients who have been diagnosed with nonvalvular atrial fibrillation (NVAf); (2) treat deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients who have been administered a parenteral anticoagulant for 5 to 10 days; and (3) reduce the risk of recurrence of DVT and PE in patients who have been previously diagnosed with NVAf. Currently, unlike the anticoagulant Warfarin, there is no specific way to reverse the anticoagulant effect of Dabigatran in the event of a major bleeding episode.

Idarucizumab is a humanized fragment antigen binding (Fab) molecule, which specifically binds to Dabigatran to deactivate the anticoagulant effect, thereby allowing thrombin to act in blood clot formation. The applicant stated that Idarucizumab represents a new pharmacologic approach to neutralizing the specific anticoagulant effect of Dabigatran in emergency situations. Idarucizumab was approved by the FDA on October 16, 2015. The applicant noted that Idarucizumab is the only FDA-approved therapy available to neutralize the anticoagulant effect of Dabigatran. Before the FDA approval of Idarucizumab, the approach for the management of the anticoagulant effect of Dabigatran prior to an invasive procedure was to withhold administration of Dabigatran, when possible, for a certain duration of time prior to the procedure to allow sufficient time for the patient's kidneys to flush out the medication. The duration of time needed to flush out the medication prior to the surgical procedure is based on the patient's kidney function. According to the applicant, if surgery cannot be delayed to allow the kidneys the necessary time to flush out the traces of Dabigatran, there is an increased risk of bleeding.

Based on the FDA indication for Idarucizumab, the product can be used in the treatment of patients who have been diagnosed with NVAf and administered Dabigatran to reverse life-threatening bleeding events, or who require emergency surgery or medical procedures and rapid reversal of the anticoagulant effects of Dabigatran is necessary and desired. The applicant received a unique ICD-10-PCS procedure code that became effective October 1, 2015. The approved procedure code is XW03331 (Introduction of Idarucizumab,

Dabigatran reversal agent into central vein, percutaneous approach, New Technology Group 1). We are inviting public comments on whether Idarucizumab meets the newness criterion.

With regard to the cost criterion, the applicant conducted two analyses. The applicant began by researching claims data in the FY 2014 MedPAR file for cases that may be eligible for Idarucizumab using a combination of ICD-9-CM diagnosis and procedure codes. Specifically, the applicant searched the database for cases reporting anticoagulant therapy diagnosis code E934.2 (Agents primarily affecting blood constituents, anticoagulants) or V58.61 (Long-term (current) use of anticoagulants) in combination with either current standard of care procedure code 99.03 (Other transfusion of whole blood), 99.04 (Transfusion of packed cells), 99.05 (Transfusion of platelets), 99.06 (Transfusion of coagulation factors), 99.07 (Transfusion of other serum), or 39.95 (Hemodialysis), and Dabigatran indication diagnosis code 427.31 (Atrial fibrillation), 453.40 (Acute venous embolism and thrombosis of unspecified deep vessels of lower extremity), 453.41 (Acute venous embolism and thrombosis of deep vessels of proximal lower extremity), 453.42 (Acute venous embolism and thrombosis of deep vessels of distal lower extremity), 453.50 (Chronic venous embolism and thrombosis of unspecified deep vessels of lower extremity), 453.51 (Chronic venous embolism and thrombosis of deep vessels of proximal lower extremity), 453.52 (Chronic venous embolism and thrombosis of deep vessels of distal lower extremity), 415.11 (Iatrogenic pulmonary embolism and infarction), 415.12 (Septic pulmonary embolism), 415.13 (Saddle embolus of pulmonary artery), 415.19 (Other pulmonary embolism and infarction), 416.2 (Chronic pulmonary embolism), V12.51 (Personal history of venous thrombosis and embolism), or V12.55 (Personal history of pulmonary embolism).

To further target potential cases that may be eligible for Idarucizumab, the applicant also excluded specific cases based on Dabigatran contraindications, including all cases representing patients who have been diagnosed with chronic kidney disease (CKD) stage V (diagnosis code 585.5), end-stage renal disease (diagnosis code 585.6), prosthetic heart valves (diagnosis code V43.3), and cases representing patients who have been diagnosed with both CKD stage IV (diagnosis code 585.4) and either DVT or PE (using the same ICD-9-CM

diagnosis codes listed above). As a result, the applicant identified 84,224 cases that mapped to 684 MS–DRGs. The applicant standardized the charges and computed an average case-weighted standardized charge per case of \$60,089.

The applicant then identified hospital charges potentially associated with the current treatments to reverse anticoagulation, specifically charges associated with pharmacy services, dialysis services, and laboratory services for blood work. Due to limitations associated with the claims data, the applicant was unable to determine the specific drugs used to reverse anticoagulation and if these cases represented patients who required laboratory services for blood work or dialysis services unrelated to the reversal of anticoagulation. Therefore, the applicant subtracted 40 percent of the charges related to these three categories from the standardized charge per case, based on the estimation that the full amount of charges associated with these services would not be incurred by hospitals when Idarucizumab is administered for use in the treatment of patients who have been diagnosed with NVAf and Dabigatran is administered during treatment. The applicant then inflated the standardized charge per case by 7.665 percent, the same inflation factor used by CMS to update the FY 2016 outlier threshold (80 FR 49784) and added charges for Idarucizumab. This resulted in an inflated average case-weighted standardized charge per case of \$67,617. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount across all 684 MS–DRGs is \$55,586 (all calculations above were performed using unrounded numbers). Because the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion under this analysis.

Further, the applicant conducted an additional analysis using the same data from the FY 2014 MedPAR file and variables used in the previous analysis. However, instead of using potentially eligible cases that mapped to 100 percent of the 684 MS–DRGs identified, the applicant used potentially eligible cases that mapped to the top 75 percent of the 684 MS–DRGs identified. By applying this limitation, the applicant identified 63,033 cases that mapped to 87 MS–DRGs. The applicant computed an inflated average case-weighted standardized charge per case of \$55,872. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount across all 87 MS–

DRGs is \$63,323 (all calculations above were performed using unrounded numbers). Because the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology also meets the cost criterion under this analysis. We are inviting public comments regarding the applicant's analyses with regard to the cost criterion.

With regard to substantial clinical improvement, according to the applicant, aside from Idarucizumab, there are no other FDA-approved antidotes to reverse the anticoagulant effects of Dabigatran. Management of the treatment of patients who have been diagnosed with NVAf and administered Dabigatran and experience bleeding may often include supportive care such as Hemodialysis and the use of fresh frozen plasma, blood factor products such as prothrombin complex concentrates (PCC), activated prothrombin complex concentrates, and recombinant factor VIIa or delayed intervention. Protamine sulfate and Vitamin K are typically used to reverse the effects of Heparin and Warfarin, respectively. However, due to the mechanism of action in Dabigatran, the applicant maintained that the use of protamine sulfate and Vitamin K may not be effective to reverse the anticoagulant effect of Dabigatran.

The applicant provided information regarding the management of major bleeding events experienced by patients who were administered Dabigatran and Warfarin during the RE–LY trial.<sup>6</sup> During this study, most major bleeding events were only managed by supportive care. Patients who were administered 150 mg of Dabigatran were transfused with pack red blood cells more often when compared to patients who were administered Warfarin (61.4 percent versus 49.9 percent, respectively). However, patients who were administered Warfarin were transfused with plasma more often when compared to patients who were administered 150 mg of Dabigatran (30.2 percent versus 21.6 percent, respectively). In addition, the use of Vitamin K in the treatment of patients who were administered Warfarin was more frequent when compared to the frequency of use in the treatment of patients who were administered 150 mg of Dabigatran (27.3 percent versus 10.3

percent, respectively). The use of PCCs, recombinant factor VIIa and other coagulation factor replacements in the treatment of patients who were administered both Warfarin and 150 mg of Dabigatran was minimal, and did not significantly differ in frequency when compared among patients assigned to either group. Hemodialysis was used in a single case.

The applicant reported that, currently, it is recommended that the administration of Dabigatran be discontinued 1 to 2 days (CrCl  $\geq$ 50 ml/min) or 3 to 5 days (CrCl <50 ml/min), if possible, before invasive or surgical procedures because of the increased risk of bleeding.<sup>7</sup> A longer period of discontinuation time should be considered for patients undergoing major surgery, spinal puncture, or placement of a spinal or epidural catheter or port, if complete hemostasis is required. The applicant stated that delaying emergency medical or surgical procedures can cause urgent conditions to become more severe if intervention is not initiated. The applicant further maintained that delaying emergency medical or surgical procedures for an extended period of time can ultimately lead to negative healthcare outcomes and increased healthcare costs. The applicant asserted that rapidly reversing the anticoagulant effect of Dabigatran administered to patients that require an urgent medical procedure or surgery allows the medical procedure or surgery to be performed in a timely manner, which in turn may decrease complications and minimize the need for more costly therapies.

The applicant also provided interim data from an ongoing Phase III trial<sup>8,9</sup> in patients who may have life-threatening bleeding, or require emergency procedures. The applicant noted that published results of the interim data based on 90 patients suggested the following: Reversal of the Dabigatran anticoagulant effect, which was evident immediately after administration; reversal was 100 percent in the first 4 hours and greater than 89 percent of patients achieved complete reversal; hemostasis in 35 patients in Group A was restored at a median of 11.4 hours. Also, the 5 gram dose of Idarucizumab was calculated to reverse the total body load of Dabigatran that was associated

<sup>7</sup> Pradaxa® (Dabigatran Etxilate Mesylate) prescribing information. Ridgefield, CT: Boehringer Ingelheim; 2014.

<sup>8</sup> Pollack C, et al. Design and rationale for RE–VERSE AD: A phase 3 study of idarucizumab, a specific reversal agent for dabigatran. *Thromb Haemost.* 2015 Jul; 114(1):198–205.

<sup>9</sup> Pollack C, et al. Idarucizumab for Dabigatran Reversal. *N Engl J Med.* 2015 Aug 6; 373(6):511–20.

<sup>6</sup> Healy, et al.: Periprocedural bleeding and thromboembolic events with dabigatran compared with Warfarin: results from the randomized evaluation of long-term anticoagulation therapy (RE–LY) randomized trial, *Circulation*, 2012; 126:343–348.

with the 99th percentile of the Dabigatran levels measured in the RE-LY trial.

The applicant provided safety data from three Phase I studies and interim data from the Phase III study. In the Phase I study, 110 healthy male patients enrolled in the study were administered dosages of Idarucizumab that ranged from 20 mg to 8 grams. In this study, 135 patients received placebo. The applicant reported that adverse events were generally mild in intensity and nonspecific. Healthy human volunteers enrolled in the Phase I study were administered Idarucizumab in dosages of 2 and 4 grams, which resulted in immediate and complete reversal of the anticoagulant effect of Dabigatran that was sustained for several hours. In the Phase III study, five thrombotic events occurred. One occurred 2 days after treatment and the remainder occurred 7, 9, 13, and 26 days after treatment. These patients were not receiving antithrombotic therapy when the events occurred, and complications or adverse effects can be attributed to patients' underlying medical conditions. Twenty-one patients (13 in Group A and 8 in Group B) had a serious adverse event. The most frequently reported adverse reactions in greater than or equal to 5 percent of the patients treated with Idarucizumab were hypokalemia, delirium, constipation, pyrexia, and pneumonia. The applicant concluded that the data from these studies demonstrated that Idarucizumab effectively, safely, and potently reverses the anticoagulant effect of Dabigatran. We are inviting public comments on whether Idarucizumab meets the substantial clinical improvement criterion.

We did not receive any written public comments in response to the February 2016 New Technology Town Hall meeting regarding this application for new technology add-on payments.

d. Titan Spine (Titan Spine Endoskeleton® nanoLOCK™ Interbody Device)

Titan Spine submitted an application for new technology add-on payments for the Titan Spine Endoskeleton® nanoLOCK™ Interbody Device (the Titan Spine nanoLOCK™) for FY 2017. The Titan Spine nanoLOCK™ is a nanotechnology-based interbody medical device with a dual acid-etched titanium interbody system used to treat patients diagnosed with degenerative disc disease (DDD). One of the key distinguishing features of the device is the surface manufacturing technique and materials, which produce macro, micro, and nano surface textures.

According to the applicant, the combination of surface topographies enables initial implant fixation, mimics an osteoclastic pit for bone growth, and produces the nano-scale features that interface with the integrins on the outside of the cellular membrane. Further, the applicant noted that these features generate better osteogenic and angiogenic responses that enhance bone growth, fusion, and stability. The applicant asserted that the Titan Spine nanoLOCK™'s clinical features also reduce pain, improve recovery time, and produces lower rates of device complications such as debris and inflammation.

On October 27, 2014, the Titan Spine nanoLOCK™ received FDA approval for the use of five lumbar interbody devices and one cervical interbody device: The nanoLOCK™ TA-Sterile Packaged Lumbar ALIF Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy; the nanoLOCK™ TAS-Sterile Packaged Lumbar ALIF Stand Alone Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy; the nanoLOCK™ TL-Sterile Packaged Lumbar Lateral Approach Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy; the nanoLOCK™ TO-Sterile Packaged Lumbar Oblique/PLIF Approach Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy; the nanoLOCK™ TT-Sterile Packaged Lumbar TLIF Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy and the nanoLOCK™ TC-Sterile Packaged Cervical Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy. The applicant received FDA approval on December 14, 2015, for the nanoLOCK™ TCS-Sterile Package Cervical Stand Alone Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy. Currently, there are no ICD-10-PCS procedure codes that uniquely describe procedures involving use of the Titan Spine nanoLOCK™ surface technology.

We note that cases reporting procedures involving lumbar and cervical interbody devices map to different MS-DRGs. As discussed in the Inpatient New Technology Add-On Payment Final Rule (66 FR 46915), two separate reviews and evaluations of the technologies are necessary in this instance because cases representing

patients receiving treatment for diagnoses associated with lumbar procedures that may be eligible for use of the technology under the first indication are not expected to be assigned to the same MS-DRGs as patients receiving treatment for diagnoses associated with cervical procedures using the technology under the second indication. Specifically, cases representing patients who have been diagnosed with lumbar DDD and received treatment that involved implanting a lumbar device map to MS-DRGs 028 (Spinal Procedures with MCC), 029 (Spinal Procedures with CC or Spinal Neurostimulators), 030 (Spinal Procedures without CC/MCC), 453 (Combined Anterior/Posterior Spinal Fusion with MCC), 454 (Combined Anterior/Posterior Spinal Fusion with CC), 455 (Combined Anterior/Posterior Spinal Fusion without CC/MCC), 456 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC), 457 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusion without MCC), 458 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions without CC/MCC), 459 (Spinal Fusion Except Cervical with MCC), and 460 (Spinal Fusion Except Cervical without MCC), while cases representing patients who have been diagnosed with cervical DDD and received treatment that involved implanting a cervical interbody device map to MS-DRGs 471 (Cervical Spinal Fusion with MCC), 472 (Cervical Spinal Fusion with CC), and 473 (Cervical Spinal Fusion without CC/MCC). Procedures involving the lumbar and cervical interbody devices are assigned to separate MS-DRGs. Therefore, the devices categorized as lumbar devices and the devices categorized as cervical devices must distinctively (each category) meet the cost criterion and the substantial clinical improvement criterion in order to be eligible for new technology add-on payments beginning in FY 2017. We discuss application of these criteria following discussion of the newness criterion.

As discussed previously in this section, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered "new" for the purposes of new technology add-on payments. We note that the substantial similarity discussion is applicable to both the lumbar and the cervical devices

because all of the devices use the Titan Spine nanoLOCK™ technology.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant stated that, for both interbody devices (the lumbar and the cervical interbody device), the Titan Spine nanoLOCK™'s surface stimulates osteogenic cellular response to assist in bone formation during fusion. During the manufacturing process, the surface produces macro, micro, and nano-surface textures. The applicant believed that this unique combination and use of these surface topographies represents a new approach to stimulating osteogenic cellular response. The applicant asserted that the macro-scale textured features are important for initial implant fixation. The micro-scale textured features mimic an osteoclastic pit for supporting bone growth. The nano-scale textured features interface with the integrins on the outside of the cellular membrane, which generates the osteogenic and angiogenic (mRNA) responses necessary to promote healthy bone growth and fusion. The applicant provided the results from *in vitro* studies, using human mesenchymal cells (MSCs), which showed positive effects on bone growth related to cellular signaling achieved by using the device's surface, and osteoblasts exhibited a more differentiated phenotype and increased bone morphogenetic protein (BMP) production using titanium alloy substrates as opposed to poly-ether-ether-ketone (PEEK) substrates. The applicant stated that Titan Spine's proprietary and unique surface technology, the Titan Spine nanoLOCK™ interbody devices, contain optimized nano-surface characteristics, which generate the distinct cellular responses necessary for improved bone growth, fusion, and stability. The applicant further stated that the Titan Spine nanoLOCK™'s surface engages with the strongest portion of the endplate, which enables better resistance to subsidence because a unique dual acid-etched titanium surface promotes earlier bone in-growth. The Titan Spine nanoLOCK™'s surface is created by using a reductive process of the titanium itself. The applicant asserted that use of the Titan Spine nanoLOCK™ significantly reduces the potential for debris generated during impaction when compared to treatments using PEEK-based implants coated with titanium. According to the results of an *in vitro* study<sup>10</sup> provided by the

applicant, which compared angiogenic factor production using PEEK-based versus titanium alloy surfaces, osteogenic production levels were greater with the use of rough titanium alloy surfaces than the levels produced using smooth titanium alloy surfaces. The results of an additional study<sup>11</sup> provided by the applicant examined whether inflammatory microenvironment generated by cells as a result of use of titanium aluminum-vanadium (Ti-alloy, TiAlV) surfaces is effected by surface microtexture, and whether it differs from the effects generated by PEEK-based substrates. The applicant noted that the use of microtextured surfaces has demonstrated greater promotion of osteoblast differentiation when compared to use of PEEK-based surfaces.

With regard to the second criterion, whether a product is assigned to the same or a different MS-DRG, cases that may be eligible for treatment involving the Titan Spine nanoLOCK™ map to the same MS-DRGs as other (lumbar and cervical) interbody devices currently available to Medicare beneficiaries and also are used for the treatment of patients who have been diagnosed with DDD (lumbar or cervical).

With regard to the third criterion, 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, the applicant stated that the Titan Spine nanoLOCK™ can be used in the treatment of patients diagnosed with similar types of diseases, such as DDD, and for a similar patient population receiving treatment involving both lumbar and cervical interbody devices.

In summary, the applicant maintained that the Titan Spine nanoLOCK™ technology has a different mechanism of action when compared to other spinal fusion devices. Therefore, the applicant did not believe that the Titan Spine nanoLOCK™ technology is substantially similar to existing technologies.

After reviewing the applicant's statements regarding nonsubstantial similarity of its technology with other existing technologies, we are still concerned that there are other titanium surfaced devices currently available on the U.S. market. While these devices do not use the Titan Spine nanoLOCK™

technology, their surfaces also are made of titanium. Therefore, we believe that the Titan Spine nanoLOCK™ interbody devices may be substantially similar to currently available titanium interbody devices.

We are seeking public comments on whether the Titan Spine Endoskeleton® nanoLOCK™ Interbody Devices are substantially similar to existing technologies and whether these devices meet the newness criterion.

(1) Titan Spine Endoskeleton® nanoLOCK™ Interbody Device for Lumbar DDD

As previously mentioned, the Titan Spine nanoLOCK™ received FDA approval for the use of five lumbar interbody devices on October 27, 2014. To demonstrate that the Titan Spine nanoLOCK™ for Lumbar DDD technology meets the cost criterion, the applicant researched claims data in the FY 2014 MedPAR file for cases assigned to MS-DRGs 028, 029, 030, 453, 454, and 455 reporting any of the ICD-9-CM procedure codes within the code series 81.xx (Repair and plastic operations on joint structures) or code series 084.6x (Replacement of spinal disk), excluding cases reporting the following ICD-9-CM procedure codes describing cervical fusion: 81.01 (Atlas-axis spinal fusion), 81.02 (Other cervical fusion, anterior technique), 81.03 (Other cervical fusion, posterior technique), 81.31 (Refusion of atlas-axis spine), 81.32 (Refusion of other cervical spine, anterior technique), or 81.33 (Refusion of other cervical spine, posterior technique). As a result, the applicant found that all cases potentially eligible for treatment using the technology mapped to MS-DRGs 456, 457, 458, 459, and 460. However, the applicant focused its analyses on MS-DRGs 028 through 030, 453 through 455, and 456 through 460 because these are the MS-DRGs to which cases treated with interbody fusion devices for degenerative disc disease would most likely be assigned. The applicant applied CMS' relative weight filtering process as described in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49424) to ensure the correct claim types were used and the charge details across the cost centers were appropriate.

According to the applicant, 78.03 percent of the 96,281 cases found in the FY 2014 MedPAR file mapped to MS-DRG 460, while the remaining 21.97 percent of cases mapped to MS-DRGs 028 through 030, 453 through 455, and 456 through 459. This resulted in an average case-weighted charge per case of \$127,082. The applicant then removed \$15,766 for associated charges for other previously used spinal devices. The

Angiogenic Factors. The Spine Journal, 2013, ep.13. 1563-1570.

<sup>11</sup> Olivares-Navrrete R, Hyzy S, Slosar P, et al. Implant Materials Generate Different Peri-implant Inflammatory Factors. SPINE. 2015; 40:6:339-404.

<sup>10</sup> Olivares-Navrrete R, Hyzy S, Gittens R. Titanium Alloys Regulate Osteoblast Production of

applicant determined the associated charges to be removed for other previously used devices based on current Titan Spine sales data for the Titan Spine nanoLOCK™ for Lumbar DDD various sizes. The applicant computed the associated charges by multiplying the weighted sales mix by the average sales price for each product in the Titan Spine nanoLOCK™ for Lumbar DDD product line. After the charges for other previously used technologies were removed, the applicant standardized the charges for all cases using the FY 2014 standardizing file posted on the CMS Web site. The applicant excluded all cases without standardized charges, resulting in a total of 96,281 cases. The applicant then inflated the average standardized case-weighted charges from 2014 to 2016 by applying a 2-year rate of inflation factor of 7.7 percent, which is the same inflation factor used by CMS to update the FY 2016 outlier threshold (80 FR 49784).

To calculate the appropriate charges for the Titan Spine nanoLOCK™ for Lumbar DDD, the applicant used a case-weighted charge because the devices implanted are produced and made available in different sizes. To calculate the case-weighted charge for different lumbar device sizes, the applicant determined the average cost to the hospital per device and divided that amount by the national average CCR for implantable devices (0.337) published in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49429). Based on sales data, the applicant then applied a factor of 1.5 per patient to the case-weighted charge by dividing the total number of products sold in the United States by the total invoices generated; with one invoice being the equivalent to one patient and a single surgery. The applicant then added the device-related charges to the inflated average standardized charge per case, which resulted in an inflated average standardized case-weighted charge per case of \$167,197. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was \$112,825 (all calculations above were performed using unrounded numbers). Because the final inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

We are inviting public comments on whether the Titan Spine nanoLOCK™ for Lumbar DDD meets the cost criterion, particularly with regard to the assumptions and methodology used in the applicant's analyses.

(2) Titan Spine Endoskeleton® nanoLOCK™ Interbody Device for Cervical DDD

As previously mentioned, Titan Spine received FDA approval for the use of the nanoLOCK™ TC-Sterile Packaged Cervical Interbody Fusion Device with nanoLOCK™ surface on October 27, 2014, and the nanoLOCK™ TCS-Sterile Package Cervical Interbody Fusion Device with nanoLOCK™ surface on December 14, 2015. To demonstrate that the Titan Spine nanoLOCK™ for Cervical DDD meets the cost criterion, the applicant researched claims data in the FY 2014 MedPAR file for cases assigned to MS-DRGs 028, 029, 030, 453, 454, and 455 reporting any of the following ICD-9-CM cervical fusion procedure codes: 81.01, 81.02, 81.03, 81.32, 81.33. The applicant found that all of the cases mapped to MS-DRGs 471, 472, and 473. However, the applicant focused its analysis on MS-DRGs 028 through 030, 453 through 455, and 471 through 473 because these are the MS-DRGs to which cases treated with the implantation of cervical spinal devices for degenerative disc disease would most likely be assigned. Similar to the sensitivity analysis submitted for the Titan Spine nanoLOCK™ for Lumbar DDD, the applicant applied CMS' relative weight filtering process as described in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49424) to ensure the correct claim types were used and the charge details across the cost centers were appropriate.

According to the applicant, 59.47 percent of the 48,187 cases mapped to MS-DRG 473 and 25.65 percent of the cases mapped to MS-DRG 472, while the remaining 14.88 percent of the cases mapped to MS-DRGs 028 through 030, 453 through 455, and 471. This resulted in an average case-weighted charge per case of \$83,841. Using the same methodology described above, the applicant removed \$4,423 for associated charges for other previously used technologies from the average case-weighted charge per case using current Titan Spine sales data for cervical device sizes and then standardized the charges. The applicant then inflated the average standardized case-weighted charges from 2014 to 2016 by applying the same 2-year rate of inflation factor used above (7.7 percent). Similar to the methodology described above, the applicant calculated \$36,023 for associated device related charges for the Titan Spine nanoLOCK™ for Cervical DDD and added this amount to the inflated average standardized case-weighted charge per case, which resulted in a final inflated average

standardized case-weighted charge per case of \$114,472. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was \$79,827 (all calculations above were performed using unrounded numbers). Because the final inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

We are inviting public comments on whether the Titan Spine nanoLOCK™ for Cervical DDD meets the cost criterion.

With regard to the substantial clinical improvement criterion for the Titan Spine Endoskeleton® nanoLOCK™ Interbody Device for Lumbar and Cervical DDD, the applicant asserted that the Titan Spine nanoLOCK™ substantially improves the treatment of Medicare beneficiaries who have been diagnosed with and receive treatment for serious spinal pathologies, such as DDD, compared to the currently available technologies and treatment options, especially in terms of improved fusion, decreased pain, greater stability, faster recovery times, and lower rates of interbody device related complications, such as debris and inflammation.

The applicant noted that the cellular process that occurs after implantation of the Titan Spine nanoLOCK™ induces the body to produce and regulate its own bone morphogenetic proteins (BMP), which help stimulate bone growth naturally in the human body. According to the applicant, this result supports new bone growth without requiring use of exogenous BMP. The applicant explained that exogenous rhBMPs trigger a significant cytokine related anti-inflammatory reaction that has resulted in adverse side effects. The applicant stated that the Titan Spine nanoLOCK™'s proprietary surface and use promotes endogenous production of osteogenic growth factors, such as BMP-2, BMP-4, BMP-7, and TGF-β1.2, which produce only the physiologic amounts necessary for bone production without the concomitant cytokine related to anti-inflammatory reaction.

The applicant also stated that the unique surface of the Titan Spine nanoLOCK™ differentiates the technology from existing interbody devices, which use materials such as PEEK-based or ceramic surfaces. The applicant explained that these materials cause stem cells to flatten on the surface of the implant and primarily differentiate into fibroblasts (fiber-producing cells). This result is avoided by using the Titan Spine nanoLOCK™ because the nano-textured surface

promotes differentiation of osteoblasts (bone-forming cells), which increases bone production around the implant site and increases the potential for a faster and more robust fusion. The applicant further stated that use of titanium and titanium alloy surfaces with rough microtopography demonstrate greater bone apposition, but use of macrotextured titanium and titanium alloy surfaces, such as the Titan Spine nanoLOCK™, promotes osteoblast differentiation and productions of factors that favor bone formation, whereas PEEK-based surfaces do not.

As previously noted, the applicant provided results from *in vitro* studies, using human MSCs, which showed positive effects on bone growth related to cellular signaling achieved from use of the device's surface, and osteoblasts exhibited a more differentiated phenotype and increased bone morphogenetic protein BMP production using titanium alloy substrates as opposed to PEEK-based substrates. The applicant believed that the Titan Spine nanoLOCK™ substantially improves the treatment of Medicare beneficiaries diagnosed with and receiving treatment for serious spinal pathologies, such as DDD, compared to currently available technologies and treatment options for Medicare beneficiaries, especially in terms of improved fusion, decreased pain, greater stability, faster recovery times, and lower rates of interbody device related complications, such as debris and inflammation.

We are concerned that the results of the *in vitro* studies may not necessarily correlate with the clinical results specified by the applicant. Specifically, because the applicant has only conducted *in vitro* studies without obtaining any clinical data from live subjects during a specific clinical trial, we are unable to substantiate the clinical results that the applicant believed the technology achieved from a clinical standpoint based on the results of the studies provided. As a result, we are concerned that the results of the studies provided by the applicant do not demonstrate that the Titan Spine nanoLOCK™ technologies meet the substantial clinical improvement criterion. We are inviting public comments on whether the Titan Spine nanoLOCK™ technologies meet the substantial clinical improvement criterion.

We did not receive any written public comments in response to the February 2016 New Technology Town Hall meeting regarding this application for new technology add-on payments.

#### e. Andexanet Alfa

Portola Pharmaceuticals, Inc. (Portola) submitted an application for new technology add-on payments for FY 2017 for use of Andexanet Alfa, an antidote used to treat patients who are receiving treatment with an oral Factor Xa inhibitor who suffer a major bleeding episode and require urgent reversal of direct and indirect Factor Xa anticoagulation. Patients at high risk for thrombosis, including those who have been diagnosed with atrial fibrillation (AF) and venous thrombosis (VTE), typically receive treatment using long-term oral anticoagulation agents, such as Warfarin. Factor Xa inhibitors are included in a new class of anticoagulants. Factor Xa inhibitors are oral anticoagulants used to prevent stroke and systemic embolism in patients who have been diagnosed with AF. These oral anticoagulants are also used to treat patients diagnosed with deep-vein thrombosis (DVT) and its complications, pulmonary embolism (PE), and patients who have undergone knee, hip, or abdominal surgery. Rivarobaxan (Xarelto®), apixaban (Eliquis®), and edoxaban (Savaysa®) also are included in the new class of Factor Xa inhibitors, and are often referred to as “novel oral anticoagulants” (NOACs) or “non-vitamin K antagonist oral anticoagulants.” Although these anticoagulants have been commercially available since 2010, there is no FDA-approved therapy used for the urgent reversal of any Factor Xa inhibitor as a result of serious bleeding episodes.

Andexanet Alfa has not received FDA approval at the time of the development of this proposed rule. The applicant anticipates receiving FDA approval for use of the technology in approximately June of 2016. Currently, there are no ICD-10-PCS procedure codes that uniquely identify the use of and administration of Andexanet Alfa. We note that the applicant submitted a request for unique ICD-10-PCS procedure codes that was presented at the March 2016 ICD-10 Coordination and Maintenance Committee meeting. If approved, the procedure codes would become effective on October 1, 2016 (FY 2017). More information on this request can be found on the CMS Web site located at: <http://www.cms.gov/Medicare/Coding/ICD10ProviderDiagnosticCodes/ICD-10-CM-C-and-M-Meeting-Materials.html>.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be

considered “new” for purposes of new technology add-on payments.

The applicant believed that, if approved, Andexanet Alfa would be the first and only antidote available used to treat patients receiving treatment with an oral Factor Xa inhibitor who suffer a major bleeding episode and require urgent reversal of direct and indirect Factor Xa anticoagulation. Therefore, the applicant asserted that the technology is not substantially similar to any other currently approved and available treatment options for Medicare beneficiaries.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, Andexanet Alfa, if approved, would be the first reversal agent that binds to direct Factor Xa inhibitors with high affinity, sequestering the inhibitors, and consequently rapidly reducing free plasma concentration of Factor Xa inhibitors and neutralizing the inhibitors' anticoagulant effect, which allows for the restoration of normal hemostasis. Andexanet Alfa also binds to and sequesters antithrombin III molecules that are complexed with indirect inhibitor molecules, disrupting the capacity of the antithrombin complex to bind to native Factor Xa inhibitors. According to the applicant, Andexanet Alfa represents a significant therapeutic advance by providing rapid reversal of anticoagulation therapy in the event of a serious bleeding episode. Other reversal agents, such as Kcentra™ and Idarucizumab, do not reverse the effects of Factor Xa inhibitors.

With regard to the second criterion, whether a product is assigned to the same or a different MS-DRG, Andexanet Alfa would be the first FDA approved reversal agent for Factor Xa inhibitors. Therefore, the MS-DRGs do not contain cases representing patients that have been treated with any reversal agents for Factor Xa inhibitors.

With regard to the third criterion, 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, Andexanet Alfa, if approved, would be the only reversal agent available for treating patients receiving direct or indirect Factor Xa therapy who experience serious, uncontrolled bleeding events or who require emergency surgery. Therefore, Andexanet Alfa would be the first type of treatment option available to this patient population. As a result, it appears that Andexanet Alfa is not substantially similar to any existing technologies. We are inviting public comments on whether Andexanet Alfa



meets the substantial similarity criteria and whether Andexanet Alfa meets the newness criterion.

With regard to the cost criterion, the applicant researched the FY 2014 MedPAR claims data file for cases that may be eligible for treatment using Andexanet Alfa. The applicant used

three sets of ICD–9–CM codes to identify these cases: (1) Codes identifying cases of patients who were treated with an anticoagulant and, therefore, are at risk of bleeding; (2) Codes identifying cases of patients with a history of conditions that were treated with Factor Xa inhibitors; and (3) codes

identifying cases of patients who experienced bleeding episodes as the reason for the current admission. The applicant included with its application the following table displaying a complete list of ICD–9–CM codes that met its selection criteria:

ICD–9–CM codes applicable	Applicable ICD–9–CM code description
V12.50 .....	Personal history of unspecified circulatory disease.
V12.51 .....	Personal history of venous thrombosis and embolism.
V12.52 .....	Personal history of thrombophlebitis.
V12.54 .....	Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits.
V12.55 .....	Personal history of pulmonary embolism.
V12.59 .....	Personal history of other diseases of circulatory system.
V43.64 .....	Hip joint replacement.
V43.65 .....	Knee joint replacement.
V58.43 .....	Aftercare following surgery for injury and trauma.
V58.49 .....	Other specified aftercare following surgery.
V58.73 .....	Aftercare following surgery of the circulatory system, NEC.
V58.75 .....	Aftercare following surgery of the teeth, oral cavity and digestive system, NEC.
V58.61 .....	Long-term (current) use of anticoagulants.
E934.2 .....	Anticoagulants causing adverse effects in therapeutic use.
99.00 .....	Perioperative autologous transfusion of whole blood or blood components.
99.01 .....	Exchange transfusion.
99.02 .....	Transfusion of previously collected autologous blood.
99.03 .....	Other transfusion of whole blood.
99.04 .....	Transfusion of packed cells.
99.05 .....	Transfusion of platelets.
99.06 .....	Transfusion of coagulation factors.
99.07 .....	Transfusion of other serum.

The applicant identified a total of 54,200 cases that mapped to 680 MS–DRGs, resulting in an average case-weighted charge per case of \$67,197. The applicant also provided an analysis limited to 80 percent of all cases (47,273 cases), which mapped to the top 147 MS–DRGs. Under this analysis, the average case-weighted charge per case was \$64,095. Under each of these two analyses, the applicant also provided sensitivity analyses based on variables representing two areas of uncertainty: (1) Whether to remove 40 percent or 60 percent of blood and blood administration charges; and (2) whether to remove pharmacy charges based on the ceiling price of factor eight inhibitor bypass activity (FEIBA), a branded anti-inhibitor coagulant complex, or on the pharmacy indicator 5 (PI5) in the MedPAR data file, which correlates to cases utilizing generic coagulation factors. Overall, the applicant conducted eight sensitivity analyses, and provided the following rationales:

- The applicant chose to remove 40 percent and 60 percent of blood and blood administration charges because patients who require Andexanet Alfa for Factor Xa reversal may still require blood and blood products to treat other conditions. Therefore, it would be inappropriate to remove all of the charges associated with blood and blood

administration because all of the charges cannot be attributed to Factor Xa reversal. The applicant maintained that the amounts of blood and blood products required for treatment vary according to the severity of the bleeding. Therefore, the use of Andexanet Alfa may replace 60 percent of blood and blood product administration charges for cases with less severity of bleeding, but only 40 percent of charges for cases with more severe bleeding.

- The applicant maintained that FEIBA is the highest priced clotting factor used for Factor Xa inhibitor reversal, and it is unlikely that pharmacy charges for Factor Xa reversal would exceed the FEIBA ceiling price of \$10,570. Therefore, the applicant capped the charges to be removed at \$10,570, which in many cases removed 100 percent of the pharmacy charges. The applicant also considered an alternative scenario in which charges associated with pharmacy indicator 5 (PI5) were removed from the costs of cases that included this indicator in the MedPAR data. On average, charges removed from the costs of cases utilizing generic coagulation factors were much lower than the total pharmacy charges.

The applicant noted that, in all eight scenarios, the average standardized case-weighted charge per case for cases

eligible for treatment using Andexanet Alfa would exceed the average case-weighted threshold amounts in Table 10 of the FY 2016 IPPS/LTCH PPS final rule by approximately \$3,247 to \$7,844, depending on the results determined by using the combination of variables of the two areas of uncertainty and the number of MS–DRGs analyzed.

The applicant’s order of operations used for each analysis follows: (1) Removing 60 percent or 40 percent of blood and blood administration charges and up to 100 percent of pharmacy charges for PI5 or FEIBA from the average unstandardized case-weighted charge per case; (2) standardizing the charges per cases using the Impact File published with the FY 2014 IPPS/LTCH PPS final rule. After removing the charges for the prior technology and standardizing charges, the applicant applied an inflation factor of 1.076647, which is the 2-year inflation factor in the FY 2016 IPPS/LTCH final rule (80 FR 49784) to update the charges from FY 2014 to FY 2016. The applicant noted that it did not add charges for Andexanet Alfa and related services. Under each scenario, the applicant stated that the inflated average standardized case-weighted charge per case exceeded the average case-weighted threshold (based on the FY 2016 IPPS Table 10 thresholds). Below

we provide a table for all eight scenarios that the applicant indicated demonstrate that the technology meets the cost criterion.

Scenario	Inflated average standardized case-weighted charge per case	Average case-weighted threshold amount
100 Percent of Cases, FEIBA, 60 Percent Removal of Blood and Blood Administration Costs .....	\$60,231	\$55,799
100 Percent of Cases, P15, 60 Percent Removal of Blood and Blood Administration Costs .....	63,643	55,799
100 Percent of Cases, FEIBA, 40 Percent Removal of Blood and Blood Administration Costs .....	61,651	55,799
100 Percent of Cases, P15, 40 Percent Removal of Blood and Blood Administration Costs .....	64,203	55,799
80 Percent of Cases, FEIBA, 60 Percent Removal of Blood and Blood Administration Costs .....	57,686	54,413
80 Percent of Cases, P15, 60 Percent Removal of Blood and Blood Administration Costs .....	60,994	54,413
80 Percent of Cases, FEIBA, 40 Percent Removal of Blood and Blood Administration Costs .....	59,096	54,413
80 Percent of Cases, P15, 40 Percent Removal of Blood and Blood Administration Costs .....	61,558	54,413

The applicant noted that 25 percent of the total volume of cases map to the following 10 MS-DRGs: MS-DRG 378 (Gastrointestinal Hemorrhage with CC), 7.56 percent of all cases; MS-DRG 812 (Red Blood Cell Disorders without MCC), 3.13 percent of all cases; MS-DRG 377 (Gastrointestinal Hemorrhage with MCC), 2.68 percent of all cases; MS-DRG 470 (Major Joint Replacement or Reattachment of Lower Extremity without MCC), 2.32 percent of all cases; MS-DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation >96 hours with MCC), 2.26 percent of all cases; MS-DRG 481 (Hip & Femur Procedures, Except Major Joint with CC), 2.08 percent of all cases; MS-DRG 811 (Red Blood Cell Disorders with MCC), 1.70 percent of all cases; MS-DRG 291 (Heart Failure and Shock with MCC), 1.22 percent of all cases; MS-DRG 379 (Gastro intestinal Hemorrhage without CC/MCC), 1.12 percent of all cases; and MS-DRG 683 (Renal Failure with CC), 1.06 percent of all cases. We are concerned that the applicant did not include sensitivity analyses for this subset of cases.

We are inviting public comments on whether Andexanet Alfa meets the cost criterion, including with regard to the concern we have raised.

With regard to the substantial clinical improvement criterion, the applicant asserted that Andexanet Alfa represents a substantial clinical improvement for the treatment of patients receiving direct or indirect Factor Xa therapy who experience serious, uncontrolled bleeding events or who require emergency surgery because it addresses an unmet medical need for a universal antidote to direct and indirect Factor Xa inhibitors; if approved, would be the only agent shown in prospective clinical trials to rapidly (within 2–5 minutes) and sustainably reverse the anticoagulation activity of Factor Xa inhibitors; is potentially non-

thrombogenic, as no serious adverse effects of thrombosis were observed in clinical trials; and could supplant current treatments for bleeding from anti-Factor Xa treatment, which have not been shown to be effective in the treatment of all patients.

With regard to addressing an unmet need for a universal antidote to direct and indirect Factor Xa inhibitors, the applicant asserted that the use of any anticoagulant is associated with an increased risk of bleeding, and bleeding complications can be life-threatening. Bleeding is especially concerning in patients treated with Factor Xa inhibitors because there are currently no antidotes to Factor Xa inhibitors available. The applicant stated that Andexanet Alfa has a unique mechanism of action and represents a new biological approach to the treatment of patients who have been diagnosed with acute severe bleeding who require immediate reversal of the Factor Xa inhibitor therapy. The applicant explained that although Andexanet Alfa is structurally very similar to native Factor Xa inhibitors, it has undergone several modifications that restrict its biological activity to reversing the effects of Factor Xa inhibitors by binding with and sequestering direct or indirect Factor Xa inhibitors, which allows native Factor Xa inhibitors to dictate the normal coagulation and hemostasis process. As a result, the applicant maintained that Andexanet Alfa represents a safe and effective therapy for the management of bleeding in a fragile patient population and a substantial clinical improvement over existing technologies and reversal strategies.

The applicant noted the following: On average, patients with a bleeding complication were hospitalized for 6.3 to 7.4 days; the most common therapies currently used to manage bleeding events in patients undergoing

anticoagulant treatment are blood transfusions, most frequently with packed red blood cells or fresh frozen plasma; and Vitamin K therapy was used only in 1 percent of Medicare beneficiaries who were receiving treatment with the indirect Factor Xa inhibitor enoxaparin.

The applicant asserted that laboratory studies have failed to provide consistent evidence of “reversal” of the anticoagulant effect of Factor Xa inhibitors across a range of different PCC products and concentrations. Results of thrombin generation assays have varied depending on the format of the assay. Despite years of experience with low molecular weight heparins and pentasaccharide anticoagulants, neither PCCs nor factor eight inhibitor bypassing activity are recognized as safe and effective reversal agents for these Factor Xa inhibitors. Unlike patients taking Vitamin K antagonists, patients receiving treatment with oral Factor Xa inhibitor drugs have normal levels of clotting factors. Therefore, a strategy based on “repleting” factor levels is of uncertain foundation and could result in supra-normal levels of coagulation factors after rapid metabolism and clearance of the oral anticoagulant.

The applicant provided results from two Phase III studies<sup>12 13</sup> in which older healthy volunteers pretreated with direct or indirect Factor Xa inhibitors (apixaban, edoxaban, rivaroxaban, and enoxaparin) demonstrated the following: Rapid and sustainable reversal of anticoagulation; reduced Factor Xa inhibitor free plasma levels by at least 80 percent below a calculated no-effect level; and reduced anti-Factor Xa activity to the lowest level of detection within 2 to 5 minutes of

<sup>12</sup> Connors, J.M. Antidote for Factor Xa Anticoagulants. N Engl J Med. 2015 Nov 13.

<sup>13</sup> Siegal DM, Curnutte JT, Connolly SJ, et al. Andexanet Alfa for the Reversal of Factor Xa Inhibitor Activity. N Engl J Med. 2015 Nov 11.

infusion. The applicant noted that decreased Factor Xa inhibitor levels have been shown to correspond to decreased bleeding complications, reconstitution of activity of coagulation factors, and correction of coagulation.

The applicant stated that the results from the two Phase III studies and previous proof-of-concept Phase II dose-finding studies<sup>2</sup> showed that use of Andexanet Alfa can rapidly reverse anticoagulation activity of Factor Xa inhibitors and sustain that reversal. Therefore, the applicant asserted that Andexanet Alfa has the potential to successfully treat patients who only need short-duration reversal of the Factor Xa inhibitor anticoagulant, as well as patients who require longer-duration reversal, such as patients experiencing a severe intracranial hemorrhage or requiring emergency surgery. Furthermore, the applicant noted that its technology's duration of action allows for a gradual return of Factor Xa inhibitor concentrations to placebo control levels within 2 hours following the end of infusion.

With regard to Andexanet Alfa's non-thrombogenic nature, as no serious adverse effects of thrombosis were observed in clinical trials, the applicant provided clinical trial data which revealed participants in Phase II and Phase III trials had no thrombotic events and there were no serious or severe adverse events reported. Results also showed that use of Andexanet Alfa has a much lower risk of thrombosis than typical procoagulants because it lacks the region responsible for inducing coagulation. Furthermore, the applicant asserted that Andexanet Alfa is not associated with the known complications seen with red blood cell transfusions.

The applicant asserted that, while the Phase II and Phase III trials and studies measured physiological hallmarks of reversal of NOACs, it is expected that the availability of a safe and reliable Factor Xa reversal will result in an overall better prognosis for patients—potentially leading to a reduction in length of hospital stay, fewer complications, and decreased mortality associated with unexpected bleeding episodes.

The applicant also stated that use of Andexanet Alfa can supplant currently available treatments used for reversing bleeding from anti-Factor Xa treatments, which have not been shown to be effective in the treatment of all patients. With regard to PCCs, NOACs, and FFP, the applicant stated that there is a lack of clinical evidence available for patients taking Factor Xa inhibitors that experience bleeding events. The

applicant noted that the case reports provide a snapshot of emergent treatment of these often medically complex anti-Factor Xa-treated patients with major bleeds. However, the applicant stated that these analyses reveal the inconsistent approach in assessing the degree of anticoagulation in the patient and the variability in treatment strategy. The applicant explained that little or no assessment of efficacy in restoring coagulation in the patients was performed, and the major outcomes measures were bleeding cessation or mortality. The applicant concluded that overall, there is very little evidence for the efficacy suggested in some guidelines, and the evidence is insufficient to draw any conclusions.

We are inviting public comments on whether Andexanet Alfa meets the substantial clinical improvement criterion.

Below is a summary of the written comments we received on the Andexanet Alfa application in response to the February 2016 New Technology Town Hall meeting and our response:

*Comment:* Two commenters supported the approval of new technology add-on payments for Andexanet Alfa. According to the commenters, Andexanet Alfa is a significant clinical improvement over existing therapies used to reverse major bleeding in patients receiving treatment using Factor Xa inhibitors. One commenter stated that Andexanet Alfa would be the first and only antidote to treat patients receiving an oral Factor Xa inhibitor who have suffered a major bleeding episode and require urgent reversal of Factor Xa anticoagulation. Based on professional experience as a first line clinician charged with stabilizing and treating patients with bleeding events or trauma such as assaults and motor vehicle accidents, the commenter stated that patients on anticoagulation therapy present a difficult scenario and they often have comorbidities, which complicate the effectiveness of medical care and put them at risk for complications. The commenter stated that major bleeding is observed in approximately five percent of patients receiving treatment using Factor Xa inhibitors, but only a small subset of those patients require urgent reversal of anti-Factor Xa activity. The commenter believed that, in spite of oral Factor Xa inhibitor's short half-life (7 to 9 hours) and similar or even lower bleeding rates than with warfarin or low molecular weight heparin, the lack of a targeted antidote that is safe for Factor Xa inhibitors is believed to limit these anticoagulants, which do not have a monitoring requirement, nor any dietary

restrictions. The commenter believed that a significant disadvantage of Factor Xa inhibitors is the lack of an effective strategy to rapidly reverse the anticoagulant effects in patients requiring emergency surgery or presenting with an emergent bleed. There is currently no agent indicated or proven to be effective for the treatment of patients with Factor Xa inhibitor related bleeding. The commenter believed that Andexanet Alfa would provide clinicians and their patients the ability to restore homeostasis in critical emergency settings for the broad range of bleeds experienced by patients receiving treatment using Factor Xa inhibitors. The commenter compared Andexanet Alfa to Kcentra<sup>TM</sup> and FEIBA, and noted that both work upstream in the coagulation cascade and thus cannot overcome the effects of the Factor Xa inhibitors. The commenter further stated that human plasma-derived clotting factors were not designed to reverse Factor Xa inhibitors. The commenter also believed that it is well recognized among clinicians that there is a critical need for a reversal agent for the new oral anticoagulants (NOAC) that will rapidly restore normal coagulation, and stated that Andexanet Alfa represents a significant clinical improvement over existing therapies that should be approved for the new technology add-on payments.

Another commenter also believed that Andexanet Alfa represents a significant clinical improvement over existing therapies. The commenter stated that, in the dire moment that a patient presents a critical care team with a life-threatening bleed, reversing coagulation immediately provides the foundation for stabilizing the patient, which is needed to prevent further morbidity and mortality. The commenter also noted Kcentra<sup>TM</sup>'s and FEIBA's inability to affect Factor Xa inhibitors because they act on upstream coagulation cascade factors. The commenter further believed that Andexanet Alfa's mechanism of action is different from the mechanism of action of existing treatments.

*Response:* We appreciate the commenters' input. We will take these comments into consideration when deciding whether to approve new technology add-on payments for Andexanet Alfa for FY 2017.

f. Defitelio<sup>®</sup> (Defibrotide)

Jazz Pharmaceuticals submitted an application for new technology add-on payments for FY 2017 for Defibrotide (Defitelio<sup>®</sup>), a treatment for patients diagnosed with hepatic veno-occlusive disease (VOD) with evidence of multi-organ dysfunction. VOD is a potentially

life-threatening complication resulting from hematopoietic stem cell transplantation (HSCT), with an incidence rate of 8 percent to 15 percent of patients experiencing its effects after HSCT. Diagnoses of VOD range in severity from what has been classically defined as a disease limited to the liver (mild) and reversible, to a severe syndrome associated with multi-organ dysfunction or failure and death. Patients treated with HSCT who develop VOD with evidence of multi-organ dysfunction face an immediate risk of death, with a mortality rate of more than 80 percent when only supportive care is used.

VOD is believed to be the result of endothelial cell damage and hepatocellular injury from high-dose conditioning regimens administered prior to receiving treatment with HSCT. Preclinical data suggest that Defitelio® stabilizes endothelial cells by reducing endothelial cell activation and by protecting endothelial cells from further damage. Defitelio® is administered as a 2-hour intravenous infusion every 6 hours. The recommended dosage is 6.25 mg/kg body weight (25mg/kg/day). Defitelio® should be administered for a minimum of 21 days. If after 21 days the signs and symptoms associated with hepatic VOD are not resolved, the administration of Defitelio® should be continued until clinical resolution.

With regard to the newness criterion, according to the manufacturer, Defitelio® received FDA approval in March 30, 2016 and is expected to be commercially available on the U.S. market on April 6, 2016. At this time, the applicant has not submitted any specific information to establish that the technology was not available on the U.S. market as of the FDA approval date or to describe the reasons for a delay of availability until the first week of April 2016. Therefore, we believe the newness period for Defitelio® would begin on March 30, 2016, the date of FDA approval.

There are currently no ICD-10-PCS codes to uniquely identify the intravenous administration of Defitelio®. The applicant submitted an application for the March 9-10, 2016 meeting of the ICD-10 Coordination and Maintenance Committee for a unique ICD-10-PCS procedure code to identify the use of Defitelio. If approved, the procedure code would become effective on October 1, 2016 (FY 2017). More information on this request can be found on the CMS Web site located at: <http://www.cms.gov/Medicare/Coding/>

*ICD10ProviderDiagnosticCodes/ICD-10-CM-C-and-M-Meeting-Materials.html.*

As discussed earlier, if a technology meets all three of the criteria for substantial similarity, it would be considered substantially similar to an existing technology and would not be considered “new” for purposes of new technology add-on payments.

With regard to the first criterion, whether the product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant maintained that Defitelio® has a unique mechanism of action that is not shared by any other drug on the market used to treat patients diagnosed with VOD with evidence of multi-organ failure. According to the applicant, there are no FDA-approved treatments for VOD other than supportive care. Anticoagulants such as heparin, antithrombin, and tissue plasminogen factor have been used to treat patients diagnosed with VOD, but there is a lack of conclusive evidence that these treatments are effective and they also present a high risk of bleeding. The applicant maintained that Defitelio® addresses the underlying pathology of VOD with evidence of multi-organ failure and its use is effective as a treatment for this form of the disease. According to the applicant, it is speculated that the mechanism of action of the Defitelio® revolves around the stabilization of endothelial cells because endothelial cell damage is believed to be a major contributing factor to the development of VOD. However, we are concerned that this mechanism of action is not well understood by the manufacturer and we are unable to determine whether Defitelio® is substantially similar to the other drugs on the market without full understanding of its distinct mechanism of action.

With regard to the second criterion, whether a product is assigned to the same or a different MS-DRG, the applicant maintained that cases potentially eligible for treatment using Defitelio® and representing the target patient population mainly group to two MS-DRGs: MS-DRG 014 (Allogeneic Bone Marrow Transplant) and MS-DRG 016 (Autologous Bone Marrow Transplant with CC/MCC). We believe that these are the same MS-DRGs that identify cases of patients treated with supportive care for VOD with multi-organ failure.

With regard to the third criterion, 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, the applicant asserted that there are no FDA-approved

treatments for VOD other than supportive care, such as dialysis or ventilation. In addition, the applicant stated that poor outcomes have been reported for patients treated with nonapproved pharmacological treatments for VOD. These treatments have largely been discontinued because of the high incidence of hemorrhagic complications, particularly among patients diagnosed with multi-organ failure. According to the applicant, Defitelio® would be the first and only FDA-approved treatment for VOD with evidence of multi-organ failure. However, we are concerned that the applicant did not include in its application data comparing the outcomes of patients treated with Defitelio® to outcomes of patients treated only for supportive care. We are concerned that Defitelio® may not produce outcomes that are significantly different than the outcomes of patients treated with supportive care.

We are inviting public comments on whether Defitelio® is substantially similar to existing technologies and whether it meets the newness criterion.

With regard to the cost criterion, the applicant conducted sensitivity analyses using claims data from 2012 through 2014 and determined the results in aggregate and by year. The applicant researched 100 percent of the 2012 through 2014 Inpatient Standard Analytic Files (SAFs) for cases eligible for Defitelio®. Because an ICD-9-CM code specific to treatment for VOD does not exist, the applicant used an algorithm to identify cases to use in its sensitivity analyses. The most appropriate ICD-9-CM diagnosis codes were identified based on clinical criteria used to diagnose VOD and were used to identify cohorts of patients diagnosed with VOD and VOD with multi-organ dysfunction. The applicant first identified claims with an ICD-9-CM procedure code indicating an HSCT (Group A) within a 30-day window; VOD most commonly occurs after receipt of HSCT. The applicant then looked for cases with ICD-9-CM diagnosis codes related to liver injury (Group B) or clinical evidence of suspected VOD symptoms based on at least two relevant ICD-9 diagnosis codes (Group C). Lastly, the applicant filtered out cases that did not show clinical evidence of multi-organ dysfunction based on at least one relevant ICD-9-CM code (Group D).

The applicant submitted the following table indicating the ICD-9-CM codes used for each category of the algorithm.

TABLE 12—ICD–9 CODES USED FOR THE PREMIER VOD ALGORITHM

Group	Title	ICD–9–CM Code	Description
A .....	Hematopoietic Stem Cell Transplant (HSCT) (at least one code).	41.00	Bone marrow transplant, not otherwise specified.
		41.01	Autologous bone marrow transplant without purging.
		41.02	Allogeneic bone marrow transplant with purging.
		41.03	Allogeneic bone marrow transplant without purging.
		41.04	Autologous hematopoietic stem cell transplant without purging.
		41.05	Allogeneic hematopoietic stem cell transplant without purging.
		41.06	Cord blood stem cell transplant.
		41.07	Autologous hematopoietic stem cell transplant with purging.
		41.08	Allogeneic hematopoietic stem cell transplant.
B .....	Liver Injury (at least one code).	453.xx	Other venous embolism and thrombosis.
		570.xx	Acute and subacute necrosis of liver.
		573.8	Other specified disorders of liver.
		573.9	Unspecified disorder of liver.
		459.89	Other specified disorders of the circulatory system.
		277.4	Disorders of bilirubin excretion.
		782.4	Hyperbilirubinemia.
C .....	VOD Symptoms (at least two codes).	789.1	Hepatomegaly.
		783.1	Abnormal weight gain.
		789.5	Ascites.
		518.8x	Acute/Chronic Respiratory Failure.
		786.09	Other respiratory abnormalities (respiratory distress, except that associated with trauma/surgery in adults, or with RDS in newborns).
D .....	Multi-Organ Dysfunction (at least one code).	799.02	Hypoxemia.
		518.81	Acute respiratory failure.
		V46.2	Other dependence on machines, supplemental oxygen.
		96.7x	Other continuous invasive mechanical ventilation.
		93.90, 93.91, 93.93, 93.99	Non-invasive mechanical ventilation.
		584.X	Acute renal failure.
		586.X	Renal failure unspecified.
		593.9	Renal Failure.
		39.27, 39.42, 39.95, 54.98	Dialysis, including hemodialysis, peritoneal dialysis, hemofiltration.

Using the above algorithm, the applicant identified a total of 267 patient cases of VOD with multi-organ dysfunction in the 2012–2014 Inpatient SAFs, with 78 patient cases in 2012, 102 patient cases in 2013, and 87 patient cases in 2014, or an average annual patient case volume of 89. The applicant determined that these cases grouped mainly into two MS–DRGs: 014 and 016. The applicant noted that there were no cases in the data from MS–DRG 017 (Autologous Bone Marrow Transplant without CC/MCC). The applicant further noted that there were no cases from MS–DRG 017 because the ICD–9–CM codes identifying VOD with multi-organ dysfunction include serious medical conditions that are listed on the MCC and CC lists. In total, 38 MS–DRGs were represented in the patient cohort, with 27 percent of cases mapping to MS–DRG 014 and 42 percent of cases mapping to MS–DRG 016. The remaining cases mapped to 1 of the 36 remaining MS–DRGs with fewer than 11 cases.

For results in the aggregate, the applicant calculated an average case-weighted charge per case of \$427,440 across 267 cases representing diagnoses of VOD with multi-organ dysfunction

from 2012 through 2014. The applicant assumed there would be a reduction in the use of selected drugs as a result of using Defitelio® and removed 50 percent of the estimated charges for heparin, furosemide, and spironolactone. The charges for these drugs were estimated based on pricing taken from the Medispan PriceRx database, whose costs were marked up according to the inverse of CCRs from cost center 073 (Drugs Charged to Patients) obtained from providers’ 2012, 2013, and 2014 cost reports. The applicant matched these CCRs with the provider numbers on each claim. The applicant removed an average of \$2,631 in charges for these drugs from the overall unstandardized charges for Defitelio®.

The applicant then standardized the charges and calculated an average standardized case-weighted charge per case of \$310,651. To update the charge data to the current fiscal year, the applicant inflated the charges based on the charge inflation factor of 1.048116 in the FY 2016 IPPS/LTCH final rule (80 FR 49779). The 1-year inflation factor was applied four times to FY 2012 claims, three times to FY 2013 claims,

and twice to FY 2014 claims to inflate all charges to 2016. The applicant computed an inflated average standardized case-weighted charge per case of \$356,015. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was \$157,951 (all calculations above were performed using unrounded numbers). Because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion. The applicant noted that it did not include charges for Defitelio® in the inflated average standardized case-weighted charge per case because the inflated average standardized case-weighted charge per case exceeded the average case-weighted threshold amount without charges for Defitelio®.

The applicant provided a similar analysis for each individual year of the SAF data rather than combining all the data from all 3 years into one analysis. Under the other three analyses, the applicant noted that the average standardized case-weighted charge per case exceeded the average case-

weighted threshold amount (as shown in the table below) without inflating the	charges and without adding any charges for Defitelio®. We are inviting public	comments on whether Defitelio® meets the cost criterion.
	SAF year	Average case-weighted threshold amount
		Average standardized case-weighted charge per case
2012 .....		\$161,469
2013 .....		150,585
2014 .....		163,434

With regard to the substantial clinical improvement criterion, the applicant maintained that Defitelio® is an effective treatment for VOD as an early onset cause of mortality following HSCT. According to the applicant, patients treated with Defitelio® have improved survival and efficacy rates compared to patients who were not treated with Defitelio®. In increasing the chances of post-HSCT survival, Defitelio® affords the transplant patient the opportunity for engraftment, which could be a potential cure for the underlying disease that required HSCT.

The applicant supported these assertions with clinical evidence from pivotal trial 2005–01, a Phase III historical control study in which patients with VOD with multi-organ failure were given Defitelio® in doses of 25/mg/kg/day for the recommended minimum treatment duration of 21 days. Patients in the historical control group were selected by an independent medical review committee (MRC) from a pool of 6,867 medical charts of patients receiving HSCT that were hospitalized from January 1995 through November 2007. The trial consisted of 102 patients in the Defitelio® treated group and 32 patients in the historical control group. The trial used the survival rate and rate of Complete Response (CR) at Day+100 as clinical endpoints. The observed survival rate at Day+100 in the Defitelio® treated group was 38.2 percent compared to 25 percent in the historical control group. Moreover, the rate of CR by Day+100 post-HSCT for the Defitelio® treated group was 25.5 percent compared to 12.5 percent in the historical control group. The applicant conducted additional analyses that showed improvements in survival outcomes among subgroups of patients with baseline prognostic factors related to worse outcomes.

According to the applicant, running a controlled, blinded, and randomized trial in a patient population with high mortality rates would be unethical. We are concerned that there are limitations to the historical control group used in

pivotal trial 2005–01. We believe that the discrepancy between the size of the treatment group (N=102) and the historical control group (N=32) may skew the trial results in favor of the treatment group. We also are uncertain, given the small sample size and historical data used, whether the historical control group is representative of patients with VOD with multi-organ failure. According to the applicant, patients in the historical control group were hospitalized between January 1995 and November 2007. Because of advancements in medicine within this timeframe, we are concerned that the patients in the historical control group cannot be appropriately compared to patients in the treatment group. Moreover, we believe that it is difficult to attribute improved survival and CR rates only to Defitelio® treatment.

We are inviting public comments on whether Defitelio® meets the substantial clinical improvement criterion.

We did not receive any written public comments in response to the February 2016 New Technology Town Hall meeting regarding this application for new technology add-on payments.

g. EDWARDS INTUITY Elite™ Valve System

Edwards Lifesciences submitted an application for new technology add-on payments for the EDWARDS INTUITY Elite™ Valve System (INTUITY) for FY 2017. The device uses a rapid deployment valve system and serves as a prosthetic aortic valve, which is inserted using surgical aortic valve replacement (AVR). The device replaces the diseased native valve in patients with aortic valve disease, including aortic stenosis. The components of the device are: (1) A bovine pericardial aortic bioprosthetic valve; (2) a balloon expandable stainless steel frame; and (3) a textured sealing cloth. The INTUITY valve shares many basic features with other tissue, bioprosthetic valves. The leaflets are made of bovine pericardium, rather than porcine valve tissue, or purely mechanical elements.

With regard to the newness criterion, the applicant submitted an application

to the FDA for pre-market approval of the INTUITY valve and anticipates FDA approval prior to July 1, 2016. The applicant indicated that the device would be available on the market shortly after approval. The applicant submitted a request for a unique ICD–10–PCS code for consideration at the March 2016 ICD–10 Coordination and Maintenance Committee meeting. If approved, the codes will be effective on October 1, 2016 (FY 2017). More information on this request can be found on the CMS Web site located at: <http://www.cms.gov/Medicare/Coding/ICD10ProviderDiagnosticCodes/ICD-10-CM-C-and-M-Meeting-Materials.html>.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered “new” for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant described three aspects of the valve system that are unique relative to existing devices. First, the valve system has a deployment mechanism that allows for rapid deployment and only requires 3 sutures, as opposed to 12 to 18 sutures used in standard valve replacement procedures. Second, the flexible deployment arm allows improved surgical access and visualization, making the surgery less challenging for the surgeon, which improves the likelihood that the surgeon can use a minimally invasive approach. Third, the assembly of the device only allows the correct valve size to be fitted, which ensures that the valve does not slip or migrate, which prevents paravalvular leaks and patient prosthetic mismatch. The applicant maintained that the INTUITY has a different mechanism of action than other prosthetic aortic valves and, therefore, is not substantially similar to those used in standard aortic valve replacement procedures.

With regard to the second and third criteria, the device is used in the same

patient population and would be assigned to the same MS-DRGs as cases involving other prosthetic aortic valves. We also received information about the Perceval aortic valve (LivaNova), which received FDA approval in January 2016 and which appears to be a substantially similar aortic valve. If the INTUITY valve were to receive approval for new technology add-on payments, we would consider whether the INTUITY valve is substantially similar to the device that has already received FDA approval. If we determine that it is substantially similar, we note that the start date for determining the duration of new technology add-on payments would be the date of FDA approval for the Perceval aortic valve.

After reviewing the information provided by the applicant with regard to

the substantial similarity criteria discussed above, we have the following concerns. First, it appears that this device uses a similar mechanism of action as standard aortic valves; the differences described in the application, with respect to how the valve is placed and secured, and the number of sutures required, do not readily distinguish the mechanism of action from other aortic valves. Second, the MS-DRGs to which cases using the INTUITY would be assigned, as indicated in the application, are the same MS-DRGs to which cases involving standard aortic valves would be assigned. Third, the device is used to treat the same disease and patient population as standard aortic valves. In light of these concerns, we believe that this device appears to be substantially similar to other valves

used in aortic valve replacement. We are inviting public comments on whether the INTUITY meets the newness criterion.

With regard to the cost criterion, the applicant researched the FY 2014 MedPAR claims data file to identify cases of patients who represent potential recipients of treatment using the INTUITY. The applicant identified claims that had an ICD-9-CM diagnosis code of 424.1 (Aortic valve disorder) in combination with an ICD-9-CM procedure code of 35.21 (Replacement of aortic valve with tissue) or 35.22 (Open and other replacement of aortic valve). The applicant also identified cases with or without a coronary artery bypass graft (CABG) using the ICD-9-CM procedure codes in the table below.

ICD-9-CM code	Code description
36.10 .....	Aortocoronary bypass for heart revascularization, not otherwise specified.
36.11 .....	(Aorto)coronary bypass of one coronary artery.
36.12 .....	(Aorto)coronary bypass of two coronary arteries.
36.13 .....	(Aorto)coronary bypass of three coronary arteries.
36.14 .....	(Aorto)coronary bypass of four or more coronary arteries.
36.15 .....	Single internal mammary-coronary artery bypass.
36.16 .....	Double internal mammary-coronary artery bypass.
36.17 .....	Abdominal-coronary artery bypass.

The applicant identified a total of 15,291 cases that mapped to MS-DRGs 216 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC), 217 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC), 218 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC), 219 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC), 220 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC), and 221 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC). The applicant calculated an average unstandardized charge per case of \$178,608 for all cases. The applicant then removed 100 percent of the charges for pacemakers, investigational devices, and other implants that would not be required for patients receiving treatment using the INTUITY.

The applicant standardized the charges and then applied an inflation factor of 1.076647, which is the 2-year inflation factor in the FY 2016 IPPS/LTCH final rule (80 FR 49784), to update the charges from FY 2014 to FY 2016. Because the price of the INTUITY has yet to be determined, the applicant

calculated the average expected charge using the same price as charged in the recent IDE trial. Although the applicant submitted data that related to the estimated clinical trial cost of the INTUITY, the applicant noted that the cost of the technology was proprietary information. To add charges for the new technology, the applicant assumed a hospital mark-up of approximately 3.0 percent, based on the current average CCR for implantable devices (0.337) as reported in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49429). Based on the FY 2016 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was \$163,173. The applicant computed an inflated average standardized case-weighted charge per case of \$185,982, which is \$22,809 above the average case-weighted threshold amount. Because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

We are concerned that the number of individual cases that were identified and provided by the applicant indicated a total of 26,520 cases that would be eligible for treatment using the INTUITY, but the applicant only included 15,291 cases in the final sensitivity analysis. We would like more

information from the applicant regarding how it decided upon which cases to include in the sensitivity analysis, as well as further details about how and on what basis the applicant weighted CABG and non-CABG cases. We are inviting public comments on whether the INTUITY meets the cost criterion, including with regard to the concerns we have raised.

With regard to the substantial clinical improvement criterion, the applicant stated that the device improves clinical outcomes for patients undergoing minimally invasive AVR and full-sternotomy AVR. The applicant also stated that the rapid deployment technology enables reduced operative time, specifically cross-clamp time, thereby reducing the period of myocardial ischemia. The applicant also indicated that the flexible deployment arm increases the likelihood that a minimally invasive approach can be used. In addition, the applicant suggested that the device offers a reduction in operative time for full-sternotomy AVR. The applicant noted that clinical results demonstrated significant patient outcome and utilization improvements, including improved patient satisfaction, faster return to normal activity, decreased post-operative pain, reduced mortality and decreased complications, including

need for reoperation due to bleeding, reduced recovery time, and reduced length of stay.

According to the applicant, the valve has been tested clinically in several programs. In the TRITON trial (Kocher et al., 2013<sup>14</sup>), 287 patients with aortic stenosis underwent surgery in 1 of 6 European centers. The first 149 patients received the first generation Model 8300A valve, and the next 138 patients received the second generation Model 8300AB. The average age of the patients was 75.7 years. Early, 30-day mortality was 1.7 percent (5/287), the post-operative valve gradient was low, and 75 percent of the patients improved functionally. A total of four valves were explanted in the final 30 days due to bleeding, and three were explanted later for paravalvular leak, endocarditis, and aortic root aneurysms. Follow-up extended to 3 years (mean 1.8 years).

Implantation of the INTUITY using minimally invasive surgery was compared with conventional aortic valve replacement in the CADENCE–MIS randomized trial (Borger et al., 2015<sup>15</sup>) of 100 patients treated in 1 of 5 centers in Germany (3). Aortic cross-clamp time was reduced from 54.0 to 41.3 minutes ( $p < 0.0001$ ), and cardiopulmonary bypass time was reduced from 74.4 to 68.8 minutes ( $p = 0.21$ ). Early clinical outcomes were similar: Two deaths in the MIS group versus one death in the conventional surgery group ( $p = 0.53$ ), reoperation in one patient in each group, and no differences in other clinical outcomes. The aortic valve gradient was significantly lower in the MIS group: 8.5 vs. 10.3 mmHg.

The applicant also provided information referring to unpublished data about the preliminary outcomes of the Transform trial; this trial included a study arm that compared MIS surgery with the INTUITY valve to historical comparators that involved MIS surgery with another valve. The applicant indicated that key findings of this trial included reduced procedure times and cross-clamp times, reduced reoperations and 30-day mortality, and reduced length of stay for the INTUITY valve relative to historical comparators that involved another valve. The applicant

did not provide any details about these outcomes, stating that the data would be submitted for publication after FDA review.

After reviewing the information provided by the applicant, we have the following concerns. We are concerned that the INTUITY does not have sufficient advantages over other alternative surgically implanted valve systems to constitute a substantial clinical improvement. While the studies included with the application demonstrate reduced aortic cross-clamp time, conventional aortic valve replacement was used in the comparison group; therefore, it is unclear whether the reduced aortic cross-clamp time is associated with the INTUITY valve or with MIS surgery in general. We understand that this issue is currently being studied in the Transform trial, which is in progress. We also note that, there have been no conducted trials of the INTUITY valve, implanted using minimally invasive surgery, versus traditional transcatheter aortic valve replacement (TAVR) procedures, which we believe would be the most relevant comparison. We also do not believe that the applicant provided evidence to support its assertion that the use of the INTUITY valve increase the likelihood of MIS surgery being performed. We are inviting public comments on whether the INTUITY valve meets the substantial clinical improvement criterion.

Below is a summary of the written comments we received on the INTUITY valve in response to the February 2016 New Technology Town Hall meeting and our response.

*Comment:* One commenter stated that the Perceval bioprosthesis is substantially similar to the INTUITY valve, in that they both map to the same MS–DRGs that 219, 220, and 221; they utilize the same ICD–10 code 02RF8Z (Replacement of aortic valve with zooplastic tissue, open approach); they are intended to treat the same or similar disease and patient population; they are intended to achieve the same therapeutic outcome; and they are both considered to be sutureless/rapid deployment aortic heart valves used for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves. The commenter cited several meta-analyses that include both the Perceval and INTUITY valves and consider them clinically equivalent technologies. The commenter also cited excerpts from articles as well as a description of the ongoing Perceval IDE study to provide support for the substantial clinical improvement of sutureless/rapid deployment heart

valves. The applicant requested that Perceval and INTUITY valves be considered in the same category for the new technology add-on payment.

*Response:* We appreciate the commenter's input. We welcome additional input from the public and will take these comments into consideration when deciding whether to approve new technology add-on payments for the INTUITY valve for FY 2017.

#### h. GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE)

W.L. Gore and Associates, Inc. submitted an application for new technology add-on payments for the GORE® EXCLUDER® Iliac Branch Endoprosthesis (GORE IBE device) for FY 2017. The device consists of two components: The Iliac Branch Component (IBC) and the Internal Iliac Component (IIC). The applicant indicated that each endoprosthesis is pre-mounted on a customized delivery and deployment system allowing for controlled endovascular delivery via bilateral femoral access. According to the applicant, the device is designed to be used in conjunction with the GORE® EXCLUDER® AAA Endoprosthesis for the treatment of patients requiring repair of common iliac or aortoiliac aneurysms. When deployed, the GORE IBE device excludes the common iliac aneurysm from systemic blood flow, while preserving blood flow in the external and internal iliac arteries.

With regard to the newness criterion, the applicant submitted an application to the FDA for pre-market approval of the GORE IBE device, but has not yet received FDA approval. The applicant submitted a request for a unique ICD–10–PCS code that was presented at the March 2016 ICD–10 Coordination and Maintenance Committee meeting. If approved, the code will be effective on October 1, 2016 (FY 2017). More information on this request can be found on the CMS Web site at: <http://www.cms.gov/Medicare/Coding/ICD10ProviderDiagnosticCodes/ICD-10-CM-C-and-M-Meeting-Materials.html>.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered “new” for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant indicated that the GORE IBE device is based on the same design principles as other endovascular repair devices, and

<sup>14</sup> Kocher AA, Laufer G, Haverich A, et al. One-year outcomes of the surgical treatment of aortic stenosis with a next generation surgical aortic valve (TRITON) trial: A prospective multicenter study of rapid-deployment aortic valve replacement with the EDWARDS INTUITY valve system. *J Thorac Cardiovasc Surg.* 2013; 145:110–116.

<sup>15</sup> Borger MA, Moustafine V, Conradi L, et al. A randomized multicenter trial of minimally invasive rapid deployment versus conventional full sternotomy aortic valve replacement. *Ann Thorac Surg* 2015; 99:17–25.



its use differs because of the specific target site for implantation. Consequently, it has a different shape and method of delivery from other endovascular devices. The GORE IBE device is similar to the GORE® EXCLUDER® AAA Endoprosthesis, primarily differing in device dimensions to fit within the iliac artery anatomy. With regard to the first criterion, we are concerned that the GORE IBE device has a similar mechanism of action to other stenting grafts used to treat patients with abdominal aortic aneurysms (AAAs) because it repairs the abdominal aortoiliac aneurysm from the inside and is inserted in a similar manner to other abdominal aortoiliac endovascular aneurysm repair devices.

With regard to the second criterion, whether a product is assigned to the same or a different MS-DRG, the applicant indicated that cases using the GORE IBE device would map to the same MS-DRGs as cases involving other stent-grafts used to treat patients with AAAs. Specifically, similar to cases involving other stent-grafts used to treat AAAs, cases involving the GORE IBE device would be assigned to MS-DRG 268 (Aortic and Heart Assist Procedures except Pulsation Balloon with MCC) and MS-DRG 269 (Aortic and Heart Assist Procedures except Pulsation Balloon without MCC).

With regard to the third criterion, 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, the applicant indicated that the GORE IBE device is intended to be used in the treatment of patients requiring repair of common iliac or aortoiliac aneurysms. The applicant stated that this device, if approved, would be the first purpose-built endovascular device for patients whose conditions (common iliac or aortoiliac aneurysm) put them at risk for negative clinical outcomes due to limitations of current treatment methods, which may not preserve internal iliac artery perfusion. The applicant described current repair options for these patients as: (a) Intentional occlusion and coverage of the internal iliac artery; (b) undergoing a more extensive surgical operation to place a bypass graft; or (c) use of combinations of devices in a nonindicated, variable, and inconsistent manner. With regard to the third criterion, we are concerned that this device appears to treat a similar type of disease to existing stent grafts.

Based on the statements above, the applicant maintained that the GORE IBE device is not substantially similar to other stent-grafts used to treat patients

with AAAs. We are inviting public comments on whether Gore IBE device is substantially similar to existing technologies and whether the technology meets the newness criterion.

With regard to the cost criterion, the applicant researched the FY 2014 MedPAR claims data to identify patients who may be eligible for treatment using the GORE IBE device. The applicant noted that cases eligible for the GORE IBE device would map to MS-DRGs 268 (Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC) and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC). The applicant provided two analyses. The first analysis searched for cases that may be potentially eligible for the GORE IBE device by identifying cases with endovascular aneurysm repair (EVAR) with iliac diagnoses. To identify these cases, the applicant searched for cases that had an ICD-9-CM primary procedure code of 39.71 (Endovascular implantation of other graft in abdominal aorta) in combination with a primary diagnosis code of 441.4 (Abdominal aneurysm without mention of rupture) or 441.02 (Dissection of aorta, abdominal). The applicant excluded cases with a diagnosis code of 441.3 (Abdominal aneurysm, ruptured), and cases with atherosclerosis of the lower extremities (ICD-9-CM diagnosis code 440.20 through 440.28). The applicant then identified a subset of cases (1,615 cases) with significant iliac involvement (which indicated use of the prior technology as well as disease extent where the new technology could be used) by searching for cases with a secondary ICD-9-CM diagnosis code of 442.2 (Aneurysm of iliac artery) or 443.22 (Dissection of iliac artery). This subset of cases was used in the analysis with 205 cases that mapped to MS-DRG 268 and 1,410 cases that mapped to MS-DRG 269. As discussed below, the remaining cases (11,926 cases) were used to help evaluate and compare subsequent offset charge calculations (base EVAR cases).

Using the 1,615 cases, the applicant calculated an average unstandardized case-weighted charge per case of \$121,527. Charges for the prior technology (implants), which would be offset by the new technology were established by subtracting the average implant charge in the 1,615 cases from the average implant charge in the base EVAR sample. The excess implant charge represents current implant charges being used in EVAR cases with iliac involvement, and was subtracted from the average unstandardized case-weighted charge per case.

The applicant compared the average unstandardized O.R. and radiology charges associated with the new technology from the clinical trial data with the unstandardized O.R. and radiology charges associated with the prior technology from the MedPAR data and noted that O.R. and radiology charges for resources related to the new technology and the prior technology were similar. However, with regard to charges in the intensive care unit (ICU), there was a reduction of 56 percent in ICU associated charges for the new technology. Therefore, the applicant offset the ICU associated charge by 56 percent and deducted this amount from the average unstandardized case-weighted charge per case. The applicant then standardized the charges, but noted that it did not inflate the charges. The applicant added charges for the GORE IBE device by converting the costs of the device to charges using the average CCR for implantable devices (0.337) as reported in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49429). The applicant noted that the cost of the technology was proprietary information. Based on the FY 2016 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was \$109,241. The applicant computed an average standardized case-weighted charge per case of \$124,129. Because the average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

The second analysis was similar to the first analysis, but searched the MedPAR claims data file for cases with an EVAR with an iliac diagnosis and procedure instead of cases with EVAR and only an iliac diagnosis. The applicant used the same ICD-9-CM procedure and diagnoses codes as used in the first analysis, but used the following ICD-9-CM procedure codes to identify cases that had an iliac procedure: 39.79 (Other endovascular procedures on other vessels) in combination with 39.29 (Other (peripheral) vascular shunt or bypass), 39.79 in combination with 39.90 (Insertion of non-drug-eluting peripheral (non-coronary) vessel stent(s) without 39.29, 39.90 in combination with 00.41 (Procedure on two vessels), 00.46 (Insertion of two vascular stents), and 00.47 (Insertion of three vascular stents) without 39.79 and 39.29. The applicant noted that the expected distribution of cases for the GORE IBE device is that 20 percent of the cases would map to MS-DRG 268 and 80 percent of the cases would map

to MS–DRG 269. Because this analysis represents cases that had an actual iliac procedure, the applicant applied this distribution to the cases. The applicant then followed the same methodology above and removed charges for the prior technology and resources related to the prior technology, standardized the charges, and then added charges related to the GORE IBE device. Based on the FY 2016 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was \$113,015. The applicant computed an inflated average standardized case-weighted charge per case of \$138,179. Because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

With regard to the second analysis, the applicant imputed the distribution of cases. We are not sure how the applicant determined which cases would map to MS–DRG 268 or MS–DRG 269, if the distribution was imputed. Also, the applicant did not disclose how many cases were found in the claims data after filtering the case volume using ICD–9–CM procedure codes identifying cases that had an iliac procedure. We are inviting public comments on whether the GORE IBE device meets the cost criterion, including with regard to the concerns we have raised.

With regard to the substantial clinical improvement criterion, the applicant indicated that current treatment approaches have substantial risks of complications that can negatively impact quality of life. Available treatment methods that do not preserve internal iliac artery perfusion increase risks for negative clinical outcomes; compared to methods that preserve the internal iliac artery, those that use contralateral hypogastric embolization result in a higher incidence of buttock claudication (15–55 percent), sexual dysfunction (5–45 percent), ischemia of the colon (2.6 percent), and rarely, ischemia of the spine. The applicant cited the “12–04” study,<sup>16</sup> which the applicant suggested showed the GORE IBE device to have 0 percent rates of buttock claudication, new onset erectile dysfunction, colonic ischemia, and spinal cord ischemia. The applicant also suggested that the 12–04 study showed the GORE IBE device to have reduced procedure time, reduced fluoroscopy time, reduced reintervention rates, and

increased patency rates. The applicant asserted that because the GORE IBE device preserves flow to the internal iliac artery, the risk of complications is reduced, which represents a substantial clinical improvement relative to current treatment approaches. The applicant also stated that, compared with historical data for procedures done using contralateral hypogastric embolization, the GORE IBE device is associated with reduced procedure time, reduced fluoroscopy time, reduced reintervention rates, reduced incidence of aneurysm enlargement, and improved patency rates.

The applicant submitted several research articles with its application, which consisted of a few very small case series of 23 total patients published,<sup>17 18 19</sup> as well as some abstracts of other case series. These publications describe the procedural results of using the device, with angiographic endpoints, and demonstrate the feasibility of insertion. The applicant also indicated that other treatment approaches, including open surgery, are done infrequently, while other approaches are not approved for this purpose. Therefore, the applicant indicated that it would be impractical to conduct comparative studies.

After reviewing the information provided by the applicant, we have the following concerns: We are concerned about the lack of clinical studies comparing the GORE IBE device with alternative methods of treatment, and note that the application did not provide data that supported its assertions that the GORE IBE device is associated with reduced procedure time, reduced fluoroscopy time, reduced reintervention rates, reduced incidence of aneurysm enlargement, and improved patency rates. We also note that the applicant’s assertions about decreased rates of complications appear to compare a small number of published cases of the use of the GORE IBE device with complication rates cited in the literature, which does not indicate whether there is a valid basis for comparison. We are inviting public comments on whether the GORE IBE

device meets the substantial clinical improvement criterion.

We did not receive any written public comments in response to the February 2016 New Technology Town Hall meeting regarding this application for new technology add-on payments.

i. Vistogard™ (Uridine Triacetate)

BTG International Inc., submitted an application for new technology add-on payments for the Vistogard™ for FY 2017. Vistogard™ (Uridine Triacetate) was developed as an antidote to Fluorouracil toxicity. Chemotherapeutic agent 5-fluorouracil (5–FU) is used to treat specific solid tumors. It acts upon deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) in the body, as uracil is a naturally occurring building block for genetic material. Fluorouracil is a fluorinated pyrimidine. As a chemotherapy agent, Fluorouracil is absorbed up by cells and causes the cell to metabolize into byproducts that are toxic and used to destroy cancerous cells. The byproducts fluorodeoxyuridine monophosphate (F–dUMP) and floxuridine triphosphate (FUTP) are believed to do the following: Reduce DNA synthesis, lead to DNA fragmentation, and disrupt RNA synthesis. Fluorouracil is used to treat a variety of solid tumors such as colorectal, head and neck, breast, and ovarian cancer. With different tumor treatments, different dosages, and different dosing schedules, there is a risk for toxicity in these patients.

Patients may suffer from fluorouracil toxicity/death if 5–FU is delivered in slight excess or at faster infusion rates than prescribed. The cause of overdose can happen for a variety of reasons including: Pump malfunction, incorrect pump programming or miscalculated doses, and accidental or intentional ingestion.

According to the applicant, current treatment for fluorouracil toxicity is supportive care, including discontinuation of the drug, hydration, filgrastim for neutropenia, as well as antibiotics, antiemetics, and treatments that are required for potential gastrointestinal and cardiovascular compromise. Vistogard™ is an antidote to Fluorouracil toxicity and is a pro-drug of uridine. Once the drug is metabolized into uridine, it competes with the toxic byproduct FUTP in binding to RNA, thus reducing the impact FUTP has on cell death.

With regard to the newness criterion, Vistogard™ received FDA approval on December 11, 2015. The applicant noted that Vistogard™ is the first FDA approved antidote used to reverse fluorouracil toxicity. Currently, there

<sup>16</sup> DeRubertis BG, Quinones-Baldrich WJ, Greenberg JI, Jimenez JC, Lee JT. Results of a double-barrel technique with commercially available devices for hypogastric preservation during aortoiliac endovascular abdominal aortic aneurysm repair. *J Vasc Surg* 2012;56:1252–1259.

<sup>17</sup> DeRubertis BG, Quinones-Baldrich WJ, Greenberg JI, Jimenez JC, Lee JT. Results of a double-barrel technique with commercially available devices for hypogastric preservation during aortoiliac endovascular abdominal aortic aneurysm repair. *J Vasc Surg* 2012;56:1252–1259.

<sup>18</sup> Ferrer C, De Crescenzo F, Coscarella C, Cao P. Early experience with the Excluder(R) iliac branch endoprosthesis. *J Cardiovasc Surg* 2014;55:679–683.

<sup>19</sup> Schönhofer S, Mansour R, Ghotbi R. Initial results of the management of aortoiliac aneurysms with GORE(R) Excluder(R) iliac branched endoprosthesis. *J Cardiovasc Surg* 2015;56:883–888.

are no ICD–10–CM procedure codes that uniquely identify the use of Vistogard™. The applicant presented an application at the March 9–10, 2016 meeting of the ICD–10 Coordination and Maintenance Committee for a unique ICD–10–PCS procedure code to identify the use of Vistogard™. If approved, the code will be effective on October 1, 2016 (FY 2017). More information on this request can be found on the CMS Web site at: <http://www.cms.gov/Medicare/Coding/ICD10ProviderDiagnosticCodes/ICD-10-CM-C-and-M-Meeting-Materials.html>.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered “new” for purposes of new technology add-on payments.

With regard to the first criterion, whether the product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant stated that Vistogard™ is the first FDA-approved antidote used to reverse fluorouracil toxicity. The applicant maintained that Vistogard™ has a unique mechanism of action that is not comparable to any other drug’s mechanism of action that is currently available on the U.S. market. The applicant described in technical detail how the novel and unique mechanism of action provides bioavailable uridine, a direct biochemical antagonist of 5–FU toxicity; quickly absorbs into the gastrointestinal tract due to its lipophilic nature; in normal cells, stops the process of cell damage and cell destruction caused by 5–FU and counteracts the effects of 5–FU toxicity; protects normal cells and allows recovery from damage caused by 5–FU, without interfering with the primary antitumor mechanism of 5–FU; and uses uridine derived from Vistogard™ to convert it into uridine triphosphate

(UTP), which competes with FUTP for incorporation into RNA, preventing further cell destruction and dose-limiting toxicities.

With regard to the second criterion, whether the product is assigned to the same or a different MS–DRG, the applicant noted that Xuriden (uridine triacetate) was also approved by the FDA on September 8, 2015, as a pyrimidine analog for uridine replacement indicated for the treatment of hereditary orotic aciduria (HOA). According to the applicant, HOA is a rare, potentially life-threatening, genetic disorder in which patients (primarily pediatric patients) lack the ability to synthesize adequate amounts of uridine and consequently can suffer from hematologic abnormalities, failure to thrive, a range of developmental delays, and episodes of crystalluria leading to obstructive uropathy. The applicant stated that, although Xuriden is approved as a chronic, once daily medication (not to exceed 8 grams) that is administered orally in the patient’s home and also used to replace uridine, Xuriden is not administered in a hospital setting and cases involving the use of Xuriden would not be assigned to the same MS–DRGs associated with the use of Vistogard™ in the treatment of patients experiencing 5–FU overdose or severe toxicity. Therefore, the applicant maintained that no other technology similar to Vistogard™ would map to the same MS–DRGs as cases involving the use of Vistogard™.

With regard to the third criterion, 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, similar to above, the applicant maintained that Vistogard™ is the first FDA approved antidote to reverse fluorouracil toxicity and, therefore, no other technology treats this disease or patient population to reverse fluorouracil toxicity.

Therefore, the applicant believed that Vistogard™ is not substantially similar to any other currently approved technology. We are inviting public comments on whether Vistogard™ is substantially similar to existing technologies and whether it meets the newness criterion.

With regard to the cost criterion, the applicant searched the claims data from the 2013 and 2014 Inpatient SAFs for cases that may be eligible for treatment involving Vistogard™. Specifically, the applicant searched for cases reporting a primary ICD–9–CM diagnosis code for colorectal cancer, head and neck cancer, gastric cancers and pancreatic cancer. The applicant further narrowed the potential target patient population by identifying cases reporting toxicity due to an antineoplastic. In order to include only patients diagnosed with severe toxicity that would be eligible for treatment using Vistogard™, using revenue center codes and ICD–9–CM V codes, the applicant included an additional cohort of cases representing patients admitted from the emergency department, an observation unit, another short-term, acute care hospital, or who have received chemotherapy treatment during the inpatient stay included on the claim. Because 5–FU toxicity is associated with a high mortality rate, the applicant identified a subgroup of patients diagnosed with chemotherapy toxicity who expired during their inpatient visit or within 7 days of discharge. The applicant provided two analyses to determine that the technology meets the cost criterion: One analysis of patients that experienced toxicity with mortality and a second analysis using the broader chemotherapy toxicity cohort, which includes patients who did not expire. The table below provides the diagnosis codes and information the applicant used to identify cases for both of these analyses.

Criterion	ICD–9 code	Description
Colorectal, head and neck, gastric, or pancreatic cancer (at least one code).	153.x .....	Malignant neoplasm of colon.
	154.x .....	Malignant neoplasm of rectum, rectosigmoid junction, and anus.
	171.0 .....	Malignant neoplasm of head, face, and neck.
	151.x .....	Malignant neoplasm of stomach.
	157.x .....	Malignant neoplasm of pancreas.
Toxicity due to an antineoplastic (at least one code) .....	963.1 .....	Poisoning by antineoplastic and immunosuppressive drugs.
	E933.1 .....	Antineoplastic and immunosuppressive drugs causing adverse effects in therapeutic use.
Admission to Inpatient Setting Admitted from ED .....	Revenue Center	Revenue Center Codes 450, 451, 452, 456, 459.
	Revenue Center	Revenue Center Codes 760, 761, 762, 769.
	N/A .....	Source of admission code = “4” “Transfer from hospital (Different facility)”.
or observation unit .....	V58.0 .....	Encounter or admission for radiation.
	V58.11 .....	Encounter for antineoplastic chemotherapy.
	V58.12 .....	Encounter for antineoplastic immunotherapy (Must be primary diagnosis on the claim).
or short-term, acute care hospital .....		
or received chemotherapy during inpatient stay .....		

Criterion	ICD-9 code	Description
Expired during inpatient stay or within seven days of discharge (at least one code) <sup>a</sup> .	N/A ..... N/A .....	Determined by patient discharge status code. If date of death in 100 percent Denominator File pertaining to the year of the claim was within 7 days of claim discharge date.

<sup>a</sup>Required only for toxicity with mortality cohort.

Source: KNG Health analysis of 2013–2014 100% Inpatient Standard Analytic Files and 2013–2014 100% Denominator Files.

Under the first analysis, the applicant found 76 cases with 18.42 percent of those cases mapping to MS–DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation > 96 hours with MCC), and the remaining number of cases mapping to MS–DRGs with less than 11 cases. According to the applicant, the results of the analysis of the MS–DRGs with less than 11 cases could not be discussed separately because of the small sample sizes. The applicant believed that it was unnecessary to remove any charges for other previously used technologies because although Vistogard™ is singular in its ability to treat 5–FU toxicity, the associated charges for palliative care would continue to be necessary to treat the symptoms of the toxicity, even though it is possible that the use of Vistogard™ may reduce a patient's hospital length of stay. To update the charge data to the current fiscal year, the applicant inflated the charges based on the charge inflation factor of 1.048116 in the FY 2016 IPPS/LTCH proposed rule (80 FR 24632). A 1-year inflation factor was applied three times for FY 2013 claims and two times for FY 2014 claims, inflating all claims to FY 2016. This resulted in an inflated average standardized case-weighted charge per case of \$51,451. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was \$46,233 (all calculations above were performed using unrounded numbers). The applicant noted that the inflated average standardized case-weighted charge per case exceeded the average case-weighted threshold amount without including charges for Vistogard™. Therefore, because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

Under the second analysis, the applicant used the same methodology it used in its first analysis, except that the analysis included cases representing patients who did not expire. The applicant found 879 cases with 8.53 percent of those cases mapping to MS–DRG 392 (Esophagitis, Gastroenteritis and Miscellaneous Digestive System Disorders without MCC), and the

remaining number of cases spread across several MS–DRGs. The inflated average standardized case-weighted charge per case was \$42,708. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was \$42,377 (all calculations above were performed using unrounded numbers). Similar to the results of the first analysis, the applicant noted that the inflated average standardized case-weighted charge per case exceeded the average case-weighted threshold amount without including charges for Vistogard™. Therefore, because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology also meets the cost criterion under the second analysis.

We note that the applicant used the inflation factor of 1.048116 from the FY 2016 IPPS/LTCH proposed rule instead of the inflation factor of 1.037616 from the FY 2016 IPPS/LTCH final rule (80 FR 49784). We believe that the applicant should use the most recent data available, which is the inflation factor from the final rule. The inflation factor from the FY 2016 IPPS/LTCH final rule is lower than the inflation factor from the proposed rule. However, the difference between these two factors is marginal. Also, as the applicant noted, it did not include charges for Vistogard™ in its analysis. Therefore, we believe that it is likely that the applicant would still meet the cost criterion under both analyses even if it used the lower inflation factor from the FY 2016 final rule. We are inviting public comments on whether Vistogard™ meets the cost criterion under both analyses.

With regard to substantial clinical improvement, the applicant maintained that Vistogard™ represents a substantial clinical improvement. The applicant noted that Vistogard™ is the first and only antidote indicated to treat adult and pediatric patients following a fluorouracil overdose, regardless of the presence of symptoms or whether a patient exhibits early-onset, severe or life-threatening toxicity within 96 hours following the conclusion of fluorouracil or capecitabine administration. The applicant provided data from two

studies (Study 1, an open-label, single arm, multi-center expanded access study and Study 2, an open-label, single arm, multi-center emergency use study), which combined enrolled 135 patients. The applicant noted that 130 patients treated with Vistogard™ survived through the 30-day treatment and observation period (95 percent Confidence Interval: 0.92, 0.99). Of the 135 patients, 30 percent were 65 years old and older, including 11 percent of patients who were 75 years old and older.

According to the applicant, the studies' results demonstrate that Vistogard™ reduced the incidence, severity and virulence of toxicities associated with 5–FU toxicity due to overdose or rapid onset. Specifically, the applicant noted the following results:

- Vistogard™ ameliorated the progression of mucositis, leukopenia and thrombocytopenia; leukopenia and thrombocytopenia were resolved in almost all patients by the 4th week, indicating recovery of the hematopoietic system; mucositis also was resolved in almost all patients within the 30-day observation period with the incidence of serious (Grade 3 or 4) mucositis being very low; and no grade 4 mucositis was observed in any patients who received treatment using Vistogard™ within 96 hours after 5–FU.

- Thirty-eight percent of patients who experienced 5–FU overdose were able to resume chemotherapy treatment in less than 30 days after 5–FU toxicity, with the majority of these patients resuming treatment within 21 days. According to the applicant, 21 percent of the patients who presented with rapid onset of serious toxicities resumed chemotherapy treatment (typically with a different agent than 5–FU) in less than 30 days, with an overall median time to resumption of chemotherapy of 19 days.

- The safety and tolerability profile of Vistogard™ is consistent with what would be expected for patients diagnosed with cancer following 5–FU chemotherapy treatment, but is generally less in severity and incidence when compared to what would be expected with patients who experience a 5–FU overdose. Specifically, during Study 1, there were no patients that

discontinued uridine triacetate treatment as a result of adverse events, and during Study 2, three patients discontinued uridine triacetate treatment as a result of adverse events, one of which was considered possibly related to uridine triacetate (nausea and vomiting).

We are inviting public comments on whether Vistogard™ meets the substantial clinical improvement criterion.

We did not receive any written public comments in response to the February 2016 New Technology Town Hall meeting regarding this application for new technology add-on payments.

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

#### A. Background

##### 1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the proposed FY 2017 hospital wage index based on the statistical areas appears under sections III.A.2. and G. 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. (CMS collects these data on the Medicare cost report, CMS Form 2552–10, Worksheet S–3, Parts II, III, and IV. The OMB control number for approved collection of this information is 0938–0050.) 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 2017 is discussed in section II.B. of the Addendum to this proposed rule.

As discussed in section III.J. of the preamble of this proposed rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The proposed budget neutrality adjustment for FY 2017 is discussed in section II.A.4.b. of the Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are proposing to apply to the FY 2017 wage index, appears under sections III.E.3. and F. of the preamble of this proposed rule.

##### 2. Core-Based Statistical Areas (CBSAs) Revisions for the Proposed FY 2017 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 delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252). We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion of our implementation of the new OMB labor market area delineations beginning with the FY 2015 wage index.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides updates to and supersedes OMB

Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. The complete list of statistical areas incorporating these changes is provided in the attachment to OMB Bulletin No. 15–01. According to OMB, “[t]his bulletin establishes revised delineations for the Nation’s Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas. The bulletin also provides delineations of Metropolitan Divisions as well as delineations of New England City and Town Areas.” A copy of this bulletin may be obtained on the Web site at: <https://www.whitehouse.gov/omb/bulletins/default>.

OMB Bulletin No. 15–01 made the following changes that are relevant to the IPPS wage index:

- Garfield County, OK, with principal city Enid, OK, which was a Micropolitan (geographically rural) area, now qualifies as an urban new CBSA 21420 called Enid, OK.
- The county of Bedford City, VA, a component of the Lynchburg, VA CBSA 31340, changed to town status and is added to Bedford County. Therefore, the county of Bedford City (SSA State county code 49088, FIPS State County Code 51515) is now part of the county of Bedford, VA (SSA State county code 49090, FIPS State County Code 51019). However, the CBSA remains Lynchburg, VA, 31340.
- The name of Macon, GA, CBSA 31420, as well as a principal city of the Macon-Warner Robins, GA combined statistical area, is now Macon-Bibb County, GA. The CBSA code remains as 31420.

We believe that it is important for the IPPS to use the latest labor market area delineations available as soon as is reasonably possible in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions (79 FR 28055). Therefore, we are proposing to implement these revisions, effective October 1, 2016, beginning with the FY 2017 wage indexes. We are proposing to use these new definitions to calculate area wage indexes in a manner that is generally consistent with the CBSA-based methodologies finalized in the FY 2005 and the FY 2015 IPPS final rules. For FY

2017, Tables 2 and 3 for this proposed rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS Web site reflect these CBSA changes. We are inviting public comments on these proposals.

#### *B. Worksheet S-3 Wage Data for the Proposed FY 2017 Wage Index*

The proposed FY 2017 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2013 (the FY 2016 wage indexes were based on data from cost reporting periods beginning during FY 2012).

##### 1. Included Categories of Costs

The proposed FY 2017 wage index includes all of 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 include 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 47317)); 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 2016, the proposed wage index for FY 2017 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The proposed FY 2017 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 Suppliers and Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index also are currently used to calculate wage indexes applicable to suppliers and other providers, such as SNFs, home health agencies (HHAs), ambulatory surgical centers (ASCs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indexes of any supplier or provider except IPPS providers and LTCHs. Such comments should be made in response to separate proposed rules for those suppliers and providers.

#### *C. Verification of Worksheet S-3 Wage Data*

The wage data for the proposed FY 2017 wage index were obtained from Worksheet S-3, Parts II and III of the Medicare cost report (Form CMS-2552-10, OMB control number 0938-0050) for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013. For wage index purposes, we refer to cost reports during this period as the "FY 2013 cost report," the "FY 2013 wage data," or the "FY 2013 data." Instructions for completing the wage index sections of Worksheet S-3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. No. 15-2), Chapter 40, Sections 4005.2 through 4005.4. The data file used to construct the proposed FY 2017 wage index includes FY 2013 data submitted to us as of February 29, 2016. As in past years, we performed an extensive review of the wage data, mostly through the use of edits for reasonableness designed to identify aberrant data.

We asked our MACs to revise or verify data elements that result in specific edit failures. For the proposed FY 2017 wage index, we identified and excluded 62 providers with aberrant data that should not be included in the proposed wage index. Of these 62 providers that we excluded from the proposed wage index, 47 have data that we do not expect to change such that the data would be included in the final wage index (for example, among the reasons these providers were excluded is they are low Medicare utilization providers, they closed and failed edits for reasonableness, or they have extremely high or low average hourly wages that are atypical for their CBSAs). If data elements for some of these providers are corrected, we intend to include those providers in the calculation of the final

FY 2017 wage index. We also adjusted certain aberrant data and included these data in the proposed wage index. For example, in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967).

In constructing the proposed FY 2017 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2013, 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 believed 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 the this proposed rule, we removed 3 hospitals that converted to CAH status on or after February 5, 2015, the cut-off date for CAH exclusion from the FY 2016 wage index, and through and including January 22, 2016, the cut-off date for CAH exclusion from the FY 2017 wage index. After removing hospitals that converted to CAH status, we calculated the proposed FY 2017 wage index based on 3,345 hospitals.

For the proposed FY 2017 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 2016 wage index (80 FR 49489 through 49491). Table 2, which contains the proposed FY 2017 wage index associated with proposed rule (available via the Internet on the CMS Web site), includes separate wage data for the campuses of 9 multicampus hospitals.

#### *D. Method for Computing the Proposed FY 2017 Unadjusted Wage Index*

The method used to compute the proposed FY 2017 wage index without an occupational mix adjustment follows the same methodology that we used to compute the FY 2012, FY 2013, FY 2014, FY 2015, and FY 2016 final wage indexes without an occupational mix adjustment (76 FR 51591 through 51593, 77 FR 53366 through 53367, 78 FR 50587 through 50588, 79 FR 49967 and

80 FR 49491 through 49492, respectively).

As discussed in the FY 2012 IPPS/LTCH PPS 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, 2012, through April 15, 2014, 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 2017. The factors used to adjust the hospital’s data were based on the midpoint of the cost reporting period, as indicated in the following table.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment factor
10/14/2012 .....	11/15/2012 .....	1.02321
11/14/2012 .....	12/15/2012 .....	1.02183
12/14/2012 .....	01/15/2013 .....	1.02040
01/14/2013 .....	02/15/2013 .....	1.01894
02/14/2013 .....	03/15/2013 .....	1.01743
03/14/2013 .....	04/15/2013 .....	1.01592
04/14/2013 .....	05/15/2013 .....	1.01443
05/14/2013 .....	06/15/2013 .....	1.01297
06/14/2013 .....	07/15/2013 .....	1.01152
07/14/2013 .....	08/15/2013 .....	1.01006
08/14/2013 .....	09/15/2013 .....	1.00859
09/14/2013 .....	10/15/2013 .....	1.00711
10/14/2013 .....	11/15/2013 .....	1.00561
11/14/2013 .....	12/15/2013 .....	1.00408
12/14/2013 .....	01/15/2014 .....	1.00260
01/14/2014 .....	02/15/2014 .....	1.00124
02/14/2014 .....	03/15/2014 .....	1.00000
03/14/2014 .....	04/15/2014 .....	0.99878

For example, the midpoint of a cost reporting period beginning January 1, 2013, and ending December 31, 2013, is June 30, 2013. An adjustment factor of 1.01152 would be applied to the wages of a hospital with such a cost reporting period.

Using the data as previously described, the proposed FY 2017 national average hourly wage (unadjusted for occupational mix) is \$41.1026.

Previously, we would also provide a Puerto Rico overall average hourly wage. As discussed in section IV.A. of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25

percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico-specific wage index that was applied to the labor share of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015, amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act, as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico-specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (unadjusted for occupational mix) (which would be \$41.1026 for this FY 2017 proposed rule) and the national wage index, which is applied to the national labor share of the national standardized amount. Accordingly, for FY 2017, we are not proposing a Puerto Rico-specific overall average hourly wage or wage index.

*E. Proposed Occupational Mix Adjustment to the FY 2017 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. Use of 2013 Occupational Mix Survey for the FY 2017 Proposed Wage Index

Section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the

Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. We collected data in 2013 to compute the occupational mix adjustment for the FY 2016, FY 2017, and FY 2018 wage indexes. A new measurement of occupational mix is required for FY 2019.

The 2013 survey included the same data elements and definitions as the previous 2010 survey and provided 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). We published the 2013 survey in the **Federal Register** on February 28, 2013 (78 FR 13679 through 13680). This survey was approved by OMB on May 14, 2013, and is available on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/Medicare-Wage-Index-Occupational-Mix-Survey2013.html>. The 2013 Occupational Mix Survey Hospital Reporting Form CMS–10079 for the Wage Index Beginning FY 2016 (in Excel format) is available on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/Medicare-Wage-Index-Occupational-Mix-Survey2013.html>. Hospitals were required to submit their completed 2013 surveys to their MACs by July 1, 2014. The preliminary, unaudited 2013 survey data were posted on the CMS Web site on July 11, 2014. As with the Worksheet S–3, Parts II and III cost report wage data, we asked our MACs to revise or verify data elements in hospitals’ occupational mix surveys that result in certain edit failures.

2. Development of the 2016 Medicare Wage Index Occupational Mix Survey for the FY 2019 Wage Index

As stated earlier, section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. We collected data in 2013 to compute the occupational mix adjustment for the FY 2016, FY 2017, and FY 2018 wage indexes. A new measurement of occupational mix is required for FY 2019. The FY 2019 occupational mix adjustment will be based on a new calendar year (CY) 2016 survey. The CY 2016 survey (CMS Form CMS–10079) is currently awaiting approval by OMB,

and can be accessed at [http://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=201512-0938-011](http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201512-0938-011).

3. Calculation of the Proposed Occupational Mix Adjustment for FY 2017

For FY 2017, we are proposing to calculate the occupational mix adjustment factor using the same methodology that we used for the FY 2012, FY 2013, FY 2014, FY 2015, and FY 2016 wage indexes (76 FR 51582 through 51586, 77 FR 53367 through 53368, 78 FR 50588 through 50589, 79 FR 49968, and 80 FR 49492 through 49493, respectively) and to apply the occupational mix adjustment to 100 percent of the FY 2017 wage index. Because the statute requires that the Secretary measure the earnings and paid hours of employment by occupational category not less than once every 3 years, 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 FY 2017 wage index. For the FY 2017 wage index, we are using the Worksheet S-3, Parts II and III wage data of 3,345 hospitals, and we are using the occupational mix surveys of 3,143 hospitals for which we also have Worksheet S-3 wage data, which represents a “response” rate of 94 percent (3,143/3,345). For the proposed FY 2017 wage index 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).

*F. Analysis and Implementation of the Proposed Occupational Mix Adjustment and the Proposed FY 2017 Occupational Mix Adjusted Wage Index*

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

As discussed in section III.E. of the preamble of this proposed rule, for FY 2017, we are proposing to apply the occupational mix adjustment to 100 percent of the FY 2017 wage index. We calculated the proposed occupational mix adjustment using data from the 2013 occupational mix survey data, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586).

Using the occupational mix survey data and applying the occupational mix adjustment to 100 percent of the FY 2017 wage index results in a proposed national average hourly wage of \$41.0651. Previously, we would also provide a Puerto Rico overall average hourly wage. As discussed in section IV.A. of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico-specific wage index that was applied to

the labor-related share of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114-113), enacted on December 18, 2015, amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016 under section 1886(d)(9)(E) of the Act, as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico-specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (adjusted for occupational mix) (which would be \$41.0651 for this FY 2017 IPPS proposed rule) and the national wage index, which is applied to the national labor share of the national standardized amount. Accordingly, for FY 2017, we are not proposing a Puerto Rico-specific overall average hourly wage or wage index.

The proposed FY 2017 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

Occupational mix nursing subcategory	Average hourly wage
National RN .....	\$38.814164598
National LPN and Surgical Technician .....	22.733613839
National Nurse Aide, Orderly, and Attendant .....	15.94875556
National Medical Assistant .....	18.058859076
National Nurse Category .....	32.844074591

The proposed national average hourly wage for the entire nurse category as computed in Step 5 of the occupational mix calculation is \$32.844074591. 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 2013 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 42.6 percent, and the national percentage of hospital employees in the all other occupations category is 57.4 percent. At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 25.6 percent in one CBSA to a high of 80.5 percent in another CBSA.

We compared the proposed FY 2017 occupational mix adjusted wage indexes for each CBSA to the proposed

unadjusted wage indexes for each CBSA. As a result of applying the occupational mix adjustment to the wage data, the proposed wage index values for 221 (54.2 percent) urban areas and 24 (51.1 percent) rural areas would increase. One hundred and three (25.2 percent) urban areas would increase by greater than or equal to 1 percent but less than 5 percent, and 6 (1.5 percent) urban areas would increase by 5 percent or more. Nine (19.1 percent) rural areas would increase by greater than or equal to 1 percent but less than 5 percent, and no rural areas would increase by 5 percent or more. However, the proposed



wage index values for 185 (45.3 percent) urban areas and 23 (48.9 percent) rural areas would decrease. Eighty-nine (21.8 percent) urban areas would decrease by greater than or equal to 1 percent but less than 5 percent, and no urban area would decrease by 5 percent or more. Seven (14.9 percent) rural areas would decrease by greater than or equal to 1 percent and less than 5 percent, and no rural areas would decrease by 5 percent or more. The largest positive impacts would be 17.4 percent for an urban area and 2.9 percent for a rural area. The largest negative impacts would be 4.9 percent for an urban area and 2.1 percent for a rural area. Two urban areas' wage indexes, but no rural area wage indexes, would remain unchanged by application of the proposed occupational mix adjustment. These results indicate that a larger percentage of urban areas (54.2 percent) would benefit from the proposed occupational mix adjustment than would rural areas (51.1 percent).

### G. Transitional Wage Indexes

#### 1. Background

In the FY 2015 IPPS/LTCH PPS proposed rule and final rule (79 FR 28060 and 49957, respectively), we stated that, overall, we believed implementing the new OMB labor market area delineations would result in wage index values being more representative of the actual costs of labor in a given area. However, we recognized that some hospitals would experience decreases in wage index values as a result of the implementation of these new OMB labor market area delineations. We also realized that some hospitals would have higher wage index values due to the implementation of the new OMB labor market area delineations.

The FY 2015 IPPS/LTCH PPS final rule (79 FR 49957) explained the methodology utilized in implementing prior transition periods when adopting changes that have significant payment implications, particularly large negative impacts. Specifically, for FY 2005, in the FY 2005 IPPS final rule (69 FR 49032 through 49034), we provided transitional wage indexes when the OMB definitions were implemented after the 2000 Census. The FY 2015 IPPS/LTCH PPS final rule (79 FR 49957 through 49962) established similar transition methodologies to mitigate any negative payment impacts experienced by hospitals due to our adoption of the new OMB labor market area delineations for FY 2015.

As finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49957

through 49960) and as discussed below, for FY 2017, we will be in the third and final year of two 3-year transition periods for wage index (1) for hospitals that, for FY 2014, were located in an urban county that became rural under the new OMB delineations, and had no form of wage index reclassification or redesignation in place for FY 2015 (that is, MGCRB reclassifications under section 1886(d)(10) of the Act, redesignations under section 1886(d)(8)(B) of the Act, or rural reclassifications under section 1886(d)(8)(E) of the Act); and (2) for hospitals deemed urban under section 1886(d)(8)(B) of the Act where the urban area became rural under the new OMB delineations.

#### 2. Transition for Hospitals in Urban Areas That Became Rural

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49957 through 49959), for hospitals that, for FY 2014, were located in an urban county that became rural under the new OMB delineations, and had no form of wage index reclassification or redesignation in place for FY 2015 (that is, MGCRB reclassifications under section 1886(d)(10) of the Act, redesignations under section 1886(d)(8)(B) of the Act, or rural reclassifications under section 1886(d)(8)(E) of the Act), we adopted a policy to assign them the urban wage index value of the CBSA in which they were physically located for FY 2014 for a period of 3 fiscal years (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied to the area wage index). FY 2017 will be the third year of this transition policy, and we are not proposing any changes to this policy in this proposed rule. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49957) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49495), we stated our belief that it is appropriate to apply a 3-year transition period for hospitals located in urban counties that would become rural under the new OMB delineations, given the potentially significant payment impacts for these hospitals. We continue to believe that assigning the wage index of the hospitals' FY 2014 area for a 3-year transition is the simplest and most effective method for mitigating negative payment impacts due to the adoption of the new OMB delineations.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49959), we noted that there were situations where a hospital could not be assigned the wage index value of the CBSA in which it geographically was located in FY 2014 because that CBSA split and no longer exists and some or all of the constituent counties

were added to another urban labor market area under the new OMB delineations. If the hospital could not be assigned the wage index value of the CBSA in which it was geographically located in FY 2014 because that CBSA split apart and no longer exists, and some or all of its constituent counties were added to another urban labor market area under the new OMB delineations, we established that hospitals located in such counties that became rural under the new OMB delineations were assigned the wage index of the urban labor market area that contained the urban county in their FY 2014 CBSA to which they were closest (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied). Any such assignment made in FY 2015 and continued in FY 2016 will continue for FY 2017, except as discussed later in this section. We continue to believe this approach minimizes the negative effects of the change in the OMB delineations.

Under the policy adopted in the FY 2015 IPPS/LTCH PPS final rule, if a hospital for FY 2014 was located in an urban county that became rural for FY 2015 under the new OMB delineations and such hospital sought and was granted reclassification or redesignation for FY 2015 or FY 2016, or such hospital seeks and is granted any reclassification or redesignation for FY 2017, the hospital will permanently lose its 3-year transitional assigned wage index status, and will not be eligible to reinstate it. We established the transition policy to assist hospitals if they experience a negative payment impact specifically due to the adoption of the new OMB delineations in FY 2015. If a hospital chooses to forego this transition adjustment by obtaining some form of reclassification or redesignation, we do not believe reinstatement of this transition adjustment would be appropriate. The purpose of the transition adjustment policy is to assist hospitals that may be negatively impacted by the new OMB delineations in transitioning to a wage index based on these delineations. By obtaining a reclassification or redesignation, we believe that the hospital has made the determination that the transition adjustment is not necessary because it has other viable options for mitigating the impact of the transition to the new OMB delineations.

As we did for FY 2015 (79 FR 49959) and FY 2016 (80 FR 49495), with respect to the wage index computation for FY 2017, we will follow our existing policy regarding the inclusion of a hospital's wage index data in the CBSA in which it is geographically located (we

refer readers to Step 6 of the method for computing the unadjusted wage index in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592)). Accordingly, for FY 2017, the wage data of all hospitals receiving this type of 3-year transition adjustment will be included in the statewide rural area in which they are geographically located under the new OMB labor market area delineations. After the 3-year transition period, beginning in FY 2018, these formerly urban hospitals will receive their statewide rural wage index, absent any reclassification or redesignation.

In addition, we established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49959) that the hospitals receiving this 3-year transition because they are in counties that were urban under the FY 2014 CBSA definitions, but are rural under the new OMB delineations, will not be considered urban hospitals. Rather, they will maintain their status as rural hospitals for other payment considerations. This is because our application of a 3-year transitional wage index for these newly rural hospitals only applies for the purpose of calculating the wage index under our adoption of the new OMB delineations.

### 3. Transition for Hospitals Deemed Urban Under Section 1886(d)(8)(B) of the Act Where the Urban Area Became Rural Under the New OMB Delineations

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49959 through 49960) and FY 2016 IPPS/LTCH PPS final rule (80 FR 49495 through 49496), there were some hospitals that, for FY 2014, were geographically located in rural areas but were deemed to be urban under section 1886(d)(8)(B) of the Act. For FY 2015, some of these hospitals redesignated under section 1886(d)(8)(B) of the Act were no longer eligible for deemed urban status under the new OMB delineations, as discussed in detail in section III.H.3. of the preamble of the FY 2015 IPPS/LTCH PPS final rule. Similar to the policy implemented in the FY 2005 IPPS final rule (69 FR 49059), and consistent with the FY 2015 policy we established for other hospitals in counties that were urban and became rural under the new OMB delineations, we finalized a policy to apply a 3-year transition to these hospitals redesignated to urban areas under section 1886(d)(8)(B) of the Act for FY 2014 that are no longer deemed urban under the new OMB delineations and revert to being rural.

For FY 2017, we are not proposing any changes to this policy and will continue the third and final year of the implementation of our policy to provide a 3-year transition adjustment to

hospitals that are deemed urban under section 1886(d)(8)(B) of the Act under the FY 2014 labor market area delineations, but are considered rural under the new OMB delineations, assuming no other form of wage index reclassification or redesignation is granted. We assign these hospitals the area wage index value of hospitals reclassified to the urban CBSA (that is, the attaching wage index) to which they were redesignated in FY 2014 (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied). If the hospital cannot be assigned the reclassified wage index value of the CBSA to which it was redesignated in FY 2014 because that CBSA was split apart and no longer exists, and some or all of its constituent counties were added to another urban labor market area under the new OMB delineations, such hospitals are assigned the wage index of the hospitals reclassified to the urban labor market area that contained the urban county in their FY 2014 redesignated CBSA to which they were closest. We assign these hospitals the area wage index of hospitals reclassified to a CBSA because hospitals deemed urban under section 1886(d)(8)(B) of the Act are treated as reclassified under current policy, under which such hospitals receive an area wage index that includes wage data of all hospitals reclassified to the area. This wage index assignment will be forfeited if the hospital obtains any form of wage index reclassification or redesignation.

### 4. Budget Neutrality

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50372 through 50373), for FY 2015, and in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49496), for FY 2016, we applied the 3-year transition wage index adjustments in a budget neutral manner. For FY 2017, we are proposing to apply the 3-year transition adjustments in a budget neutral manner. We are proposing to make an adjustment to the standardized amount to ensure that the total payments, including the effect of the transition provisions, would equal what payments would have been if we would not be providing for any transitional wage indexes under the new OMB delineations. For a complete discussion on the proposed budget neutrality adjustment for FY 2017, we refer readers to section II.A.4.b. of the Addendum to this proposed rule.

## H. Proposed Application of the Proposed Rural, Imputed, and Frontier Floors

### 1. Proposed Rural Floor

Section 4410(a) of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the “rural floor.” Section 3141 of Public Law 111–148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor. Based on the proposed FY 2017 wage index associated with this proposed rule (which is available via the Internet on the CMS Web site), we estimated that 371 hospitals would receive an increase in their FY 2017 proposed wage index due to the application of the rural floor.

### 2. Proposed Imputed Floor for FY 2017

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 six times, the last of which was adopted in the FY 2016 IPPS/LTCH PPS final rule and is set to expire on September 30, 2016. (We refer readers to further discussions of the imputed floor in the FY 2014, FY 2015, and FY 2016 IPPS/LTCH PPS final rules (78 FR 50589 through 50590, 79 FR 49969 through 49970, and 80 FR 49497 through 49498, respectively) and to the regulations at 42 CFR 412.64(h)(4).) Currently, there are three all-urban States—Delaware, New Jersey, and Rhode Island—with a range of wage indexes assigned to hospitals in these States, including through reclassification or redesignation. (We refer readers to discussions of geographic reclassifications and redesignations in section III.J. of the preamble of this proposed rule.)

In computing the imputed floor for an all-urban State under the original methodology, which was established beginning in FY 2005, we calculated the ratio of the lowest-to-highest CBSA wage index for each all-urban State as well as the average of the ratios of lowest-to-highest CBSA wage indexes of those all-urban States. We then compared the State’s own ratio to the average ratio for all-urban States and whichever is higher is multiplied by the

highest CBSA wage index value in the State—the product of which established the imputed floor for the State. As of FY 2012, there were only two all-urban States—New Jersey and Rhode Island—and only New Jersey benefitted under this methodology. Under the previous OMB labor market area delineations, Rhode Island had only one CBSA (Providence-New Bedford-Fall River, RI-MA) and New Jersey had 10 CBSAs. Therefore, under the original methodology, Rhode Island's own ratio equaled 1.0, and its imputed floor was equal to its original CBSA wage index value. However, because the average ratio of New Jersey and Rhode Island was higher than New Jersey's own ratio, this methodology provided a benefit for New Jersey, but not for Rhode Island.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53368 through 53369), we retained the imputed floor calculated under the original methodology as discussed above, and established an alternative methodology for computing the imputed floor wage index to address the concern that the original imputed floor methodology guaranteed a benefit for one all-urban State with multiple wage indexes (New Jersey) but could not benefit the other all-urban State (Rhode Island). The alternative methodology for calculating the imputed floor was established using data from the application of the rural floor policy for FY 2013. Under the alternative methodology, we first determined the average percentage difference between the post-reclassified, pre-floor area wage index and the post-reclassified, rural floor wage index (without rural floor budget neutrality applied) for all CBSAs receiving the rural floor. (Table 4D associated with the FY 2013 IPPS/LTCH PPS final rule (which is available via the Internet on the CMS Web site) included the CBSAs receiving a State's rural floor wage index.) The lowest post-reclassified wage index assigned to a hospital in an all-urban State having a range of such values then is increased by this factor, the result of which establishes the State's alternative imputed floor. We amended § 412.64(h)(4) of the regulations to add new paragraphs to incorporate the finalized alternative methodology, and to make reference and date changes. In summary, for the FY 2013 wage index, we did not make any changes to the original imputed floor methodology at § 412.64(h)(4) and, therefore, made no changes to the New Jersey imputed floor computation for FY 2013. Instead, for FY 2013, we adopted a second, alternative methodology for use in cases where an all-urban State has a range of

wage indexes assigned to its hospitals, but the State cannot benefit under the original methodology.

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

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49969 through 49970), for FY 2015, we adopted a policy to extend the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2015, as we continued to explore potential wage index reforms. In that final rule, we revised the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect the 1-year extension of the imputed floor.

As discussed in section III.B. of the preamble of that FY 2015 final rule, we adopted the new OMB labor market area delineations beginning in FY 2015. Under the new OMB delineations, Delaware became an all-urban State, along with New Jersey and Rhode Island. Under the new OMB delineations, Delaware has three CBSAs, New Jersey has seven CBSAs, and Rhode Island continues to have only one CBSA (Providence-Warwick, RI-MA). We refer readers to a detailed discussion of our adoption of the new OMB labor market area delineations in section III.B. of the preamble of the FY 2015 IPPS/LTCH PPS final rule.

Therefore, under the adopted new OMB delineations discussed in section III.B. of the preamble of the FY 2015 IPPS/LTCH PPS final rule, Delaware became an all-urban State and was subject to an imputed floor as well for FY 2015.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49497 through 49498), for FY 2016, we extended the imputed floor policy (under both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2016. In that final rule, we revised the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect this additional 1-year extension.

For FY 2017, we are proposing to extend the imputed floor policy (under both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2017, while we continue to explore potential wage index reforms. We are proposing to revise the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect this proposed additional 1-year extension. We are inviting public comments on the proposed additional 1-year extension of the imputed floor

through September 30, 2017. The wage index and impact tables associated with this FY 2017 IPPS/LTCH PPS proposed rule (which are available on the Internet via the CMS Web site) reflect the proposed continued application of the imputed floor policy at § 412.64(h)(4) and a proposed national budget neutrality adjustment for the imputed floor for FY 2017. There are 20 providers in New Jersey that would receive an increase in their proposed FY 2017 wage index due to the proposed continued application of the imputed floor policy under the original methodology, and 10 hospitals in Rhode Island that would benefit under the alternative methodology. No providers in Delaware would benefit under the original methodology or the alternative methodology.

### 3. Proposed State Frontier Floor for FY 2017

Section 10324 of Public Law 111–148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000 (we refer readers to regulations at 42 CFR 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161)). Fifty hospitals would receive the frontier floor value of 1.0000 for their FY 2017 wage index in this proposed rule. These hospitals are located in Montana, Nevada, North Dakota, South Dakota, and Wyoming.

We are not proposing any changes to the frontier floor policy for FY 2017.

The areas affected by the proposed rural, imputed, and frontier floor policies for the proposed FY 2017 wage index are identified in Table 2 associated with this proposed rule, which is available via the Internet on the CMS Web site.

#### *I. Proposed FY 2017 Wage Index Tables*

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49498 and 49807 through 49808), we finalized a proposal to streamline and consolidate the wage index tables associated with the IPPS proposed and final rules for FY 2016 and subsequent fiscal years. Prior to FY 2016, the wage index tables had consisted of 12 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 9A, and 9C) that were made available via the Internet on the CMS Web site. Effective beginning FY 2016, with the exception of Table 4E, we streamlined and consolidated 11 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4F, 4J, 9A, and 9C) into 2 tables (Tables 2 and 3). We refer readers to section VI. of the Addendum to this proposed rule for a discussion of

the proposed wage index tables for FY 2017.

*J. Proposed 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 Medicare Geographic Classification Review Board (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 (usually 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 2017, 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). In addition, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under 42 CFR 412.103. Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification in accordance with the provisions of 42 CFR 412.103.

2. MGCRB Reclassification and Redesignation Issues for FY 2017

a. FY 2017 Reclassification Requirements and Approvals

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

At the time this proposed rule was constructed, the MGCRB had completed its review of FY 2017 reclassification

requests. Based on such reviews, there are 299 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2017. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2017, hospitals reclassified beginning in FY 2015 or FY 2016 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 302 hospitals approved for wage index reclassifications in FY 2015 that will continue for FY 2017, and 266 hospitals approved for wage index reclassifications in FY 2016 that will continue for FY 2017. Of all the hospitals approved for reclassification for FY 2015, FY 2016, and FY 2017, based upon the review at the time of this proposed rule, 867 hospitals are in a reclassification status for FY 2017.

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 2017 will be incorporated into the wage index values published in the FY 2017 IPPS/LTCH PPS final rule. These changes affect not only the wage index value for specific geographic areas, but also the wage index value that 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. Requirements for FY 2018 Applications and Proposed Revisions Regarding Paper Application Requirements

Applications for FY 2018 reclassifications are due to the MGCRB by September 1, 2016 (the first working day of September 2016). We note that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under 42 CFR 412.273(d). Applications and other information about MGCRB reclassifications may be obtained, beginning in mid-July 2016, via the Internet on the CMS Web site at <https://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/index.html>, or by calling the MGCRB at (410) 786-1174. The mailing address of the MGCRB is: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244-2670.

Under existing regulations at 42 CFR 412.256(a)(1), applications for reclassification must be mailed or delivered to the MGCRB, with a copy to CMS, and may not be submitted through the facsimile (FAX) process or by other electronic means. While existing regulations exclusively require paper applications, we believe this policy to be outdated and overly restrictive. Therefore, to promote ease of application for FY 2018 and subsequent years, we are proposing to revise this policy to require applications and supporting documentation to be submitted via the method prescribed in instructions by the MGCRB, with an electronic copy to CMS. Therefore, we are proposing to revise § 412.256(a)(1) to specify that an application must be submitted to the MGCRB according to the method prescribed by the MGCRB, with an electronic copy of the application sent to CMS. We are specifying that CMS copies should be sent via email to [wageindex@cms.hhs.gov](mailto:wageindex@cms.hhs.gov). We are inviting public comments on this proposal.

c. Other Policy Regarding Reclassifications for Terminated Hospitals

Under longstanding CMS policy, if a hospital that has an approved reclassification by the MGCRB terminates its CMS certification number (CCN), we terminate the reclassification status for that hospital when calculating the wage index, because the CCN is no longer active, and because the MGCRB makes its reclassification decisions based on CCNs. We believe this policy results in more accurate reclassifications when compiling CBSA labor market wage data, as it is often the case that

hospitals that have terminated their CCNs have also terminated operations, and can no longer make timely and informed decisions regarding reclassification statuses, which could have ramifications for various wage index floors and labor market values.

However, as discussed in response to a comment in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49499 through 49500), in the case of a merger or acquisition where the acquiring hospital accepted the Medicare provider agreement of the acquired hospital located in a different market area that has an existing MGCRB reclassification, we do believe that the acquiring hospital should be able to make determinations regarding the reclassification status of the subordinate campus. While the original CCN for the acquired hospital would be considered terminated or “tied out” by CMS, in the specific situations where a hospital merges with or acquires another hospital located in a different labor market area to create a “multicampus” hospital and accepts the Medicare provider agreement of the acquired hospital, the reclassification status of the subordinate campus remains in effect. The acquired campus (that is, the hospital whose CCN is no longer active) may continue to receive its previously approved reclassification status, and the acquiring hospital is authorized to make timely requests to terminate, withdraw, or reinstate any reclassification for the subordinate campus for any remaining years of the reclassification. We believe this policy is consistent with existing regulations regarding reclassification status of “multicampus” hospitals at § 412.230(d)(2)(v). Hospitals should take care to review their status on Table 2 associated with this proposed rule (which is available via the Internet on the CMS Web site) and notify CMS if they believe a reclassification for a hospital was mistakenly terminated by CMS.

### 3. Redesignation of Hospitals Under Section 1886(d)(8)(B) of the Act

Section 1886(d)(8)(B)(i) of the Act requires the Secretary to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the urban MSA to which the greatest number of workers in the county commute if certain adjacency and commuting criteria are met. The criteria utilize standards for designating MSAs published in the **Federal Register** by the Director of the Office of Management and Budget (OMB) based on the most recently available decennial population data. Effective beginning FY 2015, we use the OMB delineations based on the

2010 Decennial Census data to identify counties in which hospitals qualify under section 1886(d)(8)(B) of the Act to receive the wage index of the urban area. Hospitals located in these counties are referred to as “Lugar” hospitals and the counties themselves are often referred to as “Lugar” counties. The chart for this FY 2017 proposed rule 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.

In an interim final rule with comment period (IFC) (CMS–1664–IFC) that appeared elsewhere in this issue of the **Federal Register**, CMS made regulatory changes in order to implement the decisions in *Geisinger Community Medical Center v. Secretary, United States Department of Health and Human Services*, 794 F.3d 383 (3d Cir. 2015) and *Lawrence + Memorial Hospital v. Burwell*, No. 15–164, 2016 WL 423702 (2d Cir. Feb. 4, 2015) in a nationally consistent manner.

Specifically, the IFC revises the regulations at § 412.230(a)(5)(ii) and removes the regulatory provision at § 412.230(a)(5)(iii) to allow hospitals nationwide to reclassify based on their acquired rural status, effective with reclassifications beginning with FY 2018. The IFC also gives hospitals with an existing MGCRB reclassification the opportunity to seek rural reclassification for IPPS payment and other purposes under § 412.103 and keep their existing MGCRB reclassification.

As a consequence of the regulatory changes in the IFC that allow a hospital to have more than one reclassification simultaneously, we are clarifying in this proposed rule that a hospital with Lugar status may simultaneously receive an urban to rural reclassification under § 412.103. The IFC provides that when there is both a § 412.103 reclassification and an MGCRB reclassification, the MGCRB reclassification controls for wage index calculation and payment purposes (the IFC can be downloaded from the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/IPPS-Regulations-and-Notices.html>). Similarly, in this proposed rule, we are clarifying that we are treating the wage data of hospitals with simultaneous Lugar status and § 412.103 reclassification as Lugar for wage index calculation and wage index payment purposes. We believe it is appropriate to apply a similar policy for simultaneous MGCRB reclassification and § 412.103 reclassifications, and simultaneous Lugar and § 412.103 reclassifications, because CMS treats Lugar status as a

reclassification for purposes of calculating the wage index in accordance with section 1886(d)(8)(C)(iii) of the Act. (Section 1886(d)(8)(C)(iii) of the Act states that the application of section 1886(d)(8)(B) of the Act or a decision of the MGCRB or the Secretary under section 1886(d)(10) of the Act may not result in the reduction of any county’s wage index to a level below the wage index for rural areas in the State in which the county is located.) The wage index associated with the Lugar status, and not the wage index associated with the § 412.103 reclassification, is reflected accordingly in Table 2 associated with this proposed rule (which is available via the Internet on the CMS Web site). We note that, for payment purposes other than the wage index, a hospital with simultaneous § 412.103 status and Lugar reclassification receives payment as a rural hospital.

### 4. Waiving Lugar Redesignation for the Out-Migration Adjustment

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS, including being considered rural for the DSH payment adjustment, effective for the fiscal year in which the hospital receives the out-migration adjustment. (We refer readers to a discussion of DSH payment adjustment under section IV.F. of the preamble of this proposed rule.)

In addition, we adopted a minor procedural change in that rule that allows a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the publication of the proposed rule) to waive its urban status for the full 3-year period for which its out-migration adjustment is effective. By doing so, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. Therefore, under the procedural change, a Lugar hospital that requests to waive its urban status in order to receive the rural wage index in addition to the out-migration adjustment would be deemed to have accepted the out-migration adjustment and agrees to be treated as rural for the duration of its 3-year eligibility period, unless, prior to its second or third year

of eligibility, the hospital explicitly notifies CMS in writing, within the required period (generally 45 days from the publication of the proposed rule), that it instead elects to return to its deemed urban status and no longer wishes to accept the out-migration adjustment. If the hospital does notify CMS that it is electing to return to its deemed urban status, it would again be treated as urban for all IPPS payment purposes.

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

#### *K. Proposed Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees for FY 2017*

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the “out-migration” adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index.

Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. When the provision of section 1886(d)(13) of the Act was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau that were derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the “long-form” survey, which the Census Bureau used at the time and which contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was “short form” only; information on where residents in each county worked was not collected as part of the 2010 Census. The Census Bureau worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked in 2010, for use in developing a new out-migration adjustment based on new commuting patterns developed from the

2010 Census data beginning with FY 2016.

To determine the out-migration adjustments and applicable counties for FY 2016, we analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-Year) Microdata. The data were compiled from responses to the ACS questions regarding the county where workers reside and the county to which workers commute. As we discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49501), the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment were applicable for FY 2016, and we are proposing to use them again for FY 2017. We have applied the same policies, procedures, and computations since FY 2012, and we believe they continue to be appropriate for FY 2017. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49500 through 49502) for a full explanation of the revised data source.

For FY 2017, until such time that CMS finalizes out-migration adjustments based on the next Census, the out-migration adjustment continues to be based on the data derived from the custom tabulation of the ACS utilizing 2008 through 2012 (5-Year) Microdata. For FY 2017, we are not proposing any changes to the methodology or data source that we used for FY 2016. (We refer readers to a full discussion of the out-migration 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 2 associated with this proposed rule (which is available via the Internet on the CMS Web site) includes the proposed out-migration adjustments for the FY 2017 wage index.

#### *L. Notification Regarding Proposed CMS “Lock-In” Date for Urban to Rural Reclassifications Under § 412.103*

Under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Specifically, section 1886(d)(8)(E) of the Act provides that, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital that satisfies certain criteria, the Secretary shall treat the hospital as being located

in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located. We refer readers to the regulations at 42 CFR 412.103 for the general criteria and application requirements for a subsection (d) hospital to reclassify from urban to rural status in accordance with section 1886(d)(8)(E) of the Act. The FY 2012 IPPS/LTCH PPS final rule (76 FR 51595 through 51596) includes our policies regarding the effect of wage data from reclassified or redesignated hospitals.

Hospitals must meet the criteria to be reclassified from urban to rural status under § 412.103, as well as fulfill the requirements for the application process. However, under existing § 412.103(b), there is no timeframe requirement as to when hospitals must apply for the urban to rural reclassification. Therefore, a hospital can apply for the urban to rural reclassification at any time, and under § 412.103(d), the effective date of the hospital’s rural status, once approved, is the filing date of the application.

There may be one or more reasons that a hospital applies for the urban to rural reclassification, and the timeframe that a hospital submits an application is often dependent on those reason(s). Because there are no timeframes for when a hospital must submit its application under § 412.103, it is the hospital’s prerogative as to when it files the application with the CMS Regional Office. Because the wage index is part of the methodology for determining the prospective payments to hospitals for each fiscal year, we believe there should be a definitive timeframe within which a hospital should apply for rural status in order for the reclassification to be reflected in the next Federal fiscal year’s wage data used for setting payment rates. As hospitals are aware, the IPPS ratesetting process that CMS undergoes each proposed and final rulemaking is complex and labor-intensive, and subject to a compressed timeframe in order to issue the final rule each year within the timeframes for publication. Accordingly, CMS must ensure that it receives, in a timely fashion, the necessary data, including, but not limited to, the list of hospitals that are reclassified from urban to rural status under § 412.103, in order to calculate the wage indexes and other IPPS rates.

Therefore, in this proposed rule, we are proposing a date by when we would “lock in” the list of hospitals that are reclassified from urban to rural status under § 412.103 in order to include them in the upcoming Federal fiscal year’s wage index calculation provided for at § 412.64(h) and budget neutrality calculations provided for at

§§ 412.64(e)(1)(ii), (e)(2), and (e)(4) that are part of the ratesetting process). The ratesetting process is described in the Addendum of the annual proposed and final rules and includes the budget neutrality adjustments in accordance with the regulations at §§ 412.64(e)(1)(ii), (e)(2), and (e)(4), as well as adjustments for differences in area wage levels provided for at § 412.64(h). We believe that this proposal would introduce additional transparency and predictability regarding the timing of accounting for urban or rural status in the IPPS ratesetting each Federal fiscal year. We are proposing that this date for “locking in” the list of hospitals with rural status achieved under § 412.103 would be the second Monday in June of each year. Therefore, if a hospital is applying for an urban to rural reclassification under § 412.103 for the purpose and expectation that its rural status be reflected in the wage index and budget neutrality calculations for setting payment rates for the next Federal fiscal year, the hospital would need to file its application with the CMS Regional Office not later than 70 days prior to the second Monday in June. Because, under 412.103(c), the CMS Regional Office must notify the hospital of its approval or disapproval of the application within 60 days of the hospital’s filing date (the date it is received by the CMS Regional Office, in accordance with § 412.103(b)(5)), we would expect that the extra 10 days would provide the CMS Regional Office with sufficient processing and administrative time to notify the CMS Central Office of the reclassification status of the applications by the second Monday in June of each year. This is the latest date that CMS would need the information in order to ensure that reclassified hospitals would be included as such in the wage index and budget neutrality calculations for setting payment rates for the next Federal fiscal year. This does not preclude a hospital from applying for reclassification under § 412.103 earlier or later than the proposed deadline. Nor does the proposed deadline change the fact that the rural reclassification is effective as of its filing date, in accordance with § 412.103(d). However, in order to ensure that a reclassification is reflected in the wage index and budget neutrality calculations for setting payment rates for the next Federal fiscal year, applications must be received by the CMS Regional Office (the filing date) by no later than 70 days prior to the second Monday in June of each year. If the CMS Central Office is informed of a

reclassification status after the second Monday in June, for wage index and budget neutrality purposes, the reclassification would not be reflected in the payment rates until the following Federal fiscal year; that is, the Federal fiscal year following the next Federal fiscal year. We are proposing to revise § 412.103(b) by adding a new paragraph (6) to incorporate this proposed policy. Proposed § 412.103(b)(6) would specify that in order for a hospital to be treated as rural in the wage index and budget neutrality calculations under §§ 412.64(e)(1)(ii), (e)(2), (e)(4), and (h) for payment rates for the next Federal fiscal year, the hospital’s filing date must be no later than 70 days prior to the second Monday in June of the current Federal fiscal year and the application must be approved by the CMS Regional Office in accordance with the requirements of § 412.103.

#### *M. Process for Requests for Wage Index Data Corrections*

The preliminary, unaudited Worksheet S–3 wage data files for the proposed FY 2017 wage index were made available on May 15, 2015, and the preliminary CY 2013 occupational mix data files on May 15, 2015, through the Internet on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html>.

On January 29, 2016, we posted a public use file (PUF) at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html> containing FY 2017 wage index data available as of January 28, 2016. This PUF contains a tab with the Worksheet S–3 wage data (which includes Worksheet S–3, Parts II and III wage data from cost reporting periods beginning on or after October 1, 2012 through September 30, 2013; that is, FY 2013 wage data), a tab with the occupational mix data (which includes data from the CY 2013 occupational mix survey, Form CMS–10079), and new for FY 2017, a tab containing the Worksheet S–3 wage data of hospitals deleted from the January 29, 2016 wage data PUF and a tab containing the CY 2013 occupational mix data (if any) of the hospitals deleted from the January 29, 2016 wage data PUF. In a memorandum dated January 21, 2016, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the January 29, 2016 wage index data PUFs, and the process and timeframe for requesting revisions in accordance with the FY 2017 Wage Index Timetable.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional PUF on our Web site that reflects the actual data that are used in computing the proposed wage index. The release of this file does not alter the current wage index process or schedule. We notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door Forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and about the dates 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 April 30, 2015, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the wage index data files and the process and timeframe for requesting revisions (including the specific deadlines listed later in this section). We also instructed the MACs to advise hospitals that these data were also made available directly through their representative hospital organizations.

If a hospital wished to request a change to its data as shown in May 15, 2015 wage data files and May 15, 2015 occupational mix data files, the hospital was to submit corrections along with complete, detailed supporting documentation to its MAC by September 2, 2015. 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 letters sent to them by their MACs.

November 4, 2015 was the date by when MACs notified State hospital associations regarding hospitals that failed to respond to issues raised during the desk reviews. The MACs notified the hospitals by mid-January 2016 of any changes to the wage index data as a result of the desk reviews and the resolution of the hospitals’ revision requests. The MACs also submitted the revised data to CMS by January 22, 2016. CMS published the proposed wage index PUFs that included hospitals’ revised wage index data on January 29, 2016. Hospitals had until February 16, 2016, to submit requests to the MACs for reconsideration of adjustments made by the MACs as a result of the desk review, and to correct errors due to CMS’ or the MAC’s mishandling of the wage index data. Hospitals also were required to submit

sufficient documentation to support their requests.

After reviewing requested changes submitted by hospitals, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by March 24, 2016. The deadline for a hospital to request CMS intervention in cases where a hospital disagreed with a MAC's policy interpretation was April 5, 2016. We note that, as we did for the FY 2016 wage index, for the FY 2017 wage index, in accordance with the FY 2017 wage index timeline posted on the CMS Web site at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html>, the April appeals have to be sent via mail and email. We refer readers to the wage index timeline for complete details.

Hospitals are given the opportunity to 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: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html>. Table 2 contains each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2013 data used to construct the proposed FY 2017 wage index. We note that the proposed hospital average hourly wages shown in Table 2 only reflect changes made to a hospital's data that were transmitted to CMS by late February 2016.

We plan to post the final wage index data PUFs in late April 2016 on the Internet at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html>. The April 2016 PUFs are made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process previously described (revisions submitted to CMS by the MACs by March 24, 2016).

After the release of the April 2016 wage index data PUFs, changes to the wage and occupational mix data can only be made in those very limited situations involving an error by the MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before March 24, 2016.

- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the January 29, 2016 wage index PUFs.

- Requests to revisit factual determinations or policy interpretations made by the MAC or CMS during the wage index data correction process.

If, after reviewing the April 2016 final wage index data PUFs, a hospital believes that its wage or occupational mix data were incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital is given the opportunity to notify both its MAC and CMS regarding why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital is required to send its request to CMS and to the MAC no later than May 23, 2016. Similar to the April appeals, beginning with the FY 2015 wage index, in accordance with the FY 2017 wage index timeline posted on the CMS Web site at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home.html>, the May appeals must be sent via mail and email to CMS and the MACs. We refer readers to the wage index timeline for complete details.

Verified corrections to the wage index data received timely by CMS and the MACs (that is, by May 23, 2016) will be incorporated into the final FY 2017 wage index, which will be effective October 1, 2016.

We created the processes previously described to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2017 payment rates. Accordingly, hospitals that do not meet the procedural deadlines set forth above will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines set forth above will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections.

Again, we believe the wage index data correction process described earlier

provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals have access to the final wage index data PUFs by late April 2016, they have the opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 2017 wage index by August 2016, and the implementation of the FY 2017 wage index on October 1, 2016. Given these processes, 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 May 23, 2016, 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 regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, "before the beginning of the fiscal year" means by the May deadline for making corrections to the wage data for the following fiscal year's wage index (for example, May 23, 2016 for the FY 2017 wage index). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS Web site prior to publishing both the proposed and final IPPS rules, and the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) The MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about



the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the May 23, 2016 deadline for the FY 2017 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the May 23, 2016 deadline for the FY 2017 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; and it can only be used for the current Federal fiscal year. In situations where our policies would allow midyear corrections other than those specified in 42 CFR 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

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

#### *N. Proposed Labor Market Share for the Proposed FY 2017 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 and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the portion of hospital costs

attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

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

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50596 through 50607), we rebased and revised the hospital market basket. We established a FY 2010-based IPPS hospital market basket to replace the FY 2006-based IPPS hospital market basket, effective October 1, 2013. In that final rule, we presented our analysis and conclusions regarding the frequency and methodology for updating the labor-related share for FY 2014. Using the FY 2010-based IPPS market basket, we finalized a labor-related share for FY 2014, FY 2015, and FY 2016 of 69.6 percent. In addition, in FY 2014, we implemented this revised and rebased labor-related share in a budget neutral manner (78 FR 51016). However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. In this proposed rule, for FY 2017, we are not proposing to make any further changes to the national average proportion of operating costs that are attributable to wages and salaries, employee benefits, contract labor, the labor-related portion of professional fees, administrative and facilities support services, and all other labor-related services. Therefore, for FY 2017, we are proposing to continue to use a labor-related share of 69.6 percent for discharges occurring on or after October 1, 2016.

As discussed in section IV.A of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we applied the Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage to the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114-113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need for us to calculate a Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage for application to the Puerto Rico-specific standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national labor-related share and nonlabor-related share percentages that are applied to the national standardized amount. Accordingly, for FY 2017, we are not proposing a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage.

Tables 1A and 1B, which are published in section VI. of the Addendum to this FY 2017 IPPS/LTCH PPS proposed rule and available via the Internet on the CMS Web site, reflect the proposed national labor-related share, which is also applicable to Puerto Rico hospitals. For FY 2017, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2017, we are proposing to apply the wage index to a proposed labor-related share of 69.6 percent of the national standardized amount.

*O. Solicitation of Comments on Treatment of Overhead and Home Office Costs in the Wage Index Calculation*

Section III.D. of the preamble of this proposed rule states that the method used to compute the proposed FY 2017 wage index without an occupational mix adjustment follows the same methodology that we used to compute the FY 2012, FY 2013, FY 2014, FY 2015, and FY 2016 final wage indexes without an occupational mix adjustment (76 FR 51591 through 51593, 77 FR 53366 through 53367, 78 FR 50587 through 50588, 79 FR 49967, and 80 FR 49491 through 49492, respectively).

As discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592), in “Step 4” of the calculation of the unadjusted wage index, for each hospital reporting both total overhead salaries and total overhead hours greater than zero, we allocate overhead costs to areas of the hospital excluded from the wage index calculation. We also compute the amounts of overhead wage-related costs to be allocated to excluded areas. Finally, we subtract the computed overhead salaries, overhead wage-related costs, and hours associated with excluded areas from the total salaries (plus allowable wage-related costs) and hours derived in “Steps 2 and 3” of the calculation of the unadjusted wage index. (We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592) for a description of the calculation of the unadjusted wage index.) We first began to remove from the wage index the overhead salaries and hours allocated to excluded areas beginning with the FY 1999 wage index calculation (63 FR 40971 and 40972). Beginning with the FY 2002 wage index calculation, we estimated and removed overhead wage-related costs allocated to excluded areas in addition to removing overhead salaries and hours allocated to excluded areas (66 FR 39863 and 39864). We began to estimate and remove overhead wage-related costs associated with excluded areas because we realized that without doing so, the formula resulted in large and inappropriate increases in the average hourly wages of some hospitals, particularly hospitals with large overhead and excluded area costs. These findings led us to believe that not all hospitals were fully or consistently allocating their overhead salaries among the lines on Worksheet S–3, Part II, of the hospital cost report for allowable wage-related costs (Worksheet S–3, Part II, lines 13 and 14 on CMS Form 2552–96, and lines 17 and 18 on CMS Form 2552–10), and nonallowable wage-

related costs associated with excluded areas (Worksheet S–3, Part II, line 15 on CMS Form 2552–96 and line 19 on CMS Form 2552–10). Therefore, we determined that it was necessary to estimate and remove overhead wage-related costs allocated to excluded areas, and we have been doing so in “Step 4” of the unadjusted wage index calculation since FY 2002.

With the implementation of CMS Form 2552–10, Worksheet S–3, Part IV was added to the cost report on which hospitals are required to itemize their wage-related costs (formerly reported on Exhibit 6 of CMS Form-339). The total amount of wage-related costs reported on Worksheet S–3, Part II, lines 17 through 25 (CMS Form 2552–10) must correspond to the total core wage-related costs on Worksheet S–3, Part IV, line 24. (We refer readers to the instructions for line 17 of Worksheet S–3, Part II, which state: “Enter the core wage-related costs from Worksheet S–3, Part IV, line 24.”) Hospitals report wage-related costs associated with excluded areas of the hospital on Worksheet S–3, Part II, line 19. We understand that hospitals use an allocation methodology to allocate total wage-related costs to each of lines Worksheet S–3, Part II, lines 17 through 25 respectively, typically based on the ratio of individual line costs to total wage-related costs on lines 17 through 25. Alternatively, we understand that hospitals use the ratio of full-time equivalent (FTE) hours of an individual line to total FTE hours for those lines 17 through 25. Because the wage-related costs of employees who work in overhead areas of the hospital are included in the wage-related costs of the hospital reported on Worksheet S–3, Part IV, and in turn, on Worksheet S–3, Part II, it is possible to conclude that hospitals’ own allocation methodologies are properly allocating an accurate amount of wage-related costs for both direct cost centers and overhead areas to line 19 for the excluded areas. Accordingly, the question has been raised whether it continues to be necessary for CMS to estimate and remove the overhead wage-related costs associated with excluded areas from the unadjusted wage index calculation.

We have tested the effect on the average hourly wages of hospitals if we would not estimate and remove the overhead wage-related costs associated with excluded areas from the unadjusted wage index calculation. The results show that the problem manifested in the formula prior to FY 2002 continues to be a concern; that is, while the average hourly wages of all hospitals with excluded areas are

impacted, hospitals that have particularly large excluded areas experience large and inappropriate increases to their average hourly wages. For example, one hospital with an excluded area percentage of 95 percent that has an average hourly wage of approximately \$32 under our current methodology would have an average hourly wage of \$128 under the formula in effect prior to FY 2002 (that is, *without* removal of overhead wage-related costs). Accordingly, we believe that, at this point, there is a need for CMS to continue to estimate and remove the overhead wage-related costs associated with excluded areas from the unadjusted wage index calculation. However, in an effort to improve consistency in hospital cost reporting practices and to improve the accuracy of the wage index, we are considering the possibility of future rulemaking or cost reporting changes, or a combination of both, where hospitals would apply a single allocation methodology between Worksheet S–3, Part IV and Worksheet S–3, Part II, lines 17 through 25. For example, one possibility is the modification and expansion of Worksheet S–3, Part IV to add columns that would correspond to each line 17 through 25 of Worksheet S–3, Part II. In addition, Worksheet S–3, Part IV could employ one or two standard statistical allocation methods, facilitating a direct flow of the allocated amounts to each line 17 through 25 of Worksheet S–3, Part II. We are soliciting comments from stakeholders to gain a better understanding of the nature of hospitals’ reporting of wage-related costs on Worksheet S–3, Part IV, statistical allocation methods that hospitals typically use to allocate their wage-related costs, the treatment of direct versus overhead employee wage-related costs, and suggestions for possible modifications to Worksheet S–3, Parts II and IV respectively, which would preempt the need for CMS to estimate and remove overhead wage-related costs associated with excluded areas from the unadjusted wage index.

Another issue about which we are concerned and would like to solicit public comments relates to inconsistent reporting of home office salaries and wage-related costs. Worksheet S–2, Part I, line 140, requires hospitals to complete Worksheet A–8–1 if they have any related organization or home office costs claimed as defined in the Provider Reimbursement Manual, CMS Pub. 15–1, Chapter 10, Section 1002, and 42 CFR 413.17. Then, line 14 of Worksheet S–3, Part II instructs hospitals to enter the salaries and wage-related costs paid to

personnel who are affiliated with a home office and/or related organization, who provide services to the hospital, and whose salaries are *not* included on Worksheet A, Column 1. Because home office salaries and wage-related costs are not included on Worksheet A, Column 1, we are concerned that hospitals are not including home office costs on Worksheet A, Column 2 or Column 6 in the appropriate cost centers on lines 4 through 17, adjusted from Worksheet A–8 or Worksheet A–8–1.<sup>20</sup> Another concern is a hospital's inadvertent inclusion on line 14 of the home office salaries or wage-related costs associated with excluded areas on Worksheet S–3, Part II, lines 9 or 10. In addition, we are concerned about the amalgam of personnel costs that hospitals report on line 14, particularly when another more precise line exists for those personnel costs to be reported. For example, if cafeteria services are provided through the home office, those wages and hours should not be reported on line 14, but instead should be reported on the more specific cost center for Cafeteria, Worksheet S–3, Part II, line 36 (corresponding to Cafeteria on Worksheet A, line 11<sup>21</sup>). We note that, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967), we reiterated our requirement that all hospitals must document salaries, wages, and hours for the purpose of reporting this information on Worksheet S–3, Part II, lines 32, 33, 34, and/or 35 (for either directly employed housekeeping and dietary employees on lines 32 and 34, and contract labor on lines 33 and 35). We have learned of instances where housekeeping or dietary services are provided through the home office, and the hospital reported those wages and hours on line 14. This is inconsistent with other hospitals' reporting of housekeeping and dietary services on lines 32 through 35. As stated in the FY 2015 IPPS/LTCH PPS final rule, we have instructed the MACs to impute housekeeping or dietary wages and hours when hospitals

have not properly completed those lines 32 through 35. Hospitals whose housekeeping or dietary services (either direct or under contract) are provided through their home office are not exempt from this requirement to report wages and hours on the specific cost centers for housekeeping and dietary. Hospitals should also take care to report housekeeping and dietary services in the appropriate cost centers on Worksheet A, lines 9 and 10 respectively. Because the nature of services provided by home office personnel are for general management or administrative services related to the provision of patient care (CMS Pub. 15–1, Chapter 21, Section 2150), and may be provided to multiple areas of the hospital, we are considering ending reporting of home office costs on line 14 of Worksheet S–3, Part II, and instead we may require reporting of home office costs as part of the overhead lines, possibly by adding lines or columns, or subscribing existing line 27 (Administrative & General), and line 28 (Administrative & General for contract labor). We are soliciting public comments to gain a better understanding of hospitals' reporting of home office salaries and wage-related costs for possible future revisions to the cost report instructions and lines.

#### **IV. Other Decisions and Changes to the IPPS for Operating Costs and Direct Graduate Medical Education (GME) and Indirect Medical Education (IME) Costs**

##### *A. Changes to Operating Payments for Subsection (d) Puerto Rico Hospitals as a Result of Section 601 of Public Law 114–113*

Prior to January 1, 2016, Puerto Rico hospitals were paid with respect to operating costs of inpatient hospital services for inpatient hospital discharges based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. As a result of the amendment made by section 601 of Public Law 114–113, on February 4, 2016, we issued Change Request 9523 which updated the payment rates for subsection (d) Puerto Rico hospitals for discharges occurring on or after January

1, 2016. Change Request 9523 can be downloaded from the CMS Web site at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2016-Transmittals-Items/R3449CP.html>.

For operating costs for inpatient hospital discharges occurring in FY 2017 and subsequent fiscal years, consistent with the provisions of section 1886(d)(9)(E) of the Act as amended by section 601 of Public Law 114–113, subsection (d) Puerto Rico hospitals will continue to be paid based on 100 percent of the national standardized amount.

In this proposed rule, we are proposing to make conforming changes to the regulations at 42 CFR 412.204 to reflect the current law that is effective for discharges occurring on or after January 1, 2016. Specifically, we are proposing to add a new paragraph (e) to § 412.204 to reflect that, beginning January 1, 2016, subsection (d) Puerto Rico hospitals are paid based on 100 percent of the national standardized amount. We also are proposing to revise paragraph (d) of § 412.204 to specify that subsection (d) Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount for discharges occurring through December 31, 2015.

##### *B. Proposed Changes in the Inpatient Hospital Update for FY 2017 (§ 412.64(d))*

###### 1. Proposed FY 2017 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 hospital operating costs by a factor called the “applicable percentage increase.” For FY 2017, we are setting the applicable percentage increase by applying the adjustments listed in this section in the same sequence as we did for FY 2016. Specifically, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. The applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to—

(a) A reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under

<sup>20</sup>CMS Pub. 15–2, Chapter 40, Section 4013, Worksheet A instructions for column 6: “Enter on the appropriate lines in column 6 the amounts of any adjustments to expenses indicated on Worksheet A–8, column 2,” and the note for line 12 of Worksheet A–8, section 4016: “Worksheet A–8–1 represents the detail of the various cost centers on Worksheet A which must be adjusted.”

<sup>21</sup>CMS Pub. 15–2, Chapter 40, Section 4013, Worksheet A instructions under Line Descriptions: “The trial balance of expenses is broken down into general service, inpatient routine service, ancillary service, outpatient service, other reimbursable, special purpose, and nonreimbursable cost center categories to facilitate the transfer of costs to the various worksheets. The line numbers on Worksheet A are used on subsequent worksheets. \* \* \*” (emphasis added).

rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act;

(b) A reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act;

(c) An adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment); and

(d) An additional reduction of 0.75 percentage point as required by section 1886(b)(3)(B)(xii) of the Act.

Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that application of the MFP adjustment and the additional FY 2017 adjustment of 0.75 percentage point may result in the applicable percentage increase being less than zero.

We note that, in compliance with section 404 of the MMA, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50596 through 50607), we replaced the FY 2006-based IPPS operating and capital market baskets with the revised and rebased FY 2010-based IPPS operating and capital market baskets for FY 2014. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49993 through 49996) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49508 through 49511), we continued to use the FY 2010-based IPPS operating and capital market baskets for FY 2015 and FY 2016 and the labor-related share of 69.6 percent, which was based on the FY 2010-based IPPS market basket. For FY 2017, we are proposing to continue using the FY 2010-based IPPS operating and capital market baskets and the proposed labor-related share of 69.6 percent, which is based on the FY 2010-based IPPS market basket.

Based on the most recent data available for this FY 2017 proposed

rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to base the proposed FY 2017 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Insight, Inc.'s (IGI's) first quarter 2016 forecast of the FY 2010-based IPPS market basket rate-of-increase with historical data through fourth quarter 2015, which is estimated to be 2.8 percent. We are proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket and the MFP adjustment), we would use such data, if appropriate, to determine the FY 2017 market basket update and the MFP adjustment in the final rule.

For FY 2017, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount as specified in the table that appears later in this section.

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. As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The Bureau of Labor Statistics (BLS) publishes the official measure of private nonfarm business MFP. We refer readers to the BLS Web

site at <http://www.bls.gov/mfp> for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. As we discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509), beginning with the FY 2016 rulemaking cycle, the MFP adjustment is calculated using the revised series developed by IGI to proxy the aggregate capital inputs.

Specifically, in order to generate a forecast of MFP, IGI forecasts BLS aggregate capital inputs using a regression model. A complete description of the MFP projection methodology is available on the CMS Web site at: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html>. As discussed in the FY 2016 IPPS/LTCH PPS final rule, if IGI makes changes to the MFP methodology, we will announce them on our Web site rather than in the annual rulemaking.

For FY 2017, we are proposing an MFP adjustment of 0.5 percentage point. Similar to the market basket update, for the proposed rule, we used the most recent data available to compute the MFP adjustment. As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2017 market basket update and MFP adjustment for the final rule.

Based on the most recent data available for this proposed rule, as described previously, we have determined four proposed applicable percentage increases to the standardized amount for FY 2017, as specified in the following table:

PROPOSED FY 2017 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2017	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Proposed Market Basket Rate-of-Increase .....	2.8	2.8	2.8	2.8
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act .....	0.0	0.0	-0.7	-0.7
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act .....	0.0	-2.1	0.0	-2.1
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act .....	-0.5	-0.5	-0.5	-0.5
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act .....	-0.75	-0.75	-0.75	-0.75

PROPOSED FY 2017 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS—Continued

FY 2017	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Proposed Applicable Percentage Increase Applied to Standardized Amount	1.55	-0.55	0.85	-1.25

We are proposing to revise the existing regulations at 42 CFR 412.64(d) to reflect the current law for the FY 2017 update. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to add a new paragraph (vii) to § 412.64(d)(1) to reflect the applicable percentage increase to the FY 2017 operating standardized amount as the percentage increase in the market basket index, subject to the reductions specified under § 412.64(d)(2) for a hospital that does not submit quality data and § 412.64(d)(3) for a hospital that is not a meaningful EHR user, less an MFP adjustment and less an additional reduction of 0.75 percentage point.

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs and MDHs also 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. We note that section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) extended the MDH program (which, under previous law, was to be in effect for discharges on or before March 31, 2015 only) for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017).

For FY 2017, we are proposing the following updates to the hospital-specific rates applicable to SCHs and MDHs: A proposed update of 1.55 percent for a hospital that submits quality data and is a meaningful EHR user; a proposed update of 0.85 percent for a hospital that fails to submit quality data and is a meaningful EHR user; a proposed update of -0.55 percent for a hospital that submits quality data and is not a meaningful EHR user; and a proposed update of -1.25 percent for a hospital that fails to submit quality data and is not a meaningful EHR user. As

mentioned previously, for this FY 2017 proposed rule, we are using IGI’s first quarter 2016 forecast of the FY 2010-based IPPS market basket update with historical data through fourth quarter 2015. Similarly, we are using IGI’s first quarter 2016 forecast of the MFP adjustment. We are proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use such data, if appropriate, to determine the update for SCHs and MDHs in the final rule.

2. Proposed FY 2017 Puerto Rico Hospital Update

As discussed in section IV.A. of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of Public Law 114–113 amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to propose an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section IV.B.1. of the preamble of this proposed rule. Accordingly, for FY 2017, we are proposing an applicable percentage increase of 1.55 percent to the standardized amount for hospitals located in Puerto Rico.

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for “subsection (d)” hospitals that do not submit quality data under the rules

established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. Accordingly, because the provisions of section 1886(b)(3)(B)(ix) of the Act are not applicable to hospitals located in Puerto Rico until FY 2022, the adjustments under this provision are not applicable for FY 2017.

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

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

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs also are 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 in which the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, that any hospital classified as an RRC by the Secretary for FY 1991 shall be classified as such an RRC for FY 1998 and each subsequent fiscal year. In the August 29, 1997 IPPS final rule with comment period (62 FR 45999), we reinstated RRC status for all hospitals that lost that status due to triennial review or MGCRB

reclassification. However, we 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 case-mix index (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) for additional discussion.) 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 2017 is based on the CMI values of all urban hospitals nationwide, and the proposed regional median CMI values for FY 2017 are based on the CMI values of all 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 2015 (October 1, 2014 through September 30, 2015), and include bills posted to CMS’ records through December 2015.

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, 2016, they must have a CMI value for FY 2015 that is at least—

- 1.6125 (national—all urban); 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
1. New England (CT, ME, MA, NH, RI, VT) .....	1.3637
2. Middle Atlantic (PA, NJ, NY) .....	1.4441
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV) .....	1.51235
4. East North Central (IL, IN, MI, OH, WI) .....	1.5324
5. East South Central (AL, KY, MS, TN) .....	1.45055
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.59535
7. West South Central (AR, LA, OK, TX) .....	1.643
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY) .....	1.6966
9. Pacific (AK, CA, HI, OR, WA) .....	1.616

We intend to update the preceding CMI values in the FY 2017 final rule to reflect the updated FY 2015 MedPAR file, which would contain data from additional bills received through March 2016.

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its 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 criteria 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. For FY 2017, we are proposing to update the regional standards based on discharges for urban hospitals’ cost reporting periods that began during FY 2014 (that is, October 1, 2013 through September 30, 2014), which are the latest cost report data available at the time this proposed rule was developed.

We are proposing that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2016, must have, as the number of discharges for its cost reporting period that began during FY 2014, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- The median number of discharges for urban hospitals in the census region in which the hospital is located as indicated in the following table.

Region	Number of discharges
1. New England (CT, ME, MA, NH, RI, VT) .....	8,090
2. Middle Atlantic (PA, NJ, NY) .....	10,745
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV) .....	10,309
4. East North Central (IL, IN, MI, OH, WI) .....	8,090
5. East South Central (AL, KY, MS, TN) .....	7,457
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,718
7. West South Central (AR, LA, OK, TX) .....	5,027
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY) .....	8,621
9. Pacific (AK, CA, HI, OR, WA) .....	8,509

We intend to update these numbers in the FY 2017 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, under this proposed rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

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

1. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital that is paid under IPPS beginning in FY 2005, and the low-volume hospital payment policy is set forth in the regulations at 42 CFR 412.101. 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. Specifically, the provisions of the Affordable Care Act amended the qualifying criteria for low-volume hospitals to specify, for FYs 2011 and 2012, that a hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 1,600 discharges of individuals entitled to, or enrolled for, benefits under Medicare Part A during the fiscal year. In addition, the statute as amended by the Affordable Care Act, provides that the low-volume hospital payment adjustment (that is, the percentage increase) is 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 Medicare Part A in the fiscal year to 0 percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal year. We revised the regulations governing the low-volume hospital payment adjustment policy at § 412.101 to reflect the changes to the qualifying criteria and the calculation of the payment adjustment for low-volume hospitals according to the provisions of the Affordable Care Act in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414).

The temporary changes to the low-volume hospital qualifying criteria and the payment adjustment originally provided for by the Affordable Care Act have been extended by subsequent legislation as follows: Through FY 2013, by the American Taxpayer Relief Act of 2012 (ATRA), Public Law 112–240; through March 31, 2014, by the Pathway for SGR Reform Act of 2013, Public Law 113–167; through March 31, 2015, by the Protecting Access to Medicare Act of 2014 (PAMA), Public Law 113–93; and most recently through FY 2017, by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Public Law 114–10. For additional details on the implementation of the previous extensions of the temporary changes to the low-volume hospital qualifying criteria and payment

adjustment originally provided for by the Affordable Care Act, we refer readers to the following **Federal Register** documents: The FY 2013 IPPS notice (78 FR 14689 through 14691); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50611 through 50612); the FY 2014 IPPS interim final rule with comment period (79 FR 15022 through 15025); the FY 2014 IPPS notice (79 FR 34444 through 34446); the FY 2015 IPPS/LTCH PPS final rule (79 FR 49998 through 50001); and the FY 2016 IPPS interim final rule with comment period (80 FR 49594 through 49595).

2. Proposed Low-Volume Hospital Definition and Payment Adjustment for FY 2017

Under section 1886(d)(12) of the Act, as amended by section 204 of the MACRA, the temporary changes in the low-volume hospital payment policy originally provided by the Affordable Care Act and extended through subsequent legislation, are effective through FY 2017. In this proposed rule, consistent with our historical approach, we are proposing to update the discharge data source used to identify qualifying low-volume hospitals and calculate the payment adjustment (percentage increase) for FY 2017. Under § 412.101(b)(2)(ii), for the applicable fiscal years, a hospital's Medicare discharges from the most recently available MedPAR data, as determined by CMS, are used to determine if the hospital meets the discharge criteria to receive the low-volume payment adjustment in the current year and to determine the applicable low-volume percentage increase for qualifying hospitals. The applicable low-volume percentage increase for FY 2017 is determined using a continuous linear sliding scale equation that results in a low-volume hospital payment adjustment ranging from an additional 25 percent for hospitals with 200 or fewer Medicare discharges to a zero percent additional payment adjustment for hospitals with 1,600 or more Medicare discharges. For FY 2017, consistent with our historical policy, we are proposing that qualifying low-volume hospitals and their payment adjustment would be determined using the most recently available Medicare discharge data from the December 2015 update of the FY 2015 MedPAR file, as these data are the most recent data available. Table 14 listed in the Addendum of this proposed rule (which is available via the Internet on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>) lists the “subsection (d)”

hospitals with fewer than 1,600 Medicare discharges based on the claims data from the December 2015 update of the FY 2015 MedPAR file and their potential proposed low-volume payment adjustment for FY 2017. Consistent with past practice, we note that this list of hospitals with fewer than 1,600 Medicare discharges in Table 14 does not reflect whether or not the hospital meets the mileage criterion. Eligibility for the low-volume hospital payment adjustment for FY 2017 also is dependent upon meeting the mileage criterion specified at § 412.101(b)(2)(ii); that is, the hospital must be located more than 15 road miles from any other IPPS hospital. In other words, eligibility for the low-volume hospital payment adjustment for FY 2017 also is dependent upon meeting (in the case of a hospital that did not qualify for the low-volume hospital payment adjustment in FY 2016) or continuing to meet (in the case of a hospital that did qualify for the low-volume hospital payment adjustment in FY 2016) the mileage criterion specified at § 412.101(b)(2)(ii). Consistent with historical practice, we are proposing that if more recent Medicare discharge data become available, we would use that updated data to determine qualifying low-volume hospitals and their payment adjustment in the final rule, and update Table 14 to reflect that updated data.

In order to receive a low-volume hospital payment adjustment under § 412.101 for FY 2017, consistent with our previously established procedure, we are proposing that a hospital must notify and provide documentation to its MAC that it meets the discharge and mileage criteria under § 412.101(b)(2)(ii). Specifically, for FY 2017, we are proposing that a hospital must make a written request for low-volume hospital status that is received by its MAC no later than September 1, 2016, in order for the applicable low-volume hospital payment adjustment to be applied to payments for its FY 2017 discharges occurring on or after October 1, 2016. Under this procedure, a hospital that qualified for the low-volume hospital payment adjustment in FY 2016 may continue to receive a low-volume hospital payment adjustment for FY 2017 without reapplying if it continues to meet the Medicare discharge criterion established for FY 2017 and the mileage criterion. However, the hospital must send written verification that is received by its MAC no later than September 1, 2016, stating that it continues to be located more than 15 miles from any

other subsection (d) hospital. This written verification could be a brief letter to the MAC stating that the hospital continues to meet the low-volume hospital mileage criterion as documented in a prior low-volume hospital status request. We also are proposing that if a hospital's written request for low-volume hospital status for FY 2017 is received after September 1, 2016, and if the MAC determines that the hospital meets the criteria to qualify as a low-volume hospital, the MAC would apply the applicable low-volume hospital payment adjustment to determine the payment for the hospital's FY 2017 discharges effective prospectively within 30 days of the date of its low-volume hospital status determination, consistent with past practice. (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) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50000 through 50001).)

We note that, in the FY 2016 IPPS interim final rule with comment period (80 FR 49595), we revised the regulations at § 412.101 to conform the text to the provisions of section 204 of the MACRA, which extended the changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals through FY 2017 (that is, through September 30, 2017). We intend to finalize the low-volume hospital provisions (as well as the Medicare-dependent small rural hospital (MDH) provisions at § 412.108) included in that FY 2016 interim final rule with comment period in the FY 2017 IPPS/LTCH PPS final rule.

#### *E. Indirect Medical Education (IME) Payment Adjustment Factor for FY 2017 (§ 412.105)*

##### 1. IME Adjustment for FY 2017

Under the IPPS, an additional payment amount is made to hospitals with residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal

years thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2017, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2017 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 Policies Related to IME

We refer readers to section IV.I. of the preamble of this proposed rule for a discussion of the proposed policy changes relating to medical residency training programs (or rural tracks) at urban hospitals that also affect payments for IME.

#### *F. Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2017 and Subsequent Years (§ 412.106)*

##### 1. General Discussion

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).

Section 3133 of the Patient Protection and Affordable Care Act, as amended by section 10316 of the same Act and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111-152), added a new section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment. (For purposes of this proposed rule, we refer to these provisions collectively as section 3133 of the Affordable Care Act.) Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under age 65 who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

As provided by section 3133 of the Affordable Care Act, section 1886(r) of the Act requires that, for FY 2014 and



each subsequent fiscal year, a subsection (d) hospital that would otherwise receive DSH payments made under section 1886(d)(5)(F) of the Act receives two separately calculated payments. Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such a subsection (d) hospital (including a Pickle hospital) 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the MedPAC in its March 2007 Report to the Congress. We refer to this payment as the “empirically justified Medicare DSH payment.”

In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospital an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act 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 were 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), and the percent of individuals who were uninsured in the most recent period for which data are available (as so calculated) 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 Director of the Congressional Budget Office to the Speaker of the House. (The March 20, 2010 letter is available for viewing on the following Web site: <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/amendreconprop.pdf>.)

For FY 2018 and subsequent fiscal 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 were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS), and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus 0.2 percentage point for FYs 2018 and 2019. Therefore, for FY 2018 and subsequent fiscal years, the statute provides some greater flexibility in the choice of the data sources to be used for the estimate of the change in the percent of uninsured individuals.

The third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data), including the use of alternative data where the Secretary determines that alternative data are available which are 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 section 1886(r) of the Act. 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 the applicable fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment determined by these factors as the “uncompensated care payment.”

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the Medicare DSH payment

methodology made by section 3133 of the Affordable Care Act for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under the regulations at 42 CFR part 412, subpart M, which were established through the exercise of the Secretary’s discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or the periods selected in order to develop such estimates.

## 2. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

As indicated earlier, the payment methodology under section 3133 of the Affordable Care Act applies to “subsection (d) hospitals” that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year in order to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that, in addition to the payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to such subsection (d) hospitals an additional amount. Because section 1886(r)(1) of the Act refers to empirically justified Medicare DSH payments, the additional payment under section 1886(r)(2) of the Act is limited to hospitals that receive empirically justified Medicare DSH payments in accordance with section 1886(r)(1) of the Act for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we provided that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments

for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). We indicated that our final determination on the hospital's eligibility for uncompensated care payments would be based on the hospital's actual DSH status at cost report settlement for that payment year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50006), we specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. We refer readers to those two final rules for a detailed discussion of our policies. In summary, we specified the following:

- *Subsection (d) Puerto Rico hospitals* that are eligible for DSH payments also are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology (78 FR 50623 and 79 FR 50006).

- *Maryland hospitals* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1886(r) of the Act because they are not paid under the IPPS. As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50007), effective January 1, 2014, the State of Maryland elected to no longer have Medicare pay Maryland hospitals in accordance with section 1814(b)(3) of the Act and entered into an agreement with CMS that Maryland hospitals will be paid under the Maryland All-Payer Model. However, under the Maryland All-Payer Model, Maryland hospitals still are not paid under the IPPS. Therefore, they remain ineligible to receive empirically justified Medicare DSH payments or uncompensated care payments under section 1886(r) of the Act.

- *SCHs that are paid under their hospital-specific rate* are not eligible for Medicare DSH payments. SCHs that are paid under the IPPS Federal rate receive interim payments 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, and if they receive interim empirically justified Medicare DSH payments in a fiscal year, they also will receive interim uncompensated care payments for that fiscal year on a per discharge basis, subject as well to settlement through the cost report. Final eligibility

determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).

- *MDHs* are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). The IPPS Federal rate used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Public Law 114–10, enacted April 16, 2015, extended the MDH program for discharges on or after April 1, 2015, through September 30, 2017. Because MDHs are paid based on the IPPS Federal rate, for FY 2017, MDHs will continue to be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments if their DPP is at least 15 percent. We will apply the same process to determine MDHs' eligibility for empirically justified Medicare DSH and uncompensated care payments, as we do for all other IPPS hospitals, through September 30, 2017. Moreover, we will continue to make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). Our final determination on the hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year. In addition, as we do for all IPPS hospitals, we calculate a numerator for Factor 3 for all MDHs, regardless of whether they are projected to be eligible for Medicare DSH payments during the fiscal year, but the denominator for Factor 3 will be based on the uncompensated care data from the hospitals that we have projected to be eligible for Medicare DSH payments during the fiscal year.

- *IPPS hospitals that have elected to participate in the Bundled Payments for Care Improvement initiative* continue to be paid under the IPPS (77 FR 53342) and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments (78 FR 50625 and 79 FR 50008).

- *Hospitals participating in the Rural Community Hospital Demonstration Program* under section 410A of the

Medicare Modernization Act do not receive DSH payments and, therefore, are excluded from receiving empirically justified Medicare DSH payments and uncompensated care payments under the new DSH payment methodology (78 FR 50625 and 79 FR 50008). There are 14 hospitals currently participating in the program; 10 will continue to participate through the end of FY 2016, and 4 will continue to participate through the scheduled end of the program on December 31, 2016. Once a hospital's participation in the demonstration program ends, the hospital will be treated like a subsection (d) hospital and subject to the IPPS. Therefore, once their participation ends, these hospitals could be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments and, if so, will be treated accordingly for interim and final payments. We will apply the same process to determining their eligibility as we do for all other IPPS hospitals, and will make interim and final DSH and uncompensated care payments accordingly.

### 3. Empirically Justified Medicare DSH Payments

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the program to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it was necessary to develop any new operational mechanisms for making such payments. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision by advising MACs to simply adjust the interim claim payments to the requisite 25 percent of what would have otherwise been paid. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments can be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the FY 2014 IPPS/LTCH PPS final rule that are available on the CMS Web site at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html>.

#### 4. Uncompensated Care Payments

As we have discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of three factors. These three factors represent our estimate of 75 percent of the amount of Medicare DSH payments that would otherwise have been paid, an adjustment to this amount for the percent change in the national rate of uninsurance compared to the rate of uninsurance in 2013, and each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals. Below we discuss the data sources and methodologies for computing each of these factors, our final policies for FYs 2014 through 2016, and our proposed policies for FY 2017.

##### a. Calculation of Proposed Factor 1 for FY 2017

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 this factor is equal to the difference between (1) the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year (as estimated by the Secretary); and (2) the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year (as so estimated). Therefore, section 1886(r)(2)(A)(i) of the Act represents the estimated Medicare DSH payments that would have been made under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year. Under a prospective payment system, we would not know the precise aggregate Medicare DSH payment amount that would be paid for a Federal fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the Federal fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount, by specifying that, for each fiscal year to which the provision applies, such amount is to be estimated by the Secretary. Similarly, section 1886(r)(2)(A)(ii) of the Act represents the estimated empirically justified Medicare DSH payments to be made in a fiscal year, as prescribed under section 1886(r)(1) of the Act. Again, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount.

Therefore, Factor 1 is the difference between our estimates of: (1) The amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of the new payment provision; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act. In other words, this factor represents our estimate of 75 percent (100 percent minus 25 percent) of our estimate of Medicare DSH payments that would otherwise be made, in the absence of section 1886(r) of the Act, for the fiscal year.

As we did for FY 2016, in order to determine Factor 1 in the uncompensated care payment formula for FY 2017, we are proposing to continue the policy established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50628 through 50630) and in the FY 2014 IPPS interim final rule with comment period (78 FR 61194) of determining Factor 1 by developing estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments to hospitals under 1886(r)(1) of the Act. These estimates will not be revised or updated after we know the final Medicare DSH payments for FY 2017.

Therefore, in order to determine the two elements of Factor 1 for FY 2017 (Medicare DSH payments *prior* to the application of section 1886(r)(1) of the Act, and empirically justified Medicare DSH payments *after* application of section 1886(r)(1) of the Act), we used the most recently available projections of Medicare DSH payments for the fiscal year, as calculated by CMS' Office of the Actuary using 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.

For purposes of calculating Factor 1 and modeling the impact of this FY 2017 IPPS/LTCH PPS proposed rule, we used the Office of the Actuary's March 2016 Medicare DSH estimates, which are based on data from the December 2015 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2016 IPPS/LTCH PPS final rule IPPS Impact file, published in conjunction with the publication of the FY 2016 IPPS/LTCH PPS final rule. Because SCHs that are projected to be

paid under their hospital-specific rate are excluded from the application of section 1886(r) of the Act, these hospitals also were excluded from the March 2016 Medicare DSH estimates. Furthermore, because section 1886(r) of the Act specifies that the uncompensated care payment is in addition to the empirically justified Medicare DSH payment (25 percent of DSH payments that would be made without regard to section 1886(r) of the Act), Maryland hospitals participating in the Maryland All-Payer Model that do not receive DSH payments are also excluded from the Office of the Actuary's Medicare DSH estimates. Because the Rural Community Hospital Demonstration program is scheduled to end on December 31, 2016, hospitals that are participating in the program are included in this estimate for FY 2017. However, we have excluded 25 percent of our estimate of DSH payments that would otherwise be made to the 4 hospitals whose participation in the program will continue through December 31, 2016, as these hospitals will be excluded from receiving DSH payments until that time. The estimate includes the total DSH payments that would be made to the 10 hospitals whose participation in the Rural Community Hospital Demonstration program will continue only through September 30, 2016.

Using the data sources discussed above, the Office of the Actuary uses the most recently submitted Medicare cost report data to identify Medicare DSH payments and the most recent Medicare 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 March 2016 Office of the Actuary estimate for Medicare DSH payments for FY 2017, without regard to the application of section 1886(r)(1) of the Act, is approximately \$14.227 billion. This estimate excludes Maryland hospitals participating in the Maryland All-Payer Model, SCHs paid under their hospital-specific payment rate, and 25 percent of payments to the 4 hospitals whose participation in the Rural Community Hospital Demonstration program will continue through December 31, 2016. Therefore, based on the March 2016 estimate, the estimate for empirically justified Medicare DSH payments for FY 2017, with the application of section 1886(r)(1) of the Act, is approximately \$3.556 billion (or 25 percent of the total amount of estimated Medicare DSH payments for

FY 2017). Under § 412.106(g)(1)(i) of the regulations, Factor 1 is the difference between these two estimates of the Office of the Actuary. Therefore, in this proposed rule, we are proposing that Factor 1 for FY 2017 is \$10,670,529,595.84, which is equal to

75 percent of the total amount of estimated Medicare DSH payments for FY 2017 (\$14,227,372,794.46 minus \$3,556,843,198.62). The Office of the Actuary’s estimates for FY 2017 begin with a baseline of \$12.154 billion in Medicare DSH

expenditures for FY 2013. The following table shows the factors applied to update this baseline through the current estimate for FY 2017:

FACTORS APPLIED FOR FY 2014 THROUGH FY 2017 TO ESTIMATE MEDICARE DSH EXPENDITURES USING 2013 BASELINE

FY	Update	Discharge	Case-mix	Other	Total	Estimated DSH payment (in billions)
2014 .....	1.009	0.9553	1.015	1.04795	1.025268	\$12.461
2015 .....	1.014	0.9894	1.005	1.0702	1.079048	13.446
2016 .....	1.009	1.0078	1.005	0.9993	1.021239	13.732
2017 .....	1.0005	1.0168	1.005	1.0134	1.036095	14.227

In this table, the discharge column shows the increase in the number of Medicare FFS inpatient hospital discharges. The figures for FYs 2014 and 2015 are based on Medicare claims data that have been adjusted by a completion factor. The discharge figure for FY 2016 is based on preliminary data for 2016. The discharge figure for FY 2017 is an assumption based on recent trends recovering back to the long-term trend and assumptions related to how many beneficiaries will be enrolled in

Medicare Advantage (MA) plans. The case-mix column shows the increase in case-mix for IPPS hospitals. The case-mix figures for FYs 2014 and 2015 are based on actual data adjusted by a completion factor. The FY 2016 and FY 2017 increases are based on the recommendation of the 2010–2011 Medicare Technical Review Panel. The “other” column shows the increase in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total

inpatient hospital discharges and the IPPS discharges, various adjustments to the payment rates that have been included over the years but are not reflected in the other columns (such as the change in rates for the 2-midnight stay policy). In addition, the “other” column includes a factor for the Medicaid expansion due to the Affordable Care Act.

The table below shows the factors that are included in the “Update” column of the above table:

FY	Market basket percentage	Affordable Care Act payment reductions	Multifactor productivity adjustment	Documentation and coding	Total update percentage
2014 .....	2.5	–0.3	–0.5	–0.8	0.9
2015 .....	2.9	–0.2	–0.5	–0.8	1.4
2016 .....	2.4	–0.2	–0.5	–0.8	0.9
2017 .....	2.8	–0.75	–0.5	–1.5	0.05

**Note:** All numbers are based on the FY 2017 President’s Budget projections.

b. Calculation of Proposed Factor 2 for FY 2017

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 that, for each of FYs 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 (1) who were 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); and (2) who are uninsured in the most recent period for which data are available (as so calculated), minus 0.1 percentage point for FY 2014 and minus 0.2 percentage point 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 were 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). The Health Care and Education Reconciliation Act (Pub. L.

111–152) was enacted on March 30, 2010. It was passed in the House of Representatives on March 21, 2010, and by the Senate on March 25, 2010. Because the House of Representatives was the first House to vote on the Health Care and Education Reconciliation Act of 2010 on March 21, 2010, we have determined that the most recent estimate available from the Director of the Congressional Budget Office “before a vote in either House on the Health Care and Education Reconciliation Act of 2010 . . .” (emphasis added) appeared in a March 20, 2010 letter from the director of the CBO to the Speaker of the House. Therefore, we believe that only the estimates in this March 20, 2010 letter meet the statutory requirement under section 1886(r)(2)(B)(i)(I) of the Act. (To view the March 20, 2010 letter, we refer readers to the Web site at: <http://>

[www.cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/amendreconprop.pdf](http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/amendreconprop.pdf).)

In its March 20, 2010 letter to the Speaker of the House of Representatives, the CBO provided two estimates of the “post-policy uninsured population.” The first estimate is of the “Insured Share of the Nonelderly Population Including All Residents” (82 percent) and the second estimate is of the “Insured Share of the Nonelderly Population Excluding Unauthorized Immigrants” (83 percent). In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50631), we used the first estimate that includes all residents, including unauthorized immigrants. We stated that we believe this estimate is most consistent with the statute, which requires us to measure “the percent of individuals under the age of 65 who are uninsured” and provides no exclusions except for individuals over the age of 65. In addition, we stated that we believe that this estimate more fully reflects the levels of uninsurance in the United States that influence uncompensated care for hospitals than the estimate that reflects only legal residents. The March 20, 2010 CBO letter reports these figures as the estimated percentage of individuals with insurance. However, because section 1886(r)(2)(B)(i) of the Act requires that we compare the percent of individuals who are uninsured in the most recent period for which data are available with the percent of individuals who were uninsured in 2013, in the FY 2014 IPPS/LTCH PPS final rule, we

used the CBO insurance rate figure and subtracted that amount from 100 percent (that is the total population without regard to insurance status) to estimate the 2013 baseline percent of individuals without insurance. Therefore, for FYs 2014 through 2017, our estimate of the uninsurance percentage for 2013 is 18 percent.

Section 1886(r)(2)(B)(i) of the Act requires that we compare the baseline uninsurance rate to the percent of such individuals who are uninsured in the most recent period for which data are available (as so calculated). In the FY 2014, FY 2015, and FY 2016 IPPS/LTCH PPS final rules (78 FR 50634, 79 FR 50014, and 80 FR 49522, respectively), we used the same data source, CBO estimates, to calculate this percent of individuals without insurance. In response to public comments, we also agreed that we should normalize the CBO estimates, which are based on the calendar year, for the Federal fiscal years for which each calculation of Factor 2 is made (78 FR 50633). Therefore, for this FY 2017 IPPS/LTCH PPS proposed rule, we used the most recently available estimate of the uninsurance rate, which is based on the CBO’s March 2015 estimates of the effects of the Affordable Care Act on health insurance coverage (which are available at <http://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2014-04-ACAtables2.pdf>). The CBO’s March 2015 estimate of individuals under the age of 65 with insurance in CY 2016 is 89 percent. Therefore, the CBO’s most recent

estimate of the rate of uninsurance in CY 2016 is 11 percent (that is, 100 percent minus 89 percent). Similarly, the CBO’s March 2015 estimate of individuals under the age of 65 with insurance in CY 2017 is 90 percent. Therefore, the CBO’s most recent estimate of the rate of uninsurance in CY 2017 available for this proposed rule is 10 percent (that is, 100 percent minus 90 percent).

The calculation of the proposed Factor 2 for FY 2017, employing a weighted average of the CBO projections for CY 2016 and CY 2017, is as follows:

- CY 2016 rate of insurance coverage (March 2015 CBO estimate): 89 percent.
  - CY 2017 rate of insurance coverage (March 2015 CBO estimate): 90 percent.
  - FY 2016 rate of insurance coverage: (89 percent \* .25) + (90 percent \* .75) = 89.75 percent.
  - Percent of individuals without insurance for 2013 (March 2010 CBO estimate): 18 percent.
  - Percent of individuals without insurance for FY 2017 (weighted average): 10.25 percent.
- $$1 - [(0.1025 - 0.18) / 0.18] = 1 - 0.4306 = 0.5694 \text{ (56.94 percent)}$$
- $$0.5694 \text{ (56.94 percent)} - .002 \text{ (0.2 percentage points for FY 2017 under section 1886(r)(2)(B)(i) of the Act)} = 0.5674 \text{ or } 56.74 \text{ percent}$$
- $$0.5674 = \text{Factor 2}$$

Therefore, the proposed Factor 2 for FY 2017 is 56.74 percent.

The FY 2017 Proposed Uncompensated Care Amount is:  
 $\$10,670,529,595.84 \times 0.5674 =$   
 $\$6,054,458,492.68.$

FY 2017 Proposed Uncompensated Care Total Available .....	\$6,054,458,492.68
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c. Calculation of Proposed Factor 3 for FY 2017

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents the quotient of (1) 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 are available that are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (2) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment

under section 1886(r) of the Act for such period (as so estimated, based on such data).

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. In order to implement the statutory

requirements for this factor of the uncompensated care payment formula, it was necessary to determine: (1) The definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (that is, the estimated uncompensated care amount for an individual hospital) and the denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive Medicare 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 such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured.

In the course of considering how to determine Factor 3 during the rulemaking process for FY 2014, we considered defining the amount of uncompensated care for a hospital as the uncompensated care costs of each hospital and determined that Worksheet S-10 of the Medicare cost report potentially provides the most complete data regarding uncompensated care costs for Medicare hospitals. However, because of concerns regarding variations in the data reported on the Worksheet S-10 and the completeness of these data, we did not propose to use data from the Worksheet S-10 to determine the amount of uncompensated care for FY 2014, the first year this provision was in effect, or for FY 2015 and FY 2016. We instead employed the utilization of insured low income patients, defined as inpatient days of Medicaid patients plus inpatient days of Medicare SSI patients as defined in § 412.106(b)(4) and § 412.106(b)(2)(i) of the regulations, respectively, to determine Factor 3. We believed that these alternative data, which are currently reported on the Medicare cost report, would be a better proxy for the amount of uncompensated care provided by hospitals. We also indicated that we were expecting reporting on the Worksheet S-10 to improve over time and remained convinced that the Worksheet S-10 could ultimately serve as an appropriate source of more direct data regarding uncompensated care costs for purposes of determining Factor 3. As discussed in section IV.F.3.d. of the preamble of this proposed rule, since the introduction of the uncompensated care payment in FY 2014, we believe that hospitals have been submitting more accurate and consistent data through Worksheet S-10 and that it is appropriate to begin incorporating Worksheet S-10 data for purposes of calculating Factor 3 starting in FY 2018. As discussed in greater detail in section IV.F.3.d. of the preamble of this proposed rule, we are proposing a methodology and timeline for incorporating Worksheet S-10 data and invite public comments on such a proposal.

For FY 2017, we believe it remains premature to propose the use of Worksheet S-10 data for purposes of determining Factor 3 because hospitals were not on notice that Worksheet S-10 would be used for purposes of computing uncompensated care

payments prior to FY 2014, which could affect the accuracy and completeness of the information reported on Worksheet S-10. As described more fully below regarding the time period of the data used to calculate Factor 3, for FY 2017, we are using data from hospital cost reports that precede FY 2014 to determine Factor 3 of the uncompensated care payments methodology. Therefore, for FY 2017, we remain concerned about the accuracy and consistency of the data reported on Worksheet S-10 and are proposing to continue to employ the utilization of insured low-income patients (defined as inpatient days of Medicaid patients plus inpatient days of Medicare SSI patients as defined in § 412.106(b)(4) and § 412.106(b)(2)(i), respectively) to determine Factor 3. We also are proposing to continue the policies that were finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50020) to address several specific issues concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers for FY 2017 and subsequent fiscal years.

We also are proposing to make a change to the data that will be used to calculate Factor 3 for Puerto Rico hospitals. We received a comment in response to the FY 2016 IPPS/LTCH PPS proposed rule that requested CMS to create a proxy for the SSI days used in the Factor 3 calculation for Puerto Rico hospitals (80 FR 49526). Specifically, commenters were concerned that residents of Puerto Rico are not eligible for SSI benefits. Although we did not have logical outgrowth to adopt any change for FY 2016, we indicated that we planned to address this issue in the FY 2017 IPPS/LTCH PPS proposed rule if we also proposed to continue using inpatient days of Medicare SSI patients as a proxy for uncompensated care in FY 2017. Because we are proposing to continue using insured low-income patient days as a proxy for uncompensated care in FY 2017, we believe it is important to consider the commenter's request regarding the data used to calculate Factor 3 for Puerto Rico hospitals. Accordingly, we are proposing to create a proxy for SSI days for Puerto Rico hospitals for use in the Factor 3 calculation. The commenter specifically mentioned the use of inpatient days for Medicare beneficiaries receiving Medicaid as this proxy. We have examined this concept and have been unable to identify a systematic source for these data for Puerto Rico hospitals. Specifically, we note that inpatient utilization for Medicare beneficiaries

entitled to Medicaid is not reported by hospitals on the Medicare cost report. Therefore, we sought an alternative method using publicly available Medicare data for determining a proxy to account for the fact that residents of Puerto Rico are not eligible for SSI, and therefore Puerto Rico hospitals have a relatively low number of Medicare SSI days in the Factor 3 computation. We believe it is appropriate to use data from the Medicare cost report to develop a Puerto Rico Medicare SSI days proxy because they are publicly available, used for payment purposes, and subject to audit. However, we acknowledge that there are other data sources that could be included to develop such a proxy, in particular the SSI ratios posted on the Medicare DSH Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html>, and therefore are soliciting public comment on their use.

To develop a Puerto Rico Medicare SSI days proxy using data from the Medicare cost report, our Office of the Actuary examined data from 2013 cost reports and analyzed the relationship between Medicare SSI days (estimated using SSI ratios on the cost report and Medicare days from the same cost report) and Medicaid days (reported by the hospitals in accordance with § 412.106(b)(4)). Nationally, excluding Puerto Rico, the Office of the Actuary found that, on average and across States, for every 100 Medicaid inpatient days, hospitals had 14 Medicare SSI days. In other words, the relationship between Medicare SSI days and Medicaid days reported by hospitals in States, excluding Puerto Rico, was approximately 14 percent. We believe it would be appropriate to extrapolate this relationship to Puerto Rico hospitals to approximate how many patient days for these hospitals would be Medicare SSI days if Puerto Rico residents were eligible to receive SSI. Therefore, to calculate Factor 3 for FY 2017, we are proposing to use a proxy for Medicare SSI days for each Puerto Rico hospital equal to 14 percent (or 0.14) of its Medicaid days. In other words, for each Puerto Rico hospital, we would compute a value that is equal to 14 percent of its Medicaid days, where Medicaid days are determined in accordance with § 412.106(b)(4). Because this is a proposed proxy for the Puerto Rico hospital's Medicare SSI days, this value would replace whatever value would otherwise be computed for the hospital under § 412.106(b)(2)(i). Specifically, we would first remove any Medicare SSI days that a Puerto Rico hospital has from our calculation for

purposes of determining the numerator of Factor 3 for the hospital and, if the hospital is projected to be eligible for DSH payments in FY 2017, the denominator of Factor 3. Second, we would add the proxy to the hospital's Medicaid days for purposes of determining the numerator of Factor 3 for the hospital and, if the hospital is projected to be eligible for DSH payments in FY 2017, the denominator of Factor 3. We note that we continue to encourage Puerto Rico hospitals to report uncompensated care costs on Worksheet S-10 of the Medicare cost report completely and accurately in light of our proposal to begin incorporating data from Worksheet S-10 in the computation of hospitals' uncompensated care payments starting in FY 2018, as described in more detail in section IV.F.3.d. of the preamble of this proposed rule.

In summary, we are inviting public comments on these proposals to continue to use insured low-income days (that is, to use data for Medicaid and Medicare SSI patient days determined in accordance with § 412.106(b)(2)(i) and (b)(4) as a proxy for uncompensated care, as permitted by statute, including a proxy for Medicare SSI days for Puerto Rico hospitals), to determine Factor 3 for FY 2017. These proposals would be codified in our regulations at § 412.106(g)(1)(iii)(C). We also are inviting public comments on our proposal to continue the policies concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers.

As we have done for every proposed rule beginning in FY 2014, for this FY 2017 IPPS/LTCH PPS proposed rule, we are publishing on the CMS Web site a table listing Factor 3 for all hospitals that we estimate would receive empirically justified Medicare DSH payments in FY 2017 (that is, hospitals that we project would receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving a Medicare DSH payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. This table also contains a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital. Hospitals have 60 days from the date of public display of this FY 2017 IPPS/LTCH PPS proposed rule to review this table and notify CMS in writing of any inaccuracies. Comments can be submitted to the CMS inbox at

*Section3133DSH@cms.hhs.gov*. After the publication of the FY 2017 IPPS/LTCH final rule, hospitals will have until August 31, 2016, to review and submit comments on the accuracy of the table published in conjunction with the final rule. Comments can be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov* through August 31, 2016, and any changes to Factor 3 will be posted on the CMS Web site prior to October 1, 2016.

The statute also allows the Secretary the discretion to determine the time periods from which we will derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for such hospital *for a period selected by the Secretary*. Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act *for such period*. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments and for those hospitals that we do not estimate will qualify for Medicare DSH payments but that may ultimately qualify for Medicare DSH payments at the time of cost report settlement.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50018), we finalized a policy of using the most recent available full year of Medicare cost report data for determining Medicaid days and the most recently available SSI ratios to calculate Factor 3. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49528), we held constant the cost reporting years used to determine Medicaid days in the calculation of Factor 3. That is, instead of calculating the numerator and the denominator of Factor 3 for hospitals based on the most recently available full year of Medicare cost report data with respect to a Federal fiscal year, we used data from the more recent of the cost

report years (2012/2011) used to determine Medicaid days in FY 2015. We made this change in order to refine the balance between the recency and accuracy of the data used in the Factor 3 calculation. Because we make prospective determinations of the uncompensated care payment without reconciliation, we believed this change would increase the accuracy of the data used to determine Factor 3, and accordingly each eligible hospital's allocation of the overall uncompensated care amount by providing hospitals with more time to submit these data before they are used in the computation of Factor 3. As in prior years, if the more recent of the two cost reporting periods did not reflect data for a 12-month period, we used data from the earlier of the two periods so long as that earlier period reflected data for a period of 12 months. If neither of the two periods reflected 12 months, we used the period that reflected a longer amount of time. We also finalized a proposal to continue to extract Medicaid days from the most recent HCRIS database update and to use Medicare SSI days from the most recent SSI ratios available to us during the time of rulemaking to calculate Factor 3. We stated that, for subsequent fiscal years, if we propose and finalize a policy of using insured low-income days in computing Factor 3, we would continue to use the most recent HCRIS database extract at the time of the annual rulemaking cycle, and to use the subsequent year of cost reports (that is, to advance the 12-month cost reports by 1 year). In addition, for any subsequent fiscal years in which we finalize a policy to use insured low-income days to compute Factor 3, our intention would be to continue to use the most recently available SSI ratio data at the time of annual rulemaking to calculate Factor 3. We believed that it was appropriate to state our intentions regarding the specific data we would use in the event Factor 3 was determined on the basis of low-income insured days for subsequent years to provide hospitals with as much guidance as possible so they may best consider how and when to submit cost report information in the future. We noted that we would make proposals with regard to our methodology for calculating Factor 3 for subsequent fiscal years through notice-and-comment rulemaking.

Since the publication of the FY 2016 IPPS/LTCH PPS final rule, we have learned that some members of the hospital community have been disadvantaged by our policy of using only one cost reporting period to

determine their share of uncompensated care. Specifically, many hospitals have reported unpredictable swings and anomalies in their low-income insured days between cost reporting periods. These hospitals expressed concern that the use of only one cost reporting period is a poor predictor of their future uncompensated care burden and results in inadequate payments. Because the data used to make uncompensated care payment determinations are not subject to reconciliation after the end of the fiscal year, we believe that it would be appropriate to expand the time period for the data used to calculate Factor 3 from one cost reporting period to three cost reporting periods. Using data from more than one cost reporting period would mitigate undue fluctuations in the amount of uncompensated care payments to hospitals from year to year and smooth over anomalies between cost reporting periods. Moreover, this policy would have the benefit of supplementing the data of hospitals that filed cost reports that are less than 12 months, such that the basis of their uncompensated care payments and those of hospitals that filed full-year 12-month cost reports would be more equitable. We believe that computing Factor 3 using data from three cost reporting periods would best stabilize hospitals' uncompensated care payments while maintaining the recency of the data used in the Factor 3 calculation. We believe that using data from two cost reporting periods would not be as stable while using data from more than three cost reporting periods could result in using overly dated information.

Therefore, for FY 2017, we are proposing to use an average of data derived from three cost reporting periods instead of one cost reporting period to compute Factor 3. That is, we would calculate a Factor 3 for each cost reporting period and calculate the average. We would calculate their average by adding these amounts together, and dividing the sum by three, in order to calculate Factor 3 for FY 2017. Consistent with the policy adopted in the FY 2016 IPPS/LTCH PPS final rule, we would advance the most recent cost report years used to obtain Medicaid days and Medicare SSI days in FY 2017 by one year and continue to extract Medicaid days data from the most recent update of HCRIS, which for FY 2017 would be the March 2015 update of HCRIS. If the hospital does not have data for one or more of the three cost reporting periods, we compute Factor 3 for the periods available and average those. In other

words, we would divide the sum of the individual Factor 3s by the number of cost reporting periods for which there are data. If a hospital has merged, we would combine data from both hospitals for the cost reporting periods in which the merger is not reflected in the surviving hospital's cost report data to compute Factor 3 for the surviving hospital. Moreover, to further reduce undue fluctuations in a hospital's uncompensated care payments, if a hospital filed multiple cost reports beginning in the same fiscal year, we are proposing to combine data from the multiple cost reports so that a hospital may have a Factor 3 calculated using more than one cost report within a cost reporting period. We are proposing to codify these changes for FY 2017 by amending the regulations at § 412.106(g)(1)(iii)(C). We are inviting public comments on this proposal, which we describe more fully below.

For the FY 2016 IPPS/LTCH PPS final rule, we used the most recent of hospitals' 12-month 2012 or 2011 cost reports and 2012 cost report data submitted to CMS by IHS hospitals to obtain the Medicaid days to calculate Factor 3. In addition, we used Medicare SSI days from the FY 2013 SSI ratios published on the following CMS Web site to calculate Factor 3: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html>.

Under our proposal to calculate Factor 3 for FY 2017 using data from three cost reporting periods, we would use data from hospitals' FY 2011, FY 2012, and FY 2013 cost reporting periods extracted from the most recent update of the hospital cost report data in the HCRIS database and the FY 2011 and FY 2012 cost report data submitted to CMS by IHS hospitals to obtain the Medicaid days to calculate Factor 3. (We note that, starting with the FY 2013 cost reports, data for IHS hospitals will be included in the HCRIS database and will no longer be submitted separately.) In addition, to calculate Factor 3 for FY 2017, we anticipate that, under our proposal discussed earlier to use the most recent available 3 years of data on Medicare SSI utilization, we would obtain Medicare SSI days from the FY 2012, FY 2013, and FY 2014 SSI ratios (or, for Puerto Rico hospitals, substitute Medicare SSI days with a proxy as described earlier). We expect the FY 2014 SSI ratios to be published on the CMS Web site when available at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html>. Under this proposal, we would calculate Factor 3 as follows:

Step 1: Calculate Factor 3 for FY 2011 by summing a hospital's FY 2011 Medicaid days and FY 2012 SSI days and dividing by all DSH eligible hospitals' FY 2011 Medicaid days and FY 2012 SSI days.

Step 2: Calculate Factor 3 for FY 2012 by summing a hospital's FY 2012 Medicaid days and FY 2013 SSI days and dividing by all DSH eligible hospitals' FY 2012 Medicaid days and FY 2013 SSI days.

Step 3: Calculate Factor 3 for FY 2013 by summing a hospital's FY 2013 Medicaid days and FY 2014 SSI days and dividing by all DSH eligible hospitals' FY 2013 Medicaid days and FY 2014 SSI days.

Step 4: Sum the Factor 3 calculated for FY 2011, FY 2012, and FY 2013 and divide by the number of cost reporting periods with data to compute an average Factor 3.

For illustration purposes, in Table 18 associated with the FY 2017 proposed rule (which is available via the Internet on the CMS Web site), we compute Factor 3 using hospitals' FY 2011, FY 2012, and FY 2013 cost reports from the December 2015 update of HCRIS to obtain Medicaid days and the FY 2012 and FY 2013 SSI ratios published on the following CMS Web site to determine Medicare SSI days: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html>. Because the FY 2014 SSI ratios are not yet available, for purposes of this proposed rule, we computed Factor 3 for FY 2013 using FY 2013 Medicaid days and FY 2013 SSI days. However, we expect that the FY 2014 SSI ratios will be available to calculate Factor 3 for the FY 2017 IPPS/LTCH PPS final rule.

For subsequent years, we are proposing to continue to use the most recent HCRIS database extract at the time of the annual rulemaking cycle and to advance the three cost reporting periods used to determine Factor 3 by 1 year as appropriate. For instance, if we were to finalize a proposal to continue using the proxy in FY 2018, we would use FY 2012, FY 2013, and FY 2014 cost reports from the most recent available extract of HCRIS for Medicaid days and FY 2013, FY 2014, and FY 2015 SSI ratios to obtain the Medicare SSI days and follow the same methodology outlined earlier to determine Factor 3. However, as discussed earlier, we believe that it is possible to begin incorporating data from Worksheet S-10 into the computation of Factor 3 starting in FY 2018 and outline a proposal for doing so using data from three cost reporting periods in the following section.

d. Proposed Calculation of Factor 3 for FY 2018 and Subsequent Years

(1) Background

In response to commenters' requests for a timeline and transition for



introducing Worksheet S–10 data into the calculation of Factor 3, in this section, we discuss our proposed plans on how to begin incorporating hospitals' Worksheet S–10 data into the calculation of Factor 3, in order to allocate payments based on a hospital's share of overall uncompensated care costs reported on Worksheet S–10. When we first discussed using Worksheet S–10 to allocate hospitals' shares of uncompensated care costs in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we explained why we believed that it was premature to use uncompensated care costs reported on Worksheet S–10 for FY 2014. Specifically, at that time, the most recent available cost reports would have been from FYs 2010 and 2011, which were submitted on or after May 1, 2010, when the new Worksheet S–10 went into effect. We believed that “[c]oncerns 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” (78 FR 50635). In addition, we believed that it would be most 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) to determine the amount of uncompensated care for purposes of Factor 3 (78 FR 50635). At the time we issued the FY 2014 IPPS/LTCH PPS final rule, we did not believe that the available data regarding uncompensated care from Worksheet S–10 met these criteria and, therefore, we believed they were not reliable enough to use for determining FY 2014 uncompensated care payments. Accordingly, for FY 2014, we concluded that utilization of insured low-income patients would be a better proxy for the costs of hospitals in treating the uninsured. For FYs 2015, 2016, and 2017, the cost reports used for calculating uncompensated care payments (that is, FYs 2011, 2012, and 2013) were also submitted prior to the time that hospitals were on notice that Worksheet S–10 could be the data source for calculating uncompensated care payments. Therefore, we believe it is also appropriate to use proxy data to calculate Factor 3 for these years.

We believe that, for FY 2018, many of these concerns would no longer be relevant. That is, as described more fully below regarding the use of Worksheet S–10 from FY 2014, hospitals were on notice as of FY 2014 that Worksheet S–10 could eventually become the data source for CMS to calculate uncompensated care

payments. Hospitals' cost reports from FY 2014 have been publically available for some time now. Furthermore, MedPAC has provided analyses that found that current Worksheet S–10 data are a better proxy for predicting audited uncompensated care costs than Medicaid/Medicare SSI days. Specifically, MedPAC submitted a public comment discussed in the FY 2016 IPPS/LTCH PPS final rule that cited its 2007 analysis of data from the Government Accountability Office (GAO) and data from the American Hospital Association (AHA), which suggests that Medicaid days and low-income Medicare days are not a good proxy for uncompensated care costs (80 FR 49525). Analysis performed by MedPAC showed that the correlation between audited uncompensated care data from 2009 and the data from FY 2011 Worksheet S–10 was over 0.80, as compared to a correlation of approximately 0.50 for 2011 Medicare SSI and Medicaid days. MedPAC concluded that use of Worksheet S–10 data was already better than using Medicare SSI and Medicaid days as a proxy for uncompensated care costs, and that the data on Worksheet S–10 would improve over time as the data are actually used to make payments.

We also have undertaken an extensive analysis of the Worksheet S–10 data, benchmarking it against the data on uncompensated care costs reported to the Internal Revenue Service (IRS) on Form 990 by not-for-profit hospitals. The purpose of this analysis, performed by Dobson DaVanzo & Associates, LLC, under contract to CMS, was to determine if Worksheet S–10 uncompensated care data are becoming more stable over time. (This analysis, included in a report entitled “Improvements to Medicare Disproportionate Share Hospital (DSH) Payments Report: Benchmarking S–10 Data Using IRS Form 990 Data and Worksheet S–10 Trend Analyses,” is available on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html> under the Downloads section.) Although we acknowledge that the analysis was limited to not-for-profit hospitals, we believe it is relevant to our assessment of the overall quality of the data reported on Worksheet S–10. Because many not-for-profit hospitals are eligible for empirically justified Medicare DSH payments and, therefore, uncompensated care payments, they represent a suitable standard of comparison. We conducted an analysis of 2010, 2011, and 2012 Worksheet S–

10 data and IRS Form 990 data from the same years. Using IRS Form 990 data for tax years 2010, 2011, and 2012 (the latest available years) as a benchmark, we compared key variables derived from Worksheet S–10 and IRS Form 990 data, such as charity care and bad debt. The analysis was completed using data from hospitals that had completed both Worksheet S–10 and IRS Form 990 across all study years, yielding a sample of 788 not-for-profit hospitals (representing 668 unique Taxpayer Identification Numbers). Because Factor 3 is used to determine the Medicare uncompensated care payment amount for each hospital, we calculated the amounts for Factor 3 for the matched hospitals using charity care and bad debt, and compared the Factor 3 distributions calculated using data from IRS Form 990 and Worksheet S–10. Key findings indicate that the amounts for Factor 3 derived using the IRS Form 990 and Worksheet S–10 data are highly correlated. In addition, the correlation coefficient between the amounts for Factor 3 calculated from the IRS Form 990 and Worksheet S–10 has increased over time, from 0.71 in 2010 to 0.80 in 2012, suggesting some convergence in the data sources over time. This strong correlation indicates that Worksheet S–10 data would be a statistically valid source to use as part of the calculation of the uncompensated care payments in FY 2018.

Accordingly, because hospitals have been on notice since the FY 2014 rulemaking that CMS intended eventually to use Worksheet S–10 as the data source for calculating uncompensated care payments, and in light of growing evidence that Worksheet S–10 data are improving over time, we believe it would be appropriate to use Worksheet S–10 as a data source for determining Factor 3 starting in FY 2018. We discuss our proposed methodology below for how we would begin to incorporate Worksheet S–10 data into the calculation of Factor 3 of the uncompensated care payment methodology.

(2) Proposed Data Source and Time Period for FY 2018 and Subsequent Years, Including Methodology for Incorporating Worksheet S–10 Data

For the reasons explained earlier, we believe that, starting with Worksheet S–10 data reported for FY 2014, it is appropriate to begin to incorporate Worksheet S–10 data into the computation of Factor 3 and the allocation of uncompensated care payments. Specifically, we are proposing to continue to use low-income insured patient days as a proxy

for uncompensated care for cost reporting periods before FY 2014 and to use Worksheet S-10 data for FY 2014 and subsequent fiscal years to calculate uncompensated care payments for FY 2018 and subsequent fiscal years, which, when combined with our proposal to use data from three cost reporting periods to calculate Factor 3, would have the effect of transitioning toward exclusive use of Worksheet S-10 data. Under this proposed approach, we would use only Worksheet S-10 data to calculate Factor 3 for FY 2020 and subsequent fiscal years.

As discussed previously, for FY 2017, we are proposing to calculate a hospital's share of uncompensated care based on the proxy of its share of low-income insured days using a time period that includes three cost reports (that is, FY 2011, FY 2012, and FY 2013 cost reports). For the reasons we described earlier, we believe it would not be appropriate to use Worksheet S-10 data for periods prior to FY 2014. For cost reporting periods prior to FY 2014, we believe it would be appropriate to continue to use low-income insured days for the reasons we have previously described. Accordingly, with a time period that includes three cost reporting periods consisting of FY 2014 and two preceding periods, we are proposing to use Worksheet S-10 data for the FY 2014 cost reporting period and the low-income insured day proxy data for the two earlier cost reporting periods, drawing three sets of data from the most recently available HCRIS extract. That is, for FY 2018, to compute Factor 3, we are proposing to continue to advance the 3-year time period we are using by 1 year and therefore to use FY 2012, FY 2013, and FY 2014 cost report data from the most recent update of HCRIS. In addition, for FY 2018, we are proposing to use Medicaid days from FY 2012 and FY 2013 cost reports and FY 2014 and FY 2015 SSI ratios. We believe this approach would have a transitioning effect of incorporating data from Worksheet S-10 into the calculation of Factor 3 starting in FY 2018.

Consistent with our proposal to determine Factor 3 using data over a period of 3 cost reporting periods, we are proposing to calculate a Factor 3 for each of the three cost reporting periods. Specifically, we are proposing to calculate Factor 3 for FY 2018 based on an average of Factor 3 calculated using low-income insured days (proxy data) determined using Medicaid days from FY 2012 and FY 2013 cost reports and FY 2014 and FY 2015 SSI ratios, and Factor 3 calculated using uncompensated care data based on FY 2014 Worksheet S-10. We are proposing

to compute this average for each hospital by—

- Step 1: Calculating Factor 3 using the low-income insured days proxy based on FY 2012 cost report data and the FY 2014 SSI ratio;
- Step 2: Calculating Factor 3 using the insured low-income days proxy based on FY 2013 cost report data and the FY 2015 SSI ratio;
- Step 3: Calculating Factor 3 based on the FY 2014 Worksheet S-10 data; and
- Step 4: Averaging the Factor 3 values that are computed in Steps 1, 2, and 3; that is, adding the Factor 3 values from FY 2012, FY 2013, and FY 2014 for each hospital, and dividing that amount by the number of cost reporting periods with data to compute an average Factor 3.

The denominator would be the sum of the averages of the FY 2012, FY 2013, and FY 2014 amounts from Step 4 for each hospital that is estimated to be eligible for Medicare DSH payments in FY 2018. For example, assuming there are only three hospitals in the IPPS and Hospitals A and B are estimated to be eligible for Medicare DSH payments in FY 2018, while Hospital C is estimated as ineligible for Medicare DSH payments in FY 2018, each hospital's proposed share of the overall amount available for uncompensated care payments would be calculated as follows:

$$\frac{[(\text{Hospital A FY 2012 Factor 3 proxy}) + (\text{Hospital A FY 2013 Factor 3 proxy}) + (\text{Hospital A FY 2014 Factor 3 S-10})] / 3 = X}$$

$$\frac{[(\text{Hospital B FY 2012 Factor 3 proxy}) + (\text{Hospital B FY 2013 Factor 3 proxy}) + (\text{Hospital B FY 2014 Factor 3 S-10})] / 3 = Y}$$

$$\frac{[(\text{Hospital C FY 2012 Factor 3 proxy}) + (\text{Hospital C FY 2013 Factor 3 proxy}) + (\text{Hospital C FY 2014 Factor 3 S-10})] / 3 = Z}$$

Hospital A's Factor 3 or proposed share of the overall uncompensated care amount in FY 2018 would be equal to  $(X) / (X+Y)$ .

Hospital B's Factor 3 or proposed share of the overall uncompensated care amount in FY 2018 would be equal to  $(Y) / (X+Y)$ .

Hospital C's Factor 3 or proposed share of the overall uncompensated care amount in FY 2018 would be equal to  $(Z) / (X+Y)$ .

We note that, under this proposal, the methodology for calculating Factor 3 for each subsequent year would remain unchanged (such as using all cost reports for eligible hospitals that begin during the relevant cost reporting years, including cost reporting periods that are

not 12 months in length, and using a proxy for Medicare SSI days for hospitals in Puerto Rico, as described earlier for the calculation of Factor 3 for FY 2017). With regard to FY 2019 and subsequent years, we believe it would continue to be appropriate to advance the 3-year time period we are using by 1 year to compute Factor 3. Accordingly, we are proposing to use FY 2013, FY 2014, and FY 2015 cost report data from the most recent available update of HCRIS to compute Factor 3 and allocate uncompensated care payments for FY 2019. As we stated earlier, with regard to the data used to compute Factor 3, we believe that it would be appropriate to use Worksheet S-10 data from FY 2014 and subsequent periods to calculate Factor 3 and hospitals' uncompensated care payments for FY 2018 and subsequent fiscal years. Because we are proposing to use FY 2013, FY 2014, and FY 2015 cost reports to determine Factor 3 for FY 2019, we are proposing to calculate Factor 3 with a proxy calculated based on FY 2013 cost report data and FY 2015 SSI ratios and based on Worksheet S-10 uncompensated care costs from FY 2014 and FY 2015 cost reports. We are proposing to calculate Factor 3 for FY 2019 based on an average of Factor 3 amounts calculated using data from the three cost reporting periods in the manner described earlier for FY 2018. For FY 2020, we are proposing to continue to advance the three cost reports used by 1 year, and we are proposing to calculate Factor 3 using only data from the Worksheet S-10, from cost reports from FY 2014, FY 2015, and FY 2016. For FY 2021 and subsequent fiscal years, we would continue to base our estimates of the amount of hospital uncompensated care on uncompensated care costs, using three cost reporting periods from the most recently available HCRIS database, and in each fiscal year, the cost reporting periods would be advanced forward by 1 year (for example, for FY 2021, FY 2015, FY 2016, and FY 2017 cost reports would be used). We are soliciting comments on the proposed data sources, time periods, and method for calculating uncompensated care costs in FY 2018 and subsequent years.

Although our proposal for FY 2018 is to calculate Factor 3 based on an average of the Factor 3 amounts calculated using 2 years of proxy data and 1 year of data from the FY 2014 Worksheet S-10, readers may find it useful to review a file posted on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html>

under the Downloads section, which shows preliminary uncompensated care costs calculated by hospital using only Worksheet S–10 data from FY 2014 cost reports extracted from the December 2015 update of HCRIS. To the extent that hospitals have either not submitted a Worksheet S–10 with their FY 2014 cost report or find errors on a submitted Worksheet S–10, we encourage hospitals to work with MACs to complete and revise, as appropriate, their FY 2014 Worksheet S–10 as soon as possible.

(3) Proposed Definition of Uncompensated Care for FY 2018 and Subsequent Fiscal Years

In the FY 2014 IPPS/LTCH PPS rulemaking, we considered three

potential definitions of uncompensated care: Charity care; charity care + bad debt; and charity care + bad debt + Medicaid shortfalls. As we explained in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50634), we considered proposing to define the amount of uncompensated care for a hospital as the uncompensated care costs of that hospital and considered potential data sources for those costs. We examined the literature on uncompensated care and the concepts of uncompensated care used in various public and private programs, and 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 components of “uncompensated care.” Therefore, a definition that incorporates the most commonly used factors within uncompensated care as reported by stakeholders would include charity care costs and bad debt costs. Worksheet S–10 employs the definition of charity care plus non-Medicare bad debt. Specifically:

$$\begin{array}{r} \text{Cost of charity care (line 23)} \\ + \text{Cost of non-Medicare bad debt expense (line} \\ \text{29)} \\ \hline \text{Cost of non-Medicare uncompensated care (line 30)} \end{array}$$

Where:

- Cost of charity care = Cost of initial obligation of patients approved for charity care (line 21) minus partial payment by patients approved for charity care (line 22).
- Cost of non-Medicare bad debt expense = Cost to charge ratio (line 1) times non-Medicare and nonreimbursable bad debt expense (line 28).

We believe a definition that incorporates the most commonly used factors within uncompensated care as reported by stakeholders would include charity care costs and non-Medicare bad debt costs which correlates to line 30 of Worksheet S–10. Therefore, we are proposing that, for purposes of calculating Factor 3 and uncompensated care costs beginning in FY 2018, “uncompensated care” would be defined as the amount on line 30 of Worksheet S–10, which is the cost of charity care and the cost of non-Medicare bad debt.

We have received many comments and questions from hospitals and hospital associations regarding whether Medicaid payment shortfalls should be included in the definition of uncompensated care. Some stakeholders argue that such payment shortfalls are unreimbursed care for low-income patients and that the definition of uncompensated care should be consistent across Medicare and Medicaid (where the longstanding Medicaid definition of uncompensated care used for Medicaid hospital-specific DSH limits includes Medicaid payment

shortfalls). Proponents of including Medicare shortfalls advance two arguments:

- Medicaid payment shortfalls represent non-covered care; therefore, hospitals have unmet costs when treating these patients.
- The goal of Medicare DSH payments is to provide partial relief from charity care that is provided to (primarily) low-income patients. Because Medicaid enrollees are low-income persons, the underpayments associated with their care are a form of charity care.

In contrast, there are several arguments to support excluding Medicaid shortfalls from the definition of uncompensated care:

- Several government agencies and key stakeholders define uncompensated care as bad debt plus charity care, without consideration for Medicaid payment shortfalls. Specifically, MedPAC, GAO, and the AHA exclude Medicaid underpayments from the definition of uncompensated care.
- Including Medicaid shortfalls in the calculation of Medicare uncompensated care payments would represent a form of cross-subsidization from Medicare to cover Medicaid costs. In the past, CMS and MedPAC have not supported such action.

- Excluding Medicaid shortfalls from the uncompensated care definition allows Medicare DSH payments to better target hospitals with a disproportionate share of

uncompensated care for patients with no insurance coverage.

We believe these arguments for excluding Medicare shortfalls from the definition of uncompensated care are compelling. In addition, we believe that it is advisable to adopt a definition that is used by several government agencies and key stakeholders. Therefore, we are proposing that, for purposes of calculating Factor 3 and the amount of uncompensated care for a hospital beginning in FY 2018, “uncompensated care” would be defined as the cost of charity care and the cost of non-Medicare bad debt. We also are proposing to exclude Medicaid shortfalls reported on Worksheet S–10 from the definition of uncompensated care for purposes of calculating Factor 3. We are proposing to codify this definition in the regulation at § 412.106(g)(1)(iii)(C) and are inviting public comment on our proposed definition. We believe that uncompensated care costs as reported on line 30 of Worksheet S–10 best reflect our proposed definition of uncompensated care at this time, but we welcome public input on this issue.

(4) Other Methodological Considerations for FY 2018 and Subsequent Fiscal Years

In the past several years, we also have received technical comments from stakeholders regarding the timing of reporting charity care and the CCRs used in determining uncompensated care costs. We discuss these issues and

how we are proposing to incorporate them into the calculation of uncompensated care costs for purposes of determining uncompensated care payments for FY 2018 and subsequent fiscal years below.

- *Timing of Reporting Charity Care.* The determination and write-off of charity care often happens outside of the hospital fiscal year in which the services are provided. Some commenters have requested that the charity care captured on Line 20 of Worksheet S–10 include only the charity care that was written off in the particular cost reporting year, regardless of when the services were provided, consistent with charity write-offs that hospitals report in accordance with GAAP. In addition, hospitals currently report non-Medicare bad debt without regard to when the services were provided. The current Worksheet S–10 does not follow this hospital practice, and specifies that charity care provided (not necessarily written off) during the period should be recorded on Line 20. (Instructions for Line 20 of Worksheet S–10 of the Medicare cost report CMS-Form-2552–10, “Enter the total initial payment obligation of patients who are given a full or partial discount based on the hospital’s charity care criteria (measured at full charges), for care delivered *during this cost reporting period* for the entire facility . . .” (emphasis added) are included in CMS Pub. 15–2, Chapter 40, Section 4012.) While these differences in reporting should average out over time for a hospital, consistency in reporting has been requested by some stakeholders. We acknowledge these concerns, and we intend to revise the current Worksheet S–10 cost report instructions for Line 20 concerning the timing of reporting charity care, such that charity care will be reported based on date of write-off, and not based on date of service.

- *Revisions to the CCR on Line 1 of Worksheet S–10.* Many commenters have requested that the CCR used to convert charges to costs should include the cost of training residents (direct GME costs). The CCR on line 1 of Worksheet S–10 currently does not include GME costs, while the charges of teaching hospitals do include charges for GME. Thus, the CCR excludes GME costs in the cost component (or numerator), but includes GME costs in the charge component (or denominator). Commenters have requested that CMS consider using the GME costs reported in Worksheet B Part I (column 24, line 118) to capture these additional costs. Unless these GME costs are included, commenters maintained that the CCRs

of teaching hospitals are artificially low, not capturing true uncompensated care costs, thereby disadvantaging teaching hospitals in the calculation of their uncompensated care costs.

Using data from FY 2011 and 2012 cost reports, we analyzed the effect on all hospitals’ uncompensated care costs when GME costs are included in the numerator. Specifically, instead of calculating the CCRs as specified currently on line 1 of Worksheet S–10 (which pulls the CCR from Worksheet C, Part I, column 3, line 202/Worksheet C, column 8, line 202), we calculated the CCRs using Worksheet B, Part I, column 24, line 118/Worksheet C, Part I, column 8, line 202. As can be seen on the file posted on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html> under the Downloads section, and as expected, including GME costs in the numerator of the CCR results in an increased share of uncompensated care payments being made to teaching hospitals. Of the more than 1,000 teaching hospitals included in the analysis, the CCRs of 830 hospitals increase by less than 5 percent, 178 hospitals’ CCRs increase by more than 5 percent but less than 10 percent, and 71 hospitals’ CCRs increase by 10 percent or more. Thirty-three hospitals experience a decrease in their CCRs, with 32 hospitals experiencing a decrease of less than 5 percent, and 1 hospital experiencing a decrease of more than 5 percent, but less than 10 percent. As we have stated previously in response to this issue, we believe that the purpose of uncompensated care payments is to provide additional payment to hospitals for treating the uninsured, not for the costs incurred in training residents. In addition, because the CCR on line 1 of Worksheet S–10 pulled from Worksheet C, Part I, is also used in other IPPS ratesetting contexts (such as high-cost outliers and the calculation of the MS–DRG relative weights) from which it is appropriate to exclude GME because GME is paid separately from the IPPS, we hesitate to adjust the CCRs in the narrower context of calculating uncompensated care costs. Therefore, at this time, we do not believe it is appropriate to modify the calculation of the CCR on line 1 of Worksheet S–10 to include GME costs in the numerator.

- *Trims to Apply to CCRs on Line 1 of Worksheet S–10.* Commenters also have suggested that uncompensated care costs reported on Worksheet S–10 should be audited due to extremely high values consistently reported by some hospitals. We believe that, just as we apply trims to hospitals’ CCRs used to

calculate high-cost outlier payments to eliminate anomalies in payment determinations (§ 412.84(h)(3)(ii)), it is appropriate to apply statistical trims to the CCRs that are considered anomalies on Worksheet S–10, Line 1. Specifically, § 412.84(h)(3)(ii) states that the Medicare contractor may use a statewide CCR for hospitals whose operating or capital CCR is in excess of 3 standard deviations above the corresponding national geometric mean (that is, the CCR “ceiling”). This mean is recalculated annually by CMS and published in the proposed and final IPPS rules each year. To control for data anomalies, we are considering proposals which would trim hospitals’ CCRs to ensure reasonable CCRs are used to convert charges to costs for purposes of determining uncompensated care costs.

One approach we are considering as a possible proposal for FY 2018 and subsequent years would be a “double trim” methodology as follows:

#### First Trim

Step 1: Prior to calculating the statewide average CCRs, all hospitals with a CCR reported on Worksheet S–10, line 1, of greater than the corresponding CCR “ceiling” (that is, the CCR “ceiling” published in the final rule of the fiscal year that is contemporaneous to the particular Worksheet S–10 data) would be removed from the calculation. We are proposing to remove the hospitals with a CCR of greater than 3 standard deviations above the corresponding national geometric mean in order to calculate the statewide average CCRs so that these aberrant CCRs do not skew the statewide average CCR.

Step 2: Using the CCRs for the remaining hospitals in Step 1, determine the statewide average CCRs using line 1 of Worksheet S–10 for hospitals within each State (including non-DSH eligible hospitals).

Step 3: Calculate the simple average CCR (not weighted by hospital size) for each State.

Step 4: First CCR Trim—Assign the statewide average CCR calculated in Step 3 to all hospitals with a CCR greater than 3 standard deviations above the corresponding national geometric mean (that is, the CCR “ceiling”).

#### Second Trim

Step 5: Calculate the natural logarithm of the CCR for all hospitals (including those with replaced CCRs and those not eligible for Medicare DSH payments).

Step 6: Calculate the geometric mean and standard deviation of the log values

across all hospitals (including those not eligible for Medicare DSH payments).

Step 7: Second CCR Trim—Assign the statewide average CCR calculated in Step 3 to each Medicare DSH eligible hospital with a CCR greater than 3.0 standard deviations above the geometric mean. All hospitals not eligible for Medicare DSH payments should be excluded from further analyses.

Analysis we performed under this “double trim” approach was based on CCRs from FY 2012 Worksheet S–10, Line 1. Under Step 1, we used the FY 2013 CCR “ceiling” of 1.146 published in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53697). (We used the FY 2013 CCR “ceiling” because it was computed from the March 2012 update of the Provider Specific File, which contained CCRs that are relatively contemporaneous to the CCRs in the FY 2012 cost reports.) Our analysis shows that 27 hospitals would receive their respective statewide average CCR. (We refer readers to our analysis posted on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html> under the Downloads section.)

Alternatively, we are considering proposing for FY 2018 and subsequent years to use the same trim process that is used for high-cost outliers under § 412.84(i), under which we calculate separate urban and rural average CCRs for each state. Thus, the CCR of an urban or rural hospital above the applicable CCR “ceiling” for a given fiscal year would be replaced by its respective urban or rural statewide average CCR. As a reference, the FY 2013 IPPS statewide average urban and rural CCRs are in Table 8A included on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download-Items/FY2013-FinalRule-CorrectionNotice-Files.html>.

After applying the applicable trims to a hospital’s CCR as appropriate, we would calculate a hospital’s uncompensated care costs as being equal to line 30, which is the sum of line 23 and line 29, as follows:

Hospital Uncompensated Care Costs =  
line 30 (=line 23 + line 29), which is equal to—  
[[Line 1 CCR *adjusted by trim if applicable* × charity care line 20) – (Payments received for charity care line 22)]  
+  
[[Line 1 CCR *adjusted by trim if applicable* × Non-Medicare and non-reimbursable Bad Debt line 28)].

We are inviting public comments on these methodological considerations.

### *G. Hospital Readmissions Reduction Program: Proposed Updates and 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 section 1886(q) to the Act, which establishes the “Hospital Readmissions Reduction Program” effective for discharges from “applicable hospitals” beginning on or after October 1, 2012. Under the Hospital Readmissions Reduction Program, payments to applicable hospitals may be reduced to account for certain excess readmissions. We refer readers to section IV.E.1. of the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49531) for a detailed discussion and additional information on the statutory history of the Hospital Readmissions Reduction Program.

#### 2. Regulatory Background

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676), we addressed the issues of the selection of readmission measures and the calculation of the excess readmissions ratio, which will be used, in part, to calculate the readmissions adjustment factor. Specifically, in that final rule, we finalized policies that relate to the portions of section 1886(q) of the Act that address the selection of and measures for the applicable conditions, the definitions of “readmission” and “applicable period,” and the methodology for calculating the excess readmissions ratio. We also established policies with respect to measures for readmission for the applicable conditions and our methodology for calculating the excess readmissions ratio.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401), we finalized policies that relate to the portions of section 1886(q) of the Act that address the calculation of the hospital readmission payment adjustment factor and the process by which hospitals can review and correct their data. Specifically, in that final rule, we addressed the base operating DRG payment amount, aggregate payments for excess readmissions and aggregate payments for all discharges, the adjustment factor, applicable hospital, limitations on review, and reporting of hospital-specific information, including the process for hospitals to review readmission information and submit corrections. We

also established a new Subpart I under 42 CFR part 412 (§§ 412.150 through 412.154) to codify rules for implementing the Hospital Readmissions Reduction Program.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676), we finalized our policies that relate to refinement of the readmissions measures and related methodology for the current applicable conditions, expansion of the “applicable conditions” for FY 2015 and subsequent fiscal years, and clarification of the process for reporting hospital-specific information, including the opportunity to review and submit corrections. We also established policies related to the calculation of the adjustment factor for FY 2014.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50024 through 50048), we made refinements to the readmissions measures and related methodology for applicable conditions for FY 2015 and subsequent fiscal years, discussed the maintenance of technical specifications for quality measures, and described a waiver from the Hospital Readmissions Reduction Program for hospitals formerly paid under section 1814(b)(3) of the Act (§ 412.154(d)). We also specified the “applicable period” for FY 2015 and made changes to the calculation of the aggregate payments for excess readmissions so as to include two additional applicable conditions for the FY 2015 payment determination. Finally, we expanded the list of applicable conditions for the FY 2017 payment determination to include the Hospital-Level, 30-Day, All-Cause, Unplanned Readmission Following Coronary Artery Bypass Graft (CABG) Surgery measure.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49543), we made a refinement to the pneumonia readmissions measure that expanded the measure cohort for the FY 2017 payment determination and subsequent years (80 FR 49532 through 49536); adopted an extraordinary circumstance exception policy to address hospitals that experience a disaster or other extraordinary circumstance beginning in FY 2016 and for subsequent years (80 FR 49542 through 49543); specified the adjustment factor floor for FY 2016 (80 FR 49537); and specified the calculation of aggregate payments for excess readmissions for FY 2016 (80 FR 49537 through 49542).

#### 3. Proposed Policies for the FY 2017 Hospital Readmissions Reduction Program

In this proposed rule, we are proposing to—

- Clarify that public reporting of excess readmission ratios will be posted on an annual basis to the *Hospital Compare* Web site as soon as is feasible following the preview period.

- Discuss the proposed methodology to include the addition of the CABG applicable condition in the calculation of the readmissions payment adjustment for FY 2017.

#### 4. Maintenance of Technical Specifications for Quality Measures

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50039) for a discussion of the maintenance of technical specifications for quality measures for the Hospital Readmissions Reduction Program. Technical specifications of the readmission measures are provided on our Web site in the Measure Methodology Reports at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>. Additional resources about the Hospital Readmissions Reduction Program and measure technical specifications are on the QualityNet Web site on the Resources page at: <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPages%2FQnetTier3&cid=1228772412995>.

We want to remind readers that, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49532), we discussed our policies regarding the use of sociodemographic factors in quality measures. We understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well

as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

#### 5. Proposed Applicable Period for FY 2017

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. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671), we finalized our policy to use 3 years of claims data to calculate the readmission measures. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53675), we codified the definition of "applicable period" in the regulations at 42 CFR 412.152 as the 3-year period from which data are collected in order to calculate excess readmissions ratios and adjustments for the fiscal year, which includes aggregate payments for excess readmissions and aggregate payments for all discharges used in the calculation of the payment adjustment.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49537), for FY 2016, consistent with the definition specified at § 412.152, we established an "applicable period" for the Hospital Readmissions Reduction Program of the 3-year period from July 1, 2011 through June 30, 2014. In other words, the excess readmissions ratios and the payment adjustment (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2016 were determined using data from the 3-year time period of July 1, 2011 through June 30, 2014.

In this proposed rule, for FY 2017, consistent with the definition specified at § 412.152, we are proposing that the "applicable period" for the Hospital Readmissions Reduction Program will be the 3-year period from July 1, 2012 through June 30, 2015. In other words, we are proposing that the excess readmissions ratios and the payment adjustment (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2017 would be calculated using

data from the 3-year time period of July 1, 2012 through June 30, 2015.

#### 6. Proposed Calculation of Aggregate Payments for Excess Readmissions for FY 2017

Section 1886(q)(3)(B) of the Act specifies the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program. It states that the ratio is equal to 1 minus the ratio of—(i) The aggregate payments for excess readmissions and (ii) the aggregate payments for all discharges. The definition of "aggregate payments for excess readmissions" and "aggregate payments for all discharges," as well as a methodology for calculating the numerator of the ratio (aggregate payments for excess readmissions) and the denominator of the ratio (aggregate payments for all discharges) are codified at § 412.154(c)(2).

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 and § 412.152 of our regulations as, for a hospital for an applicable period, the sum, for applicable conditions of the product, for each applicable condition, of: (i) The base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the excess readmissions ratio for such hospital for such applicable period minus 1.

The excess readmissions ratio is a hospital-specific ratio calculated for each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the excess readmissions ratio as the ratio of "risk-adjusted readmissions based on actual readmissions" for an applicable hospital for each applicable condition, to the "risk-adjusted expected readmissions" for the applicable hospital for the applicable condition. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673) for additional information on the methodology for the calculation of the excess readmissions ratio. "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. We codified this definition of “aggregate payments for all discharges” under the regulations at § 412.152.

“Aggregate payments for all discharges” is the denominator of the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program.

The Hospital Readmissions Reduction Program currently includes the following five applicable conditions: acute myocardial infarction (AMI), heart failure (HF), pneumonia (PN), total hip arthroplasty/total knee arthroplasty (THA/TKA), and chronic obstructive pulmonary disease (COPD). In the FY 2015 IPPS/LTCH PPS final rule effective for FY 2017 (79 FR 50033 through 50039), we finalized the inclusion of an additional applicable condition, Hospital-Level, 30-Day, All-Cause, Unplanned Readmission Following Coronary Artery Bypass Graft (CABG) Surgery.

In this section, we discuss the proposed methodology to include this additional measure in the calculation of the readmissions payment adjustment for FY 2017. Specifically, we are proposing how the addition of CABG applicable conditions would be included in the calculation of the aggregate payments for excess readmissions (the numerator of the readmissions payment adjustment). We note that this proposal does not alter our established methodology for calculating aggregate payments for all discharges; that is, the denominator of the ratio.

When calculating the numerator (aggregate payments for excess readmissions), we determine the base operating DRG payments for the applicable period. “Aggregate payments for excess readmissions” (the numerator) is defined as the sum, for applicable conditions, of the product, for each applicable condition, of: (i) The base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the excess readmissions ratio for such hospital for such applicable period minus 1.

When determining the base operating DRG payment amount for an individual hospital for such applicable period for such condition, we use Medicare inpatient claims from the MedPAR file with discharge dates that are within the same applicable period to calculate the excess readmissions ratio. We use MedPAR claims data as our data source for determining aggregate payments for excess readmissions and aggregate

payments for all discharges, as this data source is consistent with the claims data source used in IPPS rulemaking to determine IPPS rates.

For FY 2017, we are proposing to use MedPAR claims with discharge dates that are on or after July 1, 2012, and no later than June 30, 2015, consistent with our historical use of a 3-year applicable period. Under our established methodology, 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 rule.

The FY 2012 through FY 2015 MedPAR data files can be purchased from CMS. Use of these files allows the public to verify the readmissions adjustment factors. Interested individuals may order these files through the CMS Web site at: <http://www.cms.hhs.gov/LimitedDataSets/> by clicking on MedPAR Limited Data Set (LDS)-Hospital (National). This Web page describes the files and provides directions and detailed instructions for how to order the data sets.

In this proposed rule, for FY 2017, 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, 2012, and no later than June 30, 2015. However, we note that, for the purpose of modeling the proposed FY 2017 readmissions payment adjustment factors for this proposed rule, we use excess readmissions ratios for applicable hospitals from the FY 2016 Hospital Readmissions Reduction Program applicable period. For the FY 2017 final rule, applicable hospitals will have had the opportunity to review and correct data from the proposed FY 2017 applicable period of July 1, 2012 to June 30, 2015, before they are made public under our policy regarding the preview and reporting of hospital-specific information, which we discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401).

In this proposed rule, for FY 2017, we are proposing to use MedPAR data from July 1, 2012 through June 30, 2015. Specifically, for this proposed rule, we are using the March 2013 update of the FY 2012 MedPAR file to identify claims within FY 2012 with discharge dates that are on or after July 1, 2012, the March 2014 update of the FY 2013 MedPAR file to identify claims within FY 2013, the March 2015 update of the FY 2014 MedPAR file to identify claims within FY 2014, and the December 2015

update of the FY 2015 MedPAR file to identify claims within FY 2015 with discharge dates no later than June 30, 2015. For the final rule, we are proposing to use the same MedPAR files as listed above for claims within FY 2012, FY 2013 and FY 2014, and for claims within FY 2015, we are proposing to use the March 2016 update of the FY 2015 MedPAR file.

For a discussion of how we identified the applicable conditions to calculate the aggregate payments for excess readmissions for FY 2016, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49538 through 49541). For FY 2017, with the addition of the CABG measure to the applicable conditions under the Hospital Readmissions Reduction Program, we are proposing to follow this same approach.

In this proposed rule, for FY 2017, we are proposing to continue to apply the same exclusions to the claims in the MedPAR file as we applied for FY 2016 for the AMI, HF, PN, THA/TKA, and COPD applicable conditions. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49539) for a list of these exclusions. Updates to these exclusions will be posted on the QualityNet Web site at: <http://www.QualityNet.org> > Hospital-Inpatient > Claims-Based Measures > Readmission Measures > Measure Methodology.

In addition to the exclusions described above, for FY 2017, we are proposing the following steps to identify admissions specifically for CABG for the purposes of calculating aggregate payments for excess readmissions. These exclusions were previously finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50037):

- Admissions for patients who are discharged against medical advice (excluded because providers do not have the opportunity to deliver full care and prepare the patient for discharge);
- Admissions for patients who die during the initial hospitalization (these patients are not eligible for readmission);
- Admissions for patients with subsequent qualifying CABG procedures during the measurement period (a repeat CABG procedure during the measurement period very likely represents a complication of the original CABG procedure and is a clinically more complex and higher risk surgery; therefore, we select the first CABG admission for inclusion in the measure and exclude subsequent CABG admissions from the cohort); and
- Admissions for patients without at least 30 days post-discharge enrollment in Medicare FFS (excluded because the

30-day readmission outcome cannot be assessed in this group).

As noted previously, these exclusions are consistent with our current methodology, and any updates to these exclusions will be posted on the QualityNet Web site at: <http://www.QualityNet.org> > Hospital-Inpatient > Claims-Based Measures > Readmission Measures > Measure Methodology.

Furthermore, we would only identify Medicare FFS claims that meet the criteria (that is, claims paid for under Medicare Part C, Medicare Advantage, would not be included in this calculation), consistent with the methodology to calculate excess readmissions ratios based solely on admissions and readmissions for Medicare FFS patients. Therefore, consistent with our established methodology, for FY 2017, we would exclude admissions for patients enrolled in Medicare Advantage as identified in the Medicare Enrollment Database. This policy is consistent with how admissions for Medicare Advantage patients are identified in the calculation of the excess readmissions ratios under our established methodology.

In order to identify the admissions for each applicable condition for FY 2017 to calculate the aggregate payments for excess readmissions for an individual hospital, we are proposing to identify each applicable condition, including the CABG condition, using the appropriate ICD-9-CM codes. (Although the compliance date for the ICD-10-CM and ICD-10-PCS code sets was October 1, 2015, these proposed policies apply to data submitted prior to this compliance date.) Under our existing policy, we identify eligible hospitalizations and readmissions of Medicare patients discharged from an applicable hospital having a principal diagnosis for the measured condition in an applicable period (76 FR 51669). The discharge diagnoses for each applicable condition are based on a list of specific ICD-9-CM codes for that condition. The ICD-9-CM codes for the AMI, HF, PN, THA/TKA, COPD, and CABG applicable conditions can be found on the QualityNet Web site at: <http://www.QualityNet.org> > Hospital-Inpatient > Claims-Based Measures > Readmission Measures > Measure Methodology. Consistent with our established policy (76 FR 51673 through 51676), we are proposing to use the ICD-9-CM codes to identify the applicable conditions in calculation of the excess readmissions ratios, which are provided in the measure methodology reports on the QualityNet Web site, to identify each applicable condition to calculate the aggregate

payments for the excess readmissions ratios for FY 2017. For a complete list of the ICD-9-CM codes we are proposing to use to identify the applicable conditions, we refer readers to the following tables of those reports:

- 2015 Measure Updates: AMI, HF, Pneumonia, COPD, Stroke Readmission (*AMI-Version 8.0, HF-Version 8.0, Pneumonia-Version 8.0, COPD-Version 4.0, and Stroke-Version 4.0: 2015 Condition-Specific Readmission Measures Updates and Specifications Report*)—
  - ++ Table D.1.1—ICD-9-CM Codes for AMI Cohort (page 74).
  - ++ Table D.2.1—ICD-9-CM Codes for HF Cohort (page 78).
  - ++ Table D.3.1—ICD-9-CM Codes for Pneumonia Cohort (page 82).
  - ++ Table D.4.1—ICD-9-CM Codes for COPD Cohort (page 87).
- 2015 Measure Updates: THA/TKA and CABG Readmission (*THA and/or TKA-Version 4.0, CABG-Version 2.0: 2015 Procedure-Specific Readmission Measures Updates and Specifications Report*)—
  - ++ Table D.1.1—ICD-9-CM Codes Used to Identify Eligible THA/TKA Procedures (page 45).
  - ++ Table D.2.1—ICD-9-CM Codes Used to Identify Eligible CABG Procedures (page 53).

For FY 2017, we are proposing to calculate aggregate payments for excess readmissions, using MedPAR claims from July 1, 2012 to June 30, 2015, to identify applicable conditions based on the same ICD-9-CM codes used to identify the conditions for the readmissions measures, and to apply the proposed exclusions for the types of admissions (as previously discussed). To calculate aggregate payments for excess readmissions for each hospital, we are proposing to calculate the base operating DRG payment amounts for all claims in the 3-year applicable period for each applicable condition (AMI, HF, PN, COPD, THA/TKA, and CABG) based on the claims we have identified as described above. Once we have calculated the base operating DRG amounts for all the claims for the six applicable conditions, we are proposing to sum the base operating DRG payments amounts by each condition, resulting in six summed amounts, one amount for each of the six applicable conditions. We are proposing to then multiply the amount for each condition by the respective excess readmissions ratio minus 1 when that excess readmissions ratio is greater than 1, which indicates that a hospital has performed, with respect to readmissions for that applicable condition, worse

than the average hospital with similar patients. Each product in this computation represents the payments for excess readmissions for that condition. We are proposing to then sum the resulting products which represent a hospital's proposed "aggregate payments for excess readmissions" (the numerator of the ratio). Because this calculation is performed separately for each of the six conditions, a hospital's excess readmissions ratio must be less than or equal to 1 on each measure to avoid CMS' determination that there were payments made by CMS for excess readmissions (resulting in a payment reduction under the Hospital Readmissions Reduction Program). In other words, in order to avoid a payment reduction a hospital's excess readmissions ratio must be less than or equal to 1 on each measure. We note that we are not proposing any changes to our existing methodology to calculate "aggregate payments for all discharges" (the denominator of the ratio).

Section 1886(q)(3)(A) of the Act defines the "adjustment factor" for an applicable hospital for a fiscal year as equal to the greater of (i) The ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C). Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. Specifically, it states that the ratio is equal to 1 minus the ratio of—(i) the aggregate payments for excess readmissions and (ii) the aggregate payments for all discharges. The calculation of this ratio is codified at § 412.154(c)(1) of the regulations and the floor adjustment factor is codified at § 412.154(c)(2) of the regulations. Section 1886(q)(3)(C) of the Act specifies the floor adjustment factor at 0.97 for FY 2015 and subsequent fiscal years.

Consistent with section 1886(q)(3) of the Act, codified at § 412.154(c)(2), for FY 2017, the adjustment factor is either the greater of the ratio or the floor adjustment factor of 0.97. Under our established policy, the ratio is rounded to the fourth decimal place. In other words, for FY 2017, a hospital subject to the Hospital Readmissions Reduction Program will have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

We are proposing the following methodology for FY 2017 as displayed in the chart below.



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 FORMULAS TO CALCULATE THE READMISSIONS ADJUSTMENT FACTOR FOR FY 2017
 

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Aggregate payments for excess readmissions = [sum of base operating DRG payments for AMI x (Excess Readmissions Ratio for AMI-1)] + [sum of base operating DRG payments for HF x (Excess Readmissions Ratio for HF-1)] + [sum of base operating DRG payments for PN x (Excess Readmissions Ratio for PN-1)] + [sum of base operating DRG payments for COPD] x (Excess Readmissions Ratio for COPD-1)] + [sum of base operating DRG payments for THA/TKA x (Excess Readmissions Ratio for THA/TKA-1)] + [sum of base operating DRG payments for CABG x (Excess Readmissions Ratio for CABG-1)].

\* We note that if a hospital's excess readmissions ratio for a condition is less than/equal to 1, there are no aggregate payments for excess readmissions for that condition included in this calculation.

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

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

Proposed Readmissions Adjustment Factor for FY 2017 is the higher of the ratio or 0.9700.

\* Based on claims data from July 1, 2012 to June 30, 2015 for FY 2017.

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We are inviting public comment on these proposals.

#### 7. Extraordinary Circumstance Exception Policy

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49542 through 49543) for a detailed discussion of our Extraordinary Circumstance Exception policy for the Hospital Readmissions Reduction Program.

During the review of a hospital's request for an extraordinary circumstance exception, we maintain the general principle that providing high quality of care and ensuring patient safety is of paramount importance. We intend to provide relief only for hospitals whose ability to accurately or timely submit all of their claims (from which readmission measures data are derived) has been negatively impacted as a direct result of experiencing a significant disaster or other extraordinary circumstance beyond the control of the hospital. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49542 through 49543) we finalized that the request process for an extraordinary circumstance exception begins with the submission of an extraordinary circumstance exception request form by a hospital within 90 calendar days of the natural disaster or other extraordinary circumstance. Under this policy, a hospital is able to request a Hospital Readmissions Reduction Program extraordinary circumstance exception at the same time it may request a similar exception under the Hospital IQR Program, the Hospital VBP Program, and the HAC Reduction Program. The extraordinary circumstance exception request form is available on the QualityNet Web site.

The following information is required to submit the request:

- Hospital CCN;
- Hospital name;
- Hospital Chief Executive Officer (CEO) and any other designated personnel contact information, including name, email address, telephone number, and mailing address

(must include a physical address; a post office box address is not acceptable);

- Hospital's reason for requesting an exception, including:
  - ++ CMS program name (for example, the Hospital Readmissions Reduction Program, the Hospital VBP Program, or the Hospital IQR Program);
  - ++ The measure(s) and submission quarters affected by the extraordinary circumstance that the hospital is seeking an exception for should be accompanied with the specific reasons why the exception is being sought; and
  - ++ How the extraordinary circumstance negatively impacted performance on the measure(s) for which an exception is being sought;
- Evidence of the impact of the extraordinary circumstances, including but not limited to, photographs, newspaper, and other media articles; and
- The request form must be signed by the hospital's CEO or designated non-CEO contact and submitted to CMS.

The same set of information is currently required under the Hospital IQR Program and the Hospital VBP Program on the request form from a hospital seeking an extraordinary circumstance exception with respect to these programs. The specific list of required information is subject to change from time to time at the discretion of CMS.

Following receipt of the request form, CMS will: (1) Provide a written acknowledgement of receipt of the request using the contact information provided in the request form to the CEO and any additional designated hospital personnel; and (2) provide a formal response to the CEO and any additional designated hospital personnel using the contact information provided in the request notifying them of our decision. We review each request for an extraordinary circumstance exception on a case-by-case basis at our discretion. To the extent feasible, we also review requests in conjunction with any similar requests made under other IPPS quality reporting and payment programs, such

as the Hospital IQR Program and the Hospital VBP Program.

This policy does not preclude CMS from granting extraordinary circumstance exceptions to hospitals that do not request them if we determine at our discretion that a disaster or other extraordinary circumstance has affected an entire region or locale. If CMS makes such a determination to grant an extraordinary circumstance exception to hospitals in an affected region or locale, we would convey this decision through routine communication channels to hospitals, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on the QualityNet Web site. This provision aligns with the Hospital IQR Program's extraordinary circumstances extensions or exemptions policy.

#### 8. Timeline for Public Reporting of Excess Readmission Ratios on *Hospital Compare* for the FY 2017 Payment Determination

Section 1886(q)(6) of the Act requires the Secretary to make information available to the public regarding readmission rates of each subsection (d) hospital under the program, and states that such information shall be posted on the *Hospital Compare* Internet Web site in an easily understandable format. Accordingly, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53401), we indicated that public reporting for excess readmission ratios could be available on the *Hospital Compare* Web site as early as mid-October. In this proposed rule, we are clarifying that public reporting of excess readmission ratios will be posted on an annual basis to the *Hospital Compare* Web site as soon as is feasible following the review period. This may occur as early as October, but it could occur later for a particular year in order to streamline reporting and align with other hospital quality reporting and performance programs.

*H. Hospital Value-Based Purchasing (VBP) Program: Proposed Policy Changes for the FY 2018 Program Year and Subsequent Years*

1. Background

a. Statutory Background and Overview of Past Program Years

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 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.

For more of the statutory background and descriptions of our current policies for the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547); the FY 2012 IPPS/LTCH PPS final rule (76 FR 51653 through 51660); the CY 2012 OPPI/ASC final rule with comment period (76 FR 74527 through 74547); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53567 through 53614); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50676 through 50707); the CY 2014 OPPI/ASC final rule (78 FR 75120 through 75121); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50048 through 50087); and the FY 2016 IPPS/LTCH PPS final rule with comment period (80 FR 49544 through 49570).

We also have codified certain requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.167.

b. FY 2017 Program Year 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 rule for further details.

Under section 1886(o)(7)(C)(iv) of the Act, the applicable percent for the FY 2017 program year is 2.00 percent. Using the methodology we adopted in the FY 2013 IPPS/LTCH PPS final rule

(77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2017 is approximately \$1.7 billion, based on the December 2015 update of the FY 2015 MedPAR file. We intend to update this estimate for the FY 2017 IPPS/LTCH PPS final rule, using the March 2016 update of the FY 2015 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule, 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) (77 FR 53573 through 53576). We will then calculate a value-based incentive payment adjustment factor that will be applied to the base operating DRG payment amount for each discharge occurring in FY 2017, on a per-claim basis. We are publishing proxy value-based incentive payment adjustment factors in Table 16 associated with this proposed rule (which is available via the Internet on the CMS Web site). The proxy factors are based on the TPSs from the FY 2016 program year. These FY 2016 performance scores are the most recently available performance scores that hospitals have been given the opportunity to review and correct. The slope of the linear exchange function used to calculate those proxy value-based incentive payment adjustment factors is 2.7714997322. This slope, along with the estimated amount available for value-based incentive payments, is also published in Table 16.

We intend to update this table as Table 16A in the final rule (which will be available via the Internet on the CMS Web site) to reflect changes based on the March 2016 update to the FY 2015 MedPAR file. We also intend to update the slope of the linear exchange function used to calculate those updated proxy value-based incentive payment adjustment factors. The updated proxy value-based incentive payment adjustment factors for FY 2017 will continue to be based on historic FY 2016 program year TPSs because hospitals will not have been given the opportunity to review and correct their actual TPSs for the FY 2017 program year until after the FY 2017 IPPS/LTCH PPS final rule is published. After hospitals have been given an opportunity to review and correct their actual TPSs for FY 2017, we will add Table 16B (which will be available via the Internet on the CMS Web site) to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount

available for the FY 2017 program year. We expect that Table 16B will be posted on the CMS Web site in October 2016.

2. PSI 90 Measure in the FY 2018 Program and Future Program Years

a. Proposed PSI 90 Measure Performance Period Change for the FY 2018 Program Year

We previously finalized the performance period for the PSI 90: Patient Safety for Selected Indicators (Composite Measure) (then referred to as both the “PSI-90 measure” and the “AHRQ PSI Composite Measure”) for the FY 2018 program year (78 FR 50694). We have calculated and finalized performance standards for the FY 2018 program year based on a baseline period that uses ICD-9-CM claims data. The previously finalized performance period for the FY 2018 program year runs from July 1, 2014 through June 30, 2016. Because hospitals began ICD-10-CM/PCS implementation on October 1, 2015, the performance period as currently finalized for the FY 2018 program year would necessitate using both ICD-9 and ICD-10 claims data to calculate performance standards for the PSI 90 measure.

Since the ICD-10 transition was implemented on October 1, 2015, we have been monitoring our systems, and claims are processing normally. Currently, the measure steward, AHRQ, is reviewing any potential issues related to ICD-10 conversion of coded operating room procedures ([https://www.cms.gov/icd10manual/fullcode\\_cms/P1616.html](https://www.cms.gov/icd10manual/fullcode_cms/P1616.html)), which directly impact the AHRQ PSI 90 component indicators. Nevertheless, given the complexity of converting the PSI 90 component indicators from ICD-9 to ICD-10 and considering that there are approximately 70,000<sup>22</sup> ICD-10 codes, the measure steward has recommended against combining measure performance data that use both ICD-9 and ICD-10 data at this time. In addition, to meet program requirements and implementation schedules, our system requires an ICD-10 risk-adjusted version of the AHRQ QI PSI software<sup>23</sup> by December 2016 for use in the FY 2018 payment year. At this time, a risk adjusted ICD-10 version

<sup>22</sup> International Classification of Diseases (ICD-10-CM/PCS) Transition—Background. Available at: [http://www.cdc.gov/nchs/icd/icd10cm\\_pcs\\_background.htm](http://www.cdc.gov/nchs/icd/icd10cm_pcs_background.htm).

<sup>23</sup> The AHRQ QI Software is the software used to calculate PSIs and the composite measure. More information is available at: [http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical\\_Methods\\_2015.pdf](http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical_Methods_2015.pdf).

of the PSI 90 software is not expected to be available until late CY 2017.

To address the above issues, we are proposing to shorten the performance period for the FY 2018 program year. We are proposing to use a 15-month performance period from July 1, 2014 through September 30, 2015 for the FY 2018 program year. The 15-month performance period would only apply to the FY 2018 program year and would only use ICD–9 data. For the FY 2018 program year, the performance standards that were previously established and announced in past rules would not change because they were calculated based on the baseline period of July 1, 2010 through June 30, 2012, which would remain the same. In order to align the use of this measure with other hospital quality programs, we are proposing similar modifications to the FY 2018 reporting period for the PSI 90 measure for the HAC Reduction Program, as set forth in section IV.I. of the preamble of this proposed rule, and for the Hospital IQR Program, as set forth in section VIII.A. of the preamble of this proposed rule.

We are aware that the FY 2019 program year also has a performance period that contains ICD–9 and ICD–10 data (79 FR 50072 through 50073). We will continue to review our options for calculating the performance period for the FY 2019 program year and further address this in next year’s rulemaking. Therefore, we are not proposing to make any changes to the FY 2019 program year, which runs from July 1, 2015 through June 30, 2017.

We note that in proposing a shortened performance period for the PSI 90 measure, a prior reliability analysis of the PSI 90 measure shows that the majority of hospitals attain a moderate or high level of reliability for the PSI 90 measure after a 12-month period.<sup>24</sup> We do not anticipate any delay for hospitals to review their TPS for the FY 2018 program year during the review and correction period.

Prior to deciding to propose an abbreviated performance period for the FY 2018 program year, we took several factors into consideration, including the

recommendations of the measure steward, the feasibility of using a combination of ICD–9 and ICD–10 data without the availability of the appropriate measure software, minimizing provider burden, program implementation timelines, and the reliability of using shortened performance periods, as well as the importance of continuing to publicly report this measure. We believe that using a 15-month performance period for FY 2018 best serves the need to provide important information on hospital patient safety and adverse events by allowing sufficient time to process the claims data and calculate the measures, while minimizing the reporting burden and program disruption.

Furthermore, we plan to propose to adopt the modified PSI 90 measure, which includes several substantive measure updates, for the Hospital VBP Program in subsequent rulemaking, as soon as it is feasible. We discuss this future proposed adoption in section IV.H.2.b. of the preamble of this proposed rule.

We are inviting public comments on this proposed plan to shorten the performance period for the PSI 90 measure for the FY 2018 program year.

**b. Intent To Propose in Future Rulemaking To Adopt the Modified PSI 90 Measure**

The PSI 90 measure underwent NQF maintenance review in 2014. The 2014 NQF maintenance review process has been completed and has led to several changes to the measure.<sup>25</sup> Due to statutory requirements<sup>26</sup> in the Hospital VBP Program, we would not be able to adopt the NQF-endorsed modified PSI 90 measure, now known as Patient Safety and Adverse Events Composite, until a future program year. We refer readers to section VIII.A. of the preamble of this proposed rule relating to the Hospital IQR Program for a discussion of the modified PSI 90 measure update.

**3. Retention Policy, Domain Name Proposal, and Updating of Quality Measures for the FY 2019 Program Year**

**a. Retention of Previously Adopted Hospital VBP Program Measures**

Since the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592), we have retained measures from prior program years for each successive program year, unless otherwise proposed and finalized. We are not proposing any changes to this policy.

**b. Proposed Domain Name Change**

We strive to align quality measurement and value-based purchasing programs with the NQS priority and the CMS Quality Strategy. Value-based purchasing programs in particular allow us to link the CMS Quality Strategy with Medicare payments to providers and suppliers on a national scale. Given this objective, as well as our objective to focus quality measurement on the patient-centered outcome of interest to the extent possible, we proposed to reclassify the Hospital VBP Program measures into domains based on the six priorities of the CMS Quality Strategy. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50702), we proposed 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 CMS Quality Strategy. The domain name is often shortened to say PCCEC/CC. The HCAHPS measure, which includes the care transitions measure (CTM–3), currently comprises the Patient- and Caregiver-Centered Experience of Care/ Care Coordination domain.

This domain name has proven to be long and unwieldy. Therefore, we are proposing to change the domain name from Patient- and Caregiver-Centered Experience of Care/Care Coordination to, more simply, Person and Community Engagement beginning with the FY 2019 program year. We believe that this domain name captures two goals of the CMS Quality Strategy, as shown in the table below:

Hospital VBP program domain	CMS Quality strategy goal
Safety .....	Make Care Safer by Reducing Harm Caused in the Delivery of Care.

<sup>24</sup> 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](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf).

<sup>25</sup> National Quality Forum QPS Measure Description for “Patient Safety for Selected

Indicators (modified version of PSI90) (Composite Measure)” found at <https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=321&print=0&entityTypeID=3>.

<sup>26</sup> First, section 1886(o)(2)(A) of the Act requires the Program to select measures that have been specified for the Hospital IQR Program. Second, section 1886(o)(2)(C)(i) of the Act requires the Hospital VBP Program to refrain from beginning the

performance period for a new measure until data on the measure have been posted on *Hospital Compare* for at least one year. Finally, section 1886(o)(3)(C) of the Act requires that the Hospital VBP Program establish performance standards for each measure not later than 60 days prior to the beginning of the performance period.

Hospital VBP program domain	CMS Quality strategy goal
Efficiency and Cost Reduction .....	Make Care Affordable.
Clinical Care .....	Promote Effective Prevention and Treatment of Chronic Disease.
Person and Community Engagement .....	Promote Effective Communication and Coordination of Care. Strengthen Persons and Their Families as Partners in Their Care.
N/A .....	Work with Communities to Promote Best Practices of Healthy Living.

We are inviting public comments on this proposal.

**c. Proposed Inclusion of Selected Ward Non-Intensive Care Unit (ICU) Locations in Certain NHSN Measures Beginning With the FY 2019 Program Year**

The Hospital VBP Program has used the CLABSI measure since the FY 2015 program year and has used the CAUTI measure since the FY 2016 program year. Both measures use adult, pediatric, and neonatal intensive care unit (ICU) data to calculate performance standards and measure scores (79 FR 50061). In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50787), we expanded the CAUTI and CLABSI measures to selected ward (non-ICU) settings for the Hospital IQR Program, effective January 1, 2015 (78 FR 50787). Data were first posted on *Hospital Compare* in December 2015. Selected ward (non-ICU) locations are defined as adult or pediatric medical, surgical, and medical/surgical wards (78 FR 50787; 79 FR 50061). More information on the CLABSI and CAUTI measures can be found at: [http://www.cdc.gov/nhsn/pdfs/pscmanual/4psc\\_clabscurrent.pdf](http://www.cdc.gov/nhsn/pdfs/pscmanual/4psc_clabscurrent.pdf) and [http://www.cdc.gov/nhsn/pdfs/pscmanual/7psc\\_cauticurrent.pdf](http://www.cdc.gov/nhsn/pdfs/pscmanual/7psc_cauticurrent.pdf), respectively.

In the FY 2015 and FY 2016 IPPS/LTCH PPS final rules, we discussed our

intent to consider using data from selected ward (non-ICU) locations for the Hospital VBP Program beginning in the FY 2019 program year for purposes of calculating performance standards for the CAUTI and CLABSI measures (79 FR 50061; 80 FR 49556). Several public commenters supported our proposal to include performance data from non-ICU locations in the CLABSI and CAUTI measures beginning in the FY 2019 program year, noting that CLABSI and CAUTI measures are important targets for dedicated surveillance and prevention efforts outside the ICU setting (80 FR 49566).

Based on the public comments we have received in prior rulemaking, we are proposing to include the selected ward (non-ICU) locations in the CAUTI and CLABSI measures for the Hospital VBP Program beginning with the FY 2019 program year, with a baseline period of January 1, 2015 through December 31, 2015 and a performance period of January 1, 2017 through December 31, 2017. This expansion of the CAUTI and CLABSI measures aligns with the Hospital IQR Program. It also aligns with the HAC Reduction Program, which adopted the expansion of the CAUTI and CLABSI measures beginning with its FY 2018 program

year (80 FR 49576 through 49578). This expansion is also consistent with the NQF reendorsement update to these measures, which allows application of the measures beyond ICU locations (78 FR 50787). The MAP conditionally supported the expansion of the CAUTI (MUC-S0138) and CLABSI (MUC-S0139) measures for the Hospital VBP Program on the condition of gaining experience publicly reporting these measure data, as detailed in the “Spreadsheet of MAP 2015 Final Recommendations.”<sup>27</sup> We continue to believe this expansion of the measures would allow all hospitals, including hospitals that do not have ICU locations, to use the tools and resources of the NHSN for quality improvement and public reporting efforts.

We are inviting public comments on this proposal.

**d. Summary of Previously Adopted Measures and Newly Proposed Measure Refinements for the FY 2019 Program Year**

In summary, for the FY 2019 program year, we have finalized the following measure set and are proposing the refinement of certain NHSN measures, as indicated:

**PREVIOUSLY ADOPTED MEASURES AND NEWLY PROPOSED MEASURE REFINEMENTS FOR THE FY 2019 PROGRAM YEAR ±**

Short name	Domain/Measure name	NQF #
<b>Person and Community Engagement Domain *</b>		
HCAHPS .....	HCAHPS + 3-Item Care Transition Measure .....	0166 0228
<b>Clinical Care Domain</b>		
MORT-30-AMI .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT-30-HF .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0229
MORT-30-PN .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0468
THA/TKA .....	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
<b>Safety Domain</b>		
CAUTI** .....	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138

<sup>27</sup> “Spreadsheet of MAP 2015 Final Recommendations” available at: <http://www.qualityforum.org/WorkArea/>

[linkit.aspx?LinkIdentifier=id&ItemID=78711](http://linkit.aspx?LinkIdentifier=id&ItemID=78711) and “Process and Approach for MAP Pre-Rulemaking Deliberations 2015” available at: [http://www.qualityforum.org/Publications/2015/01/Process\\_and\\_Approach\\_for\\_MAP\\_Pre-Rulemaking\\_Deliberations\\_2015.aspx](http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx).

PREVIOUSLY ADOPTED MEASURES AND NEWLY PROPOSED MEASURE REFINEMENTS FOR THE FY 2019 PROGRAM YEAR ±—Continued

Short name	Domain/Measure name	NQF #
CLABSI** .....	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS—CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia .....	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) Bacteremia Outcome Measure.	1716
CDI .....	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset <i>Clostridium difficile</i> Infection (CDI) Outcome Measure.	1717
PSI 90 .....	Patient Safety for Selected Indicators (Composite Measure) .....	0531
PC—01 .....	Elective Delivery .....	0469

**Efficiency and Cost Reduction Domain**

MSPB .....	Payment-Standardized Medicare Spending Per Beneficiary (MSBP) .....	2158
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± We are changing some of the short names for measures from previous years' rulemakings to align these names with the usage in the Hospital IQR Program, and we are changing some measure names from previous years' rulemakings to use complete NQF-endorsed measure names.

\* We are proposing, in section IV.H.3.b. of the preamble of this proposed rule, to change the name of this domain from Patient- and Caregiver-Centered Experience of Care/Care Coordination domain to Person and Community Engagement domain beginning with the FY 2019 program year.

\*\* Proposed to include selected ward (non-ICU) locations in the measure as discussed in section IV.H.3.c. of the preamble of this proposed rule.

4. Newly Proposed Measures and Measure Refinements for the FY 2021 Program Year and Subsequent Years

We consider measures for adoption based on the statutory requirements, including specification under the Hospital IQR Program, posting dates on the *Hospital Compare* Web site, and our priorities for quality improvement as outlined in the current CMS Quality Strategy, available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html>.

Due to the time necessary to adopt measures, we often adopt policies for the Hospital VBP Program well in advance of the program year for which they will be applicable (for example, 76 FR 26490 through 26547; 76 FR 51653 through 51660; 76 FR 74527 through 74547; 77 FR 53567 through 53614; 78 FR 50676 through 50707; 78 FR 75120 through 75121; 79 FR 50048 through 50087; 80 FR 49556 through 49559).

a. Condition-Specific Hospital Level, Risk-Standardized Payment Measures

Providing high-value care is an essential part of our mission to provide better health care for individuals, better health for populations, and lower healthcare costs. Our aim is to encourage higher value care where there is the most opportunity for improvement, the greatest number of patients to benefit from improvements, and the largest sample size to ensure reliability. In order to incentivize innovation that promotes high-quality care at high value, we believe it is

critical to examine measures of resource use, efficiency, and cost reduction.

In prior rules we have discussed our interest in expanding the Hospital VBP Program's Efficiency and Cost Reduction domain to include condition-specific or treatment-specific Medicare payment measures, and we have sought public comments (78 FR 50688; 79 FR 50066). In response to comments, we have stated that risk-adjusted standardized Medicare payments, viewed in light of other quality measures in a program, are an appropriate indicator of efficiency because they allow us to compare hospitals without regard to factors such as geography and teaching status. This comparison is particularly important with clinically coherent episodes because it distinguishes the degree to which practice pattern variation influences the cost of care. In addition, we have stated that the granularity of condition-specific or treatment-specific payment measures may provide specific actionable feedback to hospitals to implement targeted improvements. The observed differences in episode payments revealed by these measures may also encourage hospitals to assess local, postacute health care services (for example, SNF and home health services) to ensure that efficient services are available to all patients. Given these factors, we believe that the addition of condition-specific or treatment-specific payment measures to the Hospital VBP Program is necessary not only to facilitate a better understanding of service utilization and costs associated with conditions or treatments, but also

as an important next step in the evolution of value-based purchasing to transform how Medicare pays for care and services.

We recognize that high or low payments to hospitals are difficult to interpret in isolation. Some high payment hospitals may produce better clinical outcomes when compared with low payment hospitals, while other high payment hospitals may not produce better outcomes. For this reason, payment measure results viewed in isolation are not necessarily an indication of quality. However, by viewing such information along with quality measure results, we believe that consumers, payers, and providers would be able to better assess the value of care. We believe that adopting condition-specific or treatment-specific payment measures for the Hospital VBP Program that can be more directly paired with clinical outcome measures, aligned by comparable populations, performance periods, or risk-adjustment methodologies, help move toward achievement of this goal. We also believe that adopting condition-specific or treatment-specific payment measures would create stronger incentives for appropriately reducing practice pattern variation to achieve the aim of lowering the cost of care and creating better coordinated care for Medicare beneficiaries.

In the Hospital VBP Program, we adopted the Medicare Spending per Beneficiary (MSPB) measure beginning with the FY 2015 program year to incentivize hospitals to redesign care systems in order to provide coordinated,

high-quality, and cost-efficient care (77 FR 53590). Currently, the Hospital VBP Program measures efficiency by weighting and combining the MSPB measure with other quality measures in order to calculate each hospital's TPS. However, we have previously expressed our interest in expanding the Efficiency and Cost Reduction domain and continue to believe that additional supplemental measures would create incentives for greater coordination between hospitals and physicians to optimize the care they provide to Medicare beneficiaries (78 FR 50688; 79 FR 50066).

We believe that when examining variation in payments, an episode-of-care triggered by admission is meaningful for several reasons. First, hospitalizations represent brief periods of illness that require ongoing management post-discharge, and decisions made at the admitting hospital affect payments for care in the immediate postdischarge period. Second, attributing payments for a continuous episode-of-care to admitting hospitals may reveal variations in care decision-making and resource utilization. Third, an episode-of-care with a specified time period (30 days in the case of the measures proposed below) provides a standard observation period by which to compare all hospitals. For all of the reasons described above, we are proposing to add two condition-specific payment measures in the Hospital VBP Program that can be directly paired with existing clinical outcome measures in the program.

We are inviting public comments on the proposed measures as detailed below. We are further inviting public comment on the addition of other condition-specific or treatment-specific payment measures that are directly paired with quality measures, as well as episode-based payment measures not directly paired with quality measures, for future program years.

(1) Proposed New Measure for the FY 2021 Program Year: Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI) (NQF #2431)

Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for AMI (NQF #2431) (AMI Payment) is an NQF-endorsed measure assessing hospital risk-standardized payment associated with a 30-day episode-of-care for AMI. We adopted this measure in the Hospital IQR Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50802 through

50805). 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, using administrative claims data. In general, the measure uses the same approach to risk-adjustment as our 30-day outcome measures previously adopted for the Hospital VBP Program, including the AMI mortality measure. Initial measure data were posted on *Hospital Compare* in December 2014 and the full measure specifications are available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

AMI remains a high-volume condition that is one of the top 20 conditions contributing to Medicare costs.<sup>28</sup> There is evidence of variation in payment for AMI patients among hospitals; median 30-day risk-standardized payment (in 2013 dollars) for AMI was \$21,620 and ranged from \$12,862 to \$29,802 for the July 2011 through June 2014 reporting period in the Hospital IQR Program.<sup>29</sup> This variation in payment suggests there is opportunity for improvement.

We believe it is important to adopt the AMI Payment measure because variation in payment may reflect differences in care decision-making and resource utilization (for example, treatment, supplies, or services) for patients with AMI both during hospitalization and immediately post-discharge. The AMI Payment measure also addresses the NQS priority and CMS Quality Strategy goal to make quality care more affordable. Lastly, the AMI Payment measure is intended to be paired with our 30-day AMI mortality measure, MORT-30-AMI, thereby directly linking payment to quality by the alignment of comparable populations and risk-adjustment methodologies to facilitate the assessment of efficiency and value of care.

We are proposing the AMI Payment measure beginning with the FY 2021 program year. The AMI Payment measure would be added to the

<sup>28</sup> Torio, C.M. and Andrews, R.M., 2013. National inpatient hospital costs: The most expensive conditions by payer, 2011. In Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project Statistical Brief# 160. Available at: <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb160.pdf>.

<sup>29</sup> 2015 Condition-Specific Measure Updates and Specifications Report Hospital-Level 30-Day Risk Standardized Payment Measures. AMI, HF, PN Payment Updates (zip file). Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

Efficiency and Cost Reduction domain. The proposed measure fulfills all statutory requirements for the Hospital VBP Program based on our adoption of the measure in the Hospital IQR Program, and our posting of measure data on *Hospital Compare* for at least one year before the beginning of the performance period. The AMI Payment measure (MUC15-369) was reviewed by the MAP in December 2015 and did not receive support for adoption into the Hospital VBP Program.<sup>30</sup> The result of the MAP vote was 27 percent support, 15 percent conditional support, and 58 percent do not support. MAP members expressed concern that treatment-specific or condition-specific payment measures may overlap and double count services that are already captured in the MSPB measure. In addition, stakeholders expressed a desire to have more experience with the measure in the Hospital IQR Program to understand whether there may be unintended consequences or a need to adjust for sociodemographic status (SDS).

With respect to MAP stakeholder concerns that treatment-specific or condition-specific payment measures may overlap and double count services, we note that these measures cover topics of critical importance to quality improvement in the inpatient hospital setting. As discussed above, we selected these measures because we believe that it is appropriate to provide stronger incentives for hospitals to provide high-value and efficient care. We believe that even if some services were double counted, hospitals that offer quality service and maintain better results on the MSPB and condition-specific payment measures relative to other hospitals in the Hospital VBP Program could receive an increased benefit by performing well on both quality measures and payment measures. Furthermore, because hospitals would have bigger financial incentives, they would strive to perform better, which would lead to better quality. At the same time, however, we are proposing that the Efficiency and Cost Reduction domain remain weighted at 25 percent of the TPS even as additional payment measures may be adopted for this domain in the FY 2021 program year; therefore, the impact of poor performance on the MSPB measure or on any other particular payment measure would be reduced.

<sup>30</sup> "Spreadsheet of MAP 2015-2016 Final Recommendations" available at: <http://www.qualityforum.org/map/> and "Process and Approach for MAP Pre-Rulemaking Deliberations 2016" found at: [http://www.qualityforum.org/Publications/2016/02/Process\\_and\\_Approach\\_for\\_MAP\\_Pre-Rulemaking\\_Deliberations.aspx](http://www.qualityforum.org/Publications/2016/02/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations.aspx).

In regard to MAP stakeholder concerns regarding the need to adjust for SDS, we note that the AMI Payment measure already incorporates a risk-adjustment methodology that accounts for age and comorbidities. We understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures.

NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk-adjustment model.

Furthermore, ASPE is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

Finally, we note that some MAP members did express support for the AMI Payment measure and other condition-specific payment measures. Members agreed that the increased granularity provided by condition-specific payment measures will provide valuable feedback to hospitals for targeted improvement. A recent NQF-commissioned white paper also supports the position that cost or payment measures should be interpreted in the context of quality measures and that measures that link cost and quality are the preferred method of assessing hospital

efficiency.<sup>31</sup> We believe that the condition-specific payment measures we are proposing, which directly pair with clinical outcome measures already in the Hospital VBP Program, follow this recommended approach. Based on our analysis of the issues surrounding condition-specific payment measures, we believe that the benefits of adopting this measure into the Hospital VBP Program outweigh any potential risks; however, we remain committed to monitoring for unintended consequences.

We are inviting public comments on this proposal.

(2) Proposed New Measure for the FY 2021 Program Year: Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Heart Failure (HF) (NQF #2436)

Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for HF (NQF #2436) (HF Payment) is an NQF-endorsed measure assessing hospital risk-standardized Medicare payment associated with a 30-day episode-of-care for heart failure. The measure includes Medicare FFS patients aged 65 or older admitted for heart failure and calculates payments for these patients over a 30-day episode-of-care, beginning with the index admission, using administrative claims data. In general, the measure uses the same approach to risk-adjustment as our 30-day outcome measures previously adopted for the Hospital VBP Program, including the HF mortality measure. We adopted this measure in the Hospital IQR Program in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50231 through 50235). Initial measure data were posted on *Hospital Compare* in July 2015 and the full measure specifications are available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

Heart failure is one of the leading causes of hospitalization for Americans 65 and over and costs roughly \$34 billion annually.<sup>32 33</sup> There is evidence of variation in Medicare payments at hospitals for heart failure patients; median 30-day risk-standardized

payment (in 2013 dollars) among Medicare FFS patients aged 65 or older was \$15,139, and ranged from \$11,086 to \$21,867 for the July 2011 through June 2014 reporting period in the Hospital IQR Program.<sup>34</sup> This variation in payment suggests there is opportunity for improvement.

We believe it is important to adopt the HF Payment measure because variation in payment may reflect differences in care decision making and resource utilization (for example, treatment, supplies, or services) for patients with heart failure both during hospitalization and immediately post-discharge. The HF Payment measure also addresses the NQS priority and CMS Quality Strategy goal to make quality care more affordable. Lastly, the HF Payment measure is intended to be paired with our 30-day HF mortality measure, MORT-30-HF, thereby directly linking payment to quality by the alignment of comparable populations and risk-adjustment methodologies to facilitate the assessment of efficiency and value of care.

We are proposing the HF Payment measure beginning with the FY 2021 program year. The HF Payment measure would be added to the Efficiency and Cost Reduction domain. The measure fulfills all statutory requirements for the Hospital VBP Program based on our adoption of the measure in the Hospital IQR Program and our posting of measure data on *Hospital Compare* for at least one year before the beginning of the performance period for this measure. The HF Payment measure (MUC15-322) was reviewed by the MAP in December 2015 and did not receive support for adoption into the Hospital VBP Program, due to the same concerns that we noted in our discussion of the AMI Payment measure.<sup>35</sup> The result of the MAP vote was 27 percent support, 8 percent conditional support, and 65 percent do not support. Although the final MAP decision was “do not support,” we continue to believe that the NQF-endorsed HF Payment measure provides beneficiaries and hospitals with valuable information about relative value for an episode-of-care. We support

<sup>31</sup> Ryan A.M., Tompkins C.P. Efficiency and Value in Healthcare: Linking Cost and Quality Measures. Washington, DC: NQF; 2014.

<sup>32</sup> Russo C.A., Elixhauser, A. Hospitalizations in the Elderly Population, 2003. Agency for Healthcare Research and Quality. 2006.

<sup>33</sup> Heidenriech P.A., Trogon J.G., Khavjou O.A., Butler J, Dracup K., Ezekowitz M.D., et al. Forecasting the future of cardiovascular disease in the United States: A policy statement from the American Heart Association. *Circulation*. 2011;123(8):933-44.

<sup>34</sup> 2015 Condition-Specific Measure Updates and Specifications Report Hospital-Level 30-Day Risk-Standardized Payment Measures. AMI, HF, PN Payment Updates (zip file). Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

<sup>35</sup> “Spreadsheet of MAP 2015–2016 Final Recommendations” available at: <http://www.qualityforum.org/map/> and “Process and Approach for MAP Pre-Rulemaking Deliberations 2016” found at: [http://www.qualityforum.org/Publications/2016/02/Process\\_and\\_Approach\\_for\\_MAP\\_Pre-Rulemaking\\_Deliberations.aspx](http://www.qualityforum.org/Publications/2016/02/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations.aspx).

the HF Payment measure for the same reasons that we noted in our general discussion of condition-specific payment measures in section IV.H.4.a. of the preamble of this proposed rule and in our discussion of the AMI Payment measure in section IV.H.4.a.(2) of the preamble of this proposed rule.

We note that some MAP members did express support for the HF Payment measure and other condition-specific payment measures. Members agreed that the increased granularity provided by condition-specific payment measures will provide valuable feedback to hospitals for targeted improvement. In addition, we believe that the condition-specific payment measures we are proposing, which directly pair with clinical outcome measures already in the Hospital VBP Program, follow the recommended approach outlined in the NQF white paper on how best to measure efficiency.<sup>36</sup> Based on our analysis of the issues surrounding condition-specific payment measures, we believe that the benefits of adopting this measure into the Hospital VBP program outweigh any potential risks. However, we remain committed to monitoring for unintended consequences.

We are inviting public comments on this proposal.

### (3) Proposed Scoring Methodology for the Proposed AMI Payment and HF Payment Measures

We are proposing to score the proposed AMI Payment and HF Payment measures using the same methodology we use to score the MSPB measure, so that all measures in the Efficiency and Cost Reduction domain are scored in the same manner and have the same case minimum threshold.

For achievement points, we are proposing to calculate a spending ratio of AMI spending and HF spending for each hospital to the median AMI spending and median HF spending, respectively, across all hospitals during the performance period. We would then use each hospital's AMI spending ratio and HF spending ratio to calculate between 0 and 10 achievement points. We are proposing to set the achievement thresholds at the median AMI spending ratio and HF spending ratio across all hospitals during the performance period. We are proposing to set the benchmarks at the mean of the lowest decile of the AMI spending ratios and the HF spending ratios during the performance period. Therefore, a

hospital whose individual AMI spending or HF spending ratios fall above the achievement threshold would score 0 achievement points on the measure. A hospital for which individual AMI spending or HF spending ratios fall at or below the benchmark would score the maximum 10 achievement points on the measure. A hospital for which individual AMI spending or HF spending ratios fall at or below the achievement threshold but above the benchmark would score between 1 and 9 points according to the following formula:

$$[9 * ((\text{achievement threshold} - \text{Hospital's performance period ratio}) / (\text{achievement threshold} - \text{benchmark}))] + 0.5$$

For improvement points, we are proposing to calculate a spending ratio of AMI spending and HF spending for each hospital to the median AMI spending and median HF spending, respectively, across all hospitals during the performance period. We would then use each hospital's AMI spending ratio and the HF spending ratio to calculate between 0 and 9 improvement points by comparing each hospital's ratio to its own performance during the baseline period. We are proposing to set the improvement benchmark as the mean of the lowest decile of AMI spending and HF spending ratios across all hospitals. Therefore, a hospital for which AMI spending or HF spending ratios are equal to or higher than its baseline period ratios would score 0 improvement points on the measure. If a hospital's score on the measure during the performance period is less than its baseline period score but above the benchmark, the hospital would receive a score of 0 to 9 according to the following formula:

$$[10 * ((\text{Hospital baseline period ratio} - \text{Hospital performance period ratio}) / (\text{Hospital baseline period ratio} - \text{benchmark}))] - 0.5$$

For more information about the proposed scoring methodology for the AMI Payment and HF Payment measures, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656) and to 42 CFR 412.160 where we discuss the MSPB measure's identical scoring methodology in detail.

In order to codify this scoring methodology for the proposed payment measures, we are proposing to amend our regulations at 42 CFR 412.160 to revise the definitions of "Achievement threshold" and "Benchmark" to reflect this methodology, not just for the MSPB measure, but more generally for all

measures in the Efficiency and Cost Reduction domain.

We also considered and seek public feedback on scoring the AMI Payment and HF Payment measures using the same methodology that we use to score most other measures, including the MORT-30-AMI and MORT-30-HF measures. Under that scoring methodology, hospitals receive achievement points along an achievement range, which is a scale between the achievement threshold (the minimum level of hospital performance required to receive achievement points) and the benchmark (the mean of the top decile of hospital performance during the baseline period). A hospital receives improvement points for a measure if the hospital improves upon its measure score from its own baseline period measure score (76 FR 26514). We decided to propose the scoring methodology that more closely aligns with the MSPB measure because we believe it would be helpful for hospitals to be compared against performance standards constructed from more current performance period data, given potential changes in Medicare payment policy, changes in market forces, and changes in utilization practices.

We are inviting public comment on the proposed scoring methodology in the calculation of achievement and improvement points for the AMI Payment and HF Payment measures beginning with the FY 2021 program year.

In addition, we are considering adopting a scoring methodology for a future program year that would assess quality measures and efficiency measures in tandem to produce a composite score reflective of value. To support the goals of value-based purchasing and to provide consumers and purchasers with information about value of care provided by hospitals, we are soliciting public comments on ways we can incorporate scoring value into the Hospital VBP Program. The concept of value reflects highest quality achieved with most efficiency or least costs. Currently, the Hospital VBP Program assesses quality and efficiency separately through distinct performance measures and domains. Because each domain is weighted and combined to determine each hospital's TPS, a hospital could earn a higher payment adjustment relative to other hospitals by performing well on the quality-related domains but without performing well in the Efficiency and Cost Reduction domain, or vice versa. Without a measure or score for value that reflects both quality and costs, our ability to assess value is limited.

<sup>36</sup> Ryan A.M., Tompkins C.P. Efficiency and Value in Healthcare: Linking Cost and Quality Measures. Washington, DC: NQF; 2014.



There are various different ways value could be incorporated into the Hospital VBP Program. We are seeking public comments on two general approaches. First, specific measures of value could be developed by measure developers and incorporated into the Hospital IQR Program and then the Hospital VBP Program through the measure development process. This may be a lengthy process and will depend upon interest from measure developers. However, specific measures of value could be more interpretable by consumers, and would have rates that could be trended, benchmarked, and scored using the current Hospital VBP Program scoring methodology for assessing achievement and improvement.

A second potential approach is for the Hospital VBP Program to use the Program's scoring methodology to incorporate value based on the performance of hospitals by either: (a) Comparing scores on specific quality and cost measures; or (b) comparing quality and efficiency domain scores. First, the measure-specific approach could target high-cost, high clinical-impact conditions by pairing condition-specific quality and cost measures, such as by assessing a ratio of a hospital's reported quality over costs. A value score based on the paired clinical outcome and cost measures could be incorporated into the existing Efficiency and Cost Reduction domain (or Clinical Care or Safety domains) or included in a separate new 'Value' domain. Alternatively, a domain-based value scoring approach could be similar to the current quality/cost tiering approach in the Physician Value-Based Modifier Program, which tiers providers into nine high, average, or low cost and quality (or "value") categories to determine payments. The domain-based value score could be weighted and incorporated into the calculation of a hospital's overall Hospital VBP Program TPS along with the other existing domains, or potentially as a multiplier or adjuster to additionally reward higher value hospitals.

We welcome the public's feedback and suggestions on how to appropriately incorporate the concept of value in the Hospital VBP Program, and we are inviting specific suggestions on how to measure or score value that will be meaningful to consumers, purchasers, and providers.

b. Proposed Update to an Existing Measure for the FY 2021 Program Year: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization (NQF #0468) (Updated Cohort)

The Hospital 30-Day, All-Cause, RSMR Following Pneumonia Hospitalization (NQF #0468) (MORT-30-PN (updated cohort)) measure is a risk-adjusted, NQF-endorsed mortality measure monitoring mortality rates following PN hospitalizations. As part of the CMS measure reevaluation process, the MORT-30-PN measure underwent a substantive revision, which expanded the measure cohort to include: (1) Patients with a principal discharge diagnosis of pneumonia (the current reported cohort); (2) patients with a principal discharge diagnosis of aspiration pneumonia; and (3) patients with a principal discharge diagnosis of sepsis (excluding severe sepsis) with a secondary diagnosis of pneumonia coded as present on admission. For the purposes of describing the refinement of this measure, we note that "cohort" is defined as the hospitalizations, or "index admissions," that are included in the measure and evaluated to ascertain whether the patient subsequently died within 30 days of the index admission. This cohort is the set of hospitalizations that meet all of the inclusion and exclusion criteria.

The Hospital IQR Program adopted this measure refinement of MORT-30-PN (updated cohort) in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49653 through 49660), with initial MORT-30-PN (updated cohort) data to be posted on *Hospital Compare* on or around July 21, 2016. The MORT-30-PN (updated cohort) measure (MUC-E0468) was included on the "List of Measures Under Consideration for December 1, 2014" and received conditional support from the MAP, pending NQF endorsement of the updated cohort as detailed in the "Spreadsheet of MAP 2015 Final Recommendations."<sup>37</sup> The full measure specifications are available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

This refinement to the MORT-30-PN measure was adopted to more accurately reflect quality and outcomes for patients

with pneumonia. Recent evidence has shown an increase in the use of sepsis as a principal diagnosis code among patients hospitalized with pneumonia.<sup>38</sup> In response to this emerging evidence, we examined coding patterns across hospitals caring for Medicare patients and sought to forecast the impact of enhancing or broadening the measure cohort to include the complete patient population, at each hospital, who are receiving clinical management and treatment for pneumonia. Our findings were consistent with a published study.<sup>39</sup> That is, our results suggested that there is: (1) An increasing use of sepsis as a principal discharge diagnoses for pneumonia patients; and (2) wide variation across hospitals in the use of these codes. These published studies and CMS analyses also show that hospitals that use sepsis codes for the principal diagnosis frequently have better performance on the currently adopted MORT-30-PN measure. This coding practice improves performance on the measure because patients with greatest severity of illness (for example, those with sepsis) are systematically excluded from the measure under current measure specifications, leaving only patients with less severity of illness in the cohort.

In addition to assessing the use of the principal diagnosis codes of sepsis, we also analyzed coding patterns and the impact of expanding the pneumonia measure to include patients with the principal diagnosis of aspiration pneumonia. We noted after our analyses that aspiration pneumonia: (1) Is a common reason for pneumonia hospitalization, particularly among the elderly; (2) is currently not included in the CMS hospital outcome measure specifications for pneumonia patients; and (3) appears to be similarly subject to variation in diagnosis, documentation, and coding. The findings of published studies and CMS analyses suggested that a MORT-30-PN measure with an enhanced or broader cohort would ensure that the population of patients with pneumonia is more complete and comparable across hospitals.

We are proposing this measure refinement for the Hospital VBP

<sup>38</sup> Lindenauer P.K., Lagu T., Shieh M.S., Pekow P.S., Rothberg M.B. Association of diagnostic coding with trends in hospitalizations and mortality of patients with pneumonia, 2003-2009. *Journal of the American Medical Association*. Apr 4 2012;307(13):1405-1413.

<sup>39</sup> Rothberg M.B., Pekow P.S., Priya A., Lindenauer P.K. Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: A cross-sectional analysis. *Annals of Internal Medicine*. Mar 18 2014;160(6):380-388.

<sup>37</sup> "Spreadsheet of MAP 2015 Final Recommendations" available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711> and "Process and Approach for MAP Pre-Rulemaking Deliberations 2015" available at: [http://www.qualityforum.org/Publications/2015/01/Process\\_and\\_Approach\\_for\\_MAP\\_Pre-Rulemaking\\_Deliberations\\_2015.aspx](http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx).

Program based on our adoption of the measure refinement in the Hospital IQR Program, and our posting of measure data on *Hospital Compare* for at least 1 year prior to the start of the measure performance period. In addition, the MORT-30-PN (updated cohort) measure addresses a high volume, high cost condition. The measure aligns with the NQS priority and CMS Quality Strategy Goal of “Effective Prevention and Treatment of Chronic Disease.” Based on the continued high risk of mortality after pneumonia hospitalizations, we are proposing to add it to the Clinical Care domain beginning with the FY 2021 program year.

We are inviting public comments on this proposal.

5. Proposed New Measure for the FY 2022 Program Year: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2558)

The Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following CABG Surgery (NQF #2558) (MORT-30-CABG) measure is a risk-adjusted, NQF-endorsed mortality measure monitoring mortality rates following CABG hospitalizations. This measure includes Medicare FFS patients aged 65 or older who receive a qualifying CABG procedure and assesses hospitals’ 30-day, all-cause risk-standardized rate of mortality, beginning with the date of the index procedure. The measure is calculated using administrative claims data. In general, the measure uses the same approach to risk adjustment as our 30-day outcome measures previously adopted for the Hospital VBP Program. We adopted this measure in the Hospital IQR Program in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50224 through 50227). Initial measure data were posted on *Hospital Compare* in July 2015 and the full measure specifications are available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

CABG is a priority area because it is a common procedure associated with considerable morbidity, mortality, and healthcare spending. In the United States, over 200,000 CABG procedures are performed annually, and the majority of procedures are performed on Medicare beneficiaries.<sup>40</sup> In 2012,

Medicare beneficiaries had 121,744 CABG surgery admissions, with or without percutaneous coronary intervention or valve surgery.<sup>41</sup> CABG surgeries are costly procedures that account for a large percentage of cardiac surgeries performed nationally. For example, isolated CABG surgeries accounted for almost half (40.02 percent) of all cardiac surgery hospital admissions in Massachusetts in FY 2012.<sup>42</sup> This provides an example of the frequency in which a CABG is performed for a patient admitted for cardiac surgery. The average Medicare payment was \$32,564 for CABG without valve and \$48,461 for CABG plus valve surgeries in 2011.<sup>43</sup>

Mortality rates following CABG surgery are not insignificant and vary across hospitals. For the July 2011 through June 2014 Hospital IQR Program reporting period, the median hospital-level risk-standardized mortality rate after CABG was 3.1 percent and ranged from 1.6 percent to 9.2 percent.<sup>44</sup> Variation in mortality rates following CABG surgery can be seen not only nationally, but also within a single State. Within the State of New York, the risk-adjusted mortality rate among patients who were discharged after CABG surgery (without any other major heart surgery earlier in the hospital stay) ranged from 0.0 percent to 4.58 percent in 2011.<sup>45</sup> Variation in risk-standardized mortality rates among U.S. hospitals suggests that there is room for improvement.

An all-cause, risk-adjusted mortality measure for patients who undergo CABG surgery would provide hospitals with an incentive to reduce mortality

In Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project Statistical Brief #186. Available at: <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb186-Operating-Room-Procedures-United-States-2012.pdf>.

<sup>41</sup> Culler S.D., Kugelmass A.D., Brown P.P., Reynolds M.R., Simon A.W. Trends in coronary revascularization procedures among Medicare beneficiaries between 2008 and 2012. *Circulation*. 2014 Dec 22; CIRCULATIONAHA-114.

<sup>42</sup> Massachusetts Data Analysis Center. Adult Coronary Artery Bypass Graft Surgery in the Commonwealth of Massachusetts: Hospital and Surgeons Risk-Standardized 30-Day Mortality Rates. Fiscal Year 2012 Report. Available at: <http://www.massdac.org/wp-content/uploads/CABG-FY2012-Update.pdf>.

<sup>43</sup> Pennsylvania Health Care Cost Containment Council. Cardiac Surgery in Pennsylvania 2011–2013. Harrisburg; 2013:60.

<sup>44</sup> September 2015 Medicare Hospital Performance Report on Outcome Measures: Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/OutcomeMeasures.html>.

<sup>45</sup> New York State Department of Health. Adult Cardiac Surgery in New York State 2009–2011. Available at: [https://www.health.ny.gov/statistics/diseases/cardiovascular/heart\\_disease/docs/2009-2011\\_adult\\_cardiac\\_surgery.pdf](https://www.health.ny.gov/statistics/diseases/cardiovascular/heart_disease/docs/2009-2011_adult_cardiac_surgery.pdf).

through improved coordination of perioperative care and discharge planning. This is further supported by the success of registry-based mortality measures in reducing CABG mortality rates. For example, CABG mortality in California declined from 2.9 percent in 2003, the first year that the State implemented a mandatory CABG mortality reporting measure, to 2.1 percent in 2012.<sup>46</sup>

We are proposing the MORT-30-CABG measure for the Hospital VBP Program beginning with the FY 2022 program year because it addresses a high-volume, high-cost procedure with variation in performance. The measure also aligns with the CMS Quality Strategy Goal of Effective Prevention and Treatment of Chronic Disease. The measure fulfills all statutory requirements for the Hospital VBP Program based on our adoption of the measure in the Hospital IQR Program and our posting of measure data on *Hospital Compare* for at least one year before the beginning of the measure performance period. The MAP supported the inclusion of the MORT-30-CABG measure (MUC15-395) in the Hospital VBP Program as detailed in the “Spreadsheet of MAP 2016 Final Recommendations.”<sup>47</sup> Based on the continued high risk of mortality after CABG hospitalizations, we are proposing to add this measure to the Clinical Care domain beginning with the FY 2022 program year.

We are inviting public comments on this proposal.

6. Previously Adopted and Newly Proposed Baseline and Performance Periods

a. Background

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program that begins and ends prior to the beginning of such fiscal year. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49561 through 49562) for the baseline and performance periods for the Clinical Care, Person and Community Engagement, Safety, and

<sup>46</sup> California Office of Statewide Health Planning and Development. CABG Outcomes Reporting Program. The California Report on Coronary Artery Bypass Graft Surgery: 2003–2012 Trendlines. Available at: [http://www.oshpd.ca.gov/hid/Products/Clinical\\_Data/CABG/03-12\\_Trends.html](http://www.oshpd.ca.gov/hid/Products/Clinical_Data/CABG/03-12_Trends.html) or [http://www.oshpd.ca.gov/HID/Products/Clinical\\_Data/CABG/2012/ExecutiveSummary.pdf](http://www.oshpd.ca.gov/HID/Products/Clinical_Data/CABG/2012/ExecutiveSummary.pdf).

<sup>47</sup> “Spreadsheet of MAP 2015–2016 Final Recommendations” available at: <http://www.qualityforum.org/map/> and “Process and Approach for MAP Pre-Rulemaking Deliberations 2016” found at [http://www.qualityforum.org/Publications/2016/02/Process\\_and\\_Approach\\_for\\_MAP\\_Pre-Rulemaking\\_Deliberations.aspx](http://www.qualityforum.org/Publications/2016/02/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations.aspx).

<sup>40</sup> Fingar, K.R., Stocks, C., Weiss, A.J. and Steiner, C.A., 2014. Most frequent operating room procedures performed in U.S. hospitals, 2003–2012.

Efficiency and Cost Reduction domains that we have adopted for the FY 2018 program year. In past final rules, we have proposed and adopted a new baseline and performance period for each program year for each domain in each final rule. This year, we are proposing to adopt the following baseline and performance periods for all future program years, unless otherwise noted in future rulemaking.

b. Patient- and Caregiver-Centered Experience of Care/Care Coordination Domain (Proposed Person and Community Engagement Domain)

Since the FY 2015 program year, we have adopted a 12-month baseline period and a 12-month performance period for measures in the proposed Person and Community Engagement domain (currently referred to as the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain) (77 FR 53598; 78 FR 50692; 79 FR 50072; 80 FR 49561). We continue to believe that a 12-month period provides us sufficient data on which to score hospital performance.

Therefore, we are proposing to adopt this baseline and performance period length for the FY 2019 program year and all future program years, unless otherwise noted in future rulemaking. Therefore, for the FY 2019 program year and future program years, we are proposing to adopt a performance period that runs on the calendar year 2 years prior to the applicable program year. We are proposing to adopt a baseline period that runs on the calendar year 4 years prior to the applicable program year. Applying these proposed new policies, for the FY 2019 program year, the baseline period for the Person and Community Engagement domain (proposed name change) would run from January 1, 2015 through December 31, 2015. The performance period would run from January 1, 2017 through December 31, 2017.

c. Efficiency and Cost Reduction Domain

(1) MSPB Measure

Since the FY 2016 program year, we have adopted a 12-month baseline period and a 12-month performance period for the MSPB measure in the Efficiency and Cost Reduction domain (78 FR 50692; 79 FR 50072; 80 FR 49562). We continue to believe that a 12-month period for this measure provides sufficient data on which to score hospital performance. We are proposing to adopt this baseline and performance period length for the FY 2019 program year and all future

program years, unless otherwise noted in future rulemaking. Therefore, for the FY 2019 program year and future program years, we are proposing to adopt a performance period that runs on the calendar year 2 years prior to the applicable program year. We are proposing to adopt a baseline period that runs on the calendar year 4 years prior to the applicable program year. Applying these proposed new policies, for the FY 2019 program year, the baseline period for the MSPB measure would run from January 1, 2015 through December 31, 2015. The performance period would run from January 1, 2017 through December 31, 2017.

(2) AMI Payment and HF Payment Measures in the FY 2021 Program Year

We are also proposing to adopt the AMI Payment and HF Payment measures as two new measures for the Efficiency and Cost Reduction domain beginning in the FY 2021 program year. In order to adopt the measures as early as feasible into the Hospital VBP Program, we are proposing to adopt a 36-month baseline period and a 24-month performance period. Therefore, for the FY 2021 program year, we are proposing to adopt a 24-month performance period that runs from July 1, 2017 to June 30, 2019. We are proposing to adopt a 36-month baseline period that runs from July 1, 2012 to June 30, 2015.

We believe that using a 24-month performance period for the AMI Payment and HF Payment measures, rather than a 36-month performance period, in the FY 2021 program year would accurately assess the quality of care provided by hospitals and would not substantially change hospitals' performance on the measure. To determine the viability of using a 24-month performance period to calculate the AMI Payment and HF Payment measures' scores, we compared the measure score reliability for a 24-month and 36-month performance period. We calculated the Intraclass Correlation Coefficient (ICC) to determine the extent to which assessments of a hospital using different but randomly selected subsets of patients produces similar measures of hospital performance.<sup>48</sup> We calculated the risk-standardized payment (RSP) using a random split-sample of a 36-month performance period (we used July 1, 2012 through June 30, 2015).

For both the 36-month and the 24-month performance periods, we obtained two RSPs for each hospital,

using an entirely distinct set of patients from the same time period. If the RSPs for both the 36-month and the 24-month performance periods agree, we can demonstrate that the measure assesses the quality of the hospital rather than the types of patients treated. To calculate agreement between these measure subsets, we calculated the ICC (2,1)<sup>49</sup> for both the 36-month and 24-month performance periods.

For the AMI Payment measure, there were 459,874 index admissions and 2,342 hospitals that met the minimum threshold for reporting a measure result (at least 25 cases) in the 36-month performance period. We also calculated the RSP using a random split-sample of the combined 24-month performance period (we used July 1, 2012 through June 30, 2014). There were 309,067 index admissions and 2,141 hospitals that met the minimum threshold for reporting a measure result in the 24-month performance period.

For the 36-month performance period, the ICC for the two independent assessments of each hospital was 0.775. For the 24-month performance period, the ICC for the two independent assessments of each hospital was 0.742. Therefore, the data subsets showcase "substantial" agreement of hospital performance, and we can demonstrate that, even with a 24-month performance period, the measure assesses the quality of care provided at the hospital rather than the types of patients that these hospitals treat.<sup>50</sup>

To assess whether using 24 months of data instead of 36 months of data changes the performance in the same hospital, we compared the percent change in a hospital's predicted/expected (P/E) ratio. For hospitals that met the minimum case threshold in the 24-month performance period, the median percent change was -0.06 percent (with an interquartile range of -1.7 percent to 1.5 percent). These results suggest minimal difference in same-hospital performance when using a 24-month measurement period.

To determine the viability of using a 24-month performance period for the HF Payment measure, we assessed reliability and change in hospital performance for a 24-month and 36-month performance period using the same process as the AMI Payment measure. For the HF Payment measure, there were 877,856 index admissions and 2,981 hospitals that met the

<sup>49</sup> Shrout P., Fleiss J. Intraclass Correlations: Uses in Assessing Rater Reliability. *Psychol Bull.* Mar 1979;86(2):420-428.

<sup>50</sup> Landis J, Koch G. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* Mar 1977;33(1):159-174.

<sup>48</sup> Shrout P., Fleiss J. Intraclass Correlations: Uses in Assessing Rater Reliability. *Psychol Bull.* Mar 1979;86(2):420-428.

minimum threshold for reporting a measure result (at least 25 cases) in the 36-month performance period. We also calculated the RSP using a random split-sample of a 24-month performance period (we used July 1, 2012 through June 30, 2014). There were 580,741 index admissions and 2,883 hospitals that met the minimum threshold for reporting a measure result in the 24-month performance period.

For the 36-month performance period, the ICC for the two independent assessments of each hospital was 0.83. For the 24-month performance period, the ICC for the two independent assessments of each hospital was 0.81. Therefore, the data subsets showcase “almost perfect” agreement of hospital performance, and we can demonstrate that, even with a 24-month performance period, the measure assesses the quality of care provided at the hospital rather than the types of patients that these hospitals treat.<sup>51</sup>

To assess whether using a 24-month performance period instead of a 36-month performance period changes the performance in the same hospital, we compared the percent change in a hospital’s P/E ratio. For hospitals that met the minimum case threshold in the 24-month performance period, the median percent change for hospitals’ P/E ratio using 24-month performance periods compared with 36-month performance periods was –0.02 percent (with an interquartile range of –1.9 percent to 1.8 percent). These results suggest minimal difference in same-hospital performance when using a 24-month measurement period.

Therefore, we believe that using a 24-month performance period rather than a 36-month performance period would not substantially change hospitals’ performance on the AMI Payment and HF Payment measures. In sum, based on the analyses described earlier, we believe that using 24-month performance periods, rather than 36-month performance periods, for the initial performance period for this measure would accurately assess the quality of care provided by that hospital and would not substantially change that hospital’s performance on the measure.

### (3) AMI Payment and HF Payment Measures in the FY 2022 Program Year

For the FY 2022 program year, we are proposing to adopt a 36-month performance period and a 36-month baseline period for the AMI Payment and HF Payment measures. We have

stated in past rules that we would strive to adopt 36-month performance periods and baseline periods when possible to accommodate the time needed to process measure data and to ensure that we collect enough measure data for reliable performance scoring for all mortality measures (80 FR 49588; 79 FR 50057; 78 FR 50074). Therefore, for the FY 2022 program year, we are proposing to adopt a 36-month performance period that runs from July 1, 2017 to June 30, 2020. We are proposing to adopt a 36-month baseline period that runs from July 1, 2012 to June 30, 2015.

### d. Safety Domain

Since the FY 2016 program year, we have adopted a 12-month baseline period and 12-month performance period for all measures in the Safety domain, with the exception of the PSI 90 measure (78 FR 50692; 79 FR 50071; 80 FR 49562). We continue to believe that a 12-month period for these measures provides us sufficient data on which to score hospital performance.

Therefore, we are proposing to adopt a 12-month baseline period and a 12-month performance period for all measures in the Safety domain, with the exception of the PSI 90 measure for the FY 2019 program year and all future program years, unless otherwise noted in future rulemaking. Under this proposed policy, for the FY 2019 program year and future program years, we are proposing to adopt a performance period that runs on the calendar year 2 years prior to the applicable program year. We are proposing to adopt a baseline period that runs on the calendar year 4 years prior to the applicable program year. Applying these proposed new policies, for the FY 2019 program year, the baseline period for all measures in the Safety domain except for the PSI 90 measure would run from January 1, 2015 through December 31, 2015. The performance period would run from January 1, 2017 through December 31, 2017.

As discussed in section IV.H.2.a. of the preamble of this proposed rule, we are proposing to shorten the performance period for the PSI 90 measure in the FY 2018 program year. Under this proposal, the performance period for the PSI 90 measure for the FY 2018 program year would be July 1, 2014 through September 30, 2015. As stated earlier, the baseline period for the measure for FY 2018 that we previously established would not change.

### e. Clinical Care Domain

#### (1) Currently Adopted Measures in the Clinical Care Domain

For the FY 2019, FY 2020, and FY 2021 program years, we have adopted a 36-month baseline period and a 36-month performance period for currently adopted measures in the Clinical Care domain (78 FR 50692 through 50694; 79 FR 50073; 80 FR 49563).<sup>52</sup> For the FY 2022 program year, we are proposing to adopt a 36-month performance period and a 36-month baseline period for each of the other measures in the Clinical Care domain, the MORT–30–AMI, MORT–30–HF, and MORT–30–COPD measures, as well as the newly proposed MORT–30–CABG measure. The performance periods for these measures would run for 36-months from July 1, 2017 through June 30, 2020. The baseline period would run from July 1, 2012 through June 30, 2015. We are proposing that the THA/TKA measure performance period would run from April 1, 2017 through March 31, 2020. The baseline period would run from April 1, 2012 through March 31, 2015.

#### (2) MORT–30–PN (Updated Cohort) Measure in the FY 2021 Program Year

In order to adopt the newly proposed MORT–30–PN (updated cohort) measure into the Hospital VBP Program as early as feasible, we are proposing to adopt a 36-month baseline period and a 23-month performance period for the FY 2021 program year. We are proposing to adopt a 23-month performance period because the measure will not be posted on *Hospital Compare* for one year until July 21, 2017. We are proposing to begin the performance period on August 1, 2017 to accommodate this statutory requirement.

We believe that using a 23-month performance period for the MORT–30–PN (updated cohort) measure, rather than a 36-month performance period, in the FY 2021 program year would accurately assess the quality of care provided by hospitals and would not substantially change hospitals’ performance on the measure. To determine the viability of using a 23-month performance period to calculate the MORT–30–PN (updated cohort)

<sup>52</sup> The currently adopted measures in the Clinical Care domain include: MORT–30–AMI, MORT–30–HF, MORT–30–PN, and THA/TKA. The THA/TKA measure was added for the FY 2019 program year with a 36-month baseline period and a 24-month performance period (79 FR 50072), but we have since adopted 36-month baseline and performance periods for the FY 2021 program year (80 FR 49563). We intend to continue having 36-month baseline periods and 36-month performance periods in the future for all measures in the Clinical Care domain.

<sup>51</sup> Landis J., Koch G. The Measurement of Observer Agreement for Categorical Data. *Biometrics*. Mar 1997 1977;33(1):159–174.

measure score, we compared the measure score reliability for a 23-month and a 36-month performance period. We calculated the ICC to determine the extent to which assessments of a hospital using different but randomly selected subsets of patients produces similar measures of hospital performance. We calculated the RSMR using a random split-sample of the combined 36-month performance period (we used July 1, 2012 through June 30, 2015). There were 1,292,701 index admissions and 3,103 hospitals that met the minimum threshold for reporting a measure result (at least 25 cases) in the 36-month performance period. We also calculated the RSMR using a random split-sample of the combined 23-month performance period (we used July 1, 2012 through May 31, 2014). There were 798,746 index admissions and 3,043 hospitals that met the minimum threshold for reporting a measure result in the 23-month performance period.

For both the 36-month data and the 23-month performance periods, we obtained two RSMRs for each hospital, using an entirely distinct set of patients from the same time period. If the RSMRs for both the 36-month subset and the 23-month performance periods agree, we can demonstrate that the measure assesses the quality of the hospital rather than the types of patients treated. To calculate agreement between these measure subsets, we calculated the ICC for both the 36-month and 23-month performance periods.

For the 36-month data performance period, the agreement between the two independent assessments of each hospital was 0.69. For the 23-month

data performance period, the agreement between the two independent assessments of each hospital was 0.58. Therefore, the data subsets showcase “moderate” agreement of hospital performance, and we can demonstrate that, even with a 23-month performance period, the measure moderately assesses the quality of care provided at the hospital rather than the types of patients that these hospitals treat.<sup>53</sup>

To assess whether using a 23-month performance period instead of a 36-month performance period changes the performance in the same hospital, we compared the percent change in a hospital’s RSMR. In some cases, changing the performance period from 36 months to 23 months resulted in hospitals failing to meet the case threshold to report a measure score; therefore, these hospitals were removed from the measure. For the remaining hospitals, the median percent change was 1.52 percent (with an interquartile range of 2.32 percent to 5.32 percent). These results suggest minimal difference in hospital performance when using a 23-month measurement period.

Therefore, we believe that using 23 months of data rather than 36 months of data would not substantially change hospitals’ performance on this measure. In summary, based on the analyses further described earlier, we believe that using 23 months of data, rather than 36 months of data, for the initial performance period for this measure would, with moderate accuracy, assess the quality of care provided by that hospital. In addition, it would not

substantially change that hospital’s performance on the measure.

Further, adopting this proposed performance period would enable us to include the updated measure cohort in the FY 2021 Hospital VBP Program, which would ensure that MORT–30–PN more accurately reflects quality and outcomes for patients with pneumonia. Therefore, for the MORT–30–PN (updated cohort) measure, we are proposing a performance period that would run from August 1, 2017 through June 30, 2019 for the FY 2021 program year. The baseline period would run from July 1, 2012 through June 30, 2015.

(3) MORT–30–PN (Updated Cohort) Measure in the FY 2022 Program Year

For the FY 2022 program year and subsequent years, we are proposing to lengthen the MORT–30–PN (updated cohort) performance period to nearly a 36-month performance period (35 months) and continue to adopt a 36-month baseline period. For the FY 2022 program year, we are proposing a performance period that would run from August 1, 2017 through June 30, 2020. The baseline period would run from July 1, 2012 through June 30, 2015.

f. Summary of Previously Adopted and Newly Proposed Baseline and Performance Periods for the FY 2018, FY 2019, FY 2020, FY 2021, and FY 2022 Program Years

The tables below summarize the baseline and performance periods that we are proposing to adopt (and include previously adopted baseline and performance periods for the Clinical Care domain).

NEWLY PROPOSED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2018 PROGRAM YEAR

Domain	Baseline period	Performance period
Safety: • PSI 90* .....	July 1, 2010–June 30, 2012 .....	July 1, 2014–September 30, 2015.

\* We are proposing to shorten the performance period for the PSI 90 measure for the FY 2018 program year as discussed in section IV.H.2.a. of the preamble of this proposed rule.

PREVIOUSLY ADOPTED AND NEWLY PROPOSED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2019 PROGRAM YEAR

Domain	Baseline period	Performance period
Person and Community Engagement: • HCAHPS + 3-Item Care Transition .....	January 1, 2015–December 31, 2015.	January 1, 2017–December 31, 2017.
Clinical Care: • Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–PN)* .....	• July 1, 2009–June 30, 2012 .....	• July 1, 2014–June 30, 2017.
• THA/TKA* .....	• July 1, 2010–June 30, 2013 .....	• January 1, 2015–June 30, 2017.
Safety:		

<sup>53</sup> Landis J, Koch G. The Measurement of Observer Agreement for Categorical Data. *Biometrics*. Mar 1997; 53(1):159–174.

PREVIOUSLY ADOPTED AND NEWLY PROPOSED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2019 PROGRAM YEAR—Continued

Domain	Baseline period	Performance period
<ul style="list-style-type: none"> <li>PSI 90 .....</li> <li>PC-01 and NHSN measures (CAUTI, CLABSI, SSI, CDI, MRSA).</li> </ul>	<ul style="list-style-type: none"> <li>July 1, 2011–June 30, 2013 .....</li> <li>January 1, 2015–December 31, 2015.</li> </ul>	<ul style="list-style-type: none"> <li>July 1, 2015 through June 30, 2017.</li> <li>January 1, 2017–December 31, 2017.</li> </ul>
Efficiency and Cost Reduction: <ul style="list-style-type: none"> <li>MSPB .....</li> </ul>	January 1, 2015–December 31, 2015.	January 1, 2017–December 31, 2017.

\* Previously adopted baseline and performance periods that remain unchanged (80 FR 49562 through 49563).

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2020 PROGRAM YEAR

Domain	Baseline period	Performance period
Clinical Care: <ul style="list-style-type: none"> <li>Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-PN) * .....</li> <li>THA/TKA * .....</li> </ul>	<ul style="list-style-type: none"> <li>July 1, 2010–June 30, 2013 .....</li> <li>July 1, 2010–June 30, 2013 .....</li> </ul>	<ul style="list-style-type: none"> <li>July 1, 2015–June 30, 2018.</li> <li>July 1, 2015–June 30, 2018.</li> </ul>
Safety: <ul style="list-style-type: none"> <li>PSI 90 * .....</li> </ul>	July 1, 2012–June 30, 2014 .....	July 1, 2016–June 30, 2018.

\* Previously adopted baseline and performance periods that remain unchanged (80 FR 49562 through 49563).

PREVIOUSLY ADOPTED AND NEWLY PROPOSED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2021 PROGRAM YEAR

Domain	Baseline period	Performance period
Clinical Care: <ul style="list-style-type: none"> <li>Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD) * .....</li> <li>THA/TKA * .....</li> <li>MORT-30-PN (updated cohort) .....</li> </ul>	<ul style="list-style-type: none"> <li>July 1, 2011–June 30, 2014 .....</li> <li>April 1, 2011–March 31, 2014 ...</li> <li>July 1, 2012–June 30, 2015 .....</li> </ul>	<ul style="list-style-type: none"> <li>July 1, 2016–June 30, 2019.</li> <li>April 1, 2016–March 31, 2019.</li> <li>August 1, 2017–June 30, 2019.</li> </ul>
Efficiency and Cost Reduction: <ul style="list-style-type: none"> <li>Payment (AMI Payment and HF Payment) .....</li> </ul>	July 1, 2012 to June 30, 2015 .....	July 1, 2017 to June 30, 2019.

\* Previously adopted baseline and performance periods that remain unchanged (80 FR 49562 through 49563).

NEWLY PROPOSED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2022 PROGRAM YEAR

Domain	Baseline period	Performance period
Clinical Care: <ul style="list-style-type: none"> <li>Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG).</li> <li>THA/TKA .....</li> <li>MORT-30-PN (updated cohort) .....</li> </ul>	<ul style="list-style-type: none"> <li>July 1, 2012–June 30, 2015 .....</li> <li>April 1, 2012–March 31, 2015 ...</li> <li>July 1, 2012–June 30, 2015 .....</li> </ul>	<ul style="list-style-type: none"> <li>July 1, 2017–June 30, 2020.</li> <li>April 1, 2017–March 31, 2020.</li> <li>August 1, 2017–June 30, 2020.</li> </ul>
Efficiency and Cost Reduction: <ul style="list-style-type: none"> <li>Payment (AMI Payment, HF Payment) .....</li> </ul>	July 1, 2012–June 30, 2015 .....	July 1, 2017–June 30, 2020.

We are inviting public comments on these proposals.

7. Proposed Immediate Jeopardy Policy Changes

a. Background

Section 1886(o)(1)(C) of the Act states that the Hospital VBP Program applies to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Act), but excludes from the definition of the term “hospital” with respect to a fiscal year a hospital “for which, during the performance period for such fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients.”

In 42 CFR 412.160 of our Hospital VBP Program regulations, we define the term “Cited for deficiencies that pose immediate jeopardy” to mean that “during the applicable performance period, the Secretary cited the hospital for immediate jeopardy on at least two surveys using the Form CMS-2567, Statement of Deficiencies and Plan of Correction” (OMB Control Number 0938-0391). In 42 CFR 412.160, we also adopted the definition of “immediate jeopardy” found in 42 CFR 489.3 of our regulations.

Our current interpretation of the Hospital VBP Program’s statute is that a hospital cited for deficiencies that pose immediate jeopardy during any part of

the finalized performance period for the applicable program year does not meet the definition of the term “hospital,” and thus is excluded from the Hospital VBP Program for that program year. Because the Hospital VBP Program currently uses measures with 12-month, 24-month, and 36-month performance periods, a hospital’s immediate jeopardy citations could result in its exclusion from the Hospital VBP Program for multiple program years.

b. Proposed Increase of Immediate Jeopardy Citations From Two to Three Surveys

We are proposing to amend our regulations at 42 CFR 412.160 to change the definition of the term “Cited for

deficiencies that pose immediate jeopardy” to increase the number of surveys on which a hospital must be cited for immediate jeopardy before being excluded from the Hospital VBP Program pursuant to section 1886(o)(1)(C) of the Act from two to three. In other words, we are proposing that a hospital must be cited on Form CMS–2567, Statement of Deficiencies and Plan of Correction, for immediate jeopardy on at least three surveys during the performance period in order to meet the standard for exclusion from the Hospital VBP Program under section 1886(o)(1)(C)(ii)(II) of the Act. Beginning on the effective date of this change, hospitals would be excluded from the Hospital VBP Program for a particular program year if, during the performance period for that fiscal year, they were cited three times by the Secretary for deficiencies that pose immediate jeopardy to the health or safety of patients.

Because we expect that the effective date of this change will be October 1, 2016 (the first day of the FY 2017 Hospital VBP program year), only hospitals that were cited three times during the performance period that applies to the FY 2017 program year would be excluded from the Hospital VBP Program. Hospitals that were, as of October 1, 2016, cited for immediate jeopardy on two surveys during the performance period that applies to the FY 2017 program year could participate in the Hospital VBP Program for the FY 2017 program year.

We are proposing this change to be more inclusive of hospitals and to ensure that we are not too quickly excluding a hospital from participation in the Hospital VBP Program. After reviewing the survey and certification data, we have determined that limiting exclusion to those hospitals that have been cited for immediate jeopardy three or more times during the applicable performance period, rather than two, would continue to appropriately exclude hospitals that are cited for jeopardizing patient safety while allowing hospitals with a lower number of immediate jeopardy citations over significantly longer performance periods to continue to participate in the Hospital VBP Program. Many immediate jeopardy citations involve systematic issues of patient safety, and we believe that hospitals that are, during the performance period, cited by the Secretary for three or more deficiencies that pose immediate jeopardy should be excluded from the Hospital VBP Program. This proposal would ensure that we continue to assure high quality

care while being as inclusive of hospitals as possible.

#### c. EMTALA-Related Immediate Jeopardy Citations

Hospitals are often alerted to immediate jeopardy situations when a surveyor or team of surveyors is in the process of conducting a survey of compliance with the Medicare condition of participation (CoPs) at the hospital and identifies those situations that immediately jeopardize the health and safety of patients (77 FR 53610). Following the survey, the Form CMS–2567, Statement of Deficiencies and Plan of Correction, is sent to the hospital, which contains the survey findings, including any immediate jeopardy situations. For EMTALA-related immediate jeopardy situations, however, the CMS Regional Office determines whether there was an EMTALA violation after reviewing the State Survey Agency’s report and an expert physician review’s findings, and, if so, whether it constituted an immediate jeopardy (77 FR 53610). The CMS Regional Office then sends the Form CMS–2567 to the hospital. Currently, the Automated Survey Processing Environment (ASPEN) system, an electronic system that supports our survey and certification activity, catalogs deficient practices (that is, noncompliance) identified during a survey and generates the Form CMS–2567 that is sent to the hospital after the survey. The survey end date generated in ASPEN is currently used as the date for assignment of the immediate jeopardy citation to a particular performance period (77 FR 53613). The additional processes for EMTALA-related immediate jeopardy citations can result in significant notification delays to hospitals (often several months or longer).

In the case of EMTALA-related immediate jeopardy citations only, we are proposing to change our policy regarding the date of the immediate jeopardy citation for possible exclusion from the Hospital VBP Program from the survey end date generated in ASPEN to the date of CMS’ final issuance of Form CMS–2567 to the hospital. Form CMS–2567 is not considered final until it is transmitted to the healthcare facility, either by the State Survey Agency, or, in all EMTALA cases and certain other cases, by the CMS Regional Office. The date of final issuance is also tracked in ASPEN. The date the Form CMS–2567 is sent by the CMS Regional Office to the hospital (via mail, electronically, or both) is the date of final issuance recorded in ASPEN. We believe this change would accurately reflect the date

hospitals receive official notification of an immediate jeopardy citation based on the issuance date of Form CMS–2567 as this date will be weeks, if not months, after the survey end date. Hospitals may continue to receive preliminary notice during the onsite EMTALA investigation survey that they may receive an immediate jeopardy citation based on survey findings. However, because the decision-making responsibility in EMTALA investigations always rests with the CMS Regional Office, the final determination and notification of immediate jeopardy citations will always be delayed. The Form CMS–2567 constitutes the official notice to a healthcare facility of the survey findings.

Finally, in instances where one onsite hospital survey resulted in both hospital CoP immediate jeopardy citation(s) as well as EMTALA immediate jeopardy citation(s), the survey end date would be the default date for potential exclusion from the Hospital VBP Program. CMS recognizes the hospital will receive notification of the EMTALA immediate jeopardy citation(s) at a later date than the CoP immediate jeopardy citation(s). However, because the hospital was notified of the CoP immediate jeopardy citation(s) at the time of survey, this date will be used for the performance period for potential exclusion from the Hospital VBP Program. Even though there may be separate enforcement actions resulting from the same survey, we will consider each Form CMS–2567 with immediate jeopardy findings to be one citation for purposes of the Hospital VBP Program (77 FR 53613).

We are proposing to revise our regulations at 42 CFR 412.160 to reflect the above proposal and specify use of the date of CMS’ issuance of Form CMS–2567 to the hospital for EMTALA immediate jeopardy citation(s). We also specify that in instances where one onsite hospital survey resulted in both hospital CoP immediate jeopardy citation(s) as well as EMTALA immediate jeopardy citation(s), the survey end date would be the date we use for purposes of assigning the citations to a performance period to determine whether the hospital should be excluded from the Hospital VBP Program for a particular program year.

We are inviting public comments on this proposal.

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 no later than 60 days before the beginning of the performance period for the fiscal year involved, as required by section 1886(o)(3)(C) of the Act. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for further discussion of achievement and improvement standards under the Hospital VBP Program.

In addition, when establishing the performance standards, section 1886(o)(3)(D) of the Act requires the Secretary to consider appropriate factors, such as: (1) Practical experience with the measures, including whether a significant proportion of hospitals failed to meet the performance standard

during previous performance periods; (2) historical performance standards; (3) improvement rates; and (4) the opportunity for continued improvement.

We refer readers to the FY 2013, FY 2014, and FY 2015 IPPS/LTCH PPS final rules (77 FR 53604 through 53605; 78 FR 50694 through 50698; and 79 FR 50077 through 50079) for a more detailed discussion of the general scoring methodology used in the Hospital VBP Program.

We note that the performance standards for the following measures are calculated with lower values representing better performance:

- The NHSN measures (the CLABSI, CAUTI, CDI and MRSA Bacteremia measures);
- The PSI 90 measure;
- The Colon and Abdominal Hysterectomy SSI measure;
- The THA/TKA measure;
- The MSPB measure; and,
- The proposed HF and AMI Payment measures.

This distinction is made in contrast to other measures for which higher values indicate better performance. As discussed further in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50684), the performance standards for the Colon

and Abdominal Hysterectomy SSI measure are computed separately for each procedure stratum, and we will first award achievement and improvement points to each stratum separately, then compute a weighted average of the points awarded to each stratum by predicted infections.

b. Previously Adopted and Newly Proposed Performance Standards for the FY 2019 Program Year

In accordance with our finalized methodology for calculating performance standards (discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513)), we are proposing to adopt the following additional performance standards for the FY 2019 program year. We note that the numerical values for the performance standards displayed below represent estimates based on the most recently available data, and we intend to update the numerical values in the FY 2017 IPPS/LTCH PPS final rule. We note further that the MSPB measure's performance standards are based on performance period data; therefore, we are unable to provide numerical equivalents for the standards at this time.

PREVIOUSLY ADOPTED AND NEWLY PROPOSED PERFORMANCE STANDARDS FOR THE FY 2019 PROGRAM YEAR: SAFETY, CLINICAL CARE, AND EFFICIENCY AND COST REDUCTION MEASURES

Measure ID	Description	Achievement threshold	Benchmark
<b>Safety Measures</b>			
CAUTI*	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0.438000	0.000000.
CLABSI*	National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure.	0.465000	0.000000.
CDI*	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset <i>Clostridium difficile</i> Infection (CDI) Outcome Measure.	0.823000	0.013000.
MRSA Bacteremia*	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) Bacteremia Outcome Measure.	0.812000	0.000000.
PSI 90*±	Patient Safety for Selected Indicators (Composite Measure).	0.084034	0.058946.
Colon and Abdominal Hysterectomy SSI*	American College of Surgeons—Centers for Disease Control and Prevention (ACS—CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	• 0.856000 • 0.682000	• 0.000000. • 0.000000.
PC-01	Elective Delivery	0.012384	0.000000.
<b>Clinical Care Measures</b>			
MORT-30-AMI±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0.850671	0.873263.
MORT-30-HF±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0.883472	0.908094.
MORT-30-PN±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0.882334	0.907906.



PREVIOUSLY ADOPTED AND NEWLY PROPOSED PERFORMANCE STANDARDS FOR THE FY 2019 PROGRAM YEAR: SAFETY, CLINICAL CARE, AND EFFICIENCY AND COST REDUCTION MEASURES—Continued

Measure ID	Description	Achievement threshold	Benchmark
THA/TKA *±	Hospital-Level Risk-Standardized Complication Rate (RSMR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	0.032229	0.023178.
<b>Efficiency and Cost Reduction Measure</b>			
MSPB *	Payment-Standardized Medicare Spending Per Beneficiary (MSPB).	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.

\* Lower values represent better performance.  
 ±Previously adopted performance standards.

In the past, we have used the “normalization” approach to scoring the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain (which we are proposing, in section IV.H.3.b. of the preamble of this proposed rule, to rename the Person and Community Engagement domain beginning with the FY 2019 program year). The nine dimensions of the HCAHPS measure, one of which is the CTM–3 measure, are calculated to generate the HCAHPS Base Score. For

each of the nine dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) are calculated, the larger of which is summed across the nine dimensions to create a prenormalized HCAHPS Base Score (0–90 points). The prenormalized HCAHPS Base Score is then multiplied by 8/9 (0.88888) and rounded according to standard rules (values of 0.5 and higher are rounded up, values below 0.5 are rounded down) to create the normalized HCAHPS Base Score. Each

of the nine dimensions is of equal weight, so that the normalized HCAHPS Base Score would range from 0 to 80 points. HCAHPS Consistency Points are then calculated and range from 0 to 20 points. The Consistency Points now consider scores across all nine of the Person and Community Engagement dimensions. The final element of the scoring formula is the sum of the HCAHPS Base Score and the HCAHPS Consistency Points and will range from 0 to 100 points.

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2019 PROGRAM YEAR PROPOSED PERSON AND COMMUNITY ENGAGEMENT DOMAIN \*

HCAHPS survey dimension	Floor (percent)	Achievement threshold (percent)	Benchmark (percent)
Communication with Nurses	16.32	78.59	86.81
Communication with Doctors	22.56	80.33	88.55
Responsiveness of Hospital Staff	21.91	65.00	80.27
Pain Management	16.02	70.04	78.60
Communication about Medicines	6.19	63.18	73.51
Hospital Cleanliness & Quietness	13.78	65.64	79.12
Discharge Information	60.58	86.88	91.73
3-Item Care Transition	4.26	51.35	62.73
Overall Rating of Hospital	30.52	70.58	84.68

\* We are proposing, in section IV.H.3.b. of the preamble of this proposed rule, to change the name of this domain from Patient- and Caregiver-Centered Experience of Care/Care Coordination domain to Person and Community Engagement domain beginning with the FY 2019 program year.

We are inviting public comments on these proposed performance standards.

c. Previously Adopted Performance Standards for Certain Measures for the FY 2020 Program Year

As discussed above, we have adopted certain Safety and Clinical Care domain measures for future program years in order to ensure that we can adopt

baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50062 through 50065), we adopted the PSI 90 measure in the Safety domain and the THA/TKA measure in the Clinical Care domain for the FY 2019 program year and subsequent years. In the FY 2015

IPPS/LTCH PPS final rule (79 FR 50077), we adopted performance standards for the MORT–30–AMI, MORT–30–HF, MORT–30–PN, and THA/TKA for the FY 2020 program year. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49566), we also adopted performance standards for the PSI–90 measure.

## PREVIOUSLY ADOPTED PERFORMANCE STANDARDS FOR CERTAIN CLINICAL CARE DOMAIN AND SAFETY DOMAIN MEASURES FOR THE FY 2020 PROGRAM YEAR

Measure ID	Description	Achievement threshold	Benchmark
<b>Safety Domain</b>			
PSI 90*	Patient Safety for Selected Indicators (Composite Measure)	0.778761	0.545903
<b>Clinical Care Domain</b>			
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0.853715	0.875869
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0.881090	0.906068
MORT-30-PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0.882266	0.909532
THA/TKA*	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	0.032229	0.023178

\* Lower values represent better performance.

d. Previously Adopted and Newly Proposed Performance Standards for Certain Measures for the FY 2021 Program Year

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49567), we adopted

performance standards for the FY 2021 program year for the Clinical Care domain measures (THA/TKA, MORT-30-HF, MORT-30-AMI, MORT-30-PN, and MORT-30-COPD). We are proposing to add two measures, AMI

Payment and HF Payment, beginning with the FY 2021 program year. The previously adopted and proposed performance standards for these measures are set out below.

## PREVIOUSLY ADOPTED AND PROPOSED PERFORMANCE STANDARDS FOR THE FY 2021 PROGRAM YEAR

Measure ID	Description	Achievement threshold	Benchmark
<b>Clinical Care Measures</b>			
MORT-30-AMI <sup>±</sup>	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0.860355	0.879714.
MORT-30-HF <sup>±</sup>	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0.883803	0.906144.
MORT-30-PN <sup>±</sup>	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0.886443	0.910670.
MORT-30-COPD <sup>±</sup>	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	0.923253	0.938664.
THA/TKA <sup>*±</sup>	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	0.030890	0.022304.
<b>Efficiency and Cost Reduction Measures</b>			
AMI Payment <sup>*#</sup>	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.
HF Payment <sup>*#</sup>	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure (HF).	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.

<sup>±</sup>Previously adopted performance standards.

\* Lower values represent better performance.  
 # Proposed to be scored the same as the MSPB measure.

e. Proposed Performance Standards for Certain Measures for the FY 2022 Program Year  
 We are proposing the following performance standards for the FY 2022 program year for the Clinical Care domain measures (THA/TKA, MORT-30-AMI, MORT-30-HF, MORT-30-PN, MORT-30-COPD), and the newly proposed MORT-30-CABG:

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2022 PROGRAM YEAR

Measure ID	Description	Achievement threshold	Benchmark
<b>Clinical Care Measures</b>			
MORT-30-AMI .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following (RSMR) Acute Myocardial Infarction (AMI) Hospitalization.	0.861793 .....	0.881305.
MORT-30-HF .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0.879869 .....	0.903608.
MORT-30-PN (updated cohort).	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0.836122 .....	0.870506.
MORT-30-COPD .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	0.920058 .....	0.936962.
THA/TKA * .....	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	0.029599 .....	0.021439.
MORT-30-CABG .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery.	0.979000 .....	0.968210.
<b>Efficiency and Cost Reduction Measures</b>			
AMI Payment* # .....	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period..	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period
HF Payment* # .....	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure (HF).	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.

\* Lower values represent better performance.  
 # Proposed to be scored the same as the MSPB measure.

9. FY 2019 Program Year Scoring Methodology

a. Domain Weighting for the FY 2019 Program Year for Hospitals That Receive a Score on All Domains

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49568 through 49570), we adopted equal weight of 25 percent for each of the four domains in the FY 2018 program year for hospitals that receive a score in all domains. For the FY 2019 program year, we are not proposing to remove any measures nor are we proposing to adopt any new measures. We also are not proposing any changes to the domain weighting for hospitals receiving a score on all domains.

**DOMAIN WEIGHTS FOR THE FY 2019 PROGRAM YEAR FOR HOSPITALS RECEIVING A SCORE ON ALL DOMAINS**

Domain	Weight (percent)
Safety .....	25
Clinical Care .....	25
Efficiency and Cost Reduction ...	25
Person and Community Engagement* .....	25

\*We are proposing, in section IV.H.3.b. of the preamble of this proposed rule, to change the name of this domain from Patient- and Caregiver-Centered Experience of Care/Care Coordination domain to Person and Community Engagement domain beginning with the FY 2019 program year.

b. Domain Weighting for the FY 2019 Program Year and Future Years for Hospitals Receiving Scores on Fewer Than Four Domains

For the FY 2017 program year and subsequent years, we adopted a policy that hospitals must receive domain scores on at least three of four quality domains in order to receive a TPS, and hospitals with sufficient data on only three domains will have their TPSs proportionately reweighted (79 FR 50084 through 50085).

Under these policies, in order to receive a TPS for the FY 2019 program year and future years:

- Hospitals must report a minimum number of 100 completed HCAHPS surveys for a hospital to receive a Patient- and Caregiver-Centered Experience of Care/Care Coordination domain (which we are proposing, in

section IV.H.3.b. of the preamble of this proposed rule, to rename the Person and Community Engagement domain beginning with the FY 2019 program year) score.

- Hospitals must meet the requirements to receive a MSPB measure score in order to receive an Efficiency and Cost Reduction domain score. Hospitals must report a minimum number of 25 cases for the MSPB measure (77 FR 53609 through 53610) and the AMI Payment and HF Payment measures.

- Hospitals must receive a minimum of two measure scores within the Clinical Care domain. Hospitals must report a minimum number of 25 cases for each of the mortality measures (77 FR 53609 through 53610) and the THA/TKA measure.

- Hospitals must receive a minimum of three measure scores within the Safety domain.

++ Hospitals must report a minimum of three cases for any underlying indicator for the PSI 90 measure based on AHRQ's measure methodology (77 FR 53608 through 53609).

++ Hospitals must report a minimum of one predicted infection for NHSN-based surveillance measures based on CDC's minimum case criteria (77 FR 53608 through 53609).

++ Hospitals must report a minimum of 10 cases for the PC-01 measure (76 FR 26530).

We are not proposing any changes to the minimum numbers of domain scores, cases, and measures outlined above. We continue to believe that these requirements appropriately balance our desire to enable as many hospitals as possible to participate in the Hospital VBP Program and the need for TPSs to be sufficiently reliable to provide meaningful distinctions between hospitals' performance on quality measures. We are inviting public comment on these proposals.

*I. Proposed Changes to the Hospital-Acquired Condition (HAC) Reduction Program*

1. Background

We refer readers to section V.I.1.a. of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program.

2. Statutory Basis for the HAC Reduction Program

We refer readers to section V.I.2. of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50708 through 50709) for a detailed discussion of the statutory basis of the HAC Reduction Program.

3. Overview of Previous HAC Reduction Program Rulemaking

For a further description of our policies for the HAC Reduction Program, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570 through 49581). These policies describe the general framework for implementation of the HAC Reduction Program, including: (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.

We also have codified certain requirements of the HAC Reduction Program at 42 CFR 412.170 through 412.172.

4. Implementation of the HAC Reduction Program for FY 2017

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized the following measures for use in the FY 2017 Program: PSI 90 measure for Domain 1 and the CDC NHSN measures CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI for Domain 2. We are not proposing any changes to this measure set for FY 2017. We also are not proposing to make any changes to the measures that were finalized for use in the FY 2016 program (CAUTI, CLABSI, and Colon and Abdominal Hysterectomy SSI) or the FY 2017 program (MRSA Bacteremia and CDI).

**HAC REDUCTION PROGRAM MEASURES FOR FY 2017**

Short name	Measure name	NQF No.
<b>Domain 1</b>		
PSI 90 .....	Patient Safety for Selected Indicators (Composite Measure) .....	0531

HAC REDUCTION PROGRAM MEASURES FOR FY 2017—Continued

Short name	Measure name	NQF No.
<b>Domain 2</b>		
CAUTI .....	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CDI .....	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset <i>Clostridium difficile</i> Infection (CDI) Outcome Measure.	1717
CLABSI .....	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention (ACS—CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia .....	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) Bacteremia Outcome Measure.	1716

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized and codified at 42 CFR 412.170 a 2-year period during which we collect data used to calculate the Total HAC Score. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49574), we finalized the 2-year time periods for the calculation of HAC Reduction Program measure results for FY 2017. For the Domain 1 measure (PSI 90 measure), we will use the 24-month period from July 1, 2013 through June 30, 2015. The claims for all Medicare FFS beneficiaries discharged during this period would be included in the calculations of measure results for FY 2017. For the CDC NHSN measures previously finalized for use in the FY 2017 HAC Reduction Program (CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI), we will use data from CYs 2014 and 2015.

We also note that we anticipate we will be able to provide hospitals with their confidential hospital-specific reports and discharge level information used in the calculation of their FY 2017 Total HAC Score in late summer 2016 via the QualityNet Secure Portal.<sup>54</sup> In order to access their hospital-specific reports, hospitals must register for a QualityNet Secure Portal account. We did not make any changes to the review and correction policies for FY 2016. Hospitals have a period of 30 days after the information is posted to the QualityNet Secure Portal to review and submit corrections for the calculation of their HAC Reduction Program measure scores, domain scores, and Total HAC Score for the fiscal year.

For FY 2017, we are proposing updates to the following HAC Reduction Program policies: (1) A proposal to clarify data requirements for Domain 1;

and (2) a proposal for NHSN CDC HAI data submission requirements for newly opened hospitals. Each policy is described in more detail below.

a. Clarification of Complete Data Requirements for Domain 1

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50722) we finalized our plan to use the PSI 90 measure for Domain 1. Because hospitals may not have complete data for every AHRQ indicator in the PSI 90 measure, we decided to use the same methodology used for the Hospital VBP Program to determine the minimum number of indicators with complete data to be included in the calculation of the Domain 1 measure. In addition, we finalized the following rules to determine the number of AHRQ indicators to be included in the calculation for a hospital's Domain 1 score. For Domain 1, we defined "complete data" as whether a hospital has enough eligible discharges to calculate a rate for a measure. In order to have complete data for the PSI 90 measure, a hospital must have three or more eligible discharges for at least one component indicator.

In establishing the performance period for the PSI 90 measure, we relied upon an analysis by Mathematica Policy Research, a CMS contractor, which found the measure was most reliable with a 24-month performance period. This analysis also indicated the measure was unreliable with a performance period of less than 12 months.<sup>55</sup> We have since determined that the current definition for "complete data" may result in facilities with less than 12 months of data being eligible to receive

a score on the PSI 90 measure, and that the resulting score may not be reflective of the hospital's clinical performance. While the PSI 90 measure continues to play a vital role in patient safety and is an integral part of the HAC Reduction Program, we believe that reliable data is a critical component of accurately assessing hospital performance.

To address this concern, we are proposing to clarify the term "complete data" for the PSI 90 measure within Domain 1 to require that hospitals have three or more eligible discharges for at least one component indicator and 12 months or more of data to receive a Domain 1 score. Under this proposal, hospitals with less than 12 months of PSI 90 data would not receive a Domain 1 score, regardless of the number of eligible discharges at the hospital. If a hospital has 12 months or more of PSI 90 data, the hospital would have to have three or more eligible discharges for at least one component indicator to receive a Domain 1 score. We believe this is the most favorable method for scoring measure results for hospitals.

We believe, after weighing the considerations, that this additional policy should be incorporated into the HAC Reduction Program for FY 2017 and subsequent years, primarily because this approach greatly improves the measure's assessment of quality and, therefore, its implementation should not be unnecessarily delayed. This clarification would be a change to the Domain 1 criteria and would not change our current scoring policy for Domain 2. As previously finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50722 through 50723), if a hospital does not have enough data to calculate the PSI 90 measure score for Domain 1 but has "complete data" for at least one measure in Domain 2, its Total HAC Score will depend entirely on its Domain 2 score. Similarly, if a hospital has "complete data" to calculate the PSI 90 measure

<sup>54</sup> Available at: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1228773343598>.

<sup>55</sup> Mathematica Policy Research (November 2011). Reporting period and reliability of AHRQ, CMS 30-day and HAC Quality Measures—Revised. Available at: [https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP\\_Measure\\_Reliability.pdf](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability.pdf).

score in Domain 1 but none of the measures in Domain 2, its Total HAC Score will be based entirely on its Domain 1 score. If a hospital does not have “complete data” to calculate the PSI 90 measure score for Domain 1 or any of the measures in Domain 2, we will not calculate a Total HAC Score for this hospital. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50722 through 50723) for a detailed discussion of Domain 2 scoring.

We are inviting public comments on our proposal to require that hospitals have three or more eligible discharges for at least one component indicator and 12 months or more of data to receive a Domain 1 score beginning in the FY 2017 HAC Reduction Program.

**b. Clarification of NHSN CDC HAI Data Submission Requirements for Newly Opened Hospitals**

We have encountered issues with some newly opened hospitals that do not appear to understand that they must submit CDC NHSN HAI data for the HAC Reduction Program, even when they may not be required to report under the Hospital IQR Program. As set forth in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50098), a hospital that does not have an ICU waiver *or other waiver* for the CDC NHSN HAI measures and does not submit data will receive the maximum of 10 points for that measure. We noted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50723) that, for Domain 2, we will obtain measure results that hospitals submitted to the CDC NHSN from the Hospital IQR Program.<sup>56</sup> However, we note that participation in the Hospital IQR Program is voluntary, while participation in the HAC Reduction Program is mandatory for almost all IPPS hospitals (we refer readers to section 1886(d)(1)(B) of the Act; 42 CFR 412.170 (definition of the term “applicable hospital”); and 42 CFR 412.172(e)). The HAC Reduction Program does not apply to hospitals and hospital units that are excluded from the IPPS, such as LTCHs, cancer hospitals, children’s hospitals, IRFs, IPFs, CAHs, and Puerto Rico hospitals (79 FR 50087 through 50088).

We believe that it is important to establish data submission requirements for all applicable hospitals under the HAC Reduction Program. We are proposing the following requirements for newly opened hospitals for CDC NHSN HAI data submissions. We note

that these requirements do not affect any requirements for facilities in States that are required by law to report HAI data to NHSN.

- If a hospital files a notice of participation (NOP) with the Hospital IQR Program within 6 months of opening, the hospital would be required to begin submitting data for the CDC NHSN HAI measures no later than the first day of the quarter following the NOP.

- If a hospital does not file a NOP with the Hospital IQR Program within 6 months of opening, the hospital would be required to begin submitting data for the CDC NHSN HAI measures on the first day of the quarter following the end of the 6-month period to file the NOP.

For example, if a subsection (d) hospital opens on January 1 and it intends to participate in the Hospital IQR Program, the hospital would be required to file a Hospital IQR Program NOP no later than July 1, and begin submitting data to NHSN no later than October 1. If a subsection (d) hospital opens on January 1 and it does not intend to participate in the Hospital IQR Program (that is, no NOP is filed), it must begin submitting data to NHSN no later than July 1 of that year. We believe that these data submission requirements are clear, align with the Hospital IQR Program, and are fair and equitable for all newly opened hospitals. Hospitals that are not required to submit data within the respective HAC Reduction Program year will not receive a score. These hospitals will receive a designation of “NEW,” and will not receive any points for CDC NHSN HAI measures.

We further note that this clarification does not affect the narrative rules used in calculation of the Domain 2 Score. We will continue to follow all Domain 2 scoring procedures as previously finalized, and we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49575) for further discussion of the narrative rules used in calculation of the Domain 2 Score. We believe that this proposal should be incorporated into the HAC Reduction Program for FY 2017 and subsequent years.

We are inviting public comments on our proposal to adopt these policies related to the data submission requirements beginning in the FY 2017 HAC Reduction Program.

**5. Implementation of the HAC Reduction Program for FY 2018**

For FY 2018, we are proposing the following HAC Reduction Program policies: (1) Adoption of the modified version of the NQF-endorsed PSI 90: Patient Safety and Adverse Events

Composite; (2) defining the applicable time periods for the FY 2018 HAC Reduction Program and the FY 2019 HAC Reduction Program; (3) changes to the scoring methodology; and (4) a request for comments on additional measures for potential future adoption.

**a. Proposed Adoption of Modified PSI 90: Patient Safety and Adverse Events Composite (NQF #0531)**

**(1) Background**

We are proposing to adopt refinements to the Agency for Healthcare Research and Quality (AHRQ) Patient Safety and Adverse Events Composite (NQF #0531) for the HAC Reduction Program beginning with the FY 2018 payment determination and subsequent years. In summary, the PSI 90 measure was refined to reflect the relative importance and harm associated with each component indicator to provide a more reliable and valid signal of patient safety events. We believe refining PSI 90 will provide strong incentives for hospitals to ensure that patients are not harmed by the medical care they receive, a critical consideration in quality improvement.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50712 through 50717), we adopted the PSI 90 measure (NQF #0531) in the HAC Reduction Program as an important measure of patient safety and adverse events. As previously adopted, PSI 90 consisted of eight component indicators: (1) PSI 3 Pressure Ulcer Rate; (2) PSI 6 Iatrogenic Pneumothorax Rate; (3) PSI 7 Central Venous Catheter-Related Blood Stream Infections Rate; (4) PSI 8 Postoperative Hip Fracture Rate; (5) PSI 12 Perioperative Pulmonary Embolism/Deep Vein Thrombosis Rate; (6) PSI 13 Postoperative Sepsis Rate; (7) PSI 14 Postoperative Wound Dehiscence Rate; and (8) PSI 15 Accidental Puncture and Laceration Rate.<sup>57</sup>

The currently adopted eight-indicator version of the measure underwent extended NQF maintenance reendorsement in the 2014 NQF Patient Safety Committee due to concerns with the underlying component indicators and their composite weights. In the NQF-Endorsed Measures for Patient Safety, Final Report,<sup>58</sup> the NQF Patient Safety Committee deferred its final decision for the PSI 90 measure until

<sup>57</sup> NQF-Endorsed Measures for Patient Safety, Final Report. Available at: [http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed\\_Measures\\_for\\_Patient\\_Safety\\_Final\\_Report.aspx](http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety_Final_Report.aspx).

<sup>58</sup> NQF-Endorsed Measures for Patient Safety, Final Report available at: [http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed\\_Measures\\_for\\_Patient\\_Safety\\_Final\\_Report.aspx](http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety_Final_Report.aspx).

<sup>56</sup> For a further discussion of CDC NHSN HAI Data submission requirements for the Hospital IQR Program, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536) and 42 CFR 412.140(a)(3)(i) and 412.140(b).

the following measure evaluation cycle. In the meantime, AHRQ worked to address many of the NQF stakeholders' concerns about PSI 90, which subsequently completed NQF maintenance re-review and received reendorsement on December 10, 2015.

The PSI 90 measure's extended NQF reendorsement led to several changes to the measure.<sup>59</sup> First, the name of the PSI 90 measure has changed to "Patient Safety and Adverse Events Composite" (NQF #0531) (herein referred to as the "modified PSI 90"). Second, the modified PSI 90 measure includes the addition of three indicators: (1) PSI 09 Perioperative Hemorrhage or Hematoma Rate; (2) PSI 10 Physiologic and Metabolic Derangement Rate; and (3) PSI 11 Postoperative Respiratory Failure Rate. Third, PSI 12 Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate and PSI 15 Accidental Puncture or Laceration Rate have been respecified in the modified PSI 90. Fourth, PSI 07 Central Venous Catheter-Related Blood Stream Infection Rate has been removed in the modified PSI 90. Fifth, the weighting of component indicators in the modified PSI 90 is based not only on the volume of each of the patient safety and adverse events, but also the harms associated with the events.

We consider these changes to the modified PSI 90 to be substantive changes to the measure. Therefore, we are proposing to adopt the modified PSI 90 for the HAC Reduction Program beginning with the FY 2018 payment determination and subsequent years. We explain the modified PSI 90 more fully below, and also refer readers to the measure description on the NQF Web site at: <https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=321&print=0&entityTypeID=3>.

We note that the proposed modified PSI 90 (MUC15-604) was included on a publicly available document entitled "2015 Measures Under Consideration for December 1, 2015"<sup>60</sup> in compliance with section 1890A(a)(2) of the Act, and was reviewed by the MAP. The MAP supported this measure, stating that "the PSI measures were developed to identify harmful healthcare related events that are potentially preventable. Three additional PSIs have been added

to this updated version of the measure. PSIs were better linked to important changes in clinical status with 'harm weights' that are based on diagnoses that were assigned after the complication. This is intended to allow the measure to more accurately reflect the impact of the events."<sup>61</sup> The measure received support for inclusion in the HAC Reduction Program as referenced in the MAP Final Recommendations Report.<sup>62</sup>

#### (2) Overview of the Measure Changes

First, the name of the PSI 90 measure has changed from the "Patient Safety for Selected Indicators Composite Measure" to the "Patient Safety and Adverse Events Composite" (NQF #0531) to more accurately capture the indicators included in the measure.

Second, the PSI 90 measure has expanded from 8 to 10 component indicators. The modified PSI 90 is a weighted average of the following 10 risk-adjusted and reliability-adjusted individual component PSI rates:

- PSI 03 Pressure Ulcer Rate;
- PSI 06 Iatrogenic Pneumothorax Rate;
- PSI 08 Postoperative Hip Fracture Rate;
- PSI 09 Postoperative Hemorrhage or Hematoma Rate;\*
- PSI 10 Physiologic and Metabolic Derangement Rate;\*
- PSI 11 Postoperative Respiratory Failure Rate;\*
- PSI 12 Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate;
- PSI 13 Postoperative Sepsis Rate,
- PSI 14 Postoperative Wound Dehiscence Rate; and
- PSI 15 Accidental Puncture or Laceration Rate.<sup>63</sup>

(\* Denotes new component for the modified PSI 90 measure.)

As stated above, the modified PSI 90 measure also removed PSI 07, Central Venous Catheter-Related Blood Stream Infection Rate, because of potential overlap with the CLABSI measure (NQF #0139) which has been included in the Hospital IQR Program since the FY 2011 IPPS/LTCH PPS final rule (75 FR 50201 through 50202), the HAC Reduction Program since the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), and the Hospital VBP Program since the FY 2013 IPPS/LTCH PPS final rule (77 FR 53597 through 53598).

In response to stakeholder concerns, highlighted in the NQF 2014 Patient

Safety Report,<sup>64</sup> the modified PSI 90 also respecified two component indicators, PSI 12 and PSI 15. Specifically, for PSI 12 Perioperative PE or DVT rate, the NQF received public comments concerning the inclusion of: (1) Extracorporeal membrane oxygenation (ECMO) procedures in the denominator; and (2) intra-hospital variability in the documentation of calf vein thromboses (which have uncertain clinical significance). As such, the revised PSI 12 component indicator no longer includes ECMO procedures in the denominator or isolated deep vein thrombosis of the calf veins in the numerator. PSI 15 was also respecified further to focus on the most serious intraoperative injuries—those that were unrecognized until they required a subsequent reparative procedure. The modified denominator of PSI 15 now is limited to discharges with an abdominal/pelvic operation, rather than including all medical and surgical discharges. In addition, to identify events that are more likely to be clinically significant and preventable, the PSI 15 numerator was modified to require both: (1) A diagnosis of an accidental puncture and/or laceration; and (2) an abdominal/pelvic reoperation one or more days after the index surgery.

Finally, the NQF Patient Safety Review Committee raised concerns about the weighting scheme of the component indicators. In prior versions of the measure, the weights of each component PSI were based solely on volume (numerator rates). In the modified PSI 90, the rates of each component PSI are weighted based on statistical and empirical analyses of volume, excess clinical harm associated with the PSI, and disutility (individual preference for a health state linked to a harm, such as death or disability). The final weight for each component indicator is the product of harm weights and volume weights (numerator weights). Harm weights are calculated by multiplying empirical estimates of excess harms associated with the patient safety event by utility weights linked to each of the harms. Excess harms are estimated using statistical models comparing patients with a safety event to those without a safety event in a Medicare FFS sample. Volume weights are calculated based on the number of safety events for the component

<sup>59</sup> National Quality Forum QPS Measure Description for "Patient Safety for Selected Indicators (modified version of PSI90) (Composite measure)" found at: <https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=321&print=0&entityTypeID=3>.

<sup>60</sup> 2015 Measures Under Consideration List available at: <http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367>.

<sup>61</sup> MAP Final Recommendations available at: [http://www.qualityforum.org/Publications/2016/02/MAP\\_2016\\_Considerations\\_for\\_Implementing\\_Measures\\_in\\_Federal\\_Programs\\_-\\_Hospitals.aspx](http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_Hospitals.aspx).

<sup>62</sup> Ibid.

<sup>63</sup> <http://www.qualityforum.org/QPS/0531>.

<sup>64</sup> NQF Endorsed Measures for Patient Safety, Final Report. Available at: [http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed\\_Measures\\_for\\_Patient\\_Safety\\_Final\\_Report.aspx](http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety_Final_Report.aspx).

indicators in an all-payer reference population.

For more information on the modified PSI 90 measure and component indicators, we refer readers to the Quality Indicator Empirical Methods available online at: [www.qualityindicators.ahrq.gov](http://www.qualityindicators.ahrq.gov).

### (3) Risk Adjustment

The risk adjustment and statistical modeling approaches of the models remain unchanged in the modified PSI 90. In summary, the predicted value for each case is computed using a modeling approach that includes, but is not limited to, applying a Generalized Estimating Equation (GEE) hierarchical model (logistic regression with hospital random effect) and covariates for gender, age, Modified MS-DRG (MDRG), Major Diagnostic Category, transfer in, point of origin not available, procedure days not available, and AHRQ comorbidity (COMORB).

The expected rate for each of the indicators is computed as the sum of the predicted value for each case divided by the number of cases for the unit of analysis of interest (that is, hospital). The risk-adjusted rate for each of the indicators is computed using indirect standardization as the observed rate divided by the expected rate, multiplied by the reference population rate. For more details about risk adjustment, we refer readers to: [http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical\\_Methods\\_2015.pdf](http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical_Methods_2015.pdf).

### (4) Adoption of the NQF-Endorsed Version of the Modified PSI 90

In summary, the PSI 90 measure was revised to reflect the relative importance and harm associated with each component indicator to provide a more reliable and valid signal of patient safety events. We believe that adopting the modified PSI 90 would continue to provide strong incentives for hospitals to ensure that patients are not harmed by the medical care they receive, which is a critical consideration in quality improvement. We are proposing to adopt the modified PSI 90 for the HAC Reduction Program for FY 2018 and subsequent years. We will continue to use the currently adopted eight-indicator version of the PSI 90 measure for the HAC Reduction Program for FY 2017. We are inviting public comment on our proposal to adopt the modified PSI 90 measure (NQF #0531) for the HAC Reduction Program for FY 2018.

b. Applicable Time Periods for the FY 2018 HAC Reduction Program and the FY 2019 HAC Reduction Program

Section 1886(p)(4) of the Act gives the Secretary the statutory authority to determine the applicable period for the HAC Reduction Program. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized and codified at 42 CFR 412.170 that we would use a 2-year time period of performance data to calculate the Total HAC Score. We believe the 24-month performance period provides hospitals and the public with the most current data available, while allowing sufficient time to complete the complex calculation process for these measures. The 24-month performance period was chosen because it tended to show that between 50 to 90 percent of hospitals attained a moderate or high level of reliability for AHRQ measures (78 FR 50717). Although we believe the 24-month time is the preferred length of time for performance data, there may be situations, discussed in more detail below, where the collection of 24 months of data is not operationally feasible.

Therefore, we are proposing, beginning in FY 2017 and for subsequent years, to permit flexibility to use a period other than the 2 years from which data are collected in order to calculate the Total HAC Score under the HAC Reduction Program. We also are proposing to change the definition of “applicable period,” in 42 CFR 412.170, to reflect this proposed change.

Since the ICD-10 transition was implemented on October 1, 2015, we have been monitoring our systems and so far claims are processing normally. The measure steward, AHRQ, has been reviewing the measure for any potential issues related to the conversion of approximately 70,000 ICD-10 coded operating room procedures<sup>65</sup> (<https://www.cms.gov/icd10manual/fullcode/cms/P1616.html>), which could directly affect the modified PSI 90 component indicators. In addition, to meet program requirements and implementation schedules, our system would require an ICD-10 risk-adjusted version of the AHRQ QI PSI software<sup>66</sup> by December 2016 for the FY 2018 payment determination year. At this time, a risk-

<sup>65</sup> International Classification of Diseases, (ICD-10-CM/PCS) Transition—Background. Available at: [http://www.cdc.gov/nchs/icd/icd10cm\\_pcs\\_background.htm](http://www.cdc.gov/nchs/icd/icd10cm_pcs_background.htm).

<sup>66</sup> The AHRQ QI Software is the software used to calculate PSIs and the composite measure. More information is available at: [http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical\\_Methods\\_2015.pdf](http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical_Methods_2015.pdf).

adjusted ICD-10 version of the PSI 90 Patient Safety and Adverse Events Composite software is not expected to be available until late CY 2017.

To address these issues, for the current Domain 1 measure (PSI 90 Patient Safety and Adverse Events Composite), we are proposing to use the 15-month performance period from July 1, 2014 through September 30, 2015, for the FY 2018 HAC Reduction Program. This 15-month performance period would utilize only ICD-9-CM data and only apply to the FY 2018 payment year. The claims for all Medicare FFS beneficiaries discharged during this period would be included in the calculations of measure results for FY 2018. For the FY 2019 HAC Reduction Program, we are proposing to use the 21-month performance period from October 1, 2015 through September 30, 2017. This 21-month performance period would utilize only ICD-10 data and only apply to the FY 2019 payment year. The claims for all Medicare FFS beneficiaries discharged during this period would be included in the calculations of measure results for FY 2019.

Prior to deciding to propose abbreviated data collection periods for the FY 2018 and the FY 2019 payment determinations, we took several factors into consideration. These included the recommendations of the measure steward, the feasibility of using a combination of ICD-9 and ICD-10 data, minimizing provider burden, program implementation timelines, and the reliability of using shortened data collection periods, as well as the importance of continuing to publicly report this measure. We believe that using a 15-month data collection period for FY 2018 and a 21-month data collection period for FY 2019 best serve the need to provide important information on hospital patient safety and adverse events by allowing sufficient time to process the claims data and calculate the measures, while minimizing reporting burden and program disruption.

Because this issue only impacts the PSI 90 Patient Safety and Adverse Events Composite in Domain 1, for the CDC NHSN measures previously finalized for use in the FY 2017 HAC Reduction Program (CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI), we would use the 24-month performance period from January 1, 2015 through December 31, 2016 (CYs 2015 and 2016) for the FY 2018 HAC Reduction Program. For the FY 2019 HAC Reduction Program, we are proposing to use the 24-month performance period



from January 1, 2016 through December 31, 2017 (CYs 2016 and 2017).

We believe that using a 15-month period and a 21-month performance period for Domain 1 and a 24-month performance period for Domain 2 balance the needs of the HAC Reduction Program and allow sufficient time to process the claims data and calculate the measures. We will continue to test ICD-10 data that are submitted in order to ensure the accuracy of measure calculations and to monitor and assess the translation of measure specifications to ICD-10, potential coding variation, and impacts on measure performance and payment incentive programs.

We are inviting public comment on the proposals to update the definition of “applicable period” codified at 42 CFR 412.170 for FY 2017 and subsequent years and to use these updated performance periods for calculation of measure results for the FY 2018 and the FY 2019 HAC Reduction Programs.

#### c. Proposed Changes to the HAC Reduction Program Scoring Methodology

##### (1) Current Scoring Policy

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50721), we finalized a scoring methodology that aligns with the achievement scoring methodology currently used in the Hospital VBP Program. Our intent was to reduce confusion associated with multiple scoring methodologies by aligning the scoring for the Hospital VBP Program and the HAC Reduction Program. We note that alignment benefits the hospital stakeholders who have prior experience with the Hospital VBP Program. Accordingly, we implemented a methodology for assessing the top quartile of applicable hospitals for HACs based on performance standards.

We indicated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50720 through 50725) that points will be assigned to hospitals’ performance for each measure. We finalized a decile-based methodology for assigning points, depending on the specific measures.

- For Domain 1, point assignment is based on a hospital’s score for the PSI 90 measure.
- For the Domain 1 score, 1 to 10 points are assigned to the hospital.
- For the measures in Domain 2, point assignment for each measure is based on the SIR for that measure.
- For each SIR, 1 to 10 points are assigned to the hospital for each measure.
- The Domain 2 score consists of the average of points assigned to each measure.

To calculate a Total HAC Score for each hospital, we multiply each domain score by a weighting and add together the weighted domain scores to determine the Total HAC Score (§ 412.172(e)(3)). We use each hospital’s Total HAC Score to determine the top quartile of subsection (d) hospitals that are subject to the payment adjustment beginning with discharges on or after October 1, 2014.

##### (2) Program Evaluation Efforts

As part of our ongoing efforts to evaluate the HAC Reduction Program, we recently conducted a review of our scoring methodology and assessed opportunities to strengthen the program. As part of that review, our Hospital Quality Reporting Program Support (HQRPS) contractors convened a technical expert panel (TEP) on October 19–20, 2015, with a follow-up call on December 11, 2015. The TEP examined multiple areas of the HAC Reduction Program and focused on identifying a scoring methodology that provides an incentive to hospitals to reduce HACs and distinguishes top performers from low performers. The TEP identified concerns with the current decile-based scoring methodology that included: Ties at the penalty threshold; hospitals with a limited amount of data being identified as poor performers; and situations in which hospitals with no adverse events and no Domain 2 data nonetheless become eligible for penalty.

During the FY 2016 HAC Reduction Program, a small subset of hospitals that had zero adverse events in Domain 1 and no Domain 2 score were identified as part of the worst-performing quartile. These hospitals received Domain 1 scores of 7.0, meaning they were in the 7th decile of hospitals for the PSI 90 measure despite being close to the PSI 90 measure mean value. As this subset of hospitals had no Domain 2 scores, they received a Total HAC Score equal to their Domain 1 score of 7.0. This Total HAC Score was greater than the 75th percentile cutoff for penalty determination of 6.75. CMS waived the penalty for these zero adverse event hospitals so they would not be treated as poor performers. These hospitals were potentially disadvantaged because their Total HAC Scores were determined solely on their Domain 1 Score. Because Domain 2 scores tend to be lower on average than Domain 1 scores,<sup>67</sup> other

<sup>67</sup> This is because hospitals are assigned the minimum of one point for any measure for which they have a measure result of zero. For example, for the CAUTI measure, if 13 percent of hospitals have an SIR of zero, one point is assigned to each of these hospitals, even though the decile approach is intended to assign 10 percent of hospitals to each

hospitals without Domain 2 scores are potentially treated the same as low performers in the same decile.

In addition, scoring using deciles can make it more difficult to distinguish top performers from low performers by creating a large number of ties on measure scores. For example, two hospitals with meaningfully different measure results may fall into the same decile bin and therefore be ultimately indistinguishable under the current scoring methodology. Conversely, two hospitals with performance that is not statistically distinguishable may fall into different decile bins. Furthermore, ties at the penalty threshold complicate the adjudication of payment adjustments; in both the FY 2015 and FY 2016 programs, less than 25 percent of all hospitals had Total HAC Scores above the threshold for penalties. Specifically, only 21.9 percent of hospitals in FY 2015 and 23.7 percent of hospitals in FY 2016 were subject to a payment adjustment.

To address stakeholder concerns regarding the current scoring methodology, we evaluated a number of alternatives and recommendations from the TEP. We refer readers to the Project Title: Hospital-Acquired Condition (HAC) Reduction Program Scoring Methodology Reevaluation located at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TechnicalExpertPanels.html> for a summary of the TEP’s discussion. These alternatives included replacement of the current decile-based scoring approach with the use of Winsorized<sup>68</sup> z-scores.

##### (3) Winsorized Z-Score Method

The Winsorized z-score method (z-score) uses a continuous measure score rather than forcing measure results into deciles. Z-scores represent a hospital’s distance from the national mean for a measure in units of standard deviations. Under the z-score approach, poor-performing hospitals earn a positive z-score, reflecting measure values above the national mean, and better-performing hospitals earn a negative z-score, reflecting measure values below the national mean. For each measure, a

decile. Two points would be assigned to the remaining seven percent of hospitals that would fall in the second decile. This phenomenon does not affect Domain 1 scores, since the reliability-adjusted PSI 90 measure result is not equal to zero in any hospital.

<sup>68</sup> Winsorized measure results are truncated to the 5th and 95th percentiles, replacing values between the minimum and the 5th percentile with the 5th percentile value and replacing values between the 95th percentile and the maximum with the 95th percentile value. Z-scores are then calculated based on these values.

hospital's z-score is based on the following equation that expresses the

hospital's measure value minus the average value for that measure, divided

by the standard deviation of the measure values across all hospitals:

$$Z\text{-Score} = \frac{(\text{Hospital's Measure Performance} - \text{Mean Performance for All Hospitals})}{\text{Standard Deviation for All Hospitals}}$$

To form the Total HAC Score, we would use the z-scores as hospitals' measure scores. In accordance with the current scoring methodology, we would then average the z-scores across measures within Domain 2 and assign the z-score for PSI 90 for Domain 1 to determine the domain scores. We would then multiply each domain score by the appropriate weighting and add together the weighted domain scores to determine the Total HAC Score. We would use each hospital's Total HAC Score to determine the top quartile of subsection (d) hospitals that are subject to the payment adjustment.

#### (4) Impact and Implementation

This z-score approach is straightforward to implement, easily adapted as measures are added or removed from the HAC Reduction Program, transparent, and familiar to a wide range of stakeholders. Continuous values address the limitations of decile scoring and preserve the magnitude of differences among hospitals' measure results. Thus, hospitals that differ meaningfully on their measure results will also differ meaningfully on their Total HAC Scores. Unlike the decile approach, continuous measure scores would substantially reduce ties of Total HAC Scores, which have prevented CMS from penalizing exactly 25 percent of hospitals in previous program years. The use of z-scores also improves alignment between Domains 1 and 2 and creates a more level playing field for hospitals with data in only Domain 1.

Based on FY 2016 data supplemented with MRSA Bacteremia and CDI results,<sup>69</sup> the z-score approach affects the penalty status of slightly more than 200 hospitals, relative to the decile approach. This approach brings 114 hospitals into the penalty zone and 103 hospitals out of the penalty zone and reduces the HAC Reduction Program's impact on the largest and smallest hospitals. Most importantly, because of the improvements in precision and standardization gained by implementing this approach, there is no penalization of hospitals that had zero adverse events

and no Domain 2 score in either the actual results from FY 2016 or in the results based on the FY 2016 data supplemented with MRSA Bacteremia and CDI results.

Among the 184 hospitals with fewer than 25 beds, the proportion of hospitals penalized would fall from 33 percent to 18 percent. Among the 213 hospitals with more than 500 beds, the proportion of hospitals penalized would fall from 50 percent to 42 percent. The approach leaves the proportion of teaching, urban, and high-DSH hospitals penalized largely unchanged, with one exception. The z-score approach slightly increases the penalization rate among moderately high (50 to 64 percent) DSH hospitals, from 28 percent to 35 percent. Only 172 hospitals fall into this group; therefore, the increase reflects only 11 additional hospitals in that group being penalized.

We believe that differences in performance scores must reflect true differences in performance. In addition, hospitals must be able to clearly understand performance scoring methods and performance expectations to maximize their quality improvement efforts. Therefore, we are inviting public comments on our proposal to adopt the z-score method for calculating measure results beginning in the FY 2018 HAC Reduction Program.

#### 6. Request for Comments on Additional Measures for Potential Future Adoption

We view the addition of other quality measures as a critical component of value-based purchasing, and we are seeking public comments on what additional measures we should consider adopting in the future. 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. The reduction of HACs is an important marker of quality of care and has a positive impact on both patient outcomes and cost of care. Our goal for the HAC Reduction Program is to heighten the awareness of HACs and reduce the number of incidences that occur. We seek to adopt measures for the HAC Reduction Program that promote better, safer, and more efficient care. Our overarching purpose is to support the NQS' three-part aim of better health care for individuals, better

health for populations, and lower costs for health care.

To the extent practicable, all HAC Reduction Program measures 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. Measures should take into account widely accepted criteria established in medical literature. We note that all measures proposed for the HAC Reduction Program should 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 welcome public comment and suggestions for additional HAC Reduction Program measures that will help achieve the Program goals in these or other measurement areas.

#### 7. Maintenance of Technical Specifications for Quality Measures

Technical specifications for AHRQ's PSI-90 measure in Domain 1 can be found at AHRQ's Web site at: [http://qualityindicators.ahrq.gov/Modules/PSI\\_TechSpec.aspx](http://qualityindicators.ahrq.gov/Modules/PSI_TechSpec.aspx). Technical specifications for the CDC NHSN HAI measures in Domain 2 can be found at CDC's NHSN Web site at: <http://www.cdc.gov/nhsn/acute-care-hospital/index.html>. Both Web sites provide measure updates and other information necessary to guide hospitals participating in the collection of HAC Reduction Program data.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50100), we described a policy under which we use a subregulatory process to make nonsubstantive updates to measures used for the HAC Reduction Program. We are not proposing any changes to this policy at this time.

#### 8. Extraordinary Circumstance Exception Policy for the HAC Reduction Program Beginning in FY 2016 and for Subsequent Years

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49579 through 49581) for a detailed discussion of the exception policy for hospitals located in areas that experience disasters or other extraordinary circumstances for the HAC Reduction

<sup>69</sup> Results are based on actual FY 2016 measure data with the addition of MRSA Bacteremia and CDI data for the reporting period spanning October 2012 through December 2014.

Program. We are not proposing any changes to this policy for FY 2017.

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

1. Background

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

Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the 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 payments and the IME payment adjustment 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 limit for direct GME and IME payment purposes and the manner in which FTE resident limits are calculated and applied to hospitals under certain circumstances.

Section 5503(a)(4) of the Affordable Care Act added a new section 1886(h)(8) to the Act to provide for the reduction in FTE resident caps for direct GME under Medicare for certain hospitals training fewer residents than their caps, and to authorize the redistribution of the estimated number of excess FTE resident slots to other qualified hospitals. In addition, section 5503(b) amended section 1886(d)(5)(B)(v) of the Act to require the application of the section 1886(h)(8) of the Act provisions in the same manner to the IME FTE resident caps. The policy implementing section 5503 of the Affordable Care Act was included in the November 24, 2010 final rule with comment period (75 FR 72147 through 72212) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53424 through 53434). Section 5506(a) of the Affordable Care Act amended section 1886(h)(4)(H) of the Act to add a new clause (vi) that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria up to the number of the closed hospital's FTE resident caps. The policy implementing section 5506 of the Affordable Care Act was included in the November 24, 2010 final rule with comment period (75 FR 72212 through 72238) and the FY 2013

IPPS/LTCH PPS final rule (77 FR 53434 through 53448).

2. Change in New Program Growth From 3 Years to 5 Years

a. Urban and Rural Hospitals

Section 1886(h)(4)(H)(i) of the Act requires CMS to establish rules for calculating the direct GME caps of teaching hospitals training residents in new programs established on or after January 1, 1995. Under section 1886(d)(5)(B)(viii) of the Act, these rules also apply to the establishment of a hospital's IME cap. CMS implemented these statutory requirements in the August 29, 1997 **Federal Register** (62 FR 46005) and in the May 12, 1998 **Federal Register** (63 FR 26333). Generally, when CMS (then HCFA) implemented the regulations at 42 CFR 413.79(e)(1) and 42 CFR 412.105(f)(1)(vii), these regulations provided that if a hospital did not train any allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, and it begins to participate in training residents in a new residency program (allopathic or osteopathic) on or after January 1, 1995, the hospital's unweighted FTE resident cap (which would otherwise be zero) may be adjusted based on the sum of the product of the highest number of FTE residents in any program year during the third year of the first new program, for each new residency training program established during that 3-year period, and the minimum accredited length for each type of program. This 3-year period, which we will refer to as the "3-year window" for ease of reference in this proposed rule, started when a new program began, and the teaching hospital first began to train residents for the first time in that new program, typically on July 1, and ending when the third program year of that first new program ends.

Prior to development of the FY 2013 IPPS/LTCH PPS proposed rule, the teaching hospital community expressed concerns that 3 years do not provide for a sufficient amount of time for a hospital to "grow" its new residency programs and to establish FTE resident caps that are properly reflective of the number of FTE residents that it will actually train, once the programs are fully grown. Hospitals explained that 3 years is an insufficient amount of time primarily because a period of 3 years is not compatible with program accreditation requirements, particularly in instances where the qualifying teaching hospital wishes to start more than one new program. Therefore, in the FY 2013 IPPS/LTCH PPS proposed rule

and final rule, we proposed and finalized changes to the regulations at 42 CFR 413.79(e) for direct GME and at 42 CFR 412.105(f)(1)(vii) for IME that revised the “3-year window” to a “5-year window,” for a new teaching hospital to establish and grow a new program, and thus begin training residents for the first time in new programs that are started on or after October 1, 2012. Thus, for urban hospitals that begin to train residents in a new medical residency training program for the first time on or after October 1, 2012, the cap will not be adjusted for new programs established more than 5 years after residents begin training in the first new program. However, rural hospitals are permitted to receive new cap adjustments for participating in training residents in new medical residency training programs at any time, and therefore, under § 413.79(e)(3), if a rural hospital participates in new medical residency training programs on or after October 1, 2012, the hospital’s cap is adjusted for each new program based on a 5-year growth window. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for more details on this change in the regulations regarding the 5-year window for urban hospitals training residents in new medical residency training programs for the first time and for rural hospitals participating in new medical residency training programs (77 FR 53416 through 53424).

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50111), we changed our policy regarding implementation of the FTE resident caps for new programs to be effective with the beginning of the applicable hospital’s cost reporting period that coincides with or follows the start of the sixth program year of the first new program started for hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(1), and beginning with the applicable hospital’s cost reporting period that coincides with or follows the start of the sixth program year of each individual new program started for rural hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(3). In the same final rule, we also made the effective dates of the 3-year rolling average and IME IRB ratio cap consistent with the effective date of the new program FTE resident caps. That is, beginning with the applicable hospital’s cost reporting period that coincides with or follows the start of the sixth program year of the first new program started for hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(1), and beginning with the

applicable hospital’s cost reporting period that coincides with or follows the start of the sixth program year of each individual new program started for rural hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(3), FTE residents participating in new medical residency training programs are included in the hospital’s IRB ratio cap and the 3-year rolling average.

#### b. Proposed Policy Changes Relating to Rural Training Tracks at Urban Hospitals

To encourage the training of residents in rural areas, section 407(c) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113) amended section 1886(h)(4)(H) of the Act to add a provision (subsection (iv)) that, in the case of a hospital that is not located in a rural area (an urban hospital) that establishes separately accredited approved medical residency training programs (or rural tracks) in a rural area or has an accredited training program with an integrated rural track, the Secretary shall adjust the urban hospital’s cap on the number of FTE residents under subsection (F), in an appropriate manner in order to encourage training of physicians in rural areas. Section 407(c) of Public Law 106–113 was made effective for direct GME payments to hospitals for cost reporting periods beginning on or after April 1, 2000, and for IME payments applicable to discharges occurring on or after April 1, 2000. We refer readers to the August 1, 2000 interim final rule with comment period (65 FR 47033 through 47037) and the FY 2002 IPPS final rule (66 FR 39902 through 39909) where we implemented section 407(c) of Public Law 106–113. The regulations for establishing rural track FTE limitations are located at 42 CFR 413.79(k) for direct GME and at 42 CFR 412.105(f)(1)(x) for IME.

In the August 1, 2003 IPPS final rule (68 FR 45456 through 45457), we clarified our existing policy that although the rural track provision allows an increase to the urban hospital’s FTE cap, sections 1886(h)(4)(H)(iv) and 1886(d)(5)(B) of the Act do not provide for an exclusion from the rolling average for the urban hospital for those FTE residents training in a rural track. These provisions are interpreted to mean that, except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, when an urban hospital with an FTE resident cap establishes a new rural track program or expands an existing rural track program,

FTE residents in the rural track that are counted by the urban hospital are included in the hospital’s rolling average calculation immediately. This policy is reflected in the regulation at § 412.105(f)(1)(v)(F) for IME and § 413.79(d)(7) for direct GME, and applies for IME and direct GME to cost reporting periods beginning on or after April 1, 2000.

We received questions asking whether the change in the 3-year window to the 5-year window for new programs also applies to the establishment of rural training tracks. In the FY 2013 IPPS/LTCH PPS final rule, when we amended the regulations to provide for a 5-year new program growth window at § 413.79(e) for direct GME and at § 412.105(f)(1)(vii) for IME, and in the FY 2015 IPPS/LTCH PPS final rule when we made the FTE resident caps of new programs to be effective with the applicable hospital’s cost reporting period that coincides with or follows the start of the sixth program year, we inadvertently did not also change the growth window and effective date of FTE limitations for rural training tracks, which, under existing § 413.79(k) for direct GME and § 412.105(f)(1)(x) for IME, is 3 program years, and is effective after 3 program years, respectively.

In this FY 2017 IPPS/LTCH PPS proposed rule, we are proposing to revise the regulations at § 413.79(k) (and which, in turn, would affect IME adjustments under § 412.105(f)(1)(x)) to permit that, in the first 5 program years (rather than the first 3 program years) of the rural track’s existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents training in the rural training track at the urban hospital, and beginning with the urban hospital’s cost reporting period that coincides with or follows the start of the sixth program year of the rural training track’s existence, the rural track FTE limitation would take effect. This proposed change addresses concerns expressed by the hospital community that rural training tracks, like any program, should have a sufficient amount of time for a hospital to “grow” and to establish a rural track FTE limitation that reflects the number of FTE residents that it will actually train, once the program is fully grown.

However, as stated above, due to the statutory language at sections 1886(d)(5)(B) and 1886(h)(4)(H)(iv) of the Act as implemented in our regulations at §§ 412.105(f)(1)(v)(F) and 413.79(d)(7), except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, FTE residents in a rural track training program at the

urban hospital are subject immediately to the 3-year rolling average for direct GME and IME. In addition, under the regulations at § 412.105(a)(1)(i), no exception to the IME intern- and resident-to-bed (IRB) ratio cap is provided for residents in a rural track training program (except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time). Accordingly, while we are proposing that the urban hospital's rural track FTE limitation would first be effective beginning with the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track training program's existence, the rural track training program's FTEs are included in the 3-year rolling average and are subject to the IME IRB ratio cap for hospitals with established FTE caps, even within the first 5 program years prior to the beginning of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track training program's existence.

We note that, for programs with cost reporting periods beginning on or after October 1, 2003, our regulations at §§ 413.79(k)(1) through (k)(4) are divided between rural track FTE limitation adjustments for urban hospitals where the residents rotate to a rural area for more than one half of the duration of the program (§§ 413.79(k)(1) and (k)(2)), and where the residents rotate to a rural area for less than one-half of the duration of the program (§§ 413.79(k)(3) and (k)(4)). As we explained in the August 1, 2003 IPPS final rule (68 FR 45456 through 45458), "duration of the program" refers to the minimum accredited length of the particular specialty of the rural track training program. We are clarifying under this proposal that, although the urban hospital's rural track FTE limitation would not be effective until the beginning of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track training program's existence, the rural track FTE limitation that would be provided, if any, is still subject to whether or not the urban hospital rotates the residents in the rural track training program to a rural area(s) for more than one-half of the "duration of the program," and whether or not the urban hospital complies with existing §§ 413.79(k)(5) and (k)(6), and the proposed revised § 413.79(k)(7). We are proposing to revise § 413.79(k)(7), which specifies the effect on rural track FTE limitations when previously rural statistical areas

become urban statistical areas due to updates in the OMB standards for delineating urban and rural statistical areas, because the existing paragraphs under § 413.79(k)(7) discuss the "3-year" growth period. Consequently, we need to make conforming changes by revising paragraphs (k)(7)(ii) and (iii) to account for rural track training programs started prior to October 1, 2012. (For more information regarding the effect on rural track FTE limitations when OMB makes changes to its standards for delineating statistical areas, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50113 through 50117).)

#### c. Proposed Effective Date

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50111), when we provided that the policy regarding the effective dates of the FTE residency caps, the 3-year rolling average, and the IRB ratio cap for FTE residents in new medical residency training programs would be effective with the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program started, we stated that this policy would be effective for urban hospitals that first begin to participate in training residents in their first new medical residency training program, and for rural hospitals, on or after October 1, 2012. We finalized this as the effective date because the policy providing a 5-year growth period for establishing the FTE resident caps (§§ 413.79(e)(1) and (e)(3)) was also effective for new programs started on or after October 1, 2012. Because we inadvertently did not also amend the separate regulations at § 412.105(f)(1)(x) and § 413.79(k) regarding the growth window and effective date of FTE limitations for rural track training programs when we amended the regulations regarding the 5-year growth window in the FY 2013 IPPS/LTCH PPS final rule and regarding the additional changes we made in the FY 2015 IPPS/LTCH PPS final rule, we are proposing that the effective date regarding the change in the growth window for rural track training programs from 3 years to 5 years also be effective for rural track training programs started on or after October 1, 2012. We acknowledge that there could be urban hospitals that started a rural track training program after October 1, 2012 (likely on July 1, 2013) for which rural track FTE limitations would become effective under current policy after 3 years (likely on July 1, 2016). We are proposing that, if our proposal is finalized, we would not actually apply the rural track FTE limitations that would have become effective for these

hospitals after 3 program years. Instead, the rural track FTE limitations for these hospitals would be the actual number of FTE residents training in the rural track (subject to the rolling average at § 413.79(d)(7) and the IME IRB ratio cap at § 412.105(a)(1)(i), if applicable) for an additional 2 years (from July 1, 2016 through June 30, 2018), and the rural track FTE limitations would become effective with the cost reporting period that coincides with or follows the start of the sixth program year, which in this example would be July 1, 2018.

In summary, we are proposing to revise the direct GME regulations at § 413.79(k) (and which, in turn, would affect IME adjustments under § 412.105(f)(1)(x)) to permit that, effective with rural track training programs started on or after October 1, 2012, in the first 5 program years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents (subject to the rolling average at § 413.79(d)(7) and the IME IRB ratio cap at § 412.105(a)(1)(i), if applicable), training in the rural track training program at the urban hospital, and the rural track FTE limitation would take effect beginning with the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track training program's existence.

We are inviting public comment on this proposal.

#### K. Rural Community Hospital Demonstration Program

##### 1. Background

Section 410A(a) of Public Law 108-173 required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing "rural community" hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and

- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Section 410A(a)(4) of Public Law 108–173 specified that the Secretary was to select for participation no more than 15 rural community hospitals in rural areas of States that the Secretary identified as having low population densities. Using 2002 data from the U.S. Census Bureau, we identified the 10 States with the lowest population density in which rural community hospitals were to be located in order to participate in the demonstration: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, Utah, and Wyoming. (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003.)

CMS originally solicited applicants for the demonstration in May 2004; 13 hospitals began participation with cost 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 9 hospitals participating at that time. In 2008, we announced a solicitation for up to 6 additional hospitals to participate in the demonstration program. Four additional hospitals were selected to participate under this solicitation. These 4 additional hospitals began under the demonstration payment methodology with the hospital's first cost reporting period starting on or after July 1, 2008. At that time, 13 hospitals were participating in the demonstration.

Five hospitals (3 of the hospitals were among the 13 hospitals that were original participants in the demonstration program and 2 of the hospitals were among the 4 hospitals that began the demonstration program in 2008) withdrew from the demonstration program during CYs 2009 and 2010. (Three of these hospitals indicated that they would be paid more for Medicare inpatient hospital services under the rebasing option allowed under the SCH methodology provided for under section 122 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275). One hospital restructured to become a CAH, and one hospital closed.) In CY 2011, one hospital that was among the original set of hospitals that participated in the demonstration withdrew from the demonstration. These actions left seven of the originally participating hospitals (that is, hospitals that were selected to participate in either 2004 or 2008) participating in the demonstration program as of June 1, 2011.

Sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148)

amended section 410A of Public Law 108–173, changing 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, to begin 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 period, unless the hospital makes an election to discontinue participation.

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. Further, 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. 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.

We published a solicitation for applications for additional participants in the rural community hospital demonstration program in the **Federal Register** on August 30, 2010 (75 FR 52960). Applications were due on October 14, 2010. The 20 States with the lowest population density that were eligible for the demonstration program are: Alaska, Arizona, Arkansas, Colorado, Idaho, Iowa, Kansas, Maine, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, and Wyoming (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003). We approved 19 new hospitals for participation in the demonstration program. We determined that each of these new hospitals would begin participating in the demonstration with its first cost reporting period beginning on or after April 1, 2011.

Three of these 19 hospitals declined participation prior to the start of the cost reporting periods for which they would have begun the demonstration. In addition to the 7 hospitals that were selected in either 2004 or 2008, the new selection led to a total of 23 hospitals in the demonstration. During CY 2013, one additional hospital among the set selected in 2011 withdrew from the demonstration, similarly citing a

relative financial advantage to returning to the customary SCH payment methodology, which left 22 hospitals participating in the demonstration, effective July 1, 2013. In October 2015, another hospital among those selected in 2011 closed, leaving 14 among this cohort still participating. (By this date, as described below, the 7 hospitals that were selected in either 2004 or 2008 had completed the 5-year extension period mandated by the Affordable Care Act).

Section 410A(c)(2) of Public Law 108–173 required that, in 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 12 IPPS final rules, 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 2016 IPPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, 78 FR 50740, 77 FR 50145, and 80 FR 49585, respectively), we believe that the language of the statutory budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

## 2. Budget Neutrality Offset Adjustments: Fiscal Years 2005 Through 2016

### a. Fiscal Years 2005 Through 2013

In general terms, in each of these previous years from FYs 2005 through 2016, we used available cost reports for the participating hospitals to derive an estimate of the additional costs attributable for the demonstration. For FYs 2005 through 2012, we used finalized, or settled, cost reports, as available, and “as submitted” cost reports for hospitals for which finalized cost reports were not available to derive this estimate of the additional costs attributable to the demonstration. 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 cost amounts obtained from these cost reports. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53452), we initiated two general changes to the methodology for estimating the costs of the demonstration (which we have continued to apply through FY 2016). First, we used “as submitted” cost reports for each hospital participating in the demonstration in estimating the costs of the demonstration (for FY 2013, we used cost reports for cost reporting periods ending in CY 2010). Second, 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. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53449 through 53453) for a detailed discussion of the methodology initiated in FY 2013.

In each of these fiscal 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 to update the estimated costs. 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 through 2016, 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 2013, we based the budget neutrality offset estimate on the estimated cost of the demonstration in an earlier given year. For these periods, we derived that estimated cost by subtracting the estimated amount that would otherwise be paid without the demonstration in an earlier given year from the estimated amount for the same year that would be paid under the demonstration under the reasonable cost-based methodology authorized by section 410A of Public Law 108–173. (We 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 finalized or “as submitted” cost reports as discussed earlier.) For FYs 2005 through 2012, we then updated the estimated costs described earlier to the upcoming year by multiplying them by the market basket percentage increases applicable to the years involved and the applicable annual volume adjustment. Beginning in FY 2013, as discussed earlier, we began incorporating different update factors—we used the IPPS market basket percentage increases applicable to the years involved to update the estimated amount that would be paid under the demonstration under the reasonable cost-based methodology, and the applicable percentage increases applicable to the years involved to update the amounts that would otherwise be paid without the demonstration. We continued to apply the annual volume adjustment as discussed earlier.

For the FY 2010 IPPS/R Y 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/R Y 2010 LTCH PPS final rule, we included an additional amount in the budget neutrality offset amount 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.

In the final rules for FYs 2011 through 2013, we continued to use a methodology for calculating the budget neutrality offset amount consisting of two components: (1) The estimated demonstration costs in the upcoming fiscal year; and (2) the amount by which the actual demonstration costs corresponding to an earlier, given year (which would be known once finalized cost reports became available for that year) exceeded the budget neutrality offset amount finalized in the corresponding year’s IPPS final rule. However, we noted in the FYs 2011, 2012, and 2013 IPPS final rules that, because of a delay affecting the settlement process for cost reports for IPPS hospitals occurring on a larger scale than merely for the demonstration, we were unable to finalize this component of the budget neutrality offset amount accounting for the amount by which the actual demonstration costs in an earlier 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.

### b. Fiscal Years 2014 and 2015

In the final rules for FYs 2014 and 2015, we continued to apply the general methodology discussed earlier (with the modifications initiated in FY 2013) in estimating the costs of the demonstration for the specific fiscal year, using the set of “as submitted” cost reports from the most recent calendar year for which they are available (cost reporting periods ending in 2011 and 2012, respectively), and updating the cost amounts according to the factors discussed earlier. In addition, in these final rules, because finalized cost reports for FYs 2007 and 2008 had become available, we were able to include in the budget neutrality offset adjustment the amount by which the actual demonstration costs in each of those years exceeded the budget neutrality offset amounts finalized in the IPPS final rules for these years.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR through 50744), we determined the final budget neutrality offset amount to be applied to the FY 2014 IPPS rates to be \$52,589,741. This

amount was comprised of the two distinct components identified earlier: (1) The final resulting difference between the total estimated FY 2014 reasonable cost amount to be paid under the demonstration to the 22 participating hospitals for covered inpatient hospital services, and the total estimated amount that would otherwise be paid to such hospitals without the demonstration (this amount was \$46,549,861); and (2) the amount by which the actual costs for the demonstration for FY 2007 (as shown in the finalized cost reports for cost reporting periods beginning in FY 2007 for the nine hospitals that participated in the demonstration during FY 2007) exceeded the budget neutrality offset amount that was finalized in the FY 2007 IPPS final rule (this amount was \$6,039,880).

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50141 through 50145), we determined the final budget neutrality offset amount to be applied to the FY 2015 IPPS rates to be \$64,566,915. This amount was also comprised of the two earlier referenced components: (1) The final resulting difference between the total estimated FY 2015 reasonable cost amount to be paid under the demonstration to the 22 participating hospitals for covered inpatient hospital services, and the total estimated amount that would otherwise be paid to such hospitals in FY 2015 without the demonstration (this amount was \$54,177,144); and (2) the amount by which the actual costs of the demonstration for FY 2008 (as shown in the finalized cost reports for the hospitals that participated in the demonstration during FY 2008) exceeded the budget neutrality offset amount that was finalized in the FY 2008 IPPS final rule (this amount was \$10,389,771).

### c. Fiscal Year 2016

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49586 through 49591), we continued to apply the general methodology discussed earlier for FYs 2014 and 2015 in estimating the costs of the demonstration for FY 2016, with some modifications. For FY 2016, we used the set of “as submitted” cost reports from the most recent calendar year for which they were available (cost reporting periods ending in CY 2013), and updated the cost amounts using the IPPS market basket percentage increase and applicable percentage increase applicable to the years involved as discussed earlier. Although the methodology for FY 2016 was similar to that for the previous several rules, because the demonstration began to

phase out prior to the beginning of FY 2016, appropriate changes to the calculations were made. The 7 “originally participating hospitals,” that is, those hospitals that were selected for the demonstration in either 2005 or 2008, were scheduled to end their participation in the 5-year extension period authorized by the Affordable Care Act prior to the start of FY 2016. Therefore, we did not include the financial experience of these hospitals in the calculation of either the estimated reasonable cost amount or the estimated amount that otherwise would be paid without the demonstration for FY 2016. In addition, 8 hospitals that entered the demonstration in 2011 and 2012 through the solicitation that followed the Affordable Care Act amendments expanding the demonstration, and that were still participating in the demonstration at the time of the FY 2016 IPPS/LTCH PPS final rule, were scheduled to end their participation on a rolling basis before September 30, 2016. As discussed in the FY 2016 IPPS/LTCH PPS final rule, for these 8 hospitals, the estimated reasonable cost amount and the estimated amount that would otherwise be paid without the demonstration were prorated according to the ratio of the number of months between October 1, 2015, and the end of the hospital’s cost reporting period in relation to the entire 12-month period. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49586 through 49588) for a discussion of these additional calculations.

The resulting estimate of costs of the demonstration for FY 2016 for the 15 hospitals participating in the demonstration for FY 2016 was \$26,044,620.

In addition, in the FY 2016 IPPS/LTCH PPS final rule, we were able to finalize the amounts by which the actual demonstration costs for FYs 2009 and 2010 differed from the budget neutrality offset amount finalized in the corresponding final rules for these years using the following approach:

We identified the difference between the actual cost of the demonstration for FY 2009 as indicated in the finalized cost reports for hospitals that participated in FY 2009 and that had cost reporting periods beginning in FY 2009 (this amount was \$14,332,936), and the budget neutrality offset amount that was identified in the FY 2009 IPPS final rule (73 FR 48671) (this amount was \$22,790,388). Analysis of this set of cost reports showed that the budget neutrality offset amount that was finalized to account for the demonstration costs in FY 2009 (as set forth in the FY 2009 IPPS final rule)

exceeded the actual cost of the demonstration for FY 2009 by \$8,457,452.

We included the amount by which the actual costs of the demonstration for FY 2010 (as shown in the finalized cost reports for the nine hospitals that completed a cost reporting period beginning in FY 2010) (\$16,817,922) differed from the amount that was finalized as the costs of the demonstration for FY 2010 as set forth in the FY 2010 IPPS/LTCH PPS final rule and the FY 2011 IPPS/LTCH PPS final rule (\$21,569,472). Analysis of this set of cost reports showed that the budget neutrality offset amount that was finalized to account for the demonstration costs in FY 2010 (as set forth in the FY 2010 IPPS/LTCH PPS final rule and the FY 2011 IPPS/LTCH PPS final rule) exceeded the actual cost of the demonstration for FY 2010 by \$4,751,550.

Unlike in previous years, because the budget neutrality offset amount identified in the corresponding final rules for each of FYs 2009 and 2010 exceeded the actual costs of the demonstration, we subtracted the differences between these amounts for each fiscal year (that is, \$8,457,452 applicable to FY 2009 and \$4,751,550 applicable to FY 2010) from the estimated amount of the costs of the demonstration for FY 2016 (that is, \$26,044,620). Thus, the final budget neutrality offset amount for which the adjustment to the national IPPS rates was calculated was \$12,835,618.

### 3. Proposed Budget Neutrality Methodology for FY 2017

As described earlier, we have generally incorporated two components into the budget neutrality offset amounts identified in the final IPPS rules in previous years. First, we have estimated the costs of the demonstration for the upcoming fiscal year, generally determined from historical, “as submitted” cost reports for the hospitals participating in that year. Update factors representing nationwide trends in cost and volume increases have been incorporated into these estimates, as specified in the methodology described in the final rule for each fiscal year. Second, as finalized cost reports have become available, we have determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. If the actual costs for the demonstration



for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference was added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. Conversely, if the estimated costs of the demonstration set forth in the final rule for a prior fiscal year exceeded the actual costs of the demonstration for that year, this difference was subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. We note that we have calculated this difference between the actual costs of the demonstration for FYs 2005 through 2010, as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

In this FY 2017 proposed rule, we are proposing a different methodology as compared to previous years for analyzing the costs attributable to the demonstration for FY 2017. We note that the demonstration will have substantially phased out by the beginning of FY 2017. The 7 “originally participating hospitals,” that is, those that were selected for the demonstration in 2004 and 2008, ended their participation in the 5-year extension period authorized by the Affordable Care Act prior to the start of FY 2016. In addition, the participation period for the 14 hospitals that entered the demonstration following upon the mandate of the Affordable Care Act and that are still participating will end on a rolling basis according to the end dates of the hospitals’ cost report periods, respectively, from April 30, 2016 through December 31, 2016. (As noted earlier, 1 hospital among this cohort closed in October 2015). Of these 14 hospitals, 10 will end participation on or before September 30, 2016, leaving 4 hospitals participating for the last 3 months of CY 2016 (that is, the first 3 months of FY 2017). We believe that, given the small number of participating hospitals and the limited time of participation for such hospitals during FY 2017, a revised methodology is appropriate for determining the costs of the demonstration during this period as discussed below.

We note that estimating the costs of the demonstration for these 4 hospitals for their extent of participation in the demonstration in FY 2017 would entail a prorating calculation if we followed the methodology we used for FY 2016

as described earlier, as well as application of update factors to project increases in cost. We further note that, for the 4 hospitals that will end their participation in the demonstration effective December 31, 2016, the financial experience of the last 3 months of the calendar year (that is, the first 3 months of FY 2017) will be included in the finalized cost reports for FY 2016. (Consistent with the methodology used for the final rules for previous years, a hospital’s cost report is included in the analysis of a given fiscal year if the cost reporting period begins in that fiscal year). We believe that examining the finalized cost reports for FY 2016 for these hospitals would lead to a more accurate and administratively feasible calculation of budget neutrality for the demonstration in FY 2017 than conducting an estimate of the costs of the demonstration for this 3-month period based on “as submitted cost reports” (as would occur according to the budget neutrality methodology currently in effect).

In addition, given that the extent of covered services for FY 2017 subject to the payment methodology under the demonstration is a small fraction of that in previous fiscal years, we believe that it is appropriate to forego the process of estimating the costs attributable to the demonstration for 2017 and to instead analyze the set of finalized cost reports for cost reporting periods beginning in FY 2016, which will reflect the actual cost of the demonstration, when they become available. Such an approach also would eliminate the need to perform for FY 2017 the second component of the budget neutrality methodology discussed earlier (that is, determining the amount by which the actual costs of the demonstration for the fiscal year, as determined in finalized cost reports once available, differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year). Thus, for the reasons discussed earlier, we are proposing to calculate the costs of the demonstration and the resulting budget neutrality adjustment factor for the demonstration for FY 2017 once the finalized cost reports for cost reporting periods beginning in FY 2016 become available. We are inviting public comments on this proposal.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49591), we stated that we intended to discuss in this FY 2017 IPPS/LTCH PPS proposed rule how we would reconcile the budget neutrality offset amounts identified in the IPPS final rules for FYs 2011 through 2016 with the actual costs of the demonstration for those years,

considering the fact that the demonstration will end December 31, 2016. We believe it would be appropriate to conduct this analysis for FYs 2011 through 2016 at one time, when all of the finalized cost reports for cost reporting periods beginning in FYs 2011 through 2016 are available. Such an aggregate analysis encompassing the cost experience through the end of the period of performance of the demonstration represents an administratively streamlined method, allowing for the determination of any appropriate adjustment to the IPPS rates and obviating the need for multiple fiscal-year-specific calculations and regulatory actions. Given the general lag of 3 years in finalizing cost reports, we expect any such analysis to be conducted in FY 2020.

We also note that, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49591), we indicated that we were considering whether to propose in future rulemaking that the calculation of the final costs of the demonstration for a fiscal year reflect that some of the participating hospitals would otherwise have been eligible for the payment adjustment for low-volume hospitals in that fiscal year if they had not participated in the demonstration. Our policy under the demonstration is that hospitals participating in the demonstration are not able to receive the low-volume adjustment in addition to the reasonable cost-based payment authorized by section 410A of Public Law 108–173. We refer readers to Change Request 7505 dated July 22, 2011, available on the CMS Web site at: <http://www.cms.gov>. Section 1886(d)(12) of the Act provides for a payment adjustment to account for the higher costs per discharge for low-volume hospitals under the IPPS, effective FY 2005 (69 FR 49099 through 49102). We note that sections 3125 and 10314 of the Affordable Care Act provided for temporary changes in the qualifying criteria and payment adjustment for low-volume hospitals for FYs 2011 and 2012, which have been extended through subsequent legislation: Through FY 2013, by the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) (78 FR 50610 through 50613), through March 31, 2014, by the Pathway for SGR Reform Act (Pub. L. 113–67) (79 FR 15022 through 15025); through March 21, 2015, by the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) (79 FR 49998 through 50001); and most recently through September 30, 2017, by section 204 of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub.

L. 114–110). These temporary changes have increased the number of hospitals that are eligible to receive the low-volume hospital payment adjustment.

We further stated in the FY 2016 IPPS/LTCH PPS final rule that taking the low-volume hospital payment adjustment into account in determining the costs of the demonstration would require detailed consideration of the data sources and methodology that would be used to determine which among the demonstration hospitals would have otherwise been eligible for the low-volume payment adjustment and to estimate the amount of the adjustment. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 24521), we invited public comments on this issue.

We are continuing to examine this issue and are considering whether to incorporate the low-volume payment adjustment amounts that would have otherwise been made into the calculation of the difference between the actual costs of the demonstration and budget neutrality offset amounts for FYs 2011 through 2016. We note that applying such a methodology may lower the calculated amounts of the actual costs of the demonstration compared to not applying such a methodology, making it more likely that the actual costs of the demonstration for a year will not exceed the estimated costs of the demonstration identified in the final rule for that year. We again are inviting public comments on this issue.

#### *L. Proposed Hospital and CAH Notification Procedures for Outpatients Receiving Observation Services*

##### 1. Background

###### a. Statutory Authority

On August 6, 2015, the Notice of Observation Treatment and Implication for Care Eligibility Act (the NOTICE Act), Public Law 114–42 was enacted. Section 2 of the NOTICE Act amended section 1866(a)(1) of the Act by adding new subparagraph (Y) that requires hospitals and critical access hospitals (CAHs) to provide written notification and an oral explanation of such notification to individuals receiving observation services as outpatients for more than 24 hours at the hospitals or CAHs. Section 1866(a)(1) of the Act lists requirements for providers of services to participate in the Medicare program and be eligible for payments under Medicare pursuant to provider agreements.

Section 1866(a)(1)(Y) of the Act, as added by section 2 of the NOTICE Act, specifies that the notification process must consist of a written notification as specified by the Secretary through rulemaking and containing such

language as the Secretary prescribes consistent with the statutory provision, and an oral explanation of the written notification and documentation of the provision of the explanation, as the Secretary determines to be appropriate. Notification to each individual who receives observation services as an outpatient for more than 24 hours must be provided no later than 36 hours after observation services are initiated (or sooner, if upon release from the hospital or CAH). Section 1866(a)(1)(Y)(ii) of the Act provides that the written notice must explain that the individual is an outpatient receiving observation services, and is not an inpatient of a hospital or CAH. In addition, the written notice must include the reason(s) the individual is an outpatient receiving observation services and must explain the implications of being an outpatient receiving observation services, such as cost-sharing requirements and post-hospitalization eligibility for coverage of skilled nursing facility (SNF) services under Medicare. The written notification also must include any additional information as deemed appropriate by the Secretary. Moreover, the written notification must either be signed by the individual receiving observation services as an outpatient, or a person acting on the individual's behalf, to acknowledge receipt of the notification. In cases where a signature by the individual or the person acting on the individual's behalf is refused, section 1866(a)(1)(Y)(ii)(IV)(bb) of the Act stipulates that the notification be signed by the staff member of the hospital or CAH who presented the written notification and include the name and title of the staff member, a certification statement that the notification was presented, and the date and time that the notification was presented. Finally, section 1866(a)(1)(Y)(ii)(V) of the Act provides that the notification be written and formatted using plain language and is made available in appropriate languages as determined by the Secretary.

###### b. Proposed Effective Date

Section 2 of the NOTICE ACT provides the effective date for this notification requirement as effective beginning 12 months after the date of enactment of the NOTICE Act; that is, effective on August 6, 2016. Since the date the NOTICE Act was enacted, CMS has been working to implement the statutory requirement in a timely manner. On December 14, 2015, CMS released an electronic mailbox address for individuals who wished to submit email comments on the provisions of

the NOTICE Act. In addition, CMS announced a December 21, 2015 listening session to provide individuals further opportunity to provide comment on the NOTICE Act. We thank those individuals who shared their input. The agency reviewed all comments submitted by email as well as those comments provided during the public listening session in developing the provisions of this proposed rule.

##### 2. Proposed Implementation of the NOTICE Act Provisions

###### a. Proposed Notice Process

In this proposed rule, we are proposing to implement section 1866(a)(1)(Y) of the Act by revising the requirements that providers agree to as part of participating in Medicare under a provider agreement by establishing regulations (at proposed 42 CFR 489.20(y)) that would specify a process for hospitals and CAHs to notify an individual, orally and in writing, regarding the individual's receipt of observation services as an outpatient and the implications of receiving such services as set forth below. Under this proposed process, hospitals and CAHs would be required to furnish notice to such an individual entitled to Medicare benefits if the individual receives observation services as an outpatient for more than 24 hours. We are proposing the use of a standardized notice, referred to as the Medicare Outpatient Observation Notice (MOON), to be used by all applicable hospitals and CAHs. The MOON would include all of the informational elements required by section 1866(a)(1)(Y)(ii) of the Act to fulfill the written notice requirement of the NOTICE Act.

###### b. Proposed Notification Recipients

Section 1866(a)(1)(Y) of the Act requires hospitals or CAHs to furnish notice to each individual who receives observation services as an outpatient at such hospital or CAH for more than 24 hours. Throughout section 1866 of the Act, "individual" generally refers to a person entitled to have payment made for services under Title XVIII of the Act, or a person not entitled to have payment made for services under Title XVIII if certain conditions are met. The provisions of the NOTICE Act specify that notice must be provided to individuals receiving observation services as an outpatient for more than 24 hours; the provisions do not specify qualifications related to payment for such services as a condition of notice. Accordingly, we are proposing under the new § 489.20(y) that the notification required by section 1866(a)(1)(Y) of the

Act must be provided to individuals entitled to benefits under Title XVIII of the Act, whether or not the services furnished are payable under Title XVIII, when individuals receive observation services as an outpatient for more than 24 hours. For example, an individual receiving Medicare Part A benefits who has not enrolled in Part B would still receive notice even though the observation services the individual receives as an outpatient would not be covered under Medicare for him or her, as such observation services received as an outpatient would fall under the Part B benefit and would be subject to payment under Medicare Part B.

A beneficiary enrolled in a Medicare Advantage or other Medicare health plan would receive the required notice under the existing rules that apply to hospitals and CAHs under a provider agreement governed by the provisions of section 1866(a)(1)(Y) of the Act. The Medicare Advantage regulations related to selection and credentialing of contract providers at 42 CFR 422.204(b)(3) require that, with respect to providers that meet the definition of “provider of services” as defined in section 1861(u) of the Act, basic benefits may only be provided by these providers if they have a provider agreement with CMS permitting them to provide services under original Medicare. Under section 1861(u) of the Act, the term “provider of services” means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, for purposes of section 1814(g) and section 1835(e) of the Act, a fund.

Observation services are always provided under a physician’s order that specifies the initiation of observation services. As a general matter, hospital observation services are defined in the Medicare Benefits Policy Manual (Pub. 100–02), Chapter 6, Section 20.6, as services that are medically reasonable and necessary, specifically ordered by a physician or other nonphysician practitioner authorized by State licensure law and hospital staff bylaws to admit patients to the hospital or to order outpatient services, and meet other published Medicare criteria for payment. The term “physician” will encompass these authorized qualified nonphysician practitioners for the purposes of this proposed rule. Individuals receiving observation services will always be registered as outpatients; however, not all outpatients receive observation services. “Outpatient,” as defined in the Medicare Claims Processing Manual

(Pub. 100–04), Chapter 1, Section 50.3.1, means “a person who has not been admitted as an inpatient but who is registered on the hospital or critical access hospital (CAH) records as an outpatient and receives services (rather than supplies alone) directly from the hospital or CAH.” We are proposing that the provisions in this proposed rule would apply to the subset of individuals entitled to benefits under Title XVIII of the Act who are receiving treatment as outpatients and are receiving observation services for more than 24 hours. For outpatients who are not receiving observation services, or who are receiving observation services but not for more than 24 hours, hospitals and CAHs would not be required to deliver notice.

#### c. Proposed Timing of Notice Delivery

As provided at section 1866(a)(1)(Y) of the Act, we are proposing under proposed new § 489.20(y) that hospitals and CAHs must provide notice to an individual who receives observation services as an outpatient for more than 24 hours and that such notice must be furnished no later than 36 hours after observation services are initiated, or sooner if the individual is transferred, discharged, or admitted as an inpatient.

For purposes of this proposed rule, consistent with existing billing rules, observation services are initiated when a physician orders such services. According to the Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 290.2.2, hospital reporting for observation services “begins at the clock time documented in the patient’s medical record, which coincides with the time that observation services are initiated in accordance with a physician’s order.” Because valid medical documentation for observation services will always contain the time when observation services are initiated, we believe hospitals and CAHs will be able to readily determine the timeframe within which the notice must be delivered. We expect that there will be cases where an individual receives more than 24 hours of observation services and has not yet received the MOON, but there are imminent plans for discharge to home or another facility, transfer to another unit or facility to receive care that does not include observation services, or admission to the hospital or another facility as an inpatient. In these cases, pursuant to section 1866(a)(1)(Y) of the Act, which provides that notice be provided not later than 36 hours after the time such an individual begins receiving such services (or, if sooner, upon release), we are proposing that the MOON must be given sooner than the

36-hour time limit for delivery because the MOON must be delivered before the individual is discharged, transferred, or admitted. When there are no plans to transfer, discharge, or admit an individual who receives observation services for more than 24 hours, we are proposing that the MOON must be provided within 36 hours of the initiation of observation services.

In rare circumstances where a physician initially orders inpatient services, but following internal utilization review (UR) performed while the patient is hospitalized, the hospital determines that the services do not meet its inpatient criteria and the physician concurs with UR, orders the discontinuation of inpatient services and initiation of outpatient observation services (that is, a Condition Code 44 situation), the MOON would be delivered as required by the NOTICE Act (when outpatient observation services have been ordered and furnished for more than 24 hours). If observation services are ordered when Condition Code 44 applies, the 24-hour time period for observation notification commences at the same time that observation services are initiated under a physician’s order, consistent with existing policy for observation services furnished to outpatients. (We refer readers to the Medicare Claims Processing Manual, (Pub. 100–04), Chapter 1, Section 50.3.)

As stated in the notice announcing CMS Ruling CMS–1455–R (78 FR 16614), the Part B Inpatient Billing Ruling, in cases where CMS reviewers find that an inpatient admission was not medically reasonable and necessary after the beneficiary is discharged, and thus, not appropriate for payment under Medicare Part A, the beneficiary’s patient status remains “inpatient” as of the time of the inpatient admission. The patient’s status is not changed to outpatient because the beneficiary was formally admitted as an inpatient, and there is no provision to change a beneficiary’s status after he or she is discharged from the hospital. Where CMS denies a claim after the beneficiary has been discharged because the inpatient admission was not medically reasonable and necessary, there would be no need to issue the MOON because the individual’s status remains inpatient, despite the fact that the inpatient admission was improper. Similarly, where a hospital determines through UR after a beneficiary is discharged that his or her inpatient admission was not reasonable and necessary and the hospital bills the services that were provided on a Medicare Part B claim, the NOTICE Act

notification requirements would not apply for these individuals because their status would also remain inpatient.

#### d. Proposed Requirements for Written Notice

We are proposing to implement section 1866(a)(1)(Y)(ii) of the Act, the requirement for written notification, under proposed new § 489.20(y)(1) by proposing the basic requirements for the written notice that hospitals and CAHs must use to notify individuals receiving outpatient observation services. Specifically, we are proposing that hospitals and CAHs would be required to use a proposed standardized notice (the MOON) for written notification to an individual who receives observation services as an outpatient under the appropriate circumstances. By requiring use of a standardized notice, hospitals and CAHs would be assured that they are providing all of the statutorily required elements in a manner that is understandable to individuals receiving the notice. As provided at section 1866(a)(1)(Y)(ii)(I) of the Act, we are proposing at § 489.20(y)(1)(i) that the proposed MOON would explain to individuals that they are outpatients receiving observation services and not inpatients of the hospital or CAH, and the reason(s) for such status as an outpatient receiving observation services. By definition (as specified in the Medicare Benefits Policy Manual, (Pub. 100–02), Chapter 6, Section 20.6), the reason for ordering observation services will always be the result of a physician’s decision that the individual does not currently require inpatient services and observation services are needed for the physician to make a decision regarding whether the individual needs further treatment as a hospital inpatient or if the individual is able to be discharged from the hospital. We are proposing at § 489.20(y)(1)(ii) that the proposed MOON also would provide an explanation of the implications of receiving observation services furnished by a hospital or CAH as an outpatient, including services furnished on an inpatient basis, such as those related to cost-sharing requirements for the patient under Medicare, and post-hospitalization eligibility for Medicare-covered SNF care, in standardized language to ensure that all Medicare eligible individuals receive accurate information. We are proposing the inclusion of a blank “Additional Information” section on the MOON so that hospitals and CAHs may include additional information. Finally, as required by section 1866(a)(1)(Y)(ii)(V) of the Act, the proposed MOON would include this

information in plain language written for beneficiary comprehension.

#### e. Outpatient Observation Services and Beneficiary Financial Liability

Section 20.6, Chapter 6, of the Medicare Benefit Policy Manual (Pub. 100–2) specifies that observation services furnished by hospitals and CAHs are “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 patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital.” Typically, observation services are ordered for individuals who present to the emergency department (ED) and who then require a significant period of treatment and monitoring to determine whether or not their condition warrants inpatient admission or discharge. Individuals also may receive outpatient observation services in other areas of a hospital or CAH when necessary. For example, a patient who receives a drug infusion in a hospital’s outpatient infusion center and then experiences post-infusion hypertension may require observation services. In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours. In only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours. All hospital observation services, regardless of duration of care, that are medically reasonable and necessary are covered by Medicare.

In some cases, Medicare beneficiaries receiving observation services while in a hospital or CAH may not be aware of their status as an inpatient or an outpatient, and thus may not be aware that there are significant differences in financial liability between inpatient status and outpatient status. CMS has published educational materials for Medicare beneficiaries to help inform them of financial and coverage liabilities associated with inpatient and outpatient services.<sup>70</sup> As an outpatient receiving observation services, a beneficiary may incur financial liability for Medicare Part B copayments,<sup>71</sup> the

<sup>70</sup> “Are You a Hospital Inpatient or Outpatient? If You Have Medicare—Ask!” CMS Product No. 11435. May 2014.

<sup>71</sup> A beneficiary who receives hospital outpatient services typically pays 20 percent of the Medicare payment amount for outpatient items and services after paying the annual Part B deductible (\$166 in CY 2016). The coinsurance amount for an

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 consecutive stay to be eligible for coverage of post-hospital SNF care under Medicare Part A. In contrast, as a hospital inpatient under Medicare Part A, a beneficiary pays an annual deductible (\$1,288 in CY 2016) for all inpatient services provided during the first 60 days in the hospital of each benefit period for the year. Cost-sharing requirements for individuals enrolled in Medicare Part C, known as Medicare Advantage, health plans are dependent on the particular plan’s policies. In addition, Medicare beneficiaries qualified through their State Medicaid program (QMBs) have different cost-sharing rules. For example, QMBs cannot be billed for Medicare Part A or Part B deductibles, coinsurance, and copayments and may have different rules regarding qualifying for SNF services. CMS has produced informational publications for beneficiaries that advise Medicare Advantage enrollees to check with their plans for information on coverage of observation services furnished to an outpatient.

As mentioned earlier, a beneficiary’s liability for medication costs also is likely affected by whether the individual is hospitalized as an inpatient or receiving care as an outpatient. When an individual is hospitalized under a covered Medicare Part A inpatient stay, payment for medically reasonable and necessary medications that are provided by the hospital are covered under Medicare Part A. Generally, Medicare Part B covers drugs that are usually not self-administered. Based on the statutory prohibition at section 1861(s)(2) of the Act and its implementing regulation at 42 CFR 410.29(a), Medicare Part B generally does not cover or pay for any drug or biological that can be self-administered. “Self-administered drugs” are considered prescription and over-the-counter medications that beneficiaries routinely take on their own. For safety reasons, many hospitals do not allow patients to take medications brought from home.

outpatient CAH service is based on 20 percent of charges. In most cases, the cost-sharing for each individual outpatient service should not be more than the inpatient deductible. However, Medicare beneficiaries who receive several outpatient services, or are treated for extended periods of time as hospital outpatients, may have greater cost-sharing liabilities as an outpatient under observation than they may have if they were admitted as an inpatient to the hospital.

Medicare prescription drug plans (Part D) may help pay for drugs provided by the hospital. Individuals with Medicare Part D will likely need to pay out-of-pocket costs to the hospital for these drugs and request reimbursement from their Part D plan.

In addition, whether an individual is receiving treatment or care as an inpatient admitted to the hospital or is receiving observation services as an outpatient pursuant to a doctor's orders may impact Medicare coverage for post-hospital SNF services. Section 1861(i) of the Act requires a beneficiary to be an inpatient of a hospital for not less than 3 consecutive days before discharge from the hospital in order to be eligible for coverage of post-hospital extended care services in a SNF under Medicare. For purposes of Medicare SNF coverage, the time spent receiving observation services as an outpatient does not count towards the requirement of a 3-day hospital inpatient stay because these services are outpatient.

#### f. Delivering the Medicare Outpatient Observation Notice

An English language version of the proposed MOON was submitted to OMB for approval. Once we receive OMB approval, a Spanish language version of the MOON will be made available. If the individual receiving the notice is unable to read its written contents and/or comprehend the required oral explanation, we expect hospitals and CAHs to employ their usual procedures to ensure notice comprehension. (We refer readers, for example, to the Medicare Claims Processing Manual (Pub. 100-4), Chapter 30, Section 40.3.4.3., for similar existing procedures related to notice comprehension for the Advance Beneficiary Notice of Noncoverage (ABN).) Usual procedures may include, but are not limited to, the use of translators, interpreters, and assistive technologies. Hospitals and CAHs are reminded that recipients of Federal financial assistance have an independent obligation to provide language assistance services to individuals with limited English proficiency (LEP) consistent with section 1557 of the Affordable Care Act and Title VI of the Civil Rights Act of 1964. In addition, recipients of Federal financial assistance have an independent obligation to provide auxiliary aids and services to individuals with disabilities free of charge, subject to section 1557 of the Affordable Care Act and section 504 of the Rehabilitation Act of 1973.

#### g. Proposed Oral Notice

Pursuant to the statutory requirement at section 1866(a)(1)(Y)(i) of the Act, we are proposing under proposed new § 489.20(y)(2) that hospitals and CAHs provide an oral explanation of the written notice furnished to individuals who receive observation services as outpatients. We will provide guidance for oral notification in our forthcoming Medicare manual provisions. Hospitals and CAHs are familiar with providing oral explanations of written notices (for example, surgical and procedural consent notices and the Important Message from Medicare), and we expect that oral notification will occur in conjunction with delivery of the MOON. Again, hospitals and CAHs are reminded that recipients of Federal financial assistance have an independent obligation to provide language assistance services to individuals with LEP consistent with section 1557 of the Affordable Care Act and Title VI of the Civil Rights Act of 1964. In addition, recipients of Federal financial assistance have an independent obligation to provide auxiliary aids and services to individuals with disabilities free of charge, subject to section 1557 of the Affordable Care Act and section 504 of the Rehabilitation Act of 1973.

#### h. Proposed Signature Requirements

As set forth at section 1866(a)(1)(Y)(ii)(IV) of the Act, the written notification must be either signed by the individual receiving observation services as an outpatient or a person acting on such individual's behalf to acknowledge receipt of notification. Moreover, the statute provides that if such individual or person refuses to provide a signature, the written notification is to be signed by the staff member of the hospital or CAH who presented the written notification and certain information needs to be included with such signature. Accordingly, we are proposing under proposed new § 489.20(y)(3), that the written notice be signed, as described above, in order to acknowledge receipt and understanding of the notice. The MOON would include a dedicated signature area for this purpose. In cases where the individual receiving the MOON refuses to sign the notice, we are proposing that the MOON must be signed by the staff member who presents the notice to the individual. The staff signature would include the staff member's name and title, a certification statement that the notice was presented, and the date and time that the notice was presented.

#### i. No Appeal Rights Under the NOTICE Act

Section 1866(a)(1)(Y) of the Act, as added by the NOTICE Act, does not afford appeal rights to beneficiaries regarding the notice provided pursuant to that statutory provision. To provide clarity to this point, we are proposing to amend the regulations at 42 CFR 405.926 relating to actions that are not initial determinations, by adding new paragraph (u) to explain that issuance of the MOON by a hospital or CAH does not constitute an initial determination and therefore does not trigger appeal rights under 42 CFR part 405, subpart I.

#### M. Proposed Technical Changes and Correction of Typographical Errors in Certain Regulations Under 42 CFR Part 413 Relating to Costs to Related Organizations and Medicare Cost Reports

##### 1. General Background

As part of our ongoing review of the Medicare regulations, we have identified a number of technical changes or corrections of typographical errors in 42 CFR part 413 relating to costs to related organizations and Medicare cost reports that need to be made. Below we are summarizing these proposed changes or corrections.

##### 2. Proposed Technical Change to Regulations at 42 CFR 413.17(d)(1) on Cost to Related Organizations

Prior to the enactment of section 911(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173), a provider had the right to nominate a fiscal intermediary (currently known as a Medicare Administrative Contractor (MAC) and referred to in this section as a "contractor") of its choice. Public Law 108-173 repealed the nomination provisions formerly found in section 1816 of the Act and added section 1874A (Contracts with Medicare Administrative Contractors). Currently, a provider will be assigned to the contractor that covers the geographic locale where the provider is located, as specified in the regulations at 42 CFR 421.404(b).

Because a provider is no longer permitted to select a contractor of its choice, and a contractor is now assigned to a provider, the parenthetical language of the regulation text at 42 CFR 413.17(d)(1) referring to a provider's nomination of a contractor is obsolete. Therefore, we are proposing to revise § 413.17(d)(1) to remove the parenthetical reference to a provider's nomination of a contractor.

3. Proposed Changes to 42 CFR 413.24(f)(4)(i) Relating to Electronic Submission of Cost Reports

In § 413.24(f)(4)(i), we incorrectly refer to a “Federally qualified health clinic.” The correct entity title under section 1861(aa) of the Act is “Federally qualified health center.” In this proposed rule, we are proposing to correct this error.

In addition, § 413.200(c)(1)(i) requires a histocompatibility laboratory to file a Medicare cost report in accordance with the regulations at § 413.24(f). For cost reporting periods ending on or after March 31, 2005, organ procurement organizations (OPOs) and histocompatibility laboratories are required to submit Medicare cost reports in a standardized electronic format, but histocompatibility laboratories were inadvertently omitted from the list of providers in the regulations text at § 413.24(f). As evidenced by the reference in the August 22, 2003 **Federal Register** document (68 FR 50720) to the Office of Management and Budget (OMB) approval number 0938–0102 of the Paperwork Reduction Act request for the cost reporting form entitled “Organ Procurement Agency/ Laboratory Statement of Reimbursable Costs,” histocompatibility laboratories were intended to be included in the regulation text. Both OPOs and histocompatibility laboratories have used that Medicare cost report form to report their statements of reimbursable costs since its approval by OMB for use for cost reporting periods ending on or after March 31, 2005. To correct this omission, we are proposing a technical change to § 413.24(f)(4)(i) to add “histocompatibility laboratories” to the list of providers required to submit cost reports in a standardized electronic format.

4. Proposed Technical Changes to 42 CFR 413.24(f)(4)(ii) Relating to Electronic Submission of Cost Reports and Due Dates

In this proposed rule, we are proposing a technical correction in § 413.24(f)(4)(ii) to the effective date for the submission of Medicare cost reports in a standardized electronic format for skilled nursing facilities (SNFs) and home health agencies (HHAs) from cost reporting periods ending on or after December 31, 1996 to cost reporting periods ending on or after February 1, 1997 to accurately reflect the regulation text finalized in the January 2, 1997 final rule, “Medicare Program: Electronic Cost Reporting for Skilled Nursing Facilities and Home Health

Agencies,” published in **Federal Register** at 62 FR 26 through 31.

For the same reasons articulated in section IV.M.3. of the preamble of this proposed rule, we also are proposing to revise § 413.24(f)(4)(ii) by adding histocompatibility laboratories to the list of providers required to file electronic cost reports. To correct a typographic error, we are proposing to remove the duplicate word “contractor” from the second sentence of this paragraph.

5. Proposed Technical Changes to 42 CFR 413.24(f)(4)(iv) Relating to Reporting Entities, Cost Report Certification Statement, Electronic Submission and Cost Reports Due Dates

In this proposed rule, we are proposing to revise § 413.24(f)(4)(iv) to make a technical correction to the effective date for SNFs and HHAs to submit hard copies of a settlement summary, a statement of certain worksheet totals found within the electronic file, and a certifying statement signed by its administrator or chief financial officer, from cost reporting periods ending on or after December 31, 1996, to cost reporting periods ending on or after February 1, 1997, to accurately reflect the regulation text finalized in the January 2, 1997 final rule (62 FR 26 through 31).

We are proposing to revise § 413.24(f)(4)(iv) by adding histocompatibility laboratories to the list of providers required to file electronic cost reports for the same reasons provided in section IV.M.3. of the preamble of this proposed rule. In addition, we are proposing to add histocompatibility laboratories to the list of providers required to submit hard copies of a settlement summary, a statement of certain worksheet totals found within the electronic file, and a certifying statement signed by its administrator or chief financial officer, for cost reporting periods ending on or after March 31, 2005, for the same reasons.

We also are proposing to correct a typographical error that occurred in the Medicare cost report certification statement set forth in § 413.24(f)(4)(iv) by adding the word “and” between the words “Sheet” and “Statement” to denote the two separate financial documents required to be submitted with the cost report; that is, the Balance Sheet and the Statement of Revenue and Expenses. The cost report certification statement historically correctly denoted the two separate and distinct financial forms, the Balance Sheet and the Statement of Revenue and Expenses on Worksheet S (Form CMS–2552–92) of

the Medicare cost report since the Worksheet S was first used in 1993. The Medicare cost report certification statement was later incorporated into § 413.24(f)(4)(iv) in a final rule with comment period (59 FR 26964 through 26965) issued in response to public comments received following the Uniform Electronic Cost Reporting System for Hospitals proposed rule (56 FR 41110). A typographical error excluding the word “and” occurred during the incorporation of the certification statement into the regulations text at § 413.24(f)(4)(iv).

6. Proposed Technical Correction to 42 CFR 413.200(c)(1)(i) Relating to Medicare Cost Report Due Dates for Organ Procurement Organizations and Histocompatibility Laboratories

In this proposed rule, we are proposing to make a technical correction to the reference in § 413.200(c)(1)(i) to the due date for the Medicare cost report for organ procurement organizations (OPOs) and histocompatibility laboratories from “three months” to “5 months” after the end of the fiscal year. Section 413.200(c)(1)(i) requires independent OPOs and histocompatibility laboratories to file a cost report in accordance with § 413.24(f). In the 1995 final rule (60 FR 33137), we revised § 413.24(f) to extend the Medicare cost report due date for all providers required to file a cost report from 3 months to 5 months after the end of a provider’s fiscal year end, but inadvertently neglected to make a conforming change to § 413.200(c)(1)(i), which we are proposing to correct in this proposed rule.

*N. Clarification Regarding the Medicare Utilization Requirement for Medicare-Dependent, Small Rural Hospitals (MDHs) (§ 412.108)*

1. Background

Section 1886(d)(5)(G) of the Act provides special payment protections under the IPPS to Medicare-dependent, small rural hospitals (MDHs). (For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684).) As we discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50287) and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684), section 3124 of the Affordable Care Act extended the expiration of the MDH program from the end of FY 2011 (that is, for discharges occurring before October 1, 2011) to the end of FY 2012 (that is, for discharges

occurring before October 1, 2012). Under prior law, as specified in section 5003(a) of Public Law 109–171 (DRA 2005), the MDH program was to be in effect through the end of FY 2011 only.

Since the extension of the MDH program through FY 2012 provided by section 3124 of the Affordable Care Act, the MDH program has been further extended multiple times. First, section 606 of the ATRA (Public L. 112–240) extended the MDH program through FY 2013 (that is, for discharges occurring before October 1, 2013). Second, section 1106 of the Pathway for SGR Reform Act of 2013 (Public L. 113–67) extended the MDH program through the first half of FY 2014 (that is, for discharges occurring before April 1, 2014). Third, section 106 of the PAMA (Public L. 113–93) extended the MDH program through the first half of FY 2015 (that is, for discharges occurring before April 1, 2015). Fourth and most recently, section 205 of the MACRA (Public L. 114–10) extended the MDH program through FY 2017 (that is, for discharges occurring before October 1, 2017). For additional information on the extensions of the MDH program after FY 2012, we refer readers to the following **Federal Register** documents: The FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405 and 53413 through 53414); the FY 2013 IPPS notice (78 FR 14689); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50647 through 50649); the FY 2014 IPPS interim final rule with comment period (79 FR 15025 through 15027); the FY 2014 IPPS notice (79 FR 34446 through 34449); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50022 through 50024); and the FY 2016 interim final rule with comment period (80 FR 49596 through 49597).

## 2. Clarification of Medicare Utilization Criterion for MDH Classification

Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (that is, not less than 60 percent of its inpatient days or discharges during the cost reporting period beginning in FY 1987 or two of the three most recently audited cost reporting periods for which the Secretary has a settled cost report were attributable to inpatients entitled to benefits under Part A). The regulations at 42 CFR 412.108 set forth the criteria that a hospital must meet to be classified as an MDH.

The Medicare utilization requirement is set forth at section 1886(d)(5)(G)(iv)(IV) of the Act and implemented by regulation at 42 CFR

412.108(a)(1)(iii). Consistent with the policy noted in the FY 1991 IPPS final rule (55 FR 35995) and further discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50287), in order to not disadvantage hospitals that receive payment from a Medicare Advantage (MA) organization under Medicare Part C for inpatient care provided to Medicare beneficiaries enrolled in Medicare Part C plans, we count the days and discharges for those stays toward the 60-percent Medicare utilization requirement for MDH classification.

In accordance with the regulations at § 412.108(b)(5), Medicare contractors (MACs) evaluate, on an ongoing basis, whether or not a hospital continues to qualify for MDH status. For hospitals that qualify for MDH status under § 412.108(a)(1)(iii)(C) and in accordance with the regulations at § 412.108(b)(5), at each cost report settlement, the MAC will determine whether the hospital has a Medicare utilization of at least 60 percent in at least two of the last three most recent audited cost reports for which the Secretary has a settled cost report by including the newly settled cost report in the evaluation.

Medicare policy requires hospitals that receive certain additional payments such as IME, direct GME, and DSH, to submit claims for services furnished to individuals enrolled in a MA plan under Medicare Part C. Specifically, teaching hospitals that provide services to individuals enrolled in a MA plan under Medicare Part C must submit timely claims in order to receive the supplemental IME and direct GME payments for services provided to these individuals. Likewise, hospitals that operate nursing or allied health education programs and incur costs associated with individuals enrolled in a MA plan under Medicare Part C also must submit timely claims in order to receive the additional payment amount for those MA enrollees. In addition, hospitals that are eligible for DSH payments are required to submit claims in a timely manner for individuals enrolled in a MA plan under Medicare Part C in order for these days to be captured in the DSH calculation. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53409) for more information and background on the requirements for filing no pay bills for services furnished to individuals enrolled in a MA plan under Medicare Part C.

Consistent with this policy, for a hospital that is eligible for IME, direct GME, or DSH payments, CMS only includes MA days or discharges as reported on the cost report and verified

by the properly and timely submitted claims for the services furnished to individuals enrolled in a MA plan under Medicare Part C associated with those days or discharges in calculating Medicare utilization for MDH purposes. CMS verifies the accuracy of the MA days and discharges reported on the cost report using claims data; once verified, the cost report data can then be properly applied in the Medicare utilization calculation.

For a hospital that is not eligible for IME, direct GME, or DSH payments and is not required to submit bills for services furnished to individuals enrolled in a MA plan under Medicare Part C, we are clarifying that CMS will include the MA days or discharges associated with those services in the Medicare utilization calculation, regardless of whether the hospital submitted claims for services associated with those days or discharges provided that the hospital submits proper documentation, such as provider logs, that allow the MAC to verify the MA days or discharges as reported on the hospital's cost report. However, we note that, while not required, timely submission of claims for the services furnished to individuals enrolled in a MA plan under Medicare Part C allows CMS to establish whether the hospital meets the MDH classification criteria in an expeditious and timely manner.

## O. Adjustment to IPPS Rates Resulting From 2-Midnight Policy

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50906 through 50954), we adopted the 2-midnight policy, effective for dates of admission on or after October 1, 2013. Under the 2-midnight policy, an inpatient admission is generally appropriate for Medicare Part A payment if the physician (or other qualified practitioner) admits the patient as an inpatient based upon the reasonable expectation that the patient will need hospital care that crosses at least 2 midnights. In assessing the expected duration of necessary care, the physician (or other qualified practitioner) may take into account outpatient hospital care received prior to inpatient admission. If the patient is expected to need less than 2 midnights of care in the hospital, the services furnished should generally be billed as outpatient services. We note that revisions were made to this policy in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70545). Our actuaries estimated that the 2-midnight policy would increase expenditures by approximately \$220 million in FY 2014 due to an expected net increase in inpatient encounters. We used our

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 rates, and we used our authority under section 1886(g) of the Act to make a reduction of 0.2 percent to the national capital Federal rate and the Puerto Rico-specific capital rate, in order to offset this estimated \$220 million in additional IPPS expenditures in FY 2014. We indicated that although our exceptions and adjustments authority should not be routinely used in the IPPS system, we believed that the systemic and widespread nature of this issue justified an overall adjustment to the IPPS rates and such an adjustment is authorized under section 1886(d)(5)(I)(i) of the Act.

In *Shands Jacksonville Medical Center, Inc. v. Burwell*, No. 14–263 (D.D.C.) and consolidated cases, hospitals challenged the 0.2 percent reduction in IPPS rates to account for the estimated \$220 million in additional FY 2014 expenditures resulting from the 2-midnight policy. In its Memorandum Opinion, issued September 21, 2015, the Court found that the “Secretary’s interpretation of the exceptions and adjustments provision is a reasonable one” for this purpose. However, the Court also ordered the 0.2 percent reduction remanded back to the Secretary, without vacating the rule, to correct certain procedural deficiencies in the promulgation of the 0.2 percent reduction and reconsider the adjustment. The Court did not believe it would be appropriate to vacate the rule because such action would, in effect, dictate a substantive outcome based on a procedural error and concluded that the disruptive consequences would be considerable.

In accordance with the Court’s order, we published a notice with comment period that appeared in the December 1, 2015 **Federal Register** (80 FR 75107), which discussed the basis for the 0.2 percent reduction and its underlying assumptions and invited comments on the same in order to facilitate our further consideration of the FY 2014 reduction. We received numerous public comments on the notice with comment period.

In considering these public comments, and those on the same topic received in response to the CY 2016 OPPS/ASC proposed rule, we continue to recognize that the 0.2 percent reduction issue is unique in many ways. The underlying question of patient status, which resulted in the creation of the 2-midnight policy, is a complex one with a long history, including large improper payment rates in short-stay

hospital inpatient claims, requests to provide additional guidance regarding the proper billing of those services, and concerns about increasingly long stays of Medicare beneficiaries as outpatients due to hospital uncertainties about payment. (For further discussion of this history, we refer readers to the FY 2014 IPPS/LTCH PPS proposed and final rules (78 FR 27644 through 27649 and 78 FR 50906 through 50954, respectively).)

The 2-midnight policy itself and our implementation and enforcement of it have also evolved over time as a result of a combination of statutory, regulatory, and operational changes. For example, as part of our efforts to provide education to stakeholders on the new 2-midnight policy, CMS hosted numerous “Open Door Forums,” conducted national provider calls, and shared information and answers to frequently asked questions on the CMS Web site. In addition, we instructed MACs to conduct a “Probe and Educate” process for inpatient claims with dates of admission on or after October 1, 2013 through September 30, 2014, to assess provider understanding and compliance with the new 2-midnight policy. We also prohibited Recovery Auditor’s post-payment medical reviews of inpatient hospital patient status for claims with dates of admission between October 1, 2013 and September 30, 2014.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) was enacted. Section 111 of Public Law 113–93 permitted CMS to continue medical review activities under the Inpatient Probe and Educate process through March 31, 2015. The same law also extended the prohibition on Recovery Auditor reviews of inpatient hospital patient status for claims with dates of admission through March 31, 2015, absent evidence of systematic gaming, fraud, abuse, or delays in the provision of care by a provider of services. On April 16, 2015, the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) was enacted. Section 521 of Public Law 114–10 permitted CMS to further extend the medical review activities under the Inpatient Probe and Educate process for inpatient claims through September 30, 2015, and extended the prohibition of Recovery Auditor reviews of inpatient hospital patient status for claims with dates of admission through September 30, 2015. CMS then announced in August 2015 that it would not approve Recovery Auditors to conduct patient status reviews for dates of admission of October 1, 2015 through December 31, 2015.

As we indicated in the CY 2016 OPPS/ASC final rule with comment period, throughout the Probe and Educate process, we saw positive effects and improved provider understanding of the 2-midnight policy. We also discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70545 through 70549) a number of additional changes we had made and were continuing to make to the Recovery Audit Program and changes to the medical review responsibilities for Quality Improvement Organizations (QIOs) in regard to short hospital stay claims.

With respect to the 2-midnight policy itself, in light of stakeholder concerns and in our continued effort to develop the most appropriate and applicable framework for determining when payment under Medicare Part A is appropriate for inpatient admissions, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70545), we modified the original “rare and unusual” exceptions policy under the 2-midnight policy to allow for Medicare Part A payment on a case-by-case basis for inpatient admissions that do not satisfy the 2-midnight benchmark, if the documentation in the medical record supports the admitting physician’s determination that the patient requires inpatient hospital care despite an expected length of stay that is less than 2 midnights.

We also recognized in reviewing the public comments we received on the 0.2 percent reduction in response to the December 1, 2015 notice with comment period and the CY 2016 OPPS/ASC proposed rule that, in addition to the long history of the question of patient status underlying the 2-midnight policy and the statutory, regulatory, and operational changes that have occurred since its initial implementation, the original estimate for the 0.2 percent reduction had a much greater degree of uncertainty than usual. As indicated in the Office of the Actuary’s August 19, 2013 memorandum (which was included as Appendix A of the December 1, 2015 notice with comment period (80 FR 75112 through 75114)), the estimate depended critically on the assumed utilization changes in the inpatient and outpatient hospital settings, relatively small changes would have a disproportionate effect on the estimated net costs, the estimate was subject to a much greater degree of uncertainty than usual, and the actual results could differ significantly from the estimate.

Lastly, in reviewing the public comments we received on the December 1, 2015 notice with comment period, we



also considered the fact that our actuaries' most recent estimate of the impact of the 2-midnight policy varies between a savings and a cost over the FY 2014 to FY 2015 time period. The memorandum describing this new analysis is available on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>.

We still believe the assumptions underlying the 0.2 percent reduction to the rates put in place beginning in FY 2014 were reasonable at the time we made them in 2013. Nevertheless, taking all the foregoing factors into account, in the context of this case, we believe it would be appropriate to use our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to prospectively remove, beginning in FY 2017, the 0.2 percent reduction to the rates put in place beginning in FY 2014. The 0.2 percent reduction was implemented by including a factor of 0.988 in the calculation of the FY 2014 standardized amount, the hospital-specific payment rates, and the national capital Federal rate, permanently reducing the rates for FY 2014 and future years until the 0.988 is removed. We are proposing to permanently remove the 0.988 reduction beginning in FY 2017 by including a factor of (1/0.998) in the calculation of the FY 2017 standardized amount, the hospital-specific payment rates, and the national capital Federal rate.

In addition, taking all the foregoing factors into account, and given the unique nature of this situation in which the court has ordered us to further explain the assumptions underlying an adjustment applicable to past years, we believe it would be appropriate to use our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to temporarily increase the rates, only for FY 2017, to address the effect of the 0.2 percent reduction to the rates in effect for FY 2014, the 0.2 reduction to the rates in effect for FY 2015 (recall the 0.988 factor included in the calculation of the FY 2014 rates permanently reduced the rates for FY 2014 and future years until it is removed), and the 0.2 reduction to the rates in effect for FY 2016. We believe that the most transparent, expedient, and administratively feasible method to accomplish this is a temporary one-time prospective increase to the FY 2017 rates of 0.6 percent (= 0.2 percent + 0.2 percent + 0.2 percent). Specifically, we are proposing to include a factor of 1.006 in the calculation of the standardized amount, the hospital-specific payment rates, and the national capital Federal rate in FY 2017 and then

remove this temporary one-time prospective increase by including a factor of (1/1.006) in the calculation of the rates for FY 2018. While we generally do not believe it is appropriate in a prospective system to retrospectively adjust rates even where we believe a prospective change in policy is warranted, we take this action in the specific context of this unique situation, in which we have been ordered by a Federal court to further explain the basis of an adjustment we have imposed for past years.

In summary, for the reasons described above, we are proposing to include a permanent factor of (1/0.998) and a temporary one-time factor of (1.006) in the calculation of the FY 2017 standardized amount, the hospital-specific payment rates, and the national capital Federal rate. We also are proposing to include a factor of (1/1.006) in the calculation of the FY 2018 standardized amount, the hospital-specific payment rates, and the national capital Federal rate to remove the temporary one-time factor of 1.006.

We are inviting public comments on all aspects these proposals. The foregoing discussion and proposals constitute the final notice required by the Court in the *Shands Jacksonville Medical Center, Inc. v. Burwell*, No. 14–263 (D.D.C.) and consolidated cases.

## V. Proposed Changes to the IPPS for Capital-Related Costs

### A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services in accordance with a prospective payment system established by the Secretary. Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the Federal fiscal year (FY) 1992 IPPS final rule (56 FR 43358). In that final rule, we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based payment methodology to a prospective payment methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period that was 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 the regulations at 42 CFR 412.312. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

$$(\text{Standard Federal Rate}) \times (\text{DRG Weight}) \times (\text{Geographic Adjustment Factor (GAF)}) \times (\text{COLA for hospitals located in Alaska and Hawaii}) \times (1 + \text{Capital DSH Adjustment Factor} + \text{Capital IME Adjustment Factor, if applicable}).$$

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 42 CFR 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, the regulations at 42 CFR 412.300(b) define 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. Proposed Changes in Payments for Hospitals Located in Puerto Rico

The regulations at 42 CFR 412.374 provide 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 currently 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. The capital-related payment rate for hospitals located in Puerto Rico is derived using only the costs of hospitals located in Puerto Rico, while the national Federal rate for capital-related costs is derived using the costs of all acute care hospitals participating in the IPPS (including hospitals located in Puerto Rico). 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. Historically, we have established a capital IPPS blended payment rate structure for hospitals located in Puerto Rico that parallels the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico. Capital IPPS payments to hospitals located in Puerto Rico are currently 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).)

As noted in section IV.A. of the preamble of this proposed rule, section 601 of the Consolidated Appropriations Act, 2016 (Public L. 114–113) increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. Consistent with historical practice, under the broad authority of the

Secretary granted under section 1886(g) of the Act, we are proposing to revise the calculation of capital IPPS payments to hospitals located in Puerto Rico to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, beginning in FY 2017. Accordingly, we are proposing to revise § 412.374 of the regulations to provide that, for discharges occurring on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico would be based on 100 percent of the capital Federal rate; that is, payments would no longer be derived from a blend of the capital Puerto Rico rate and the capital Federal rate. As discussed in section I.I. of Appendix A (Economic Analyses) of this proposed rule, this proposed change would result in a slight increase in capital IPPS payments to hospitals located in Puerto Rico because adjusted capital IPPS payments based on the capital Federal rate are generally higher than capital IPPS payments based on the capital Puerto Rico rate. In addition, we note that this proposed change is similar to the changes in capital IPPS payments to hospitals located in Puerto Rico beginning in FY 1998 and FY 2005 that paralleled the corresponding statutory changes in the blended payment amount calculation required for operating IPPS payments to hospitals located in Puerto Rico, as provided by section 4406 of Public Law 105–33 (62 FR 46048) and section 504 of Public Law 108–173 (69 FR 49185), respectively.

### C. Proposed Annual Update for FY 2017

The proposed annual update to the capital PPS Federal rate, as provided for at § 412.308(c), for FY 2017 is discussed in section III. of the Addendum to this proposed rule. Consistent with our proposal to revise the calculation of capital IPPS payments to hospitals located in Puerto Rico to be based on 100 percent of the capital Federal rate (and no longer based on a blend of the capital Puerto Rico rate and the capital Federal rate), we would discontinue use of the Puerto Rico capital rate in the calculation of capital IPPS payments to hospitals located in Puerto Rico.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50906 through 50954), we adopted the 2-midnight policy effective for dates of admission on or after October 1, 2013, under which an inpatient admission is generally appropriate for Medicare Part A payment if the physician (or other qualified practitioner) admits the patient as an inpatient based upon the reasonable expectation that the patient will need hospital care that crosses at least 2 midnights. At that time, our

actuaries estimated that the 2-midnight policy would increase expenditures by approximately \$220 million in FY 2014 due to an expected net increase in inpatient encounters. In that same final rule, consistent with the approach taken for the operating IPPS standardized amount, the Puerto Rico-specific standardized amount, and the hospital-specific payment rates, and using our authority under section 1886(g) of the Act, we made a reduction of 0.2 percent (an adjustment factor of 0.998) to the national capital Federal rate and the Puerto Rico-specific capital rate to offset the estimated increase in capital IPPS expenditures associated with the projected increase in inpatient encounters that was expected to result from the new inpatient admission guidelines (78 FR 50746 through 50747).

As discussed in section IV.O. of the preamble of this proposed rule, in *Shands Jacksonville Medical Center, Inc. v. Burwell*, No. 14–263 (D.D.C.) and consolidated cases, hospitals challenged the 0.2 percent reduction in IPPS rates to account for the estimated \$220 million in additional FY 2014 expenditures resulting from the 2-midnight policy. In accordance with the Court's order, we published a notice with comment period that appeared in the December 1, 2015 **Federal Register** (80 FR 75107), which discussed the basis for the 0.2 percent reduction and its underlying assumptions and invited comments on the same in order to facilitate our further consideration of the FY 2014 reduction. In section IV.O. of the preamble of this proposed rule, we discuss that, in considering the public comments we received on that notice with comment period and those on the same topic we received in response to the CY 2016 OPPS/ASC proposed rule, we continue to recognize that the 0.2 percent reduction issue is unique in many ways. As we discuss in that section, the 2-midnight policy itself and our implementation and enforcement of it have also evolved over time as a result of a combination of statutory, regulatory, and operational changes. Finally, in reviewing the public comments received on the December 1, 2015 notice with comment period, we also considered the fact that our actuaries' most recent estimate of the impact of the 2-midnight policy varies between a savings and a cost over the FY 2014 to FY 2015 time period. (For additional details, we refer readers to section IV.O. of the preamble of this proposed rule.)

We still believe the assumptions underlying the 0.2 percent reduction to the rates put in place beginning in FY 2014 were reasonable at the time we

made them in 2013. Nevertheless, taking all of these factors into account and in the context of this case, as we discuss in more detail in section IV.O. of the preamble of this proposed rule, consistent with the approach proposed for the operating IPPS rates, we believe it would be appropriate to use our authority under section 1886(g) of the Act to permanently remove the 0.2 percent reduction to the capital IPPS rate beginning in FY 2017. (As explained previously, we are proposing to discontinue use of the Puerto Rico capital rate in the calculation of capital IPPS payments to hospitals located in Puerto Rico beginning in FY 2017.) Specifically, we are proposing to make an adjustment of (1/0.998) to the national capital Federal rate to remove the 0.2 percent reduction, consistent with the proposed adjustment to the operating IPPS standardized amount and the hospital-specific payment rates. In addition, consistent with the approach proposed for the operating IPPS standardized amount and hospital-specific payment rates and for the reasons discussed in section IV.O. of the preamble of this proposed rule, we believe it would be appropriate to use our authority under section 1886(g) of the Act to adjust the FY 2017 capital IPPS rate to address the effects of the 0.2 percent reduction to the national capital Federal rates in effect for FY 2014, FY 2015, and FY 2016 by proposing a one-time prospective adjustment of 1.006 in FY 2017 to the national capital Federal rate. For FY 2018, we also are proposing to remove the effects of this one-time prospective adjustment through an adjustment of (1/1.006) to the national capital Federal rate, consistent with the approach proposed for the operating IPPS standardized amount and hospital-specific payment rates (as discussed in section IV.O. of the preamble of this proposed rule). We are inviting public comments on these proposals.

We also note that, in section II.D. of the preamble of this proposed rule, we present a discussion of the MS-DRG documentation and coding adjustment, including previously finalized policies and historical adjustments, as well as the recoupment adjustment to the standardized amounts under section 1886(d) of the Act that we are proposing for FY 2017 in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110-90 by section 631 of the ATRA. Because section 631 of the ATRA requires us to make a recoupment adjustment only to the operating IPPS standardized amount, we are not proposing to make a similar adjustment to the capital IPPS rate (or to the

operating IPPS hospital-specific rates). This approach is consistent with our historical approach regarding the application of the recoupment adjustment authorized by section 7(b)(1)(B) of Public Law 110-90.

## **VI. Proposed Changes for Hospitals Excluded From the IPPS**

### *A. Proposed Rate-of-Increase in Payments to Excluded Hospitals for FY 2017*

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting period, the updated target amount is multiplied by total Medicare discharges during that period and applies as an aggregate upper limit (the ceiling as defined in § 413.40(a) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, RNHCIs also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, cancer hospitals, and RNHCIs. Consistent with §§ 412.23(g), 413.40(a)(2)(ii)(A), and 413.40(c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update the target amounts for short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. As we finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50156 through 50157), for FY 2017, we will continue to use the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin

Islands, Guam, the Northern Mariana Islands, and American Samoa. Accordingly, for FY 2017, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is the FY 2017 percentage increase in the FY 2010-based IPPS operating market basket.

For this FY 2017 proposed rule, based on IHS Global Insight, Inc.'s 2016 first quarter forecast, we estimate that the FY 2010-based IPPS operating market basket update for FY 2017 is 2.8 percent (that is, the estimate of the market basket rate-of-increase). Therefore, the FY 2017 rate-of-increase percentage that would be applied to the FY 2016 target amounts in order to calculate the FY 2017 target amounts for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is 2.8 percent, in accordance with the applicable regulations at 42 CFR 413.40. 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 2017.

### *B. Critical Access Hospitals (CAHs)*

#### 1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation under 42 CFR part 485, subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413.

#### 2. Frontier Community Health Integration Project (FCHIP) Demonstration

Section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275), as amended by section 3126 of the Affordable Care Act of 2010, authorizes a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to

Medicare beneficiaries. The demonstration is titled “Demonstration Project on Community Health Integration Models in Certain Rural Counties,” and is commonly known as the Frontier Community Health Integration Project (FCHIP) demonstration.

The authorizing statute states the eligibility criteria for entities to be able to participate in the demonstration. An eligible entity, as defined in section 123(d)(1)(B) of Public Law 110–275, as amended, is an MRHFP grantee under section 1820(g) of the Act (that is, a CAH); and is located in a State in which at least 65 percent of the counties in the State are counties that have 6 or less residents per square mile.

The authorizing statute stipulates several other requirements for the demonstration. Section 123(d)(2)(B) of Public. L. 110–275, as amended, limits participation in the demonstration to eligible entities in not more than 4 States. Section 123(f)(1) of Public. L. 110–275 requires the demonstration project to be conducted for a 3-year period. In addition, section 123(g)(1)(B) of Public. L. 110–275 requires that the demonstration be budget neutral. Specifically, this provision states that in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Furthermore, section 123(i) of Public. L. 110–275 states that the Secretary may waive such requirements of titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration project, thus allowing the waiver of Medicare payment rules encompassed in the demonstration.

In January 2014, CMS released a request for applications (RFA) for the FCHIP demonstration. We refer readers to the RFA on the CMS Web site at: <https://innovation.cms.gov/initiatives/Frontier-Community-Health-Integration-Project-Demonstration/>. Using 2013 data from the U.S. Census Bureau, CMS identified Alaska, Montana, Nevada, North Dakota, and Wyoming as meeting the statutory eligibility requirement for participation in the demonstration. The RFA solicited CAHs in these five States to participate in the demonstration, stating that participation would be limited to CAHs in four of the States. To apply, CAHs were required to meet the eligibility requirements in the authorizing legislation, and, in addition, to describe a proposal to enhance

health-related services that would complement those currently provided by the CAH and better serve the community’s needs. In addition, in the RFA, CMS interpreted the eligible entity definition in the statute as meaning a CAH that receives funding through the Rural Hospital Flexibility Program. The RFA identified four intervention prongs, under which specific waivers of Medicare payment rules would allow for enhanced payment for telemedicine, nursing facility, ambulance, and home health services, respectively. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

Since the due date for applications on May 5, 2014, we have assessed the feasibility of the applying CAHs’ service delivery proposals, as well as the potential impacts of the payment enhancement interventions on the overall expenditures for Medicare services. We are selecting CAHs to participate in the demonstration, with the period of performance for each CAH expected to start August 1, 2016.

We have specified the payment enhancements for the demonstration, and are basing our selection of CAHs for participation, with the goal of maintaining the budget neutrality of the demonstration on its own terms (that is, the demonstration will produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments resulting from the demonstration). However, because of the small size of this demonstration and uncertainty associated with projected Medicare utilization and costs, we are proposing a contingency plan to ensure that the budget neutrality requirement in section 123 of Public. L. 110–275 is met. Accordingly, if analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as of other data sources, including cost reports for these CAHs, shows that increases in Medicare payments under the demonstration during the 3-year period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. Because of the small scale of the demonstration, we do not believe it would be feasible to implement budget neutrality by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration were not implemented, we are proposing to

comply with the budget neutrality requirement by reducing payments to all CAHs, not just those participating in the demonstration. We believe it is appropriate to make any payment reductions across all CAHs because the FCHIP demonstration is specifically designed to test innovations that affect delivery of services by the CAH provider category. We believe that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public. L. 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Based on actuarial analysis using cost report settlements for FYs 2013 and 2014, the demonstration is projected to satisfy the budget neutrality requirement and likely yield a total net savings. We estimate that the total impact of the payment recoupment would be no greater than 0.03 percent of CAHs’ total Medicare payments within 1 fiscal year (that is, Medicare Part A and Part B). For the FCHIP demonstration, the final budget neutrality estimates will be based on the demonstration period, which is August 1, 2016 through July 31, 2019. The demonstration is projected to impact payments to participating CAHs under both Medicare Part A and Part B. Thus, in the event that we determine that aggregate payments under the demonstration exceed the payments that would otherwise have been made, we are proposing that CMS would recoup payments through reductions of Medicare payments to all CAHs under both Medicare Part A and Part B.

Given the 3-year period of performance of the FCHIP demonstration and the time needed to conduct the budget neutrality analysis, we anticipate that, in the event the demonstration is found not to have been budget neutral, any excess costs would be recouped over a period of 3 cost reporting years, beginning in CY 2020. We are proposing a 3-year period for recoupment to allow for a reasonable timeframe for the payment reduction and to minimize any impact on CAHs’ operations.

## VII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2017

### 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 an 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 (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 an 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 this section of the preamble of this proposed rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, an 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 an 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).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we implemented the provisions of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which mandated the application of the “site neutral” payment rate under the LTCH PPS for discharges that do not meet the statutory criteria for exclusion beginning in FY 2016. For cost reporting periods beginning on or after October 1, 2015, discharges that do not meet certain statutory criteria for exclusion are paid based on the site neutral payment rate. Discharges that do meet the statutory criteria continue to receive payment based on the LTCH PPS standard Federal payment rate. For more information on the statutory requirements of the Pathway for SGR Reform Act of 2013, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).

Section 231 of Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted December 18, 2015, provides for a temporary exception to the application of the site neutral payment rate for certain discharges representing severe wound care cases from specific LTCHs. We will address this statutory provision in a separate rulemaking.

#### 2. Criteria for Classification as an LTCH

##### a. Classification as an LTCH

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv)(I) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. Alternatively, § 412.23(e)(2)(ii) states

that, for cost reporting periods beginning on or after August 5, 1997, a hospital that was first excluded from the PPS in 1986 and can demonstrate that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in FY 1997 have a principal diagnosis that reflects a finding of neoplastic disease must have an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days (referred to as “subclause (II)” LTCHs).

#### 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). This discussion was further clarified in the RY 2005 LTCH PPS final rule (69 FR 25676). In keeping with those discussions, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, consistent with other established hospital prospective payment systems, § 412.507 currently provides that an LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87 and for items and services specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. If the Medicare payment was for a SSO case (§ 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient remaining Medicare days, the LTCH is currently also permitted to

charge the beneficiary for services delivered on those uncovered days (§ 412.507). In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49623), we amended our regulations to limit the charges that may be imposed on beneficiaries whose discharges are paid at the site neutral payment rate under the LTCH PPS. In section VII.G. of the preamble of this proposed rule, we are proposing to amend the existing regulations relating to the limitation on charges to address beneficiary charges for LTCH services provided by subclause (II) LTCHs as part of our proposed refinement of the payment adjustment for subclause II LTCHs under § 412.526. We also are proposing to amend the regulations under § 412.507 to clarify our existing policy that blended payments made to an LTCH during its transitional period (that is, payment for discharges occurring in cost reporting periods beginning in FY 2016 or 2017) are considered to be a site neutral payment rate payment.

#### 4. Administrative Simplification Compliance Act (ASCA) and Health Insurance Portability and Accountability Act (HIPAA) Compliance

Claims submitted to Medicare must comply with both the Administrative Simplification Compliance Act (ASCA) (Pub. L. 107–105), and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191). Section 3 of the ASCA requires that the Medicare Program deny payment under Part A or Part B for any expenses incurred for items or services for which a claim is submitted other than in an electronic form specified by the Secretary. Section 1862(h) of the Act (as added by section 3(a) of the ASCA) provides that the Secretary shall waive such denial in two specific types of cases and may also waive such denial in such unusual cases as the Secretary finds appropriate (68 FR 48805). Section 3 of the ASCA operates in the context of the HIPAA regulations, which include, among other provisions, the transactions and code sets standards requirements codified under 45 CFR parts 160 and 162 (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including covered health care providers, to conduct certain electronic health care transactions according to the applicable transactions and code sets standards.

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of health information technology and promote

nationwide health information exchange to improve health care. The Office of the National Coordinator for Health Information Technology (ONC) leads these efforts in collaboration with other agencies, including CMS and the Office of the Assistant Secretary for Planning and Evaluation (ASPE). Through a number of activities, including several open government initiatives, HHS is promoting the adoption of electronic health record (EHR) technology certified under the ONC Health Information Technology (HIT) Certification Program (<https://www.healthit.gov/policy-researchers-implementers/2015-edition-final-rule>) developed to support secure, interoperable, health information exchange. We believe that the use of certified EHRs by LTCHs (and other types of providers that are ineligible for the Medicare and Medicaid EHR Incentive Programs) can effectively and efficiently help providers improve internal care delivery practices, support the exchange of important information across care partners and during transitions of care, and enable the reporting of electronically specified clinical quality measures (eCQMs) (as described elsewhere in this proposed rule). In 2015, ONC released a document entitled “Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap” (available at: <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>). In the near term, the Roadmap focuses on actions that will enable individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017. The Roadmap’s goals also align with the Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185) (IMPACT Act), which requires assessment data to be standardized and interoperable to allow for exchange of the data. Moreover, the vision described in the Roadmap significantly expands the types of electronic health information, information sources, and information users well beyond clinical information derived from EHRs. The Roadmap identifies four critical pathways that health IT stakeholders should focus on now in order to create a foundation for long-term success: (1) Improve technical standards and implementation guidance for priority data domains and associated elements; (2) rapidly shift and align Federal, State, and commercial payment policies from fee-for-service to value-based models to stimulate the demand for

interoperability; (3) clarify and align Federal and State privacy and security requirements that enable interoperability; and (4) align and promote the use of consistent policies and business practices that support interoperability and address those that impede interoperability, in coordination with stakeholders. To support of the goals of the Roadmap, ONC released the 2016 Interoperability Standards Advisory (available at: <https://www.healthit.gov/standards-advisory/2016>), which suggests some of the best available standards, terminology, and implementation guides as well as emerging standards to enable priority health information exchange functions. Providers, payers, and vendors are encouraged to take these “best available standards” into account as they implement interoperable health information exchange across the continuum of care.

#### *B. Proposed Modifications to the Application of the Site Neutral Payment Rate (§ 412.522)*

##### 1. Background

Section 1206 of Pathway for SGR Reform Act (Pub. L. 113–67) mandated significant changes to the LTCH PPS beginning with LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2015. Specifically, section 1206 required the establishment of a site neutral payment rate (as an alternative to the LTCH PPS standard Federal payment rate) for Medicare inpatient discharges from an LTCH that fail to meet certain statutorily defined criteria. Discharges that meet the statutory criteria for exclusion from the site neutral payment rate continue to be paid based on the LTCH PPS standard Federal payment rate. Discharges that do not meet the statutory criteria for exclusion are paid based on the site neutral payment rate. We implemented the application of the site neutral payment rate in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623) and codified the requirements in the regulations at 42 CFR 412.522. The criteria for exclusion from the site neutral payment rate specified under section 1886(m)(6)(A)(ii) of the Act and as implemented at § 412.522(b) are as follows: (1) The discharge from the LTCH does not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; (2) admission to the LTCH was immediately preceded by discharge from a subsection (d) hospital; and (3) the immediately preceding stay in a subsection (d) hospital included at least

3 days in an intensive care unit (ICU) (referred to as the ICU criterion) or the discharge from the LTCH is assigned to a MS–LTC–DRG based on the patient’s receipt of ventilator services of at least 96 hours (referred to as the ventilator criterion). (We note that, for the remainder of this section VII. of this preamble, the phrase “LTCH PPS standard Federal payment rate case” refers to an LTCH PPS case that meets the criteria for exclusion from the site neutral payment rate as specified under § 412.522(a)(2), and the phrase “site neutral payment rate case” refers to an LTCH PPS case that does not meet the statutory patient-level criteria as specified under § 412.522(a)(1) and, therefore, is paid the applicable site neutral payment rate.)

##### 2. Technical Correction of Definition of “Subsection (d) Hospital” for the Site Neutral Payment Rate (§ 412.503)

In the FY 2016 IPPS/LTCH PPS final rule, we implemented section 1206(a) of Public Law 113–67, which established the new dual payment rate structure under the LTCH PPS that began with LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2015. Section 1206(a) required the establishment of a site neutral payment rate (as an alternate to the LTCH PPS standard Federal payment rate) under the LTCH PPS for Medicare inpatient LTCH discharges that fail to meet certain statutorily defined criteria for exclusion. Discharges that meet the statutory criteria for exclusion from the site neutral payment rate continue to be paid based on the LTCH PPS standard Federal payment rate. Discharges that do not meet the statutory criteria for exclusion are paid based on the new site neutral payment rate. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we codified the requirements for the application of the site neutral payment rate under the LTCH PPS under the regulations at § 412.522. The statutory criteria for exclusion from the site neutral payment rate include a criterion that requires that the admission to the LTCH was immediately preceded by discharge from a “subsection (d) hospital.” To implement this criterion for purposes of the application of the site neutral payment rate under § 412.522, we added a definition of a “subsection (d) hospital” under § 412.503 of the regulations. However, we made an inadvertent cross-reference error under § 412.503 by referencing “§ 412.526” (payment provisions to a subclause II LTCH) instead of referencing “§ 412.522” (application of site neutral

payment) (80 FR 49767). That is, currently § 412.503 specifies that a subsection (d) hospital means “for purposes of § 412.526,” when the language should have read “for purposes of § 412.522”. Therefore, we are proposing to revise § 412.503 to correct this cross-reference error.

#### *C. Proposed Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2017*

##### 1. Background

Section 123 of the BBRA required that the Secretary implement a PPS for LTCHs to replace the cost-based payment system under TEFRA. 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 the LTCH PPS on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients.

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 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, consistent with section 123(a)(1) of the BBRA (Pub. L. 106–113).

As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) were adopted under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development, implementation, and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying

the provisions of 42 CFR part 412, subpart O applicable to LTCHs for policy descriptions and payment calculations, all references to LTC-DRGs would be considered a reference to MS-LTC-DRGs. For the remainder of this section, we present the discussion in terms of the current MS-LTC-DRG patient classification system unless specifically referring to the previous LTC-DRG patient classification system that was in effect before October 1, 2007.)

The MS-DRGs adopted in FY 2008 represent an increase in the number of DRGs by 207 (that is, from 538 to 745) (72 FR 47171). The MS-DRG classifications are updated annually. There are currently 758 MS-DRG groupings. For FY 2017, there are 757 MS-DRG groupings that we are proposing in conjunction with all of the changes discussed in section II.F. of the preamble of this proposed rule. Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS-LTC-DRGs based on clinical characteristics and estimated resource needs. We then assign an appropriate weight to the MS-LTC-DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs. In this section of the proposed rule, we provide a general summary of our existing methodology for determining the proposed FY 2017 MS-LTC-DRG relative weights under the LTCH PPS.

In this proposed rule, in general, for FY 2017, we are using our existing methodology to determine the MS-LTC-DRG relative weights (as discussed in greater detail in section VII.C.3. of the preamble of this proposed rule). As we established when we implemented the dual rate LTCH PPS payment structure codified under § 412.522, beginning with FY 2016, the annual recalibration of the MS-LTC-DRG relative weights are determined: (1) Using only data from available LTCH PPS claims that would have qualified for payment under the new LTCH PPS standard Federal payment rate if that rate were in effect when claims data from time periods before the dual rate LTCH PPS payment structure applies were used to calculate the relative weights; and (2) using only data from available LTCH PPS claims that qualify for payment under the new LTCH PPS standard Federal payment rate when claims data from time periods after the dual rate LTCH PPS payment structure applies are used to calculate

the relative weights (80 FR 49624). That is, under our current methodology, the MS-LTC-DRG relative weights are not used to determine the LTCH PPS payment for cases paid at the site neutral payment rate under § 412.522(c)(1) and data from cases paid at the site neutral payment rate or that would have been paid at the site neutral payment rate if the dual rate LTCH PPS payment structure had been in effect are not used to develop the relative weights. For the remainder of this discussion, we use the phrase “applicable LTCH cases” or “applicable LTCH data” when referring to the resulting claims data set used to calculate the relative weights (as described later in greater detail in section VII.C.3.c. of the preamble of this proposed rule). In addition, we are proposing to continue to exclude the data from all-inclusive rate providers and LTCHs paid in accordance with demonstration projects, as well as any Medicare Advantage claims from the MS-LTC-DRG relative weight calculations for the reasons discussed in section VII.C.3.c. of the preamble of this proposed rule.

Furthermore, for FY 2017, in using data from applicable LTCH cases to establish proposed MS-LTC-DRG relative weights, we are proposing to continue to establish low-volume MS-LTC-DRGs (that is, MS-LTC-DRGs with less than 25 cases) using our quintile methodology in determining the proposed MS-LTC-DRG relative weights because LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. Therefore, for purposes of determining the proposed 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 charges per discharge. Then, under our existing methodology, we are proposing to account for adjustments made to LTCH PPS standard Federal payments for short-stay outlier (SSO) cases (that is, cases where the covered length of stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay for the MS-LTC-DRG), and we are proposing to make adjustments to account for nonmonotonically increasing weights, when necessary. The methodology is premised on more severe cases under the MS-LTC-DRG system requiring greater expenditure of medical care resources and 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 each of these components of our MS-LTC-DRG relative weight methodology in greater detail in section VII.C.3.g. of the preamble of this proposed rule.)

## 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 previously 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-10-PCS procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKGs), or minor surgical procedures (for example, a biopsy of skin and subcutaneous tissue (procedure code 86.11)) do not affect the MS-LTC-DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge and that payment varies by the MS-LTC-DRG to which a beneficiary's stay is assigned. Cases are classified into MS-LTC-DRGs for payment based on the following six data elements:

- Principal diagnosis;
- Additional or secondary diagnoses;
- Surgical procedures;
- Age;
- Sex; and
- Discharge status of the patient.

Currently, for claims submitted on the 5010 format, up to 25 diagnosis codes and 25 procedure codes are considered for an MS-DRG assignment. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. (For additional information on the processing of up to 25 diagnosis codes and 25 procedure codes on hospital inpatient claims, we refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (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(c)).

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, 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, both of which became effective October 1, 2015 (45 CFR 162.1002(c)(2) and (3)). For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.F.1. of the preamble of this proposed rule. Additional coding instructions and examples are published in the AHA's *Coding Clinic for ICD–10–CM/PCS*.

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).

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 2017

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, 2016, through September 30, 2017 (FY 2017), consistent with the proposed changes to specific MS–DRG classifications presented in section II.F. of the preamble of this proposed rule. Accordingly, the proposed MS–LTC–DRGs for FY 2017 presented in this proposed rule are the same as the proposed MS–DRGs that would be used under the IPPS for FY 2017. In addition, because the proposed MS–LTC–DRGs for FY 2017 are the same as the proposed MS–DRGs for FY 2017, the other proposed changes that affect proposed MS–DRG (and by extension

proposed MS–LTC–DRG) assignments under GROUPER Version 34.0 as discussed in section II.G. of the preamble of this proposed rule, including the proposed changes to the MCE software and the ICD–10–CM/PCS coding system, also would be applicable under the LTCH PPS for FY 2017. (We note the GROUPER Version 34 is based on ICD–10–CM/PCS diagnoses and procedure codes, consistent with the requirement to use ICD–10 beginning October 1, 2015.)

#### 3. Development of the Proposed FY 2017 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. In order to make these annual adjustments under the dual rate LTCH PPS payment structure, beginning with FY 2016, we recalibrate the MS–LTC–DRG relative weighting factors annually using data from applicable LTCH cases (80 FR 49614 through 49617). Under this policy, the resulting MS–LTC–DRG relative weights would continue to be used to adjust the LTCH PPS standard Federal payment rate when calculating the payment for LTCH PPS standard Federal payment rate cases.

The established methodology to develop the proposed MS–LTC–DRG relative weights is generally consistent with the methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). However, there have been 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, along with the change made in conjunction with the implementation of the dual rate LTCH PPS payment structure beginning in FY 21016 to use LTCH claims data from only LTCH PPS standard Federal payment rate cases (or LTCH PPS cases that would have qualified for payment under the LTCH PPS standard Federal payment rate if

the dual rate LTCH PPS payment structure were in effect at the time of the discharge) that began in FY 2016. (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550). For details on the change in our historical methodology to use LTCH claims data only from LTCH PPS standard Federal payment rate cases to determine the MS–LTC–DRG relative weights, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49614 through 49617). 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 an MS–LTC–DRG with a relative weight of 2 would, on average, cost twice as much to treat as cases in an MS–LTC–DRG with a relative weight of 1.

#### b. Development of the Proposed MS–LTC–DRG Relative Weights for FY 2017

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49625 through 49634), we presented our policies for the development of the MS–LTC–DRG relative weights for FY 2016.

In this proposed rule, we are proposing to continue to use our current methodology to determine the MS–LTC–DRG relative weights for FY 2017, including the application of established policies related to, the hospital-specific relative value methodology, the treatment of severity levels in the MS–LTC–DRGs, low-volume and no-volume MS–LTC–DRGs, adjustments for nonmonotonicity, the steps for calculating the MS–LTC–DRG relative weights with a budget neutrality factor, and only using data from applicable LTCH cases (which includes our policy of only using cases that would meet the criteria for exclusion from the site neutral payment rate (or, for discharges occurring prior to the implementation of the dual rate LTCH PPS payment structure, would have met the criteria for exclusion had those criteria been in effect at the time of the discharge)).

In this section, we present our proposed methodology for determining

the proposed MS–LTC–DRG relative weights for FY 2017, and we discuss the effects of our proposed policies concerning the data used to determine the proposed FY 2017 MS–LTC–DRG relative weights on the various components of our existing methodology in the discussion that follows.

#### c. Data

For this proposed rule, to calculate the proposed MS–LTC–DRG relative weights for FY 2017, we obtained total charges from FY 2015 Medicare LTCH claims data from the December 2015 update of the FY 2015 MedPAR file, which are the best available data at this time, and we are proposing to use Version 34 of the GROUPEER to classify LTCH cases. Consistent with our historical practice, we use those data and the proposed Version 34 of the MS–LTC–DRGs in establishing the proposed FY 2017 MS–LTC–DRG relative weights in this proposed rule. To calculate the proposed FY 2017 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, we are proposing to continue to use applicable LTCH data, which includes our policy of only using cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had they been in effect at the time of the discharge) (80 FR 49624). Specifically, we are proposing to begin by first evaluating the LTCH claims data in the December 2015 update of the FY 2015 MedPAR file to determine which LTCH cases would meet the criteria for exclusion from the site neutral payment rate under § 412.522(b) had the dual rate LTCH PPS payment structure been in effect at the time of discharge. We identified the FY 2015 LTCH cases that were not assigned to proposed MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945 and 946, which identify LTCH cases that do not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; and that either—

- The admission to the LTCH was “immediately preceded” by discharge from a subsection (d) hospital and the immediately preceding stay in that subsection (d) hospital included at least 3 days in an ICU, as we define under the ICU criterion; or

- The admission to the LTCH was “immediately preceded” by discharge from a subsection (d) hospital and the claim for the LTCH discharge includes the applicable procedure code that indicates at least 96 hours of ventilator services were provided during the LTCH stay, as we define under the ventilator criterion. Claims data from the FY 2015

MedPAR file that reported ICD–9–CM procedure code 96.72 were used to identify cases involving at least 96 hours of ventilator services in accordance with the ventilator criterion (as FY 2015 discharges occurred prior to the adoption of ICD–10–CM/PCS). (We note that the corresponding ICD–10–PCS code for cases involving at least 94 hours of ventilation services is 5A1955Z, effective October 1, 2016) (80 FR 49626 through 49627). We note that, for purposes of developing the proposed FY 2017 MS–LTC–DRG relative weights using our current methodology, we did not identify any cases that would have been excluded from the site neutral payment rate under the temporary statutory provision for certain wound care discharges from certain LTCHs provided by Public Law 114–113 had the dual rate LTCH PPS payment structure been in effect at the time of the discharge. At this time, it is uncertain how many LTCHs and how many cases in the claims data we are using for this proposed rule would have met the statutory criteria to be excluded from the site neutral payment rate under that statutory provision (had the dual rate LTCH PPS payment structure been in effect at the time of the discharge). Therefore, for the remainder of this section, when we refer to LTCH claims only from cases that meet the criteria for exclusion from the site neutral payment rate (or would meet the criteria had they been in effect at the time of the discharge), such data do not include any cases that would have been paid based on the LTCH PPS standard Federal payment rate under the provisions of section 231 of Public Law 114–113, had the dual rate LTCH PPS payment structure been in effect at the time of the discharge.

Then, consistent with our historical methodology, we are proposing to exclude any claims in the resulting data set that were submitted by LTCHs that are all-inclusive rate providers and LTCHs that are reimbursed in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. In addition, consistent with our historical practice, we would exclude the Medicare Advantage (Part C) claims that were in the resulting data set based on the presence of a GH0 Paid indicator value of “1” in the MedPAR files. The claims that remained after these three trims (that is, the applicable LTCH data) were then used to calculate the proposed MS–LTC–DRG relative weights for FY 2017.

In summary, in general, in identifying the claims data for the development of

the proposed FY 2017 MS–LTC–DRG relative weights in this proposed rule, we are proposing to use claims data after we trim the claims data of 10 all-inclusive rate providers reported in the December 2015 update of the FY 2015 MedPAR file, as well as any Medicare Advantage claims data for cases that would meet the criteria for exclusion from the site neutral payment rate under § 412.522(b) if the dual rate LTCH PPS payment structure were in effect at the time of discharge. (We note that there were no data from any LTCHs that are paid in accordance with a demonstration project reported in the December 2015 update of the FY 2015 MedPAR file. However, had there been we would trim the claims data from those LTCHs as well, in accordance with our established policy.) We would use the remaining data (that is, the applicable LTCH data) to calculate the proposed relative weights for FY 2017.

#### **d. Hospital-Specific Relative Value (HSRV) Methodology**

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients. Some case types (MS–LTC–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 2017. We believe that this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we are reducing the impact of the variation in charges across providers on any particular MS–LTC–DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH).

The average relative weight for a LTCH is its case-mix; therefore, 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 applicable LTCH cases it treats relative to the complexity of the applicable LTCH cases treated by all other LTCHs (the average LTCH PPS case-mix of all applicable LTCH cases across all LTCHs).

In accordance with our established methodology, for FY 2017, we are proposing to continue to standardize charges for each applicable LTCH case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in section VII.C.3.g. (Step 3) of the preamble of this proposed rule) by the average adjusted charge for all applicable LTCH 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 would be multiplied by that LTCH's case-mix index to determine the standardized charge for the case.

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. By standardizing charges in this manner, we count charges for a Medicare patient at a LTCH with high average charges as less resource intensive than they would be at a LTCH with low average charges. For example, a \$10,000 charge for a case at a LTCH with an average adjusted charge of \$17,500 reflects a higher level of relative resource use than a \$10,000 charge for a case at a LTCH with the same case-mix, but an average adjusted charge of \$35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

#### **e. Treatment of Severity Levels in Developing the Proposed MS–LTC–DRG Relative Weights**

For purposes of determining the proposed MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–DRGs based on volume of cases within specific MS–LTC–DRGs: (1) MS–LTC–DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described later in this section of the proposed rule) and assigned the relative weight of the quintile; and (3) no-volume MS–LTC–DRGs that 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). For FY 2017, we are proposing to continue to use applicable LTCH cases to establish the same volume-based categories to calculate the proposed FY 2017 MS–LTC–DRG relative weights.

In determining the proposed FY 2017 MS–LTC–DRG relative weights, when necessary, we are proposing to make adjustments to account for nonmonotonicity, as discussed in greater detail later in Step 6 of section VII.C.3.g. of the preamble of this proposed rule. 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 MS–LTC–DRGs with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology, we are proposing to continue to employ the quintile methodology for proposed low-volume MS–LTC–DRGs, such that we grouped the “low-volume MS–LTC–DRGs” (that is, proposed MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995; 72 FR 47283 through 47288; and 80 FR 49628). In cases where the initial assignment of a low-volume MS–LTC–DRG to a quintile resulted in nonmonotonicity within a base-DRG, we are proposing to make adjustments to the resulting low-volume

MS–LTC–DRGs to preserve monotonicity, as discussed in detail in section VII.C.3.g. (Step 6) of the preamble of this proposed rule.

In this proposed rule, based on the best available data (that is, the December 2015 update of the FY 2015 MedPAR files), we identified 259 proposed MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. This list of proposed MS–LTC–DRGs was then divided into one of the 5 low-volume quintiles, each containing 51 proposed MS–LTC–DRGs (259/5 = 51, with a remainder of 4). We assigned the proposed low-volume MS–LTC–DRGs to specific low-volume quintiles 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 the proposed rule, the number of proposed MS–LTC–DRGs with less than 25 applicable LTCH cases is not evenly divisible by 5. Therefore, we are proposing to employ our historical methodology for determining which of the low-volume quintiles contain the additional proposed low-volume MS–LTC–DRG. Specifically for this proposed rule, after organizing the proposed MS–LTC–DRGs by ascending order by average charge, we assigned the first 51st (1st through 51st) of proposed low-volume MS–LTC–DRGs (with the lowest average charge) into Quintile 1. The 51 proposed MS–LTC–DRGs with the highest average charge cases were assigned into Quintile 5. Because the average charge of the 52nd proposed low-volume MS–LTC–DRG in the sorted list was closer to the average charge of the 51st proposed low-volume MS–LTC–DRG (assigned to Quintile 1) than to the average charge of the 53rd proposed low-volume MS–LTC–DRG (assigned to Quintile 2), we assigned it to Quintile 1 (such that Quintile 1 contains 52 proposed low-volume MS–LTC–DRGs before any adjustments for nonmonotonicity, as discussed below). This results in 4 of the 5 proposed low-volume quintiles containing 52 proposed MS–LTC–DRGs (Quintiles 1, 2, 3 and 4) and one proposed low-volume quintile containing 51 proposed MS–LTC–DRGs (Quintile 5). Table 13A, listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site, lists the composition of the proposed low-volume quintiles for MS–LTC–DRGs for FY 2017.

In order to determine the proposed FY 2017 relative weights for the proposed low-volume MS–LTC–DRGs, we are proposing to use the five proposed low-volume quintiles described previously. We determined a proposed relative

weight and (geometric) average length of stay for each of the five proposed low-volume quintiles using the methodology described in section VII.C.3.g. of the preamble of this proposed rule. We are proposing to assign the same proposed relative weight and average length of stay to each of the proposed low-volume MS–LTC–DRGs that make up an individual 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 applicable LTCH cases would vary in the future. Furthermore, we note that we continue to monitor the volume (that is, the number of applicable LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS–LTC–DRG relative weights result in appropriate payment for LTCH cases grouped to low-volume MS–LTC–DRGs 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 2017 MS–LTC–DRG Relative Weights

In this proposed rule, we are proposing to continue to use our current methodology to determine the proposed FY 2017 MS–LTC–DRG relative weights.

In summary, to determine the proposed FY 2017 MS–LTC–DRG relative weights, we are proposing to group applicable LTCH cases to the appropriate proposed MS–LTC–DRG, while taking into account the proposed low-volume quintiles (as described above) and proposed cross-walked no-volume MS–LTC–DRGs (as described later in this section). After establishing the appropriate proposed MS–LTC–DRG (or proposed low-volume quintile), we calculate the proposed FY 2017 relative weights by first removing cases with a length of stay of 7 days or less and statistical outliers (Steps 1 and 2 below). Next, we adjust the number of applicable LTCH cases in each proposed MS–LTC–DRG (or proposed low-volume quintile) for the effect of SSO cases (Step 3 below). After removing applicable LTCH cases with a length of stay of 7 days or less (Step 1 below) and statistical outliers (Step 2 below), which are the SSO-adjusted applicable LTCH cases and corresponding charges (step 3 below), we calculate “relative adjusted weights” for each proposed MS–LTC–DRG (or low-volume quintile) using the HSRV method.

*Step 1—Remove cases with a length of stay of 7 days or less.*

The first step in our calculation of the proposed FY 2017 MS–LTC–DRG relative weights would be to 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 2017 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at a LTCH by including data from these very short stays. Therefore, consistent with our existing relative weight methodology, in determining the proposed FY 2017 MS–LTC–DRG relative weights, we are proposing to remove LTCH cases with a length of stay of 7 days or less from applicable LTCH cases. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

*Step 2—Remove statistical outliers.*

The next step in our calculation of the proposed FY 2017 MS–LTC–DRG relative weights would be to remove statistical outlier cases from the LTCH cases with a length of stay of at least 8 days. Consistent with our existing 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 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 relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among those MS–LTC–DRGs. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.) After removing cases with a length of stay of 7 days or less and statistical outliers, we are left with applicable LTCH cases that have a length of stay greater than or equal to 8 days. In this proposed rule, we refer to

these cases as “trimmed applicable LTCH cases.”

*Step 3*—Adjust charges for the effects of SSOs.

As the next step in the calculation of the proposed FY 2017 MS–LTC–DRG relative weights, consistent with our historical approach, we are proposing to adjust each LTCH’s charges per discharge for those remaining cases (that is, trimmed applicable LTCH cases) for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503). Specifically, 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 LTCH cases with no adjustment in determining the proposed FY 2017 MS–LTC–DRG relative weights would lower the proposed FY 2017 MS–LTC–DRG relative weight for affected proposed MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a proposed MS–LTC–DRG. This would result in an “underpayment” for non-SSO cases and an “overpayment” for SSO cases. Therefore, we are proposing to continue to adjust for SSO cases under § 412.529 in this manner because it would result in more appropriate payments for all LTCH PPS standard Federal payment rate 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 2017 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, we are proposing to calculate the proposed FY 2017 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. First, for each SSO-adjusted trimmed applicable LTCH case, we would calculate a hospital-specific relative charge value by dividing the charge per discharge after adjusting for SSOs of the LTCH case (from Step 3) by the average charge per SSO-adjusted discharge for the LTCH in which the case occurred. The resulting ratio was

then would be multiplied by the LTCH’s case-mix index to produce an adjusted hospital-specific relative charge value for the case. We use an initial case-mix index value of 1.0 for each LTCH.

For each proposed MS–LTC–DRG, we would calculate the proposed FY 2017 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases for the proposed MS–LTC–DRG (that is, the sum of the hospital-specific relative charge value from above divided by the sum of equivalent cases from Step 3 for each proposed MS–LTC–DRG) by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value from above divided by the sum of equivalent applicable LTCH cases from Step 3 for each proposed MS–LTC–DRG). Using these recalculated MS–LTC–DRG relative weights, each LTCH’s average relative weight for all of its SSO-adjusted trimmed applicable LTCH cases (that is, its case-mix) would be calculated by dividing the sum of all the LTCH’s MS–LTC–DRG relative weights by its total number of SSO-adjusted trimmed applicable LTCH cases. The LTCHs’ hospital-specific relative charge values (from previous) were then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values would then be used to calculate a new set of MS–LTC–DRG relative weights across all LTCHs. This iterative process continues until there is convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

*Step 5*—Determine a proposed FY 2017 relative weight for MS–LTC–DRGs with no applicable LTCH cases.

Using the trimmed applicable LTCH cases, we are proposing to identify the proposed MS–LTC–DRGs for which there were no claims in the December 2015 update of the FY 2015 MedPAR file and, therefore, for which no charge data was available for these proposed MS–LTC–DRGs. Because patients with a number of the diagnoses under those proposed MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we would generally assign a proposed relative weight to each of the no-volume proposed MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of “transplant” proposed MS–LTC–DRGs, “error” proposed MS–LTC–DRGs, and proposed MS–LTC–DRGs that indicate a principal

diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the “psychiatric or rehabilitation” MS–LTC–DRGs), as discussed later in this section of the proposed rule). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

We are proposing to cross-walk each no-volume proposed MS–LTC–DRG to another proposed MS–LTC–DRG for which we would calculate a proposed relative weight (determined in accordance with the methodology described above). Then, the “no-volume” proposed MS–LTC–DRG would be 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 in this section of the proposed rule).

Of the 757 proposed MS–LTC–DRGs for FY 2017, we identified 358 proposed MS–LTC–DRGs for which there are no trimmed applicable LTCH cases (the number identified includes the 8 “transplant” proposed MS–LTC–DRGs, the 2 “error” proposed MS–LTC–DRGs, and the 15 “psychiatric or rehabilitation” proposed MS–LTC–DRGs, which are discussed below). We are proposing to assign proposed relative weights to each of the 333 no-volume proposed MS–LTC–DRGs that contained trimmed applicable LTCH cases based on clinical similarity and relative costliness to one of the remaining 399 (757 – 358 = 399) proposed MS–LTC–DRGs for which we would calculate proposed relative weights based on the trimmed applicable LTCH cases in the FY 2015 MedPAR file data using the steps described previously. (For the remainder of this discussion, we refer to the “cross-walked” proposed MS–LTC–DRGs as the proposed MS–LTC–DRGs to which we cross-walked one of the 333 “no volume” proposed MS–LTC–DRGs.) Then, we generally assigned the 333 no-volume proposed MS–LTC–DRG the proposed relative weight of the cross-walked proposed MS–LTC–DRG. (As explained below in Step 6, when necessary, we made adjustments to account for nonmonotonicity.)

We are proposing to cross-walk the no-volume proposed MS–LTC–DRG to a proposed MS–LTC–DRG for which we would calculate proposed relative weights based on the December 2015 update of the FY 2015 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. (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 no-volume proposed MS-LTC-DRGs in FY 2017, the proposed relative weights assigned based on the cross-walked MS-LTC-DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on clinical similarity and relative costliness, would be expected to generally require equivalent relative resource use.

We are proposing to then assign the proposed relative weight of the cross-walked proposed MS-LTC-DRG as the proposed relative weight for the no-volume proposed MS-LTC-DRG such that both of these proposed MS-LTC-DRGs (that is, the no-volume proposed MS-LTC-DRG and the cross-walked proposed MS-LTC-DRG) have the same proposed relative weight (and average length of stay) for FY 2017. We note that, if the cross-walked proposed MS-LTC-DRG had 25 applicable LTCH cases or more, its proposed relative weight (calculated using the methodology described in Steps 1 through 4 above) was assigned to the no-volume proposed MS-LTC-DRG as well. Similarly, if the proposed MS-LTC-DRG to which the no-volume proposed MS-LTC-DRG was cross-walked had 24 or less cases and, therefore, was designated to one of the proposed low-volume quintiles for purposes of determining the proposed relative weights, we assigned the proposed relative weight of the applicable proposed low-volume quintile to the no-volume proposed MS-LTC-DRG such that both of these proposed MS-LTC-DRGs (that is, the no-volume proposed MS-LTC-DRG and the proposed cross-walked MS-LTC-DRG) have the same proposed relative weight for FY 2017. (As we noted previously, in the infrequent case where nonmonotonicity involving a no-volume proposed MS-LTC-DRG resulted, additional adjustments as described in Step 6 are required in order to maintain monotonically increasing relative weights.)

For this proposed rule, a list of the no-volume proposed MS-LTC-DRGs and the proposed MS-LTC-DRGs to which each would cross-walk (that is, the cross-walked proposed MS-LTC-DRGs) for FY 2017 is shown in Table 13B, which is listed in section VI. of the Addendum to this proposed rule and is

available via the Internet on the CMS Web site.

To illustrate this methodology for determining the proposed relative weights for the FY 2017 proposed MS-LTC-DRGs with no applicable LTCH cases, we are providing the following example, which refers to the no-volume proposed MS-LTC-DRGs crosswalk information for FY 2017 provided in Table 13B.

*Example:* There were no trimmed applicable LTCH cases in the FY 2015 MedPAR file that we are using 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) is similar clinically and based on resource use to proposed MS-LTC-DRG 61. Therefore, we assigned the same proposed relative weight (and average length of stay) of proposed MS-LTC-DRG 70 of 0.9156 for FY 2017 to proposed MS-LTC-DRG 61 (refer to Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the Internet on the CMS Web site).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS-LTC-DRGs with no volume would vary in the future. Consistent with our historical practice, we used the most recent available claims data to identify the trimmed applicable LTCH cases from which we determined the proposed relative weights in this proposed rule.

For FY 2017, consistent with our historical relative weight methodology, we are proposing to establish a relative weight of 0.0000 for the following transplant proposed 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 only covers 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 transplant proposed 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).) In addition, consistent with our historical policy and we are proposing to establish a relative weight of 0.0000 for the 2 “error” proposed MS-LTC-DRGs (that is, MS-LTC-DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS-LTC-DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these proposed MS-LTC-DRGs cannot be properly assigned to an MS-LTC-DRG according to the grouping logic.

In this proposed rule, for FY 2017, we are proposing to establish a proposed relative weight equal to the respective FY 2015 relative weight of the MS-LTC-DRGs for the following “psychiatric or rehabilitation” proposed MS-LTC-DRGs: MS-LTC-DRG 876 (O.R. Procedure with Principal Diagnoses of Mental Illness); MS-LTC-DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS-LTC-DRG 881 (Depressive Neuroses); MS-LTC-DRG 882 (Neuroses Except Depressive); MS-LTC-DRG 883 (Disorders of Personality & Impulse Control); MS-LTC-DRG 884 (Organic Disturbances & Mental Retardation); MS-LTC-DRG 885 (Psychoses); MS-LTC-DRG 886 (Behavioral & Developmental Disorders); MS-LTC-DRG 887 (Other Mental Disorder Diagnoses); MS-LTC-DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama); MS-LTC-DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy); MS-LTC-DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); MS-LTC-DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC); MS-LTC-DRG 945 (Rehabilitation with CC/MCC); and MS-LTC-DRG 946 (Rehabilitation without CC/MCC). As we discussed when we implemented the dual rate LTCH PPS payment structure, LTCH discharges that are grouped to these 15 “psychiatric and rehabilitation” MS-LTC-DRGs do not meet the criteria for exclusion from the site neutral payment rate. As such, under the criterion for a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation, there are no applicable LTCH cases to use in calculating a relative weight for the “psychiatric and rehabilitation” proposed MS-LTC-DRGs. In other words, any LTCH PPS discharges grouped to any of the 15 “psychiatric

and rehabilitation” proposed MS–LTC–DRGs will always be paid at the site neutral payment rate, and, therefore, those proposed MS–LTC–DRGs will never include any LTCH cases that meet the criteria for exclusion from the site neutral payment rate. However, section 1886(m)(6)(B) of the Act establishes a transitional payment method for cases that would be paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017. Under the transitional payment method for site neutral payment rate cases, for LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2016, and on or before September 30, 2017, site neutral payment rate cases are paid a blended payment rate, calculated as 50 percent of the applicable site neutral payment rate amount for the discharge and 50 percent of the applicable LTCH PPS standard Federal payment rate. Because the LTCH PPS standard Federal payment rate is based on the relative weight of the MS–LTC–DRG, in order to determine the transitional blended payment for site neutral payment rate cases grouped to one of the “psychiatric or rehabilitation” proposed MS–LTC–DRGs in FY 2017, we are proposing to assign a proposed relative weight to these proposed MS–LTC–DRGs for FY 2017, that would be the same as the FY 2015 relative weight (which is also the same as the FY 2016 relative weight). We believe that using the respective FY 2015 relative weight for each of the “psychiatric or rehabilitation” proposed MS–LTC–DRGs results in appropriate payments for LTCH cases that are paid at the site neutral payment rate under the transition policy provided by the statute because there are no clinically similar MS–LTC–DRGs for which we were able to determine relative weights based on applicable LTCH cases in the FY 2015 MedPAR file data using the steps described above. Furthermore, we believe that it would be administratively burdensome and introduce unnecessary complexity to the MS–LTC–DRG relative weight calculation to use the LTCH discharges in the MedPAR file data to calculate a relative weight for those 15 “psychiatric and rehabilitation” proposed MS–LTC–DRGs to be used for the sole purpose of determining half of the transitional blended payment for site neutral payment rate cases during the transition period. (80 FR 49631 through 49632)

In summary, for FY 2017, we are proposing to establish a proposed relative weight (and average length of stay thresholds) equal to the respective

FY 2015 relative weight of the proposed MS–LTC–DRGs for the 15 “psychiatric or rehabilitation” proposed MS–LTC–DRGs listed previously (that is, MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945, and 946). Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet on the CMS Web site, reflects this proposal.

*Step 6*—Adjust the proposed FY 2017 MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights.

The MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one secondary diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as “without CC/MCC.” When data do not support the creation of three severity levels, the base MS–DRG is subdivided into either two levels or the base MS–DRG is not subdivided. The two-level subdivisions could consist of the MS–DRG with CC/MCC and the MS–DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the MS–DRG with MCC and the MS–DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the “without CC/MCC” MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the “with CC/MCC” MS–LTC–DRG (in the case of a two-level split) or both the “with CC” and the “with MCC” MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and would result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher relative weight than one with MCC, or the 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). Therefore, in determining the proposed FY 2017 MS–LTC–DRG relative weights, consistent with our historical methodology, we are proposing to continue to combine MS–LTC–DRG severity levels within a base 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 2017 MS–LTC–DRG relative weights in this proposed rule by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet on the CMS Web site.

*Step 7*—Calculate the proposed FY 2017 MS–LTC–DRG reclassification and recalibration 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). To achieve the budget neutrality requirement at § 412.517(b), under our established methodology, 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 2017 based on the most recent available LTCH data for applicable LTCH cases, and to continue to apply a budget neutrality adjustment in determining the FY 2017 MS–LTC–DRG relative weights.

To ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology. Therefore, in this proposed rule, in the first step of our MS–LTC–DRG budget neutrality methodology, for FY 2017, we are proposing to calculate and apply a normalization factor to the recalibrated relative weights (the result of Steps 1 through 6 discussed previously) to ensure that estimated payments are not affected by changes in the composition of case types or the changes to the classification system. That is, the proposed normalization adjustment is intended to ensure that the recalibration of the MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the proposed normalization factor for FY 2017 (the first step of our budget neutrality methodology), we used the following three steps: (1.a.) Use the most recent available applicable LTCH cases from the most recent available data (that is, LTCH discharges from the FY 2015 MedPAR file) and grouped them using the proposed FY 2017 GROUPER (that is, proposed Version 34 for FY 2017) and the recalibrated FY 2017 MS–LTC–DRG relative weights (determined in Steps 1 through 6 above) to calculate the average case-mix index; (1.b.) group the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2016 GROUPER (Version 33) and FY 2016 MS–LTC–DRG relative weights and calculated the average case-mix index; and (1.c.) compute the ratio of these average case-mix indexes by dividing the average CMI for FY 2016 (determined in Step 1.b.) by the average case-mix index for FY 2017 (determined in Step 1.a.). As a result, in determining the proposed MS–LTC–DRG relative weights for FY 2017, each recalibrated MS–LTC–DRG relative weight is multiplied by the proposed normalization factor of 1.28094 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produces “normalized relative weights.”

In the second step of our MS–LTC–DRG budget neutrality methodology, we are proposing to calculate a second budget neutrality factor consisting of the ratio of estimated aggregate FY 2017

LTCH PPS standard Federal payment rate payments for applicable LTCH cases (the sum of all calculations under Step 1.a. mentioned previously) after reclassification and recalibration to estimated aggregate payments for FY 2017 LTCH PPS standard Federal payment rate payments for applicable LTCH cases before reclassification and recalibration (that is, the sum of all calculations under Step 1.b. mentioned previously).

That is, for this proposed rule, for FY 2017, under the second step of the budget neutrality methodology, we determined the budget neutrality adjustment factor using the following three steps: (2.a.) Simulate estimated total FY 2017 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the normalized relative weights for FY 2017 and proposed GROUPER Version 34 (as described above); (2.b.) simulate estimated total FY 2016 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2016 GROUPER (Version 33) and the FY 2016 MS–LTC–DRG relative weights in Table 11 of the FY 2016 IPPS/LTCH PPS final rule available on the Internet, as described in section VI. of the Addendum of that final rule; and (2.c.) calculate the ratio of these estimated total payments by dividing the value determined in Step 2.b. by the value determined in Step 2.a. In determining the proposed FY 2017 MS–LTC–DRG relative weights, each proposed normalized relative weight was then multiplied by a proposed budget neutrality factor of 0.998723 (the value determined in Step 2.c.) in the second step of the budget neutrality methodology to achieve the budget neutrality requirement at § 412.517(b).

Accordingly, in determining the proposed FY 2017 MS–LTC–DRG relative weights in this proposed rule, consistent with our existing methodology, we are proposing to apply a proposed normalization factor of 1.28094 and a proposed budget neutrality factor of 0.998723. Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet on the CMS Web site, lists the proposed MS–LTC–DRGs and their respective proposed relative weights, geometric mean length of stay, five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)), and the “IPPS Comparable Thresholds” (used in determining SSO payments under § 412.529(c)(3)), for FY 2017.

#### *D. Proposed Rebasings of the LTCH Market Basket*

##### 1. Background

The input price index (that is, the market basket) that was used to develop the LTCH PPS for FY 2003 was the “excluded hospital with capital” market basket. That market basket was based on 1997 Medicare cost report data and included data for Medicare-participating IRFs, IPFs, LTCHs, cancer hospitals, and children’s hospitals. Although the term “market basket” technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that mix. Accordingly, the term “market basket,” as used in this section, refers to an input price index.

Beginning with RY 2007, LTCH PPS payments were updated using a 2002-based market basket reflecting the operating and capital cost structures for IRFs, IPFs, and LTCHs (hereafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). We excluded cancer and children’s hospitals from the RPL market basket because their payments are based entirely on reasonable costs subject to rate-of-increase limits established under the authority of section 1886(b) of the Act, which are implemented in regulations at 42 CFR 413.40. Those types of hospitals are not paid under a PPS. Also, the 2002 cost structures for cancer and children’s hospitals are noticeably different from the cost structures for freestanding IRFs, freestanding IPFs, and LTCHs. A complete discussion of the 2002-based RPL market basket can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51756), we finalized the rebasing and revising of the 2002-based RPL market basket by creating and implementing a 2008-based RPL market basket. We also discussed the creation of a stand-alone LTCH market basket and received several public comments, all of which supported deriving a stand-alone LTCH market basket (76 FR 51756 through 51757). In the FY 2013 IPPS/LTCH PPS final rule, we finalized the adoption of a stand-alone 2009-based LTCH-specific market basket that reflects the cost structures of LTCHs only (77 FR 53467 through 53479).

For this FY 2017 proposed rule, we are proposing to rebase and revise the 2009-based LTCH-specific market basket. The proposed LTCH market basket is primarily based on Medicare cost report data for LTCHs for 2013,



which are for cost reporting periods beginning on and after October 1, 2012, and before October 1, 2013. We are proposing to use data from cost reports beginning in FY 2013 because these data are the latest available complete data for purposes of calculating cost weights for the market basket. In the following discussion, we provide an overview of the proposed LTCH market basket and describe the methodologies we are proposing to use for determining the operating and capital portions of the proposed 2013-based LTCH market basket.

## 2. Overview of the Proposed 2013-Based LTCH Market Basket

Similar to the 2009-based LTCH-specific market basket, the proposed 2013-based LTCH market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix (that is, intensity) of goods and services purchased over time are not measured.

The index itself is constructed using three steps. First, a base period is selected (in this proposed rule, we are proposing to use 2013 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called “cost weights” or “expenditure weights.” Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a “price proxy.” In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish hospital services. The

effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a hospital hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the hospital, but would not be factored into the price change measured by a fixed-weight hospital market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect a recent mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care.

## 3. Development of the Proposed 2013-Based LTCH Market Basket Cost Categories and Weights

We are inviting public comments on our proposed methodology, discussed below, for deriving the proposed 2013-based LTCH market basket.

### a. Use of Medicare Cost Report Data

The proposed 2013-based LTCH market basket consists of six major cost categories derived from the 2013 LTCH Medicare cost reports (CMS Form 2552–10), including wages and salaries, employee benefits, contract labor, pharmaceuticals, professional liability insurance, and capital. After we calculate these cost categories, we are left with a residual cost category, which reflects all other input costs other than those captured in the six cost categories above. This is the same number of cost categories derived for the 2009-based LTCH-specific market basket using the 2009 Medicare cost report data (CMS Form 2552–96). These 2013 Medicare cost reports include data for cost reporting periods beginning on and after October 1, 2012, and before October 1, 2013. We are proposing to use 2013 as the base year because we believe that the 2013 Medicare cost reports represent the most recent, complete set of Medicare cost report data available to develop cost weights for an LTCH market basket. Medicare cost report data include costs for all patients, including Medicare, Medicaid, and private payer.

Because our goal is to measure cost shares for facilities that serve Medicare beneficiaries, and are reflective of case-mix and practice patterns associated with providing services to Medicare beneficiaries in LTCHs, we are proposing to limit our selection of Medicare cost reports to those from LTCHs that have a Medicare average length of stay (LOS) that is within a

comparable range of their total facility average LOS. We define the Medicare average LOS based on data reported on the Medicare cost report (CMS Form 2552–10) Worksheet S–3, Part I, Line 14. We believe that applying the LOS edit results in a more accurate reflection of the structure of costs for Medicare covered days. For the 2009-based LTCH-specific market basket, we used the cost reports submitted by LTCHs with Medicare average LOS within 15 percent (that is, 15 percent higher or lower) of the total facility average LOS for the hospital.

Based on our analysis of the 2013 Medicare cost reports, for the proposed 2013-based LTCH market basket, we are proposing to use the cost reports submitted by LTCHs with Medicare average LOS within 25 percent (that is, 25 percent higher or lower) of the total facility average LOS for the hospital (this edit excludes 6 percent of LTCH providers). Applying the proposed trim results in a subset of LTCH Medicare cost reports with an average Medicare LOS of 27 days, average facility LOS of 28 days, and aggregate Medicare utilization (as measured by Medicare inpatient LTCH days as a percentage of total facility inpatient LTCH days) of 66 percent. If we were to apply the same trim as was applied for the 2009-based LTCH-specific market basket, we would exclude 11 percent of LTCH providers, but the results would be very similar with an average Medicare LOS of 27 days, average facility LOS of 27 days, and aggregate Medicare utilization of 66 percent. The 6 percent of providers that are excluded from the proposed 2013-based LTCH market basket have an average Medicare LOS of 29 days, average facility LOS of 77 days, and aggregate Medicare utilization of 12 percent. We believe that the use of this proposed trim, instead of the trim used to develop the 2009-based LTCH-specific market basket, is a technical improvement because data from more LTCHs are used while still being reflective of case-mix and practice patterns associated with providing services to Medicare beneficiaries.

Using the resulting set of Medicare cost reports, we are proposing to calculate cost weights for seven major cost categories of the proposed 2013-based LTCH market basket (wages and salaries, employee benefits, contract labor, professional liability insurance, pharmaceuticals, capital, and an “all other” residual cost category). The methodology used to develop the proposed 2013-based LTCH market basket cost weights is generally the same methodology used to develop the 2009-based LTCH-specific market basket

cost weights. We describe the detailed methodology for obtaining costs for each of these seven cost categories below.

#### (1) Wages and Salaries Costs

We are proposing to derive wages and salaries costs as the sum of inpatient salaries, ancillary salaries, and a proportion of overhead (or general service cost center) salaries as reported on Worksheet A, Column 1. Because overhead salary costs are attributable to the entire LTCH, we are proposing to only include the proportion attributable to the Medicare allowable cost centers. Similar to the 2009-based LTCH-specific market basket major cost weights, we define Medicare allowable total costs (routine, ancillary and capital) as costs that are eligible for payment through the LTCH PPS. We are proposing to estimate the proportion of overhead salaries that are attributed to Medicare allowable costs centers by multiplying the ratio of Medicare allowable cost centers' salaries to total salaries (Worksheet A, Column 1, Line 200) by total overhead salaries. A similar methodology was used to derive wages and salaries costs in the 2009-based LTCH-specific market basket.

#### (2) Employee Benefit Costs

Similar to the 2009-based LTCH-specific market basket, we are proposing to calculate employee benefit costs using Worksheet S3, Part II. The completion of Worksheet S-3, Part II is only required for IPPS hospitals. However, for 2013, we found that roughly 35 percent of all LTCHs voluntarily reported these data (similar to prior years). We note that this worksheet is only required to be completed by IPPS hospitals. Our analysis of the Worksheet S-3, Part II data submitted by these LTCHs indicates that we had a large enough sample to enable us to produce a reasonable employee benefits cost weight. Specifically, we found that when we recalculated the cost weight after weighting to reflect the characteristics of the universe of LTCHs (type of control (nonprofit, for-profit, and government) and by region), the recalculation did not have a material effect on the resulting cost weight. Therefore, we are proposing to use Worksheet S-3, Part II data (as was done for the 2009-based LTCH-specific market basket) to calculate the employee benefit cost weight in the proposed 2013-based LTCH market basket.

We note that, effective with the implementation of CMS Form 2552-10 for cost reporting periods beginning on or after May 1, 2010, CMS began collecting employee benefits and contract labor data on Worksheet S-3, Part V, which is applicable to LTCHs. Only a few LTCHs reported these data and, therefore, we were unable to use such a small sample to accurately reflect these costs. Therefore, we encourage all LTCHs to report employee benefit and contract labor costs on Worksheet S-3, Part V.

#### (3) Contract Labor Costs

Contract labor costs are primarily associated with direct patient care services. Contract labor costs for services such as accounting, billing, and legal are estimated using other government data sources as described below. As was done for the 2009-based LTCH-specific market basket, we are proposing to derive the contract labor cost weight for the proposed 2013-based LTCH market basket using voluntarily reported data from Worksheet S-3, Part II. Approximately 48 percent of LTCHs voluntarily reported contract labor cost on the Worksheet S-3, Part II. Our analysis of these data indicates that we have a large enough sample to enable us to produce a reasonable contract labor cost weight. Specifically, we found that when we recalculated the cost weight after weighting to reflect the characteristics of the universe of LTCHs (type of control (nonprofit, for-profit, and government) and by region), the recalculation did not have a material effect on the resulting cost weight. Therefore, as was done for the 2009-based LTCH-specific market basket, we are proposing to use Worksheet S-3, Part II to calculate the contract labor cost weight in the proposed 2013-based LTCH market basket.

#### (4) Pharmaceutical Costs

We are proposing to calculate pharmaceutical costs using nonsalary costs reported on Worksheet A, Column 7, minus the amount on Worksheet A, Column 1, for the pharmacy cost center (Line 15) and drugs charged to patients cost center (Line 73). A similar methodology was used for the 2009-based LTCH-specific market basket using the CMS Form 2552-96.

#### (5) Professional Liability Insurance Costs

We are proposing that professional liability insurance (PLI) costs (often

referred to as malpractice costs) be equal to premiums, paid losses and self-insurance costs reported on Worksheet S2, Part I, Line 118, Columns 1 through 3. A similar methodology was used for the 2009-based LTCH-specific market basket using the CMS Form 2552-96.

#### (6) Capital Costs

We are proposing that capital costs be equal to Medicare allowable capital costs as reported on Worksheet B, Part II, Column 26. We are proposing to define Medicare allowable costs as cost centers: 30 through 35, 50 through 76 (excluding 52, 61, and 75), 90 through 91 and 93. A similar methodology was used for the 2009-based LTCH-specific market basket using the CMS Form 2552-96.

#### b. Final Major Cost Category Computation

In addition to our proposals to derive costs for the major cost categories for each provider using the Medicare cost report data as previously described, we are proposing to address outlier cases using the following steps. First, for each provider, we are proposing to divide the costs for each of the six categories by the total Medicare allowable costs to obtain cost weights for the universe of LTCH providers. We are proposing to define total Medicare allowable costs reported on Worksheet B, Part I, Column 26 for cost centers: 30 Through 35, 50 through 76 (excluding 52, 61, and 75), 90 through 91 and 93.

We then are proposing to remove those providers whose derived cost weights fall in the top and bottom 5 percent of provider-specific derived cost weights to ensure the removal of costs for outlier cases. After the costs for outlier cases have been removed in this manner, we are proposing to sum the costs for each category across all remaining providers, and then divide this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the proposed 2013-based LTCH market basket for the given category. Finally, we are proposing to calculate a seventh major cost weight—the residual “All Other” cost weight to reflect all remaining costs that are not captured in the previous six cost categories listed. We refer readers to Table VII-1 below for the resulting proposed cost weights for these major cost categories.

TABLE VII-1—MAJOR COST CATEGORIES AND THEIR RESPECTIVE COST WEIGHTS AS CALCULATED FROM MEDICARE COST REPORTS

Major cost categories	Proposed 2013-based LTCH market basket cost weight (percent of total costs)	2009-based LTCH-specific market basket cost weight (percent of total costs)
Wages and Salaries .....	41.5	40.4
Employee Benefits .....	6.5	7.0
Contract Labor .....	5.9	6.9
Professional Liability Insurance (Malpractice) .....	0.9	0.8
Pharmaceuticals .....	7.6	8.9
Capital .....	9.7	9.8
All Other .....	27.8	26.1

The wages and salaries cost weight calculated from the Medicare cost reports for the proposed 2013-based LTCH market basket is approximately 1 percentage point higher than the wages and salaries cost weight for the 2009-based LTCH-specific market basket, while the contract labor cost weight is approximately 1 percentage point lower. The proposed 2013-based pharmaceuticals cost weight also is roughly 1 percentage point lower than the cost weight for the 2009-based LTCH-specific market basket.

As we did for the 2009-based LTCH market basket, we are proposing to allocate the contract labor cost weight to the wages and salaries and employee benefits cost weights based on their relative proportions 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. This rounded percentage is 86 percent. Therefore, we are proposing to allocate 86 percent of the contract labor cost weight to the wages and salaries cost weight and 14 percent to the employee benefits cost weight. We refer readers to Table VII-2 below that shows the proposed wages and salaries and employee benefit cost weights after contract labor cost weight allocation for both the proposed 2013-based LTCH market basket and the 2009-based LTCH-specific market basket.

TABLE VII-2—WAGES AND SALARIES AND EMPLOYEE BENEFITS COST WEIGHTS AFTER CONTRACT LABOR ALLOCATION

Major cost categories	Proposed 2013-based LTCH cost weight (percent of total costs)	2009-based LTCH-specific cost weight (percent of total costs)
Wages and Salaries .....	46.6	46.3
Employee Benefits .....	7.3	8.0
Compensation .....	53.9	54.3

After the allocation of the contract labor cost weight, the proposed 2013-based wages and salaries cost weight is 0.3 percentage point higher, while the employee benefit cost weight is 0.7 percentage point lower, relative to the respective cost weights for the 2009-based LTCH-specific market basket. As a result, in the proposed 2013-based LTCH market basket, the compensation cost weight is 0.4 percentage point lower than the compensation cost weight for the 2009-based LTCH-specific market basket.

c. Derivation of the Detailed Operating Cost Weights

To further divide the “All Other” residual cost weight estimated from the 2013 Medicare cost report data into more detailed cost categories, we are proposing to use the 2007 Benchmark Input-Output (I-O) “Use Tables/Before Redefinitions/Purchaser Value” for

NAICS 622000, Hospitals, published by the Bureau of Economic Analysis (BEA). These data are publicly available at the following Web site: [http://www.bea.gov/industry/io\\_annual.htm](http://www.bea.gov/industry/io_annual.htm).

The BEA Benchmark I-O data are scheduled for publication every 5 years with the most recent data available for 2007. The 2007 Benchmark I-O data are derived from the 2007 Economic Census and are the building blocks for BEA’s economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.<sup>72</sup> BEA also produces Annual I-O estimates. However, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to

<sup>72</sup> [http://www.bea.gov/papers/pdf/IOManual\\_092906.pdf](http://www.bea.gov/papers/pdf/IOManual_092906.pdf).

revision when benchmark data becomes available. Instead of using the less detailed Annual I-O data, we are proposing to inflate the 2007 Benchmark I-O data forward to 2013 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2007 Benchmark I-O data. We repeated this practice for each year. We then calculated the cost shares that each cost category represents of the 2007 data inflated to 2013. These resulting 2013 cost shares were applied to the “All Other” residual cost weight to obtain the detailed cost weights for the proposed 2013-based LTCH market basket. For example, the cost for Food: Direct Purchases represents 6.5 percent of the sum of the “All Other” 2007 Benchmark I-O Hospital Expenditures inflated to 2013. Therefore, the Food: Direct Purchases cost weight represents

6.5 percent of the proposed 2013-based LTCH market basket's "All Other" cost category (27.8 percent), yielding a "final" Food: Direct Purchases proposed cost weight of 1.8 percent in the proposed 2013-based LTCH market basket ( $0.065 \times 27.8 \text{ percent} = 1.8 \text{ percent}$ ).

Using this methodology, we are proposing to derive 18 detailed LTCH market basket cost category weights from the proposed 2013-based LTCH market basket residual cost weight (27.8 percent). These categories are: (1) Electricity; (2) Fuel, Oil, and Gasoline; (3) Water and Sewerage; (4) Food: Direct Purchases; (5) Food: Contract Services; (6) Chemicals; (7) Medical Instruments; (8) Rubber and Plastics; (9) Paper and Printing Products; (10) Miscellaneous Products; (11) Professional Fees: Labor-Related; (12) Administrative and Facilities Support Services; (13) Installation, Maintenance, and Repair Services; (14) All Other Labor-Related Services; (15) Professional Fees: Nonlabor-Related; (16) Financial Services; (17) Telephone Services; and (18) All Other Nonlabor-Related Services.

#### d. Derivation of the Detailed Capital Cost Weights

As described in section VII.D.3.b. of the preamble of this proposed rule, we are proposing a capital-related cost weight of 9.7 percent as calculated from the 2013 Medicare cost reports for LTCHs after applying the proposed trims described above. We are proposing to then separate this total capital-related cost weight into more detailed cost categories.

Using 2013 Medicare cost reports, we are able to group capital-related costs into the following categories: Depreciation, Interest, Lease, and Other Capital-Related costs. For each of these categories, we are proposing to determine what proportion of total capital-related costs the category represents using the data reported by the LTCH on Worksheet A-7, which is the same methodology used for the 2009-based LTCH-specific market basket.

We also are proposing to allocate lease costs across each of the remaining detailed capital-related cost categories as was done in the 2009-based LTCH-specific market basket. This would result in three primary capital-related cost categories in the proposed 2013-based LTCH market basket: Depreciation, Interest, and Other Capital-Related costs. Lease costs are unique in that they are not broken out as a separate cost category in the

proposed 2013-based LTCH market basket. Rather, we are proposing to proportionally distribute these costs among the cost categories of Depreciation, Interest, and Other Capital-Related, reflecting the assumption that the underlying cost structure of leases is similar to that of capital-related costs in general. As was done for the 2009-based LTCH-specific market basket, we are proposing to assume that 10 percent of the lease costs as a proportion of total capital-related costs (62.3 percent) represents overhead and to assign those costs to the Other Capital-Related cost category accordingly. Therefore, we are assuming that approximately 6.2 percent ( $62.3 \text{ percent} \times 0.1$ ) of total capital-related costs represent lease costs attributable to overhead, and we are proposing to add this 6.2 percent to the 5.9 percent Other Capital-Related cost category weight. We are then proposing to distribute the remaining lease costs (56.1 percent, or  $62.3 \text{ percent} - 6.2 \text{ percent}$ ) proportionally across the three cost categories (Depreciation, Interest, and Other Capital-Related) based on the proportion that these categories comprise of the sum of the Depreciation, Interest, and Other Capital-Related cost categories (excluding lease expenses). For example, the Other Capital-Related capital cost category represented 15.5 percent of all three cost categories (Depreciation, Interest, and Other Capital-Related) prior to any lease expenses being allocated. This 15.5 percent is applied to the 56.1 percent of remaining lease expenses so that another 8.7 percent of lease expenses as a percent of total capital-related costs is allocated to the Other Capital-Related cost category. Therefore, the resulting proposed Other Capital-Related cost weight is 20.8 percent ( $5.9 \text{ percent} + 6.2 \text{ percent} + 8.7 \text{ percent}$ ). This is the same methodology used for the 2009-based LTCH-specific market basket. The proposed allocation of these lease expenses are shown in Table VII-3.

Finally, we are proposing to further divide the Depreciation and Interest cost categories. We are proposing to separate Depreciation cost category into the following two categories: (1) Building and Fixed Equipment and (2) Movable Equipment. We also are proposing to separate the Interest cost category into the following two categories: (1) Government/Nonprofit; and (2) For-profit.

To disaggregate the depreciation cost weight, we needed to determine the percent of total depreciation costs for LTCHs (after the allocation of lease costs) that are attributable to building

and fixed equipment, which we hereafter refer to as the "fixed percentage." We are proposing to use depreciation and lease data from Worksheet A-7 of the 2013 Medicare cost reports, which is the same methodology used for the 2009-based LTCH-specific market basket. Based on the 2013 LTCH Medicare cost report data, we have determined that depreciation costs for building and fixed equipment account for 39 percent of total depreciation costs, while depreciation costs for movable equipment account for 61 percent of total depreciation costs. As mentioned above, we are proposing to allocate lease expenses among the Depreciation, Interest, and Other Capital cost categories. We determined that leasing building and fixed equipment expenses account for 86 percent of total leasing expenses, while leasing movable equipment expenses account for 14 percent of total leasing expenses. We are proposing to sum the depreciation and leasing expenses for building and fixed equipment, as well as sum the depreciation and leasing expenses for movable equipment. This results in the proposed building and fixed equipment depreciation cost weight (after leasing costs are included) representing 73 percent of total depreciation costs and the movable equipment depreciation cost weight (after leasing costs are included) representing 27 percent of total depreciation costs.

To disaggregate the interest cost weight, we needed to determine the percent of total interest costs for LTCHs that are attributable to government and nonprofit facilities, which we hereafter refer to as the "nonprofit percentage," because price pressures associated with these types of interest costs tend to differ from those for for-profit facilities. We are proposing to use interest costs data from Worksheet A-7 of the 2013 Medicare cost reports for LTCHs, which is the same methodology used for the 2009-based LTCH-specific market basket. The nonprofit percentage determined using this method is 23 percent.

Table VII-3 below provides the proposed detailed capital cost shares obtained from the Medicare cost reports. Ultimately, if finalized, these detailed capital cost shares would be applied to the total capital-related cost weight determined in section VII.D.3.b. of the preamble of this proposed rule to separate the total capital-related cost weight of 9.7 percent into more detailed cost categories and weights.

TABLE VII-3—DETAILED CAPITAL COST WEIGHTS FOR THE PROPOSED 2013-BASED LTCH MARKET BASKET

Cost categories	Proposed cost shares obtained from Medicare cost reports (percent of total costs)	Proposed detailed capital cost shares after allocation of lease expenses (percent of total costs)
Depreciation .....	22.0	54.8
Building and Fixed Equipment .....	16.1	40.1
Movable Equipment .....	5.9	14.7
Interest .....	9.8	24.4
Government/Nonprofit .....	2.2	5.6
For-profit .....	7.6	18.8
Lease .....	62.3	.....
Other .....	5.9	20.8

Note: Total may not add to 100 due to rounding.

e. Proposed 2013-Based LTCH Market Basket Cost Categories and Weights      the proposed 2013-based LTCH market basket compared to the 2009-based LTCH-specific market basket.

Table VII-4 below shows the proposed cost categories and weights for

TABLE VII-4—PROPOSED 2013-BASED LTCH COST WEIGHTS COMPARED TO 2009-BASED LTCH COST WEIGHTS

Cost category	Proposed 2013-based LTCH cost weight	2009-based LTCH cost weight
Total .....	100.0	100.0
Compensation .....	53.9	54.3
Wages and Salaries .....	46.6	46.3
Employee Benefits .....	7.3	8.0
Utilities .....	2.2	1.8
Electricity .....	1.0	1.4
Fuel, Oil, and Gasoline .....	1.1	0.3
Water & Sewerage .....	0.1	0.1
Professional Liability Insurance .....	0.9	0.8
All Other Products and Services .....	33.2	33.3
All Other Products .....	16.3	19.5
Pharmaceuticals .....	7.6	8.9
Food: Direct Purchases .....	1.8	3.4
Food: Contract Services .....	1.1	0.5
Chemicals .....	0.7	1.3
Medical Instruments .....	2.4	2.1
Rubber & Plastics .....	0.6	1.3
Paper and Printing Products .....	1.2	1.2
Apparel .....	.....	0.3
Machinery and Equipment .....	.....	0.1
Miscellaneous Products .....	0.8	0.4
All Other Services .....	16.9	13.7
Labor-Related Services .....	8.3	5.3
Professional Fees: Labor-related .....	3.5	2.3
Administrative and Facilities Support Services .....	0.9	0.5
Installation, Maintenance, and Repair Services .....	2.0	.....
All Other: Labor-related Services .....	1.9	2.6
Nonlabor-Related Services .....	8.6	8.4
Professional Fees: Nonlabor-related .....	3.6	5.3
Financial services .....	2.9	1.0
Telephone Services .....	0.7	0.5
Postage .....	.....	0.8
All Other: Nonlabor-related Services .....	1.4	0.7
Capital-Related Costs .....	9.7	9.8
Depreciation .....	5.3	5.7
Fixed Assets .....	3.9	3.8
Movable Equipment .....	1.4	1.9
Interest Costs .....	2.4	2.4
Government/Nonprofit .....	0.5	0.7
For Profit .....	1.8	1.7
Other Capital-Related Costs .....	2.0	1.7

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

Similar to the 2012-based IRF and 2012-based IPF market baskets, the proposed 2013-based LTCH market basket does not include separate cost categories for Apparel, Machinery and Equipment, and Postage. Due to the small weights associated with these detailed categories and relatively stable price growth in the applicable price proxy, we are proposing to include Apparel and Machinery and Equipment in the Miscellaneous Products cost category and Postage in the All-Other Nonlabor-Related Services cost category. We note that the machinery and equipment expenses are for equipment that is paid for in a given year and not depreciated over the asset's useful life. Depreciation expenses for movable equipment are reflected in the capital-related cost weight of the proposed 2013-based LTCH market basket. For the proposed 2013-based LTCH market basket, we also are proposing to include a separate cost category for Installation, Maintenance, and Repair Services in order to proxy these costs by a price index that better reflects the price changes of labor associated with maintenance-related services.

#### 4. Selection of Proposed Price Proxies

After computing the cost weights for the proposed 2013-based LTCH market basket, it was necessary to select appropriate wage and price proxies to reflect the rate of price change for each expenditure category. With the exception of the proxy for Professional Liability Insurance, all of the proposed proxies for the operating portion of the proposed 2013-based LTCH market basket are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

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

- *Consumer Price Indexes*—Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by the typical consumer. Because they may not represent the price encountered by a producer, we are proposing to use CPIs

only if an appropriate PPI is not available, or if the expenditures are more like those faced by retail consumers in general rather than by purchasers of goods at the wholesale level. For example, the CPI for food purchased away from home is proposed to be used as a proxy for contracted food services.

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

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

Table VII–7 lists the price proxies that we are proposing to use for the proposed 2013-based LTCH market basket. Below we present a detailed explanation of the price proxies that we are proposing for each cost category weight. We note that many of the proxies that we are proposing to use for the proposed 2013-based LTCH market basket are the same as those used for the 2009-based LTCH-specific market basket. For further discussion on the 2009-based LTCH market basket, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53479).

##### a. Price Proxies for the Operating Portion of the Proposed 2013-Based LTCH Market Basket

###### (1) Wages and Salaries

We are proposing to use the ECI for Wages and Salaries for All Civilian Workers in Hospitals (BLS series code CIU102622000000I) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

###### (2) Employee Benefits

We are proposing to use the ECI for Total Benefits for All Civilian Workers in Hospitals to measure the price growth

of this cost category. This ECI is calculated using the ECI for Total Compensation for All Civilian Workers in Hospitals (BLS series code CIU101622000000I) and the relative importance of wages and salaries within total compensation. This is the same price proxy used in the 2009-based LTCH-specific market basket.

###### (3) Electricity

We are proposing to use the PPI Commodity for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

###### (4) Fuel, Oil, and Gasoline

We are proposing to change the proxy used for the Fuel, Oil, and Gasoline cost category. The 2009-based LTCH-specific market basket uses the PPI Industry for Petroleum Refineries (BLS series code PCU32411–32411) to proxy these expenses.

For the proposed 2013-based LTCH market basket, we are proposing to use a blend of the PPI Industry for Petroleum Refineries (BLS series code PCU32411–32411) and the PPI Commodity for Natural Gas (BLS series code WPU0531). Our analysis of the Bureau of Economic Analysis' 2007 Benchmark Input-Output data (use table before redefinitions, purchaser's value for NAICS 622000 [Hospitals]), shows that petroleum refineries expenses accounts for approximately 70 percent and natural gas accounts for approximately 30 percent of the fuel, oil, and gasoline expenses. Therefore, we are proposing a blended proxy of 70 percent of the PPI Industry for Petroleum Refineries (BLS series code PCU32411–32411) and 30 percent of the PPI Commodity for Natural Gas (BLS series code WPU0531). We believe that these two price proxies are the most technically appropriate indices available to measure the price growth of the Fuel, Oil, and Gasoline cost category in the proposed 2013-based LTCH market basket.

###### (5) Water and Sewage

We are proposing to use the CPI for Water and Sewerage Maintenance (All Urban Consumers) (BLS series code CUUR0000SEHG01) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

###### (6) Professional Liability Insurance

We are proposing to proxy price changes in hospital professional liability

insurance premiums (PLI) using percentage changes as estimated by the CMS Hospital Professional Liability Index. To generate these estimates, we collected commercial insurance premiums for a fixed level of coverage while holding nonprice factors constant (such as a change in the level of coverage). This is the same price proxy used in the 2009-based LTCH-specific market basket.

(7) Pharmaceuticals

We are proposing to use the PPI Commodity for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(8) Food: Direct Purchases

We are proposing to use the PPI Commodity for Processed Foods and

Feeds (BLS series code WPU02) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(9) Food: Contract Services

We are proposing to use the CPI for Food Away From Home (All Urban Consumers) (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(10) Chemicals

We are proposing to continue to use a four-part blended PPI composed of the PPI Industry for Industrial Gas Manufacturing (BLS series code PCU325120325120P), the PPI Industry for Other Basic Inorganic Chemical Manufacturing (BLS series code PCU32518–32518), the PPI Industry for

Other Basic Organic Chemical Manufacturing (BLS series code PCU32519–32519), and the PPI Industry for Soap and Cleaning Compound Manufacturing (BLS series code PCU32561–32561). We are proposing to update the blended weights using 2007 Benchmark I–O data, which we also are proposing to use for the proposed 2013-based LTCH market basket. The 2009-based LTCH-specific market basket included the same blended chemical price proxy, but used the 2002 Benchmark I–O data to determine the weights of the blended chemical price index. The 2007 Benchmark I–O data shows more weight for organic chemical products and less weight for inorganic chemical products compared to the 2002 Benchmark I–O data.

Table VII–5 below shows the proposed weights for each of the four PPIs used to create the blended PPI.

TABLE VII–5—BLENDED CHEMICAL PPI WEIGHTS

Name	Proposed 2013-based LTCH weights	2009-based LTCH weights	NAICS
PPI Industry for Industrial Gas Manufacturing .....	32%	35%	325120
PPI Industry for Other Basic Inorganic Chemical Manufacturing .....	17	25	325180
PPI Industry for Other Basic Organic Chemical Manufacturing .....	45	30	325190
PPI Industry for Soap and Cleaning Compound Manufacturing .....	6	10	325610

(11) Medical Instruments

We are proposing to use a blend for the Medical Instruments cost category. The 2007 Benchmark Input-Output data shows an approximate 50/50 split between Surgical and Medical Instruments and Medical and Surgical Appliances and Supplies for this cost category. Therefore, we are proposing a blend composed of 50 percent of the PPI Commodity for Surgical and Medical Instruments (BLS code WPU1562) and 50 percent of the PPI Commodity for Medical and Surgical Appliances and Supplies (BLS code WPU1563). The 2009-based LTCH-specific market basket used the single, higher level PPI Commodity for Medical, Surgical, and Personal Aid Devices (BLS series code WPU156). We believe that the proposed price proxy better reflects the mix of expenses for this cost category as obtained from the 2007 Benchmark I–O data.

(12) Rubber and Plastics

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

used in the 2009-based LTCH-specific market basket.

(13) Paper and Printing Products

We are proposing to use the PPI Commodity for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(14) Miscellaneous Products

We are proposing to use the PPI Commodity for Finished Goods Less Food and Energy (BLS series code WPUFD4131) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(15) Professional Fees: Labor-Related

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. It includes occupations such as legal, accounting, and engineering services. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(16) Administrative and Facilities Support Services

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(17) Installation, Maintenance, and Repair Services

We are proposing to use the ECI for Total compensation for All Civilian Workers in Installation, Maintenance, and Repair (BLS series code CIU1010000430000I) to measure the price growth of this new cost category. Previously these costs were included in the All Other: Labor-Related Services category and were proxied by the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I). We believe that this index better reflects the price changes of labor associated with maintenance-related services and its incorporation represents a technical improvement to the market basket.

(18) All Other: Labor-Related Services

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU20100003000001) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(19) Professional Fees: Nonlabor-Related

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU20100001200001) to measure the price growth of this category. This is the same price proxy that we are proposing to use for the Professional Fees: Labor-related cost category and the same price proxy used in the 2009-based LTCH-specific market basket.

(20) Financial Services

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Financial Activities (BLS series code CIU201520A0000001) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(21) Telephone Services

We are proposing to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(22) All Other: Nonlabor-Related Services

We are proposing to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. We believe that using the CPI for All Items Less Food and Energy avoids double counting of changes in food and energy prices as they are already captured elsewhere in the market basket. This is the same price proxy used in the 2009-based LTCH-specific market basket.

b. Price Proxies for the Capital Portion of the Proposed 2013-Based LTCH Market Basket

(1) Capital Price Proxies Prior to Vintage Weighting

We are proposing to apply the same price proxies to the detailed capital-related cost categories as were applied in the 2009-based LTCH-specific market basket, which are described and provided in Table VII-7. We also are proposing to continue to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. This

vintage weighting method is the same method that was used for the 2009-based LTCH-specific market basket and is described in section VII.D.4.b.(2) of the preamble of this proposed rule.

We are proposing to proxy the Depreciation: Building and Fixed Equipment cost category by BEA's Chained Price Index for Nonresidential Construction for Hospitals and Special Care Facilities (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type); the Depreciation: Movable Equipment cost category by the PPI Commodity for Machinery and Equipment (BLS series code WPU11); the Nonprofit Interest cost category by the average yield on domestic municipal bonds (Bond Buyer 20-bond index); the For-Profit Interest cost category by the average yield on Moody's Aaa bonds (Federal Reserve); and the Other Capital-Related cost category by the CPI-U for Rent of Primary Residence (BLS series code CUUS0000SEHA). We believe that these are the most appropriate proxies for LTCH capital-related costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

(2) Vintage Weights for Price Proxies

Because capital is acquired and paid for over time, capital-related expenses in any given year are determined by both past and present purchases of physical and financial capital. The vintage-weighted capital-related portion of the proposed 2013-based LTCH market basket is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital-related purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest. We are proposing to use vintage weights to compute vintage-weighted price changes associated with depreciation and interest expenses.

Capital-related costs are inherently complicated and are determined by complex capital-related purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual non-vintage 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 LTCH capital-related costs. The

capital-related component of the proposed 2013-based LTCH market basket reflects the underlying stability of the capital-related acquisition process.

To calculate the vintage weights for depreciation and interest expenses, we first needed a time series of capital-related purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital-related purchases by hospitals for all of the above components of capital purchases. The early Medicare cost reports did not have sufficient capital-related data to meet this need. Data we obtained from the American Hospital Association (AHA) did not include annual capital-related purchases. However, we were able to obtain data on total expenses back to 1963 from the AHA.

Consequently, we are proposing to use data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We then are proposing to use 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 2013. We are proposing to separate these depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation as determined earlier. From these annual depreciation amounts, we derived annual end-of-year book values for building and fixed equipment and movable equipment using the expected life for each type of asset category. While data are not available that are specific to LTCHs, we believe that this information for all hospitals serves as a reasonable alternative for the pattern of depreciation for LTCHs. We used the AHA data and methodology to derive the FY 2010-based IPPS capital market basket (78 FR 50604), and the capital components of the 2012-based IRF (80 FR 47062) and 2012-based IPF market baskets (80 FR 46672).

To continue to calculate the vintage weights for depreciation and interest expenses, we also needed to account for the expected lives for building and fixed equipment, movable equipment, and interest for the proposed 2013-based LTCH market basket. We are proposing to calculate the expected lives using Medicare cost report data for LTCHs. The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the



estimated expected life of an asset if the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. Using this proposed method, we determined the average expected life of building and fixed equipment to be equal to 18 years, and the average expected life of movable equipment to be equal to 8 years. For the expected life of interest, we believe that vintage weights for interest should represent the average expected life of building and fixed equipment because, based on previous research described in the FY 1997 IPPS final rule (61 FR 46198), the expected life of hospital debt instruments and the expected life of buildings and fixed equipment are similar. We note that for the 2009-based LTCH-specific market basket, we used 2009 Medicare cost reports for LTCHs to determine the expected life of building and fixed equipment and movable equipment (77 FR 53467 through 53479). The 2009-based LTCH-specific market basket was based on an expected average life of building and fixed equipment of 20 years and an expected average life of movable equipment of 8 years.

Multiplying these expected lives by the annual depreciation amounts results in annual year-end asset costs for building and fixed equipment and

movable equipment. We then calculated a time series, beginning in 1964, of annual capital purchases by subtracting the previous year's asset costs from the current year's asset costs.

For the building and fixed equipment and movable equipment vintage weights, we are proposing to use the real annual capital-related purchase amounts for each asset type to capture the actual amount of the physical acquisition, net of the effect of price inflation. These real annual capital-related purchase amounts are produced by deflating the nominal annual purchase amount by the associated price proxy as provided earlier in this proposed rule. For the interest vintage weights, we are proposing to use the total nominal annual capital-related purchase amounts to capture the value of the debt instrument (including, but not limited to, mortgages and bonds). Using these capital-related purchase time series specific to each asset type, we are proposing to calculate the vintage weights for building and fixed equipment, for movable equipment, and for interest.

The vintage weights for each asset type are deemed to represent the average purchase pattern of the asset over its expected life (in the case of building and fixed equipment and

interest, 18 years, and in the case of movable equipment, 8 years). For each asset type, we are proposing to use the time series of annual capital-related purchase amounts available from 2013 back to 1964. These data allow us to derive thirty-three 18-year periods of capital-related purchases for building and fixed equipment and interest, and forty-three 8-year periods of capital-related purchases for movable equipment. For each 18-year period for building and fixed equipment and interest, or 8-year period for movable equipment, we are proposing to calculate annual vintage weights by dividing the capital-related purchase amount in any given year by the total amount of purchases over the entire 18-year or 8-year period. This calculation was done for each year in the 18-year or 8-year period and for each of the periods for which we have data. We then calculated the average vintage weight for a given year of the expected life by taking the average of these vintage weights across the multiple periods of data.

The vintage weights for the capital-related portion of the proposed 2013-based LTCH market basket and the 2009-based LTCH-specific market basket are presented in Table VII-6 below.

TABLE VII-6—PROPOSED 2013-BASED LTCH MARKET BASKET AND 2009-BASED LTCH-SPECIFIC MARKET BASKET VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES

Year <sup>1</sup>	Building and fixed equipment		Movable equipment		Interest	
	2013-based 18 years	2009-based 20 years	2013-based 8 years	2009-based 8 years	2013-based 18 years	2009-based 20 years
1	0.044	0.034	0.104	0.102	0.029	0.021
2	0.046	0.037	0.110	0.108	0.031	0.024
3	0.048	0.039	0.117	0.114	0.034	0.026
4	0.050	0.042	0.124	0.123	0.037	0.029
5	0.051	0.043	0.128	0.129	0.039	0.032
6	0.051	0.045	0.132	0.134	0.042	0.035
7	0.051	0.046	0.140	0.142	0.043	0.037
8	0.052	0.047	0.145	0.149	0.046	0.040
9	0.053	0.049	.....	.....	0.049	0.043
10	0.056	0.051	.....	.....	0.054	0.047
11	0.058	0.053	.....	.....	0.059	0.050
12	0.059	0.053	.....	.....	0.063	0.053
13	0.061	0.053	.....	.....	0.068	0.055
14	0.062	0.054	.....	.....	0.072	0.059
15	0.062	0.055	.....	.....	0.076	0.062
16	0.063	0.057	.....	.....	0.080	0.068
17	0.066	0.059	.....	.....	0.086	0.073
18	0.067	0.059	.....	.....	0.091	0.077
19	.....	0.061	.....	.....	.....	0.082
20	.....	0.062	.....	.....	.....	0.086
Total	1.000	1.000	1.000	1.000	1.000	1.000

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

<sup>1</sup> Vintage weight in the last year (for example, year 18 for the proposed 2013-based LTCH market basket) is applied to the most recent data point and prior vintage weights are applied going back in time. For example, year 18 vintage weight would be applied to the 2017q3 price proxy level, year 17 vintage weight would be applied to the 2016q3 price proxy level, etc.

The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table VII-6 is applied to the most recent data point. We have provided on the CMS Web site an example of how the vintage weighting price proxies are calculated, using example vintage weights and example

price indices. The example can be found under the following CMS Web site link: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html> in the zip file titled “Weight Calculations as described in the IPPS FY 2010 Proposed Rule.”

c. Summary of Price Proxies of the Proposed 2013-Based LTCH Market Basket

Table VII-7 below shows both the operating and capital price proxies that we are proposing to use for the proposed 2013-based LTCH market basket.

TABLE VII-7—PROPOSED PRICE PROXIES FOR THE PROPOSED 2013-BASED LTCH MARKET BASKET

Cost description	Price proxies	Weight
Total .....	.....	100.0
Compensation .....	.....	53.9
Wages and Salaries .....	ECI for Wages and Salaries for All Civilian Workers in Hospitals.	46.6
Employee Benefits .....	ECI for Total Benefits for All Civilian Workers in Hospitals .....	7.3
Utilities .....	.....	2.2
Electricity .....	PPI Commodity for Commercial Electric Power .....	1.0
Fuel, Oil, and Gasoline .....	Blend of the PPI Industry for Petroleum Refineries and PPI Commodity for Natural Gas.	1.1
Water & Sewerage .....	CPI-U for Water and Sewerage Maintenance .....	0.1
Professional Liability Insurance .....	.....	0.9
Malpractice .....	CMS Hospital Professional Liability Insurance Premium Index	0.9
All Other Products and Services .....	.....	33.2
All Other Products .....	.....	16.3
Pharmaceuticals .....	PPI Commodity for Pharmaceuticals for human use, prescription.	7.6
Food: Direct Purchases .....	PPI Commodity for Processed Foods and Feeds .....	1.8
Food: Contract Services .....	CPI-U for Food Away From Home .....	1.1
Chemicals .....	Blend of Chemical PPIs .....	0.7
Medical Instruments .....	Blend of the PPI Commodity for Surgical and Medical Instruments and PPI Commodity for Medical and Surgical Appliances and Supplies.	2.4
Rubber & Plastics .....	PPI Commodity for Rubber and Plastic Products .....	0.6
Paper and Printing Products .....	PPI Commodity for Converted Paper and Paperboard Products.	1.2
Miscellaneous Products .....	PPI Commodity for Finished Goods Less Food and Energy ....	0.8
All Other Services .....	.....	16.9
Labor-Related Services .....	.....	8.3
Professional Fees: Labor-related .....	ECI for Total Compensation for Private Industry Workers in Professional and Related.	3.5
Administrative and Facilities Support Services .....	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support.	0.9
Installation, Maintenance & Repair Services .....	ECI for Total Compensation for Civilian Workers in Installation, Maintenance, and Repair.	2.0
All Other: Labor-related Services .....	ECI for Total Compensation for Private Industry Workers in Service Occupations.	1.9
Nonlabor-Related Services .....	.....	8.6
Professional Fees: Nonlabor-related .....	ECI for Total Compensation for Private Industry Workers in Professional and Related.	3.6
Financial services .....	ECI for Total Compensation for Private Industry Workers in Financial Activities.	2.9
Telephone Services .....	CPI-U for Telephone Services .....	0.7
All Other: Nonlabor-related Services .....	CPI-U for All Items Less Food and Energy .....	1.4
Capital-Related Costs .....	.....	9.7
Depreciation .....	.....	5.3
Fixed Assets .....	BEA chained price index for nonresidential construction for hospitals and special care facilities—vintage weighted (18 years).	3.9
Movable Equipment .....	PPI Commodity for machinery and equipment—vintage weighted (8 years).	1.4
Interest Costs .....	.....	2.4
Government/Nonprofit .....	Average yield on domestic municipal bonds (Bond Buyer 20 bonds)—vintage weighted (18 years).	0.5
For Profit .....	Average yield on Moody's Aaa bonds—vintage weighted (18 years).	1.8
Other Capital-Related Costs .....	CPI-U for Rent of Primary Residence .....	2.0

Note: Sum of the cost weights for the detailed categories may not add to total cost weight for subcategory or total market basket due to rounding.

d. Proposed FY 2017 Market Basket Update for LTCHs

For FY 2017 (that is, October 1, 2016, through September 30, 2017), we are proposing to use an estimate of the proposed 2013-based LTCH market basket to update payments to LTCHs based on the best available data. Consistent with historical practice, we estimate the LTCH market basket update for the LTCH PPS based on IHS Global Insight, Inc.'s (IGI's) forecast using the most recent available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

Based on IGI's first quarter 2016 forecast with history through the fourth quarter of 2015, the projected market basket update for FY 2017 is 2.7 percent. Therefore, consistent with our historical practice of estimating market

basket increases based on the best available data, we are proposing a market basket update of 2.7 percent for FY 2017. Furthermore, because the proposed FY 2017 annual update is based on the most recent market basket estimate for the 12-month period (currently 2.7 percent), we also are proposing that if more recent data become subsequently available (for example, a more recent estimate of the market basket), we would use such data, if appropriate, to determine the FY 2017 annual update in the final rule. (As discussed in greater detail in section V.A.2. of the Addendum to this proposed rule, we are proposing an annual update of 2.7 percent to the LTCH PPS standard Federal payment rate for FY 2017 under proposed § 412.523(c)(3)(xiii) of the regulations.)

Using the current 2009-based LTCH-specific market basket and IGI's first quarter 2016 forecast for the market

basket components, the FY 2017 market basket update would be 2.8 percent (before taking into account any statutory adjustment). Therefore, the update based on the proposed 2013-based LTCH market basket is currently 0.1 percentage point lower. This lower update is primarily due to the lower pharmaceutical cost weight in the proposed 2013-based market basket (7.6 percent) compared to the 2009-based LTCH-specific market basket (8.9 percent). This is partially offset by the higher cost weights associated with All Other Services (such as Professional Fees and Installation, Maintenance, and Repair Services) for the proposed 2013-based LTCH market basket relative to the 2009-based LTCH-specific market basket. Table VII-8 below compares the proposed 2013-based LTCH market basket and the 2009-based LTCH-specific market basket percent changes.

TABLE VII-8—PROPOSED 2013-BASED LTCH MARKET BASKET AND 2009-BASED LTCH-PECIFIC MARKET BASKET PERCENTAGE CHANGES, FY 2011 THROUGH FY 2019

Fiscal year (FY)	Proposed 2013-based LTCH market basket index percent change	2009-based LTCH market basket index percent change
Historical data:		
FY 2011 .....	2.3	2.6
FY 2012 .....	1.9	2.3
FY 2013 .....	2.1	2.3
FY 2014 .....	1.8	1.9
FY 2015 .....	1.8	2.2
Average 2011–2015 .....	2.0	2.3
Forecast:		
FY 2016 .....	2.0	2.2
FY 2017 .....	2.7	2.8
FY 2018 .....	3.0	3.1
FY 2019 .....	3.1	3.1
Average 2016–2019 .....	2.7	2.8

Note that these market basket percent changes do not include any further adjustments as may be statutorily required. Source: IHS Global Insight, Inc. 1st quarter 2016 forecast.

Over the time period covering 2011 through 2015, the average growth rate of the proposed 2013-based LTCH market basket is roughly 0.3 percentage point lower than the 2009-based LTCH-specific market basket. The lower growth rate is primarily a result of the lower pharmaceutical cost weight in the proposed 2013-based market basket compared to the 2009-based LTCH-specific market basket. Historically, the price growth of pharmaceutical costs has exceeded the price growth rates for most of the other market basket cost categories. Therefore, a lower pharmaceutical cost weight would, all else equal, result in a lower market basket update. As stated above, the pharmaceutical cost weights for the proposed 2013-based LTCH market basket and the 2009-based LTCH-

specific market basket are based on the 2013 and 2009 Medicare cost report data for LTCHs, respectively.

e. Proposed FY 2017 Labor-Related Share

As discussed in section V.B. of the Addendum to this proposed rule, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS payments to account for differences in LTCH area wage levels (§ 412.525(c)). The labor-related portion of the LTCH PPS standard Federal payment rate, hereafter referred to as the labor-related share, is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index.

The labor-related share is determined by identifying the national average

proportion of total costs that are related to, influenced by, or vary with the local labor market. As discussed in more detail below and similar to the 2009-based LTCH-specific market basket, we classify a cost category as labor-related and include it in the labor-related share if the cost category is defined as being labor-intensive and its cost varies with the local labor market. As stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49798), the labor-related share for FY 2016 was defined as the sum of the FY 2016 relative importance of Wages and Salaries; Employee Benefits; Professional Fees; Labor-Related Services; Administrative and Facilities Support Services (formerly referred to as Administrative and Business Support Services); All Other: Labor-related Services; and a portion of the Capital

Costs from the 2009-based LTCH-specific market basket.

We proposed to continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market. Given this, based on our definition of the labor-related share and the cost categories in the proposed 2013-based LTCH market basket, we are proposing to include in the labor-related share for FY 2017 the sum of the FY 2017 relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services; and a portion of the Capital-Related cost weight from the proposed 2013-based LTCH market basket. As noted in section VII.D.3.e. of the preamble of this proposed rule, for the proposed 2013-based LTCH market basket, we have proposed the creation of a separate cost category for Installation, Maintenance, and Repair services. These expenses were previously included in the “All Other” Labor-related Services cost category in the 2009-based LTCH-specific market basket, along with other services, including, but not limited to, janitorial, waste management, security, and dry cleaning/laundry services. Because these services tend to be labor-intensive and are mostly performed at the facility (and, therefore, unlikely to be purchased in the national market), we continue to believe that they meet our definition of labor-related services.

For the development of the 2009-based LTCH-specific market basket, in an effort to more accurately determine the share of professional fees for services such as accounting and auditing services, engineering services, legal services, and management and consulting services that should be included in the labor-related share, we used data from a survey of IPPS hospitals regarding the proportion of those fees that go to companies that are located beyond their own local labor market. The results from this survey were then used to separate a portion of the Professional Fees cost category into labor-related and nonlabor-related costs. These results and our allocation methodology are discussed in more detail in the FY 2012 IPPS/LTCH PPS

final rule (76 FR 51766). For the proposed 2013-based LTCH market basket, we are proposing to apply these survey results using this same methodology to separate the Professional Fees cost category into Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories. We believe that using the survey results serves as an appropriate proxy for the purchasing patterns of professional services for LTCHs because they also are providers of institutional care.

In addition to the professional services listed above, we are proposing to classify expenses under NAICS 55, Management of Companies and Enterprises, into the Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories, as was done for the 2009-based LTCH-specific market basket. The NAICS 55 industry is mostly comprised of corporate, subsidiary, and regional managing offices (otherwise referred to as home offices). As stated above, we classify a cost category as labor-related and include it in the labor-related share if the cost category is labor-intensive and if its costs vary with the local labor market. We believe that many of the costs associated with NAICS 55 are labor-intensive and vary with the local labor market. However, data indicate that not all LTCHs with home offices have home offices located in their local labor market. Therefore, we are proposing to include in the labor-related share only a proportion of the NAICS 55 expenses based on the methodology described below.

For the 2009-based LTCH-specific market basket, we used data primarily from the Medicare cost reports and a CMS database of Home Office Medicare Records (HOMER) (a database that provides city and state information (addresses) for home offices) and determined that 13 percent of the total number of LTCHs that had home offices had those home offices located in their respective local labor markets—defined as being in the same Metropolitan Statistical Area (MSA). Therefore, we classified 13 percent of these costs into the “Professional Fees: Labor-related Services” cost category and the remaining 87 percent into the “Professional Fees: Nonlabor-related

Services” cost category. For a detailed discussion of this analysis, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53478).

For the proposed 2013-based LTCH market basket, we conducted a similar analysis of home office data. For consistency, we believe that it is important for our analysis on home office data to be conducted on the same LTCHs used to derive the proposed 2013-based LTCH market basket cost weights. The Medicare cost report requires a hospital to report information regarding their home office provider. Approximately 56 percent of LTCHs reported some type of home office information on their Medicare cost report for 2013 (for example, home office number, city, state, zip code, or name). For those providers for which we were able to identify which MSA the LTCH’s home office was located, we then compared the home office MSA with the LTCH facility’s MSA.

We found that 7 percent of the LTCHs with home offices had those home offices located in the same MSA as their facilities. We then concluded that these providers were located in the same local labor market as their home office. As a result, we are proposing to apportion the NAICS 55 expense data by this percentage. Therefore, we are proposing to classify 7 percent of these costs into the “Professional Fees: Labor-related Services” cost category and the remaining 93 percent of these costs into the “Professional Fees: Nonlabor-related Services” cost category.

Using this proposed method and the IGI forecast for the first quarter 2016 of the proposed 2013-based LTCH market basket, the proposed LTCH labor-related share for FY 2017 would be the sum of the FY 2017 relative importance of each labor-related cost category. Consistent with our proposal to update the labor-related share with the most recent available data, the labor-related share for this proposed rule reflects IGI’s first quarter 2016 forecast of the proposed 2013-based LTCH market basket. Table VII–9 below shows the proposed FY 2017 relative importance labor-related share using the proposed 2013-based LTCH market basket and the FY 2016 relative importance labor-related share using the 2009-based LTCH-specific market basket.

TABLE VII–9—LTCH LABOR-RELATED SHARE

	FY 2017 Proposed labor- related share <sup>1</sup>	FY 2016 Final labor related share <sup>2</sup>
Wages and Salaries .....	46.6	44.6
Employee Benefits .....	7.3	8.1

TABLE VII-9—LTCH LABOR-RELATED SHARE—Continued

	FY 2017 Proposed labor- related share <sup>1</sup>	FY 2016 Final labor related share <sup>2</sup>
Professional Fees: Labor-related .....	3.5	2.2
Administrative and Facilities Support Services .....	0.9	0.5
Installation, Maintenance, and Repair Services <sup>3</sup> .....	2.1	—
All Other: Labor-related Services .....	1.9	2.5
Subtotal .....	62.3	57.9
Labor-related portion of capital (46%) .....	4.3	4.1
<b>Total Labor-Related Share .....</b>	<b>66.6</b>	<b>62.0</b>

<sup>1</sup> Based on the proposed 2013-based LTCH Market Basket, IHS Global Insight, Inc. 1st quarter 2016 forecast.

<sup>2</sup> Federal Register, 80 FR 49478.

<sup>3</sup> Installation, Maintenance, and Repair services costs were previously included in the All Other: Labor-related Services cost weight of the 2009-based LTCH-specific market basket.

The proposed labor-related share for FY 2017 is the sum of the proposed FY 2017 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 (2013) and FY 2017. The sum of the proposed relative importance for FY 2017 for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair Services, All Other: Labor-related Services) would be 62.3 percent, as shown in Table VII-9 above. We are proposing that the portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the 2009-based LTCH-specific market basket (77 FR 53478). Because the relative importance for capital-related costs under our proposals would be 9.4 percent of the proposed 2013-based LTCH market basket in FY 2017, we are proposing to take 46 percent of 9.4 percent to determine the proposed labor-related share of capital-related costs for FY 2017 ( $.46 \times 9.4$ ). The result would be 4.3 percent, which we are proposing to add to 62.3 percent for the operating cost amount to determine the total proposed labor-related share for FY 2017. Therefore, the labor-related share that we are proposing to use for the LTCH PPS in FY 2017 would be 66.6 percent. This proposed labor-related share is determined using the same methodology as employed in calculating all previous LTCH labor-related shares. We also are proposing that, if more recent data become available, (for example, an updated estimate of the labor-related share) we would use such data to determine the FY 2017 labor-related share for the final rule.

The proposed FY 2017 labor-related share using the proposed 2013-based

LTCH market basket is 4.6 percentage points higher than the FY 2016 labor-related share using the 2009-based LTCH-specific market basket. The primary reason for a higher labor-related share, which we describe in more detail below, is a result of the change in the quantity of labor, particularly for professional services, outpacing the change in quantity of products (which are not included in the labor-related share) between 2009 and 2013, which more than offsets the faster relative growth in prices for products.

Roughly three-quarters of the 4.6 percentage point difference is the result of higher base year cost weights for the Professional Fees: Labor-Related, Administrative and Facilities Support Services, All Other: Labor-Related services, and Installation, Maintenance, and Repair services cost categories for the proposed 2013-based LTCH market basket compared to the 2009-based LTCH-specific market basket. We refer to these cost categories collectively as “Labor-Related Services.” As stated earlier, installation, maintenance and repair costs were previously classified in the All Other: Labor-Related services cost category of the 2009-based LTCH-specific market basket.

In aggregate, the base year cost weights for the Labor-Related Services cost categories in the proposed 2013-based LTCH market basket are 3.0 percentage points higher than the 2009-based LTCH-specific market basket cost weights. As described in section VII.D.3.e. of the preamble of this proposed rule, the detailed cost categories of the LTCH market basket (including the Labor-Related Services cost categories) are derived by multiplying the “All Other” residual cost weight (which reflects all remaining costs that are not captured in the six major cost category weights calculated using the LTCH Medicare Cost Report data (Wages and Salaries,

Employee Benefits, Contract Labor, Professional Liability Insurance, Pharmaceuticals, and Capital)) by the detailed cost weights calculated from the Benchmark I-O data. Therefore, the differences between the Labor-related Services cost weights between the proposed 2013-based LTCH market basket and the 2009-based LTCH-specific market basket are a function of the change in the “All Other” residual cost category weight and changes to the Benchmark I-O data. Approximately 0.6 percentage point of the 3.0 percentage point difference is attributable to the higher “All Other” residual cost category weight of the proposed 2013-based LTCH market basket compared to the 2009-based LTCH-specific market basket, while the remaining 2.4 percentage points is due to the changes in the Benchmark I-O cost weights derived from the 2007 data used in the proposed 2013-based LTCH market basket and the 2002 data used in the 2009-based LTCH-specific market basket.

Roughly one-quarter of the 4.6 percentage point difference between the proposed FY 2017 labor-related share using the proposed 2013-based LTCH market basket and the FY 2016 labor-related share using the 2009-based LTCH-specific market basket is a result of the Compensation cost weight. There are two key factors causing this differential. First, using the 2013 Medicare cost reports, we calculated a Compensation cost weight that is 53.9 percent for the proposed 2013-based LTCH market basket, which reflects both the change in price and change in quantity of compensation. This is 0.9 percentage point higher than the FY 2013 relative importance moving average using the 2009-based LTCH-specific market basket (53.0 percent), which only reflects relative price changes between 2009 and 2013. Second, the relative price growth from

FY 2013 to the payment year between the 2009-based LTCH-specific market basket and the proposed 2013-based LTCH market basket also contributes to the difference. For the 2009-based LTCH-specific market basket, the relative importance for compensation decreases from 53.0 percent in FY 2013 to 52.7 percent in FY 2016, a reduction of 0.3 percentage point. For the proposed 2013-based LTCH market basket, the base weight of 53.9 percent in 2013 is the same as the relative importance in FY 2017. These two factors combined produce the 1.2 percentage point difference in the relative importance for compensation in FY 2016 and FY 2017 as shown in Table VII-9.

As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. 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 mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care.

#### *E. Proposed Changes to the LTCH PPS Payment Rates and Other Proposed Changes to the LTCH PPS for FY 2017*

##### 1. Overview of Development of the LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal prospective payment rates is currently set forth at 42 CFR 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 payment rate for FY 2017, that is, effective for LTCH discharges occurring on or after October 1, 2016 through September 30, 2017. Under the dual rate LTCH PPS payment structure required by statute, beginning with FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate specified at § 412.523. (For additional details on our finalized policies related to the dual rate LTCH PPS payment structure required by statute, we refer readers to the FY 2016

IPPS/LTCH PPS final rule (80 FR 49601 through 49623).)

For details on the development of the initial FY 2003 standard Federal rate, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the LTCH PPS standard Federal rate as implemented under § 412.523(c)(3), we refer readers to the following final rules: RY 2004 LTCH PPS final rule (68 FR 34134 through 34140); RY 2005 LTCH PPS final rule (68 FR 25682 through 25684); RY 2006 LTCH PPS final rule (70 FR 24179 through 24180); RY 2007 LTCH PPS final rule (71 FR 27819 through 27827); RY 2008 LTCH PPS final rule (72 FR 26870 through 27029); RY 2009 LTCH PPS final rule (73 FR 26800 through 26804); FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44021 through 44030); FY 2011 IPPS/LTCH PPS final rule (75 FR 50443 through 50444); FY 2012 IPPS/LTCH PPS final rule (76 FR 51769 through 51773); FY 2013 IPPS/LTCH PPS final rule (77 FR 53479 through 53481); FY 2014 IPPS/LTCH PPS final rule (78 FR 50760 through 50765); FY 2015 IPPS/LTCH PPS final rule (79 FR 50176 through 50180) and FY 2016 IPPS/LTCH PPS final rule (80 FR 49634 through 49637).

In this FY 2017 proposed rule, we present our proposed policies related to the annual update to the LTCH PPS standard Federal payment rate for FY 2017, which includes the annual market basket update. Consistent with our historical practice of using the best data available, we also are proposing to use more recent data to determine the FY 2017 annual market basket update to the LTCH PPS standard Federal payment rate in the final rule.

The application of the proposed update to the LTCH PPS standard Federal payment rate for FY 2017 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 payment rate for FY 2017 are discussed below, including the reduction to the annual update for LTCHs that fail to submit quality reporting data for FY 2017 as required by the statute (as discussed in section VII.E.2.c. of the preamble of this proposed rule). In addition, we are proposing to make an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the proposed changes to the area wage level adjustment for FY 2017 on estimated aggregate LTCH PPS payments, in accordance with § 412.523(d)(4) (as discussed in section

V.A. of the Addendum to this proposed rule).

##### 2. Proposed FY 2017 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update

###### a. Overview

Historically, the Medicare program has used a market basket to account for input 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. We adopted the 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 53476). For FY 2017, we are proposing to rebase and revise the 2009-based LTCH-specific market basket. The proposed LTCH market basket is primarily based on Medicare cost report data for LTCHs for 2013. We refer readers to section VII.D. of this preamble of this proposed rule for a complete discussion of the proposed LTCH market basket and a description of the methodologies we are proposing to use for determining the operating and capital-related portions of the proposed 2013-based LTCH market basket.

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the LTCH PPS standard Federal payment rate and refers to the timeframes associated with such adjustments as a “rate year” (which are discussed in more detail in section VII.C.2.b. of the preamble of this proposed rule.) We note that because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term “fiscal year” (FY) rather than “rate year” (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as “rate year,” consistent with our change in the terminology used under the LTCH PPS from “rate year” to “fiscal year,” for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use

“fiscal year” rather than “rate year” for 2011 and subsequent years.

b. Proposed Market Basket Under the LTCH PPS for FY 2017

Under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we adopted a 2009-based LTCH-specific market basket for use under the LTCH PPS beginning in FY 2013. The 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 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 2017, as noted earlier, we are proposing to rebase and revise the 2009-based LTCH-specific market basket to reflect a 2013 base year. We are proposing to use 2013 cost reports beginning in FY 2013 because these represent the most recent, complete set of Medicare cost report data for purposes of calculating cost weights for the LTCH market basket.

We believe that the proposed 2013-based LTCH market basket appropriately reflects the cost structure of LTCHs, as discussed in greater detail in section VII.D. of the preamble of this proposed rule. In this proposed rule, we are proposing to use the proposed 2013-based LTCH market basket to update the LTCH PPS standard Federal payment rate for FY 2017.

c. 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 LTCH PPS standard Federal payment 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 fiscal year update period. In addition, the MFP adjustment that is applied in determining any annual update to the LTCH PPS standard Federal payment 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. (We refer readers to section IV.A.1. of the preamble of FY 2016 IPPS/LTCH PPS final rule for more information on the current MFP adjustment.)

d. Proposed Adjustment to the LTCH PPS Standard Federal Payment Rate Under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

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 Program (LTCH QRP). The reduction in the annual update to the LTCH PPS standard Federal payment rate for failure to report quality data under the LTCH QRP for FY 2014 and subsequent fiscal years is codified under § 412.523(c)(4) of the regulations. (As previously noted, 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.) The LTCH QRP, as required for FY 2014 and subsequent fiscal years by section 1886(m)(5)(A)(i) of the Act, applies a 2.0 percentage point reduction to any update under § 412.523(c)(3) for an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year (that is, in the form and manner and at the time specified by the Secretary under the LTCH QRP) (§ 412.523(c)(4)(i)). 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 (§ 412.523(c)(4)(iii)). 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 (§ 412.523(c)(4)(ii)). We discuss the application of the 2.0 percentage point reduction under § 412.523(c)(4)(i) in our discussion of the proposed annual market basket update to the LTCH PPS standard Federal payment rate for FY 2017 in section VII.E.2.e. of the preamble of this proposed rule. (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section VIII.C. of the preamble of this proposed rule.)

e. Proposed Annual Market Basket Update Under the LTCH PPS for FY 2017

Consistent with our historical practice, we 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 2016 forecast, the FY 2017 full market basket increase for the LTCH PPS using the proposed 2013-based LTCH market basket is 2.7 percent, as discussed in section VII.D.4.d. of the preamble of this proposed rule. The current estimate of the MFP adjustment for FY 2017 based on IGI’s first quarter 2016 forecast is 0.5 percent, as discussed in section IV.B. of the preamble of this proposed rule. In addition, consistent with our historical practice, we are proposing to use a more recent estimate of the market basket increase and the MFP adjustment to determine the FY 2017 market basket update and the MFP adjustment for FY 2017 in the final rule.

For FY 2017, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the LTCH PPS standard Federal payment 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 2017 market basket increase by the proposed FY 2017 MFP adjustment. To determine

the proposed market basket update for LTCHs for FY 2017, as reduced by the MFP adjustment, consistent with our established methodology, we subtracted the proposed FY 2017 MFP adjustment from the proposed FY 2017 market basket update. Furthermore, sections 1886(m)(3)(A)(ii) and 1886(m)(4)(F) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate for FY 2017 be reduced by the “other adjustment” described in paragraph (4), which is 0.75 percentage point for FY 2017. Therefore, following application of the productivity adjustment, we are proposing to further reduce the proposed adjusted market basket update (that is, the proposed full market basket increase less the proposed MFP adjustment) by the “other adjustment” specified by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act. (For additional details on our established methodology for adjusting the market basket increase by the MFP and the “other adjustment” required by the statute, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).)

For FY 2017, section 1886(m)(5) of the Act requires that, for LTCHs that do not submit quality reporting data as required under the LTCH QRP, any annual update to an LTCH PPS standard Federal payment rate, after application of the adjustments required by section 1886(m)(3) of the Act, shall be further reduced by 2.0 percentage points. Therefore, the proposed update to the LTCH PPS standard Federal payment rate for FY 2017 for LTCHs that fail to submit quality reporting data under the LTCH QRP, the full LTCH PPS market basket increase, 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 2017 full market basket increase of 2.7 percent (based on IGI’s first quarter 2016 forecast of the proposed 2013-based LTCH market basket) by the proposed FY 2017 MFP adjustment of 0.5 percentage point (based on IGI’s first quarter 2016 forecast). Following application of the proposed productivity adjustment, the proposed adjusted market basket update of 2.2 percent (2.7 percent minus 0.5 percentage point) was then reduced by 0.75 percentage point, as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4)(F) of the Act. Therefore,

under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we are proposing an annual market basket update under to the LTCH PPS standard Federal payment rate for FY 2017 of 1.45 percent (that is, the most recent estimate of the proposed LTCH PPS market basket increase of 2.7 percent, less the proposed MFP adjustment of 0.5 percentage point, and less the 0.75 percentage point required under section 1886(m)(4)(F) of the Act). Accordingly, we are proposing to revise § 412.523(c)(3) by adding a new paragraph (xiii), which would specify that the LTCH PPS standard Federal payment rate for FY 2017 is the LTCH PPS standard Federal payment rate for the previous LTCH PPS year updated by 1.45 percent, and as further adjusted, as appropriate, as described in § 412.523(d). For LTCHs that fail to submit quality reporting data under the LTCH QRP, under § 412.523(c)(3)(xiii) in conjunction with § 412.523(c)(4), we are proposing to further reduce the proposed annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points in accordance with section 1886(m)(5) of the Act. Accordingly, we are proposing an annual update to the LTCH PPS standard Federal payment rate of -0.55 percent (that is, 1.45 percent minus 2.0 percentage points) for FY 2017 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. As stated above, consistent with our historical practice, we are proposing to use more recent estimate of the market basket and the MFP adjustment to establish an annual update to the LTCH PPS standard Federal payment rate for FY 2017 under § 412.523(c)(3)(xiii) in the final rule. (We note that, consistent with historical practice, we also are proposing to adjusted the proposed FY 2017 LTCH PPS standard Federal payment rate by an area wage level budget neutrality factor in accordance with § 412.523(d)(4) (as discussed in section V.B.5. of the Addendum to this proposed rule).)

### 3. Proposed Update Under the Payment Adjustment for “Subclause (II)” LTCHs

Under the LTCH PPS payment adjustment for “subclause (II) LTCHs” at § 412.526(c)(1)(ii), we established that, for cost reporting periods beginning during fiscal years after FY 2015, the target amount (used to determine the adjusted payment for Medicare inpatient operating costs under reasonable cost-based reimbursement rules) will equal the hospital’s target amount for the previous cost reporting period updated by the

applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period (79 FR 50197). For FY 2017, in accordance with § 412.526(c)(1)(ii) of the regulations, we are proposing that, for cost reporting periods beginning during FY 2017, the update to the target amount for the payment adjustment for “subclause (II)” LTCHs would be 2.8 percent, which is the estimated market basket update for FY 2017 to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis (that is, the applicable annual rate-of-increase percentage under § 413.40(c)(3)), which is discussed in section VI. of the preamble of this proposed rule, is the FY 2017 rate-of-increase percentage estimate for updating the target amounts, and is equal to the estimated percentage increase in the FY 2010-based IPPS operating market basket, in accordance with applicable regulations at § 413.40.

Based on IGI’s 2016 first quarter forecast, with historical data through the 2015 fourth quarter, we estimate that the FY 2010-based IPPS operating market basket update for FY 2017 is 2.8 percent (that is, the estimate of the market basket rate-of-increase). Therefore, the proposed rate-of-increase percentage that would be applied to the FY 2016 target amounts in order to determine the FY 2017 target amounts for “subclause (II) LTCHs” under § 412.526(c)(1)(i) is 2.8 percent. This is the same applicable annual rate-of-increase percentage that would be provided for FY 2017 under § 413.40(c)(3), as discussed in section VI. of the preamble of this proposed rule. Consistent with our historical practice of using the best available data, if more recent data become available (for example, a more recent estimate of the market basket increase), we propose to use such data, if appropriate, to determine the FY 2017 rate-of-increase percentage to determine the FY 2017 target amounts for “subclause (II) LTCHs” in the final rule.

### F. Proposed Modifications to the “25-Percent Threshold Policy” Payment Adjustments (§§ 412.534 and 412.536)

The “25-percent threshold policy” is a per discharge payment adjustment in the LTCH PPS that is applied to payments for Medicare patient discharges from an LTCH when the number of such patients originating from any single referring hospital is in excess of the applicable threshold for a given cost reporting period (such threshold is generally set at 25 percent, with exceptions for rural and urban single or MSA-dominant hospitals). If an LTCH exceeds the applicable



threshold during a cost reporting period, payment for the discharge that puts the LTCH over its threshold and all discharges subsequent to that discharge in the cost reporting period from the referring hospital are adjusted at cost report settlement (discharges not in excess of the threshold are unaffected by the 25-percent threshold policy). Each cost reporting period begins a new threshold determination, so subsequent cost reporting periods are unaffected by failure to meet the applicable percentage threshold requirements in a prior period.

The adjusted payment amount for those discharges that are subject to the current 25-percent threshold policy is calculated as the lesser of the applicable LTCH PPS payment amount or the IPPS equivalent amount. We note that the IPPS equivalent amount under the 25-percent threshold policy differs somewhat from the IPPS comparable per diem amount applicable under the site neutral payment rate policy at § 412.522(c)(1)(i) and the short-stay outlier (SSO) policy at § 412.529(d)(4). For a discussion of the calculation of the IPPS comparable per diem amount under § 412.529(d)(4) and the IPPS equivalent amount under existing §§ 412.534(f) and 412.536(e), including details on the differences in the calculations, we refer readers to our response to comments in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50772).

The 25-percent threshold policy was originally established in the FY 2005 IPPS final rule for LTCH hospital-within-hospitals (HwHs) and satellites (69 FR 49191 through 49214). It addressed patient shifting driven by financial considerations, rather than patient benefit. Specifically, it addressed the negative incentives that result from the co-location of facilities which created incentives for behaviors which result in two hospital stays, and two Medicare payments, for what was essentially one episode of patient care—and a financial windfall for both providers, as compared to acute care hospitals that were not co-located with an LTCH. It also addressed statutory limits for LTCHs, namely concerns that these LTCHs were, in essence, behaving as long-term care “units” of the co-located hospitals (an arrangement prohibited under section 1886(d)(1)(B) of the Act). In order to discourage such activities, CMS initially established a payment adjustment at § 412.534 for discharges in which the patient was admitted to the LTCH location from a co-located referring hospital in excess of an applicable percentage threshold. Implementation was phased in, but

ultimately was generally set at a 25-percent threshold after specified phase-in periods. A full discussion of the original 25-percent threshold policy is contained in the FY 2005 IPPS final rule (69 FR 49191 through 49214).

While initially limited to co-located facilities, in keeping with the suggestions of MedPAC and certain other commenters, CMS noted that it would continue to monitor claims data for signs that common ownership between hospitals that did not share a location also encouraged discharge and admission decisions based on reimbursement rather than clinical considerations (69 FR 49202 through 19203). This continued monitoring, including analysis of discharge patterns from the FY 2005 MedPAR files, identified additional patterns of patient shifting and worrisome admission practices between LTCHs and referring hospitals that were not co-located that were similar to the patterns identified in the FY 2004 MedPAR files between co-located LTCHs and their host hospitals. In response to these findings, CMS expanded the 25-percent threshold policy in the RY 2008 LTCH PPS final rule to include all LTCHs and LTCH satellite facilities through the amendment of § 412.534 (including those certain LTCHs which had been grandfathered from the original policy established in the FY 2005 rule) and the addition of § 412.536 (governing patients admitted from hospitals not co-located with the LTCH). A full discussion of this policy can be found in the RY 2008 LTCH PPS final rule (72 FR 26919 through 26944).

The resulting 25-percent threshold policy was to have been phased in over 3 years, and, when fully implemented, the 25-percent threshold policy would have applied to nearly all LTCHs or LTCH satellites and remote locations admitting patients from any hospital, regardless of the location or ownership of the referring hospital. (For the remainder of this section, we refer to the policies under § 412.534 and § 412.536 collectively as the “25-percent threshold policy” unless otherwise indicated.) However, several laws mandated delayed implementation of the policy, including, most recently, section 1206 of the Pathway for Sustainable Growth Rate (SGR) Reform Act (Pub. L. 113–67). Section 1206(b)(1)(B) provides a permanent exemption from the application of the 25-percent threshold policy for co-located LTCHs that were excluded from the original policy in the FY 2005 IPPS final rule. Section 1206(b)(1)(A) extended prior moratoria on the full implementation of the 25-percent threshold policy until cost

reporting periods beginning on or after either July 1, 2016 (for LTCHs subject to 42 CFR 412.534) or October 1, 2016 (for LTCHs subject to 42 CFR 412.536). For more details on the various laws that delayed the full implementation of the 25 percent threshold policy, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50356 through 50357).

With the impending expiration of the most recent statutory delay of the full implementation of the 25-percent threshold policy and the recent implementation of a dual rate payment system for the revised LTCH PPS for cost reporting periods beginning on or after October 1, 2015, we have received many questions concerning the mechanics of the revised payment system, especially in relation to the application of the 25-percent threshold policy under § 412.534 and § 412.536, and how those sections will interact. The questions generally involved how CMS would implement the policy for LTCHs with multiple locations. Other questions included how site neutral payment rate discharges would be treated under the policy and how CMS would determine whether a hospital was located in a rural or MSA-dominant area. As a result of the confusion reflected in those questions, we are proposing to revise our existing policies in an effort to simplify the application of the 25-percent threshold policy.

Specifically, we are proposing to sunset both §§ 412.534 and 412.536 and adopt a unified 25-percent threshold policy at new § 412.538. If finalized, this provision would apply to payments for discharges occurring on or after October 1, 2016. The applicable percentage thresholds would generally remain at 25 percent. In keeping with our current policy at § 412.534(h) and § 412.536(a)(2), under proposed new § 412.538(a), the adjustment would not be applicable to “subclause (II)” LTCHs described at section 1886(d)(1)(B)(iv)(II) of the Act and § 412.23(e)(2)(ii) or, consistent with the statute and as codified in the regulations at § 412.534(a) and § 412.536(a)(1)(ii), those HwHs described in § 412.23(e)(2)(i) that meet the criteria in § 412.22(f) (“grandfathered HwHs”). (Section 1206(b)(1)(B) of the Pathway for SGR Reform Act provides for a statutory exclusion from the 25-percent threshold policy for “grandfathered HwHs,” which was codified in the regulations at § 412.534(a) and § 412.536(a)(1)(ii) in the FY 2015 IPPS/LTCH PPS final rule at (79 FR 50186)).

In keeping with our current policy at § 412.534(c)(2) and § 412.536(h)(2), we are further proposing that LTCH discharges that reached high-cost outlier

status at the referring hospital would not be subject to the 25-percent threshold policy (that is, LTCH discharges which had been high-cost outlier cases at the referring hospital would only be included in an LTCH's total Medicare discharges and, therefore, would not count as having been admitted from that referring hospital. In other words, LTCH discharges that were high-cost outlier cases at the referring hospital would not be counted in the numerator (but would be counted in the denominator) when determining whether the LTCH exceeded the applicable percentage threshold from that referring hospital). As we discussed in the FY 2005 IPPS final rule, we continue to believe that it is appropriate to treat high-cost outlier cases as though they had come from a different hospital because a case which reaches high-cost outlier status has received a full complement of services and, therefore, any transfer from a hospital to an LTCH cannot be said to be premature or inappropriate. In addition, consistent with our current policy, under this proposal, both the LTCH PPS standard Federal payment rate cases and the site neutral payment rate cases would be subject to the 25-percent threshold policy at proposed new § 412.538 and, therefore, would be included in the determination of whether an LTCH has exceeded its threshold. In conjunction with this proposal, we are proposing conforming changes to § 412.522(c)(2) (adjustments for payments under the site neutral payment rate) and § 412.525(d)(5) (adjustments for payments under the LTCH PPS standard Federal payment rate) to include the proposed adjustment for the limitation on LTCH admissions from referring hospitals (that is, the proposed revised 25-percent threshold policy) under new § 412.538. Lastly, we are also proposing that Medicare Advantage (MA) discharges would not be considered under the revised 25-percent threshold policy at proposed new § 412.538, consistent with our current policy. (Consistent with these proposals, for the remainder of this section, when we refer to "Medicare discharges," we mean a hospital's Medicare discharges that were not paid under an MA plan (and in the case of an LTCH, all LTCH PPS discharges, that is, both the LTCH PPS standard Federal payment rate cases and the site neutral payment rate cases).)

Under our proposed revised 25-percent threshold policy at proposed new § 412.538, we are proposing to calculate the numerator and denominator for the "applicable percentage threshold" by using the CMS

Certification Number (CCN) on hospital claims submitted to Medicare. Specifically, we would determine whether the applicable percentage threshold was exceeded based on the Medicare discharges from the entire LTCH that were admitted from each referring hospital. The CCN is used on Medicare claims to identify the hospital which discharged the patient, and thus we believe that using the CCN to identify the discharging LTCH and referring hospital is an appropriate and administratively straight-forward process to implement this proposed revision. We believe that this proposed approach would simplify the application of the 25-percent threshold policy because it provides transparency in identifying both the discharging LTCH and the referring hospital. Under this proposed approach, an LTCH's percentage of Medicare discharges from a given referring hospital would be determined during settlement of a cost report by dividing the LTCH's total number of Medicare discharges in the cost reporting period (based on the CCN on the claims) that were admitted directly from a given referring hospital (again determined by the CCN on the referring hospital's claims) that did not receive a high-cost outlier payment (based on the referring hospital's claims) by the LTCH's total number of Medicare discharges in the cost reporting period. In other words, at cost report settlement, each LTCH's Medicare discharges from a given referring hospital (that did not receive a high-cost outlier payment) during that cost reporting period would be evaluated chronologically based on the discharge date from the LTCH, such that the Medicare discharge that results in the LTCH exceeding or remaining in excess of its applicable percentage threshold would be subject to the payment adjustment at proposed new § 412.538(c). Attribution of the Medicare discharge from a specific LTCH and a specific referring hospital would be determined according to the CCN on the Medicare claim submitted by the provider (that is, the LTCH's CCN would be determined from the LTCH's claim; the referring hospital's CCN by its claim), which generally comprises all locations of a single hospital (and for a single LTCH, includes satellite facilities and remote locations, as applicable). For example, the CCN of an LTCH with 3 locations is "902000" and the CCN of a specific referring hospital with 2 locations is "900001." During its cost reporting period, LTCH "902000" has a total of 60 Medicare discharges (10 discharges from the first location, 20 discharges from the second location,

and 30 discharges from the third location). Of those 60 Medicare discharges, 25 Medicare discharges (that did not receive a high-cost outlier payment) came directly from hospital "900001" (10 discharges from the first location, and 15 discharges from the second location). LTCH "902000's" percentage of Medicare discharges from referring hospital "900001" would be calculated as 25 divided by 60, or 41.7 percent. The location of the discharging LTCH and the referring hospital is not relevant, and only the aggregate Medicare discharge counts would be used in the proposed calculation when determining if a payment adjustment under proposed new § 412.538 is applicable at cost report settlement.

Under proposed new §§ 412.538 (b) and (c), we are proposing, in general, that payment would be adjusted for LTCH Medicare discharges originating from a single referring hospital during a given cost reporting period when that Medicare discharge results in a percentage of Medicare discharges (that did not receive a high-cost outlier payment) from that referring hospital that exceeds that LTCH's applicable percentage threshold (that is, goes above "25 percent" of that LTCH's total Medicare discharges). In other words, in general, we would continue to calculate separate percentages for each hospital from which an LTCH admits patients, and compare those referring hospitals' percentage of Medicare discharges (excluding those cases that received a high-cost outlier payment) to the LTCH's applicable percentage threshold, and the payment adjustment would then be applied to any of the Medicare discharges that cause the LTCH to exceed or remain in excess of the applicable percentage threshold. Medicare discharges not in excess of the threshold (which includes those that received a high-cost outlier payment at the referring hospital) would continue to be unaffected by the 25-percent threshold policy. As adjusted, the net payment amount to an LTCH for each of its Medicare discharges beyond the applicable percentage threshold would continue to be the lesser of the applicable LTCH PPS payment amount or an IPPS equivalent amount. The IPPS equivalent amount under the current 25-percent threshold policy is set forth in existing regulations at § 412.534(f) and § 412.536(e). As we are proposing to sunset these provisions, we are proposing to codify the existing definition of "IPPS equivalent amount" under our proposed revised 25-percent threshold policy at proposed new § 412.538(f). (For a detailed description

of the calculation of the IPPS equivalent amount, we refer readers to the RY 2007 LTCH PPS proposed rule (71 FR 4698 through 4700), which was finalized in the corresponding final rule (71 FR 27875)). As noted previously, the IPPS equivalent amount under the 25-percent threshold policy differs somewhat from the IPPS comparable amount applicable under the site neutral payment rate and the SSO policy (78 FR 50772).

In addition, consistent with our existing policy at § 412.534(d) and § 412.536(c), under proposed new § 412.538(f), we are proposing a 50-percent threshold for rural LTCHs (as defined under § 412.503) in lieu of the generally applicable 25-percent threshold. If finalized, payment to such LTCHs would not be adjusted unless the rural LTCH's Medicare discharges from a single referring hospital (excluding those that received a high-cost outlier payment), which exceeded 50 percent of the LTCH's total Medicare discharges (that is, we would continue to apply an applicable percentage threshold of 50 percent from any single referring hospital to rural LTCHs).

We also are proposing to maintain at proposed new § 412.538(e)(3) the current special treatment of an LTCH located in an MSA with an MSA-dominant hospital at § 412.534(e) and § 412.536(d). As defined in those regulations, an MSA-dominant hospital is a hospital that has discharged more than 25 percent of the total hospital's Medicare discharges in the MSA in which it is located. For LTCHs located in an MSA-dominant area (that is located in an MSA with an MSA-dominant hospital), the LTCH's applicable percentage threshold would continue to be the percentage of total Medicare hospital discharges in the MSA from the MSA-dominant hospital during the LTCH's applicable cost reporting period, but in no case is less than 25 percent or more than 50 percent. (That is, as is the case under our current policy, for an LTCH located in an MSA-dominant area, it would have a single applicable percentage threshold for all of that LTCH's referring hospitals under the special treatment provided under proposed new § 412.538(e)(3). We are proposing to use our existing definition of "MSA-dominant hospital" under both § 412.534(e) and § 412.536(d) of the regulations to also define the term under § 412.103. We are further proposing to codify definitions for the terms "MSA" (which we are proposing to define as an Metropolitan Statistical Area, as defined by the Executive Office of Management and Budget) and "MSA-dominant area" (which we are proposing to define as an

MSA in which an MSA-dominant hospital is located) under § 412.103. (Information on OMB's MSA delineations based on the 2010 standards can be found at: [http://www.whitehouse.gov/sites/default/files/omb/assets/fedreg\\_2010/06282010\\_metro\\_standards-Complete.pdf](http://www.whitehouse.gov/sites/default/files/omb/assets/fedreg_2010/06282010_metro_standards-Complete.pdf).)

Under this proposed special treatment at §§ 412.538(e)(2) and (3) for LTCHs with multiple locations, we are further proposing that all locations of the LTCH paid under the LTCH PPS must be rural or located in an MSA-dominant area (as applicable); otherwise the special treatment would not apply and the applicable percentage threshold would be 25 percent. Under our existing regulations, the applicable percentage threshold for each location is determined independently of any other location of the hospital (meaning that, if an LTCH had one rural and one urban location, the applicable percentage threshold for the rural location would be 50 percent and the applicable percentage threshold for the urban location would be 25 percent). However, under our proposal, the applicable percentage threshold would apply to the LTCH as a whole entity (based on its CCN). Therefore, we believe that it would be appropriate to apply the rural and MSA-dominant "special" applicable percentage thresholds based on the LTCH as a whole as well. Furthermore, we believe that LTCHs with locations that do not fall in these special treatment categories would have sufficient access across its locations to admit patients from multiple hospitals such that, as a whole, the LTCH should be able to draw from a diverse enough population to meet the proposed 25-percent threshold criteria. For these reasons, at this time we do not believe that it would be appropriate or necessary to apply these special percentages unless the LTCH is exclusively rural or located exclusively in an MSA-dominant area (as applicable). Therefore, we are proposing to require all locations of an LTCH to be rural or located within an MSA-dominant area in order to qualify for special treatment under proposed new §§ 412.538(e)(2) and (3) (that is, an adjusted applicable percentage threshold).

In summary, for discharges occurring on or after October 1, 2016, we are proposing to establish a single consolidated admission threshold policy (generally a 25-percent threshold policy) at proposed new § 412.538, in conjunction with proposing to sunset the existing 25-percent threshold policies at §§ 412.534 and 412.536, effective October 1, 2016. Under this

proposed single 25-percent threshold policy, LTCH PPS payment for LTCH discharges from a single referring hospital in excess of the LTCH's applicable percentage threshold for that referring hospital would be adjusted. We are proposing that the applicable percentage threshold would generally be 25 percent (with proposed special treatment for exclusively rural LTCHs and LTCHs exclusively located in an MSA-dominant area). The proposed 25-percent threshold policy would be applicable to all LTCHs except "subclause (II)" LTCHs and "grandfathered HwHs." Under this proposal, LTCH discharges which reached high-cost outlier status at the referring hospital from which the patient was discharged directly to the LTCH would be treated as though they had come from a different referring hospital and, therefore, would not be counted as a Medicare discharge from that referring hospital. We also are proposing that MA discharges would not be included in this proposed policy. In addition, the proposed revised 25-percent policy would apply to all LTCH PPS discharges (that is, both LTCH PPS standard Federal payment rate and site neutral payment rate cases).

Under this proposal, we would evaluate the "applicable percentage threshold" based on the sum of the locations covered by the LTCH's and referring hospitals' Medicare provider agreement, and would implement this policy using the LTCH's and the referring hospitals' CCN. We are proposing that an LTCH's percentage of Medicare discharges from a given hospital would be determined by dividing the LTCH's number of Medicare discharges in the cost reporting period (based on the LTCH's CCN) that were admitted directly from a given referring hospital (based on the hospital's CCN) that did not receive a high-cost outlier payment during the stay at that referring hospital by the LTCH's total number of Medicare discharges in the cost reporting period (based on the LTCH's CCN). Under proposed new § 412.538, in general, the LTCH PPS payment would be adjusted for LTCH Medicare discharges from a single referring hospital (that did not receive a high cost-outlier payment) that exceed the applicable percentage threshold (generally 25 percent). If an LTCH exceeds its applicable threshold during a cost reporting period, which would be determined at cost report settlement, we are proposing to adjust payment for Medicare discharges in excess of the applicable percentage threshold (including the Medicare

discharge which causes the LTCH to exceed the applicable percentage threshold), and Medicare discharges not in excess of the applicable percentage threshold would continue to be unaffected by the 25-percent threshold policy (that is, the payment for such discharges would not be adjusted). As adjusted, the payment amount for a LTCH Medicare discharge that is found to be at or beyond the applicable percentage threshold would continue to receive the lesser of the applicable LTCH PPS payment amount or an IPPS equivalent amount.

#### *G. Proposed Refinement to the Payment Adjustment for “Subclause II” LTCHs*

As part of our FY 2015 IPPS/LTCH PPS rulemaking cycle, under the authority provided by section 1206(d)(2) of the Pathway to SGR Reform Act (Pub. L. 113–67), we adopted an adjustment to the LTCH PPS payment for LTCHs classified under section 1886(d)(1)(B)(iv)(II) of the Act (“subclause (II) LTCHs”), which are described in 42 CFR 412.23(e)(2)(ii). Under this adjustment, subclause (II) LTCHs receive payment under the LTCH PPS that is generally equivalent to an amount determined under the reasonable cost-based payment rules for both operating and capital-related costs under 42 CFR part 413 (that is, an amount generally equivalent to an amount determined under the TEFRA payment system methodology, which could be called a “TEFRA-like” methodology). For more information on this adjustment, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50193 through 50197). As initially adopted, this “TEFRA-like” payment adjustment for subclause (II) LTCHs did not incorporate the limitation on charges to Medicare beneficiaries policies under the TEFRA payment system. Alignment of the limitation on charges to beneficiaries and related billing requirements would result in administrative simplification for the cost report submission and settlement process under the payment adjustment for subclause (II) LTCHs specified at § 412.526.

In this proposed rule, we are proposing to revise the limitation on charges to beneficiaries policy and related billing requirements for subclause (II) LTCHs like what is done in the TEFRA payment system context for cost reporting periods beginning on or after October 1, 2016, which would align our beneficiary charge policies (and related billing procedures) with the reasonable cost-based “TEFRA-like” payment adjustment under § 412.526. The adjusted LTCH PPS payment to

subclause (II) LTCHs under § 412.526 is considered the full LTCH PPS payment (that is, the LTCH PPS standard Federal payment rate or site neutral payment rate, as applicable), and as such, under current policy that payment applies to the LTCH’s costs for services furnished until the high-cost outlier threshold is met (existing § 412.507(a)). Under this proposal, for a subclause (II) LTCH, the Medicare payment would only apply to the LTCH’s costs incurred for the days used to calculate the Medicare payment (that is, days for which the patient has a benefit day available). Furthermore, in addition to the applicable Medicare deductible and coinsurance amounts (and for items and services as specified under § 489.20(a)), we would specify that the LTCH may only charge the beneficiary for services provided during the stay that were not the basis for the adjusted LTCH PPS payment amount under § 412.526. If finalized, subclause (II) LTCHs would be treated the same as IPPS-excluded hospitals paid under the TEFRA payment system for purposes of the limitation on charges to beneficiaries and related billing requirements.

In this proposed rule, using the broad authority conferred upon the Secretary under section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA, in conjunction with the authority provided under section 1206(d)(2) of Public Law 113–67, we are proposing to revise § 412.507 to limit allowable charges to beneficiaries treated at subclause (II) LTCHs as is done under the TEFRA payment system in order to align our beneficiary charge policies with the reasonable cost-based “TEFRA-like” payment adjustments under § 412.526. Specifically, we are proposing to revise § 412.507 to specify that, for cost reporting periods beginning on or after October 1, 2016, the Medicare payment made to subclause (II) LTCHs (as defined at § 412.23(e)(2)(ii)) only applies to the hospital’s costs on the days used to calculate the Medicare payment (that is, days for which the patient has a benefit day available). Furthermore, proposed revised § 412.507 would specify that, for cost reporting periods beginning on or after October 1, 2016, the hospital may only charge the Medicare beneficiary for the applicable deductible and coinsurance amounts (under §§ 409.82, 409.83 and 409.87) for items and services as specified under § 489.20(a), and for services provided during the stay that were not the basis for the adjusted LTCH PPS payment amount under § 412.526.

#### **VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers**

We seek to promote higher quality and more efficient healthcare for Medicare beneficiaries. This effort is supported by the adoption of widely agreed-upon quality measures. We have worked with relevant stakeholders to define quality measures for most settings and to measure various aspects of care for most Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, care coordination, and improving patient outcomes.

We have implemented quality reporting programs for multiple care settings, including:

- Hospital inpatient services under the Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program);
- Hospital outpatient services under the Hospital Outpatient Quality Reporting (OQR) Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP));
- Care furnished by physicians and other eligible professionals under the Physician Quality Reporting System (PQRS, formerly referred to as the Physician Quality Reporting Program Initiative (PQRI));
- Inpatient rehabilitation facilities under the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP);
- Long-term care hospitals under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP) (also referred to as the LTCHQR Program);
- PPS-exempt cancer hospitals under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program;
- Ambulatory surgical centers under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program;
- Inpatient psychiatric facilities under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program;
- Home health agencies under the home health quality reporting program (HH QRP); and
- Hospice facilities under the Hospice Quality Reporting Program.

We have also implemented the End-Stage Renal Disease Quality Incentive Program, Hospital Readmissions Reduction Program, HAC Reduction Program, and Hospital VBP Program (described further below) that link payment to performance.

In implementing the Hospital IQR Program and other quality reporting programs, we have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries. Our goal for the future is to align the clinical quality measure requirements of the Hospital IQR Program with various other Medicare and Medicaid programs, including those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act, so that the reporting burden on providers will be reduced. As appropriate, we will consider the adoption of clinical quality measures with electronic specifications so that the electronic collection of performance information is a seamless component of care delivery. Establishing such a system will require interoperability between EHRs and CMS data collection systems, additional infrastructure development on the part of hospitals and CMS, and adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. However, once these activities are accomplished, adoption of measures that rely on data obtained directly from EHRs will enable us to expand the Hospital IQR Program measure set with less cost and reporting burden to hospitals. We believe that in the near future, collection and reporting of data elements through EHRs will greatly simplify and streamline reporting for various CMS quality reporting programs, and that hospitals will be able to switch primarily to EHR-based data reporting for many measures that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

We also have implemented a Hospital VBP Program under section 1886(o) of the Act, described in the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547). We most recently adopted additional policies for the Hospital VBP Program in section IV.I. of the FY 2016 IPPS/LTCH PPS final rule (80 FR 49544 through 49570). Under the Hospital VBP Program, hospitals receive value-based incentive payments based on their performance with respect to performance standards for a performance period for the fiscal year involved. The measures under the Hospital VBP Program must be selected from the measures (other than readmission measures) specified under the Hospital IQR Program as required by section 1886(o)(2)(A) of the Act.

In selecting measures for the Hospital IQR Program, we are mindful of the conceptual framework we have developed for the Hospital VBP

Program. Because measures adopted for the Hospital VBP Program must first have been adopted and reported under the Hospital IQR Program, these two programs are linked and the reporting infrastructure for the programs overlap. We view the Hospital VBP Program as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare from a passive payer of claims into an active purchaser of quality healthcare for its beneficiaries. Value-based purchasing is an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations.

We also view the HAC Reduction Program, authorized by section 1886(p) of the Act, as added by section 3008 of the Affordable Care Act, and the Hospital VBP Program, as related but separate efforts to reduce HACs. The Hospital VBP Program is an incentive program that awards payments to hospitals based on quality performance on a wide variety of measures, while the HAC Reduction Program creates a payment adjustment resulting in payment reductions for poorly performing hospitals based on their rates of HACs.

In the preamble of this proposed rule, we are proposing changes to the following Medicare quality reporting systems:

- In section VIII.A, the Hospital IQR Program.
- In section VIII.B., the PCHQR Program.
- In section VIII.C., the LTCH QRP.
- In section VIII.D., the IPFQR Program.

In addition, in section VIII.E. of the preamble of this proposed rule, we are proposing changes to the Medicare and Medicaid EHR Incentive Programs for eligible hospitals and CAHs.

#### *A. Hospital Inpatient Quality Reporting (IQR) Program*

##### 1. Background

###### a. History of the Hospital IQR Program

We refer readers to the FY 2010 IPPS/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 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692) for the measures we have adopted for the Hospital IQR Program measure set through the FY 2019 payment determination and subsequent years.

###### b. Maintenance of Technical Specifications for Quality Measures

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49640 through 49641) for a discussion of the maintenance of technical specifications for quality measures for the Hospital IQR Program. We also refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50202 through 50203) for additional detail on the measure maintenance process.

In addition, we believe that it is important to have in place a subregulatory process to incorporate nonsubstantive updates to the measure specifications for measures we have adopted for the Hospital IQR Program so that these measures remain up-to-date. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203) for our policy for using a subregulatory process to make nonsubstantive updates to measures used for the Hospital IQR Program. We recognize that some changes made to measures undergoing maintenance review are substantive in nature and might not be appropriate for adoption using a subregulatory process. We will continue to use rulemaking to adopt substantive updates made to measures we have adopted for the Hospital IQR Program.

In this proposed rule, we are not proposing any changes to our policies on the measures maintenance process or for using the subregulatory process to make nonsubstantive updates to measures used for the Hospital IQR Program.

###### c. Public Display of Quality Measures

Section 1886(b)(3)(B)(viii)(VII) of the Act was amended by the Deficit Reduction Act (DRA) of 2005. Section 5001(a) of the DRA 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 refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50776 through 50778) for a more detailed discussion about public display of quality measures.

The *Hospital Compare* Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care to those who need to select a hospital. For more information on measures reported to *Hospital Compare*, we refer readers to the Web site at: <http://www.medicare.gov/hospitalcompare>. Other information not reported to

*Hospital Compare* may be made available on other CMS Web sites, such as <https://data.medicare.gov>.

In this proposed rule, we are not proposing any changes to these policies.

## 2. Process for Retaining Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53513), for our finalized measure retention policy. Pursuant to this policy, when we adopt measures for the Hospital IQR Program beginning with a particular payment determination, we automatically readopt these measures for all subsequent payment determinations unless we propose to remove, suspend, or replace the measures. In this proposed rule, we are not proposing any changes to this policy.

## 3. Removal and Suspension of Hospital IQR Program Measures

### a. Considerations in Removing Quality Measures From the Hospital IQR Program

As discussed above, we generally retain measures from the previous year's Hospital IQR Program measure set for subsequent years' measure sets except when we specifically propose to remove, suspend, or replace a measure. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204) for more information on the criteria we consider for removing quality measures. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49641 through 49643) for more information on the additional factors we consider in removing quality measures and the factors we consider in order to retain measures. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204), we also finalized our proposal to clarify the criteria for determining when a measure is "topped-out." In this proposed rule, we are not proposing any changes to these policies.

### b. Proposed Removal of Hospital IQR Program Measures for the FY 2019 Payment Determination and Subsequent Years

We are proposing to remove the following 15 measures for the FY 2019 payment determination and subsequent years. Some of these measures we are proposing to remove in their entirety; one of these measures, VTE-6 Incidence of Potentially Preventable Venous Thromboembolism, we are proposing to

remove just in the electronic form as discussed further below:

- AMI-2: Aspirin Prescribed at Discharge for AMI (NQF #0142);
- AMI-7a: Fibrinolytic Therapy Received Within 30 minutes of Hospital Arrival;
- AMI-10: Statin Prescribed at Discharge;
- HTN: Healthy Term Newborn (NQF #0716);
- PN-6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF #0147);
- SCIP-Inf-1a: Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision (NQF #0527);
- SCIP-Inf-2a: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528);
- SCIP-Inf-9: Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero;
- STK-4 Thrombolytic Therapy (NQF #0437);
- VTE-3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373);
- VTE-4: Venous Thromboembolism Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram);
- VTE-5: Venous Thromboembolism Discharge Instructions;
- VTE-6: Incidence of Potentially Preventable Venous Thromboembolism;
- Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care; and
- Participation in a Systematic Clinical Database Registry for General Surgery.

Removal of these measures is discussed in more detail below.

#### (1) Proposed Removal of Structural Measures

We are proposing to remove two structural measures for the FY 2019 payment determination and subsequent years: (1) Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care; and (2) Participation in a Systematic Clinical Database Registry for General Surgery, because performance on these measures does not result in better patient outcomes—removal factor 4 (80 FR 49641). These measures were originally adopted in the RHQDAPU Program FY 2010 IPPS/RV 2010 LTCH PPS final rule (74 FR 43870 through 43872) to monitor participation in systematic clinical database registries for the Hospital IQR Program. By design, the measures do not provide information on patient outcomes,

because hospitals are asked only whether they participate in registries. In the future, we will consider other more effective measures to include in the program. As a result, we believe that the burden to retain these measures outweighs the benefits. Therefore, we are proposing to remove these two structural measures from the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

#### (2) Proposed Removal of "Topped-Out" Chart-Abstracted Measures

We are proposing to remove two measures in their chart-abstracted forms: (1) STK-4: Thrombolytic Therapy (NQF #0437) and (2) VTE-5: VTE Discharge Instructions, because measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made ("topped-out" measures)—removal factor 1 (80 FR 49641). The chart-abstracted version of STK-4 was adopted into the program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51634); and the chart-abstracted version of VTE-5 was adopted into the program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51636). One factor we consider in determining whether a measure should be retained or removed from the program is whether the measure is "topped-out." We have previously adopted two criteria for determining the "topped-out" status of Hospital IQR Program measures: (1) Statistically indistinguishable performance at the 75th and 90th percentiles; and (2) truncated coefficient of variation  $\leq 0.10$  (80 FR 49642). These measures meet both of these criteria. We believe that the burdens of retaining these measures outweigh the benefits, and therefore, are proposing to remove the chart-abstracted versions of STK-4 and VTE-5 for the FY 2019 payment determination and subsequent years.

#### (3) Proposed Removal of Certain eQMs

We are proposing to remove the electronic versions of AMI-7a, HTN, PN-6, SCIP-Inf-9, VTE-3, VTE-4, VTE-5, VTE-6, STK-4, AMI-2, AMI-10, SCIP-Inf-1a, and SCIP-Inf-2a, beginning with the FY 2019 payment determination. Each measure is discussed in more detail below.

#### (a) Removal of eQMs in Alignment With the Medicare and Medicaid EHR Incentive Programs

We are proposing to remove 13 eQMs from both the Hospital IQR Program and the Medicare and Medicaid EHR Incentive Programs in order for hospitals to focus on a smaller,

more specific subset of eCQMs while keeping the programs aligned.

We refer readers to section VIII.A.8.a. and section VIII.A.10.d. of the preamble of this proposed rule for details on our proposed changes to eCQM reporting requirements for the Hospital IQR Program to align with the Medicare and Medicaid EHR Incentive Programs. We also refer readers to section VIII.A.3.b.(3) of the preamble of this proposed rule for our proposals to remove these 13 eCQMs from the Medicare and Medicaid EHR Incentive Programs. We believe that a coordinated reduction in the overall number of eCQMs in both programs would reduce burden on hospitals and improve the quality of reported data by enabling hospitals to focus on a smaller, more specific subset of eCQMs. We are proposing these changes in response to public comments for the Hospital IQR Program in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49694), which recommended that CMS adopt a lesser number of eCQMs.

(i) AMI-7a

We are proposing to remove the AMI-7a: Fibrinolytic Therapy Received Within 30 minutes of Hospital Arrival eCQM, because performance or improvement on this measure does not result in better patient outcomes—removal factor 4 (80 FR 49641). In the FY 2016 IPPS/LTCH PPS final rule, we removed the chart-abstracted version of AMI-7a because the reporting burden outweighed the benefit of posting very few hospitals' measure rates. This measure's specifications resulted in very high denominator exclusion rates. Consequently, the vast majority of abstracted AMI cases were excluded from AMI-7a measure rates. Most acute myocardial infarction (AMI) patients receive percutaneous coronary intervention (PCI) instead of fibrinolytic therapy (80 FR 49647). We do not believe that the mode of reporting (eCQM versus chart-abstracted) would cause the number of cases reported to differ since most AMI patients would still receive PCI instead of fibrinolytic therapy. In the FY 2016 IPPS/LTCH PPS final rule, we retained the electronic version of this measure for alignment purposes with the Medicare and Medicaid EHR Incentive Programs (80 FR 49644). As discussed above, we are proposing to focus on a smaller, more specific subset of eCQMs in both the Hospital IQR and Medicare and Medicaid EHR Incentive Programs. As a result, the burdens related to retaining this measure outweigh the benefits. Therefore, we are proposing to remove the AMI-7a eCQM from the Hospital

IQR Program for the FY 2019 payment determination and subsequent years.

(ii) STK-4, AMI-2, AMI-10, SCIP-Inf-1a, and SCIP-Inf-2a

We are proposing to remove the: (1) STK-4: Thrombolytic Therapy (NQF #0437); (2) AMI-2: Aspirin Prescribed at Discharge for AMI (NQF #0142); (3) AMI-10: Statin Prescribed at Discharge; (4) SCIP-Inf-1a: Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision (NQF #0527); and (5) SCIP-Inf-2a: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528) eCQMs, because measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made—removal factor 1 (80 FR 49641). We note that the NQF has changed the endorsement designations of the AMI-2, AMI-10, SCIP-Inf-1a, and SCIP-Inf-2a chart abstracted measures and eCQM versions to either “reserve status” or “endorsement removed” (available at: <http://www.qualityforum.org/QPS/QPSTool.aspx>), because there is no opportunity for improvement.

We refer readers to section VIII.A.3.b.(2) of the preamble of this proposed rule for our proposal also to remove the chart-abstracted form of the STK-4 measure due to “topped-out” status. The electronic version of the STK-4 measure was adopted into the Hospital IQR Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50784) to promote programmatic alignment, as it was a part of a measure set that was already included in the Medicare and Medicaid EHR Incentive Programs' Electronic Reporting Pilot for Eligible Hospitals and CAHs (75 FR 44418 and 76 FR 74489).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50781), we removed the chart-abstracted versions of AMI-2 and AMI-10 due to “topped-out” status. However, as noted in FY 2015 IPPS/LTCH PPS final rule (79 FR 50245), we readopted these measures, though only in the electronic form, because we believed that we should continue aligning the Hospital IQR Program and the Medicare EHR Incentive Program in order to minimize reporting burden and to facilitate the transition to reporting of eCQMs. We believed that voluntary reporting of these measures would further that aim. In addition, we believed that allowing hospitals the option to electronically report “topped-out” measures would provide them with an opportunity to test the accuracy of their EHR reporting systems.

Similarly, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50208), we

removed the chart-abstracted versions of SCIP-Inf-1a and SCIP-Inf-2a, previously referred to as SCIP-Inf-1 and SCIP-Inf-2 respectively, due to their “topped-out” status. However, as stated in that rule, we retained the electronic versions of these measures, because we believed this provided CMS with an opportunity to monitor “topped-out” measures for performance decline. It also simplified alignment between the Hospital IQR and Medicare EHR Incentive Program for eligible hospitals and provided a more straight-forward approach to educate stakeholders on electronic reporting options (79 FR 50208).

As discussed above, we are proposing to focus on a smaller, more specific subset of eCQMs for the Hospital IQR Program and both the Medicare and Medicaid EHR Incentive Programs. Therefore, in light of their “topped out” status, the burden of retaining these measures outweighs the benefits. Thus, we are proposing to remove the STK-4, AMI-2, AMI-10, SCIP-Inf-1a, and SCIP-Inf-2a eCQMs from the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

(b) HTN

We are proposing to remove the HTN: Healthy Term Newborn (NQF #0716) eCQM, because it is no longer feasible to implement the measure specifications—removal factor 7 (80 FR 49642). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50249), we added HTN, only as an eCQM, not as a claims-based measure. Although the claims-based version of the HTN measure has never been part of the Hospital IQR Program, the claims-based HTN measure concept was used to develop the HTN eCQM. The measure steward has made substantial revisions to the claims-based version of this measure such that the focus is no longer on the number of healthy term newborns, but the number of unexpected complications in term newborns. The numerator of the revised measure has been restructured to assess the presence of severe or moderate complications after term birth, while the original measure looked for the absence of several types of complications after term birth. For the revised measure specifications, we refer readers to: <https://www.cmqcc.org/focus-areas/quality-metrics/unexpected-complications-term-newborns>. In addition, the measure steward is no longer maintaining the claims-based version of HTN or supporting the maintenance of the original eCQM version of HTN that was developed by CMS and adopted in the Hospital IQR Program. Therefore, it is not feasible to

continue to include a measure that is no longer supported by the steward. As a result, we are proposing to remove the HTN eCQM from the Program for the FY 2019 payment determination and subsequent years.

(c) PN–6 and SCIP–Inf–9

We are proposing to remove the: (1) PN–6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF #0147) and (2) SCIP–Inf–9: Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero eCQMs, because it is no longer feasible to implement the measure specifications—removal factor 7 (80 FR 49642). While the electronic versions were retained, the chart-abstracted versions of PN–6 and SCIP–Inf–9 were determined to be “topped-out” and were removed from the Hospital IQR Program measure set in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50204 through 50208).

These two eCQMs have undergone significant changes to their logic expression during the previous annual update.<sup>73</sup> There are a number of data capture requirements that cannot be represented adequately in the eCQM form due to their conceptual complexity. Specifically, for PN–6, hospital feedback has indicated difficulties with interpreting several critical timing requirements, such as for intensive care unit populations, emergency department and inpatient admission transitions, steroid therapy, and pre-admission medications. In addition, hospitals raised concern about the inability to account for variation in recording of the interpretation of laboratory results. For SCIP–Inf–9, feedback from hospitals has indicated that it is difficult to interpret the appropriate timing of elements associated with both the insertion and removal of a catheter. This is

particularly problematic, because of the variety of patient locations encountered before and after surgery, as well as transfers among units. While these variations for both PN–6 and SCIP–Inf–9 can be accounted for through chart-based manual abstraction, we have had great difficulties in translating and maintaining these options for electronic reporting. Therefore, we are proposing to remove both the PN–6 and SCIP–Inf–9 eCQMs from the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

(d) VTE–3, VTE–4, VTE–5, and VTE–6

We are proposing to remove the four VTE eCQMs: (1) VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373); (2) VTE–4: Venous Thromboembolism Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram); (3) VTE–5: Venous Thromboembolism Discharge Instructions; and (4) VTE–6: Incidence of Potentially Preventable Venous Thromboembolism, because it is no longer feasible to implement the measures specifications—removal factor 7 (80 FR 49642). Many of the chart-abstracted versions of these measures were determined to be “topped-out”. While the electronic versions of VTE–3 and VTE–4 were retained, the chart-abstracted versions were determined to be “topped-out” and were removed from the Hospital IQR Program measure set in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49643) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50205), respectively. In addition, as described above in section VIII.A.3.b.(2) of the preamble of this proposed rule, we are proposing to remove the chart-abstracted version of VTE–5 for the FY 2019 payment determination and subsequent years due to its “topped-out” status. The electronic version of

VTE–5 was adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50784). Finally, the chart-abstracted version of VTE–6, however, continues to be included in the Hospital IQR Program measure set because chart abstractors can manually find required data elements in clinical notes and not in structured data fields.

Nonetheless, a majority of hospitals do not have the ability to capture required data elements, such as diagnostic study results/reports and location of the specific vein in which deep vein thrombosis was diagnosed, in discrete structured data fields to support these eCQMs, because they are often found as free text in clinical notes instead. It is exceedingly difficult for hospitals to implement the measure specifications in the absence of these functional requirements. Furthermore, as discussed above, we are proposing to focus on a smaller, more specific subset of eCQMs in the Hospital IQR Program and both the Medicare and Medicaid EHR Incentive Programs. Therefore, in light of their “topped out” statuses and the infeasibility of implementing the measure specifications, the burden of retaining these measures outweighs the benefits. As a result, we are proposing to remove the VTE–3, VTE–4, VTE–5, and VTE–6 eCQMs from the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

(4) Summary of Measures Proposed for Removal

The table below lists the measures we are proposing for removal. We are inviting public comment on our proposals to remove these 15 measures (eCQMs, structural, and chart-abstracted) from the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

We note that STK–4 and VTE–5 are listed twice—once as an eCQM and again as a chart-abstracted measure.

## MEASURES PROPOSED FOR REMOVAL FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

### Electronic Clinical Quality Measures

- AMI–2: Aspirin Prescribed at Discharge for AMI (NQF #0142)
- AMI–7a: Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival
- AMI–10: Statin Prescribed at Discharge
- HTN: Healthy Term Newborn (NQF #0716)
- PN–6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF #0147)
- SCIP–Inf–1a: Prophylactic Antibiotic Received within 1 Hour Prior to Surgical Incision (NQF #0527)
- SCIP–Inf–2a: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528)
- SCIP–Inf–9: Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero
- STK–4: Thrombolytic Therapy (NQF #0437)
- VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373)
- VTE–4: Venous Thromboembolism Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram)

<sup>73</sup> Technical Release Notes: 2015 Annual Update of 2014 Eligible Hospitals and Eligible Professionals

Electronic Clinical Quality Measures (eCQMs). Available at: [https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EHandEPTRNs.pdf)

[Guidance/Legislation/EHRIncentivePrograms/Downloads/EHandEPTRNs.pdf](https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EHandEPTRNs.pdf).



MEASURES PROPOSED FOR REMOVAL FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—  
Continued

**Electronic Clinical Quality Measures**

- VTE-5: Venous Thromboembolism Discharge Instructions
- VTE-6: Incidence of Potentially Preventable VTE \*

**Structural Measures**

- Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care
- Participation in a Systematic Clinical Database Registry for General Surgery

**Chart-Abstracted Measures**

- STK-4: Thrombolytic Therapy (NQF #0437)
- VTE-5: VTE Discharge Instructions

\* Retained in chart-abstracted form.

4. Previously Adopted Hospital IQR Program Measures for the FY 2018 and FY 2019 Payment Determination and Subsequent Years

The Hospital IQR Program has previously finalized 68 measures as outlined in the table below:

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Short name	Measure name	NQF #
<b>NHSN</b>		
CAUTI .....	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CDI .....	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset <i>Clostridium difficile</i> Infection (CDI) Outcome Measure.	1717
CLABSI .....	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS—CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
HCP .....	Influenza Vaccination Coverage Among Healthcare Personnel .....	0431
MRSA Bacteremia .....	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) Bacteremia Outcome Measure.	1716
<b>Chart-Abstracted</b>		
ED-1 * .....	Median Time from ED Arrival to ED Departure for patients Admitted ED Patients .....	0495
ED-2 * .....	Admit Decision Time to ED Departure Time for Admitted Patients .....	0497
Imm-2 .....	Influenza Immunization .....	1659
PC-01 * .....	Elective Delivery (Collected in aggregate, submitted via Web-based tool or electronic clinical quality measure).	0469
Sepsis .....	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure) .....	0500
STK-04 * .....	Thrombolytic Therapy .....	0437
VTE-5 * .....	Venous Thromboembolism Discharge Instructions .....	+
VTE-6 * .....	Incidence of Potentially Preventable Venous Thromboembolism .....	+
<b>Claims-Based Outcome</b>		
MORT-30-AMI .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT-30-CABG .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
MORT-30-COPD .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
MORT-30-HF .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0229
MORT-30-PN .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0468
MORT-30-STK .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke	N/A
READM-30-AMI .....	Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0505

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2018 PAYMENT DETERMINATION AND  
SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
READM-30-CABG .....	Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2515
READM-30-COPD .....	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1891
READM-30-HF .....	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization.	0330
READM-30-HWR .....	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR) .....	1789
READM-30-PN .....	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization.	0506
READM-30-STK .....	30-Day Risk Standardized Readmission Rate Following Stroke Hospitalization .....	N/A
READM-30-THA/TKA .....	Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1551
AMI Excess Days .....	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction .....	N/A
HF Excess Days .....	Excess Days in Acute Care after Hospitalization for Heart Failure .....	N/A
Hip/knee complications .....	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
PSI 04 .....	Death Rate among Surgical Inpatients with Serious Treatable Complications .....	0351
PSI 90 .....	Patient Safety for Selected Indicators (Composite Measure) .....	0531
<b>Claims-Based Payment</b>		
AMI payment .....	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	2431
HF Payment .....	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF).	2436
PN Payment .....	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia.	2579
THA/TKA Payment .....	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty.	N/A
MSPB .....	Payment-Standardized Medicare Spending Per Beneficiary (MSPB) .....	2158
<b>Electronic Clinical Quality Measures (eCQMs)</b>		
AMI-2 .....	Aspirin Prescribed at Discharge for AMI .....	0142
AMI-7a .....	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival .....	+
AMI-8a .....	Primary PCI Received Within 90 Minutes of Hospital Arrival .....	0163
AMI-10 .....	Statin Prescribed at Discharge .....	+
CAC-3 .....	Home Management Plan of Care Document Given to Patient/Caregiver .....	+
EHDI-1a .....	Hearing Screening Prior to Hospital Discharge .....	1354
ED-1* .....	Median Time from ED Arrival to ED Departure for Admitted ED Patients .....	0495
ED-2* .....	Admit Decision Time to ED Departure Time for Admitted Patients .....	0497
HTN .....	Healthy Term Newborn .....	0716
PC-01* .....	Elective Delivery (Collected in aggregate, submitted via Web-based tool or electronic clinical quality measure).	0469
PC-05 .....	Exclusive Breast Milk Feeding** .....	0480
PN-6 .....	Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients.	0147
SCIP-Inf-1a .....	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision .....	0527
SCIP-Inf-2a .....	Prophylactic Antibiotic Selection for Surgical Patients .....	0528
SCIP-Inf-9 .....	Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero.	+
STK-02 .....	Discharged on Antithrombotic Therapy .....	0435
STK-03 .....	Anticoagulation Therapy for Atrial Fibrillation/Flutter .....	0436
STK-04* .....	Thrombolytic Therapy .....	0437
STK-05 .....	Antithrombotic Therapy by the End of Hospital Day Two .....	0438
STK-06 .....	Discharged on Statin Medication .....	0439
STK-08 .....	Stroke Education .....	+
STK-10 .....	Assessed for Rehabilitation .....	0441
VTE-1 .....	Venous Thromboembolism (VTE) Prophylaxis .....	0371
VTE-2 .....	Intensive Care Unit Venous Thromboembolism (VTE) Prophylaxis .....	0372
VTE-3 .....	Venous Thromboembolism Patients with Anticoagulation Overlap Therapy .....	0373
VTE-4 .....	Venous Thromboembolism Patients Receiving Unfractionated Heparin with Dosages/Platelet Count Monitoring by Protocol (or Nomogram).	+
VTE-5* .....	Venous Thromboembolism Discharge Instructions .....	+
VTE-6* .....	Incidence of Potentially Preventable Venous Thromboembolism .....	+
<b>Patient Survey</b>		
HCAHPS .....	HCAHPS + 3-Item Care Transition Measure (CTM-3) .....	0166 0228

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
<b>Structural</b>		
Registry for Nursing Sensitive Care.	Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care .....	N/A
Registry for General Surgery .....	Participation in a Systematic Clinical Database Registry for General Surgery .....	N/A
Patient Safety Culture .....	Hospital Survey on Patient Safety Culture .....	N/A
Safe Surgery Checklist .....	Safe Surgery Checklist Use .....	N/A

\* Measure listed twice, as both chart-abstracted and electronic clinical quality measure.  
 \*\* Measure name has been shortened. Please refer to annually updated measure specifications on the CMS eCQI Resource Center Page for further information: <https://www.healthit.gov/newsroom/ecqi-resource-center>.  
 + Endorsement removed.

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Short name	Measure name	NQF #
<b>Claims-Based Payment</b>		
Cellulitis Payment .....	Cellulitis Clinical Episode-Based Payment Measure .....	N/A
GI Payment .....	Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure .....	N/A
Kidney/UTI Payment .....	Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure .....	N/A

5. Expansion and Updating of Quality Measures

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. In this proposed rule, we are not proposing any changes to these policies.

6. Proposed Refinements to Existing Measures in the Hospital IQR Program

We are proposing refinements to two claims-based measures: (1) PN Payment: Hospital-Level, Risk-Standardized 30-Day Episode-of-Care Payment Measure for Pneumonia; and (2) PSI 90: Patient Safety and Adverse Events Composite (previously known as the Patient Safety for Selected Indicators Composite Measure). We discuss these proposed refinements in more detail below. In addition, we refer readers to section VIII.A.9.a. of the preamble of this proposed rule where we are inviting public comment on our intent to update the MORT-30-STK measure to include the NIH Stroke Scale as a measure of stroke severity in the risk-adjustment in future rulemaking.

a. Proposed Expansion of the Cohort for the PN Payment Measure: Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Pneumonia (NQF #2579)

(1) Background

For FY 2018 payment determination and subsequent years, we are proposing

a refinement of the CMS hospital-level, risk-standardized payment associated with a 30-day episode-of-care for pneumonia (NQF #2579) (PN Payment). The proposed refinement expands the measure cohort to align with the following Hospital IQR Program measures: (1) Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization (NQF #0468) (MORT-30-PN); (2) Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization (NQF #0506) (READM-30-PN); and (3) Excess Days in Acute Care After Hospitalization for Pneumonia (an improved measure to the previously developed measure entitled “30-day Post-Hospital Pneumonia Discharge Care Transition Composite” (NQF #0707) (PN Excess Days).

The expansion of the measure cohort for the MORT-30-PN and the READM-30-PN was finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660) and is expected to be publicly reported beginning in July 2016. We refer readers to section VIII.A.7.b. of the preamble of this proposed rule where we are proposing the PN Excess Days measure for inclusion in the Hospital IQR Program for FY 2019 payment determination and subsequent years.

For the purposes of describing the refinement of this measure, we note that “cohort” is defined as the hospitalizations, or “index admissions,” that are included in the measure and evaluated to ascertain the total payments made on behalf of the

Medicare beneficiary for a 30-day episode-of-care. The cohort is the set of hospitalizations that meets all of the inclusion and exclusion criteria. We are proposing an expansion to this set of hospitalizations.

The previously adopted PN Payment measure (79 FR 50227 through 50231) includes hospitalizations for patients with a principal discharge diagnosis of pneumonia using the International Classification of Diseases, 9th Edition, Clinical Modification (ICD-9-CM), which includes viral and bacterial pneumonia. For more cohort details on the measure as currently implemented, we refer readers to the measure methodology report, with the measure risk adjustment statistical model, in the AMI, HF, PN, and Hip/Knee Arthroplasty Payment Updates zip file on our Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

This proposed measure refinement would expand the measure cohort to include hospitalizations for patients with a: (1) Principal discharge diagnosis of pneumonia, including not only viral or bacterial pneumonia, but also aspiration pneumonia; and (2) principal discharge diagnosis of sepsis (but not severe sepsis) with a secondary diagnosis of pneumonia (including viral or bacterial pneumonia and aspiration pneumonia) coded as present on admission (POA). This refinement to the pneumonia cohort was proposed for several reasons, which were previously

discussed in the FY 2016 IPPS/LTCH PPS final rule for the MORT-30-PN and READM-30-PN measures (80 FR 49653 through 49660). We believe that refining this measure is appropriate for the following reasons. First, recent evidence has shown an increase in the use of sepsis as principal discharge diagnosis codes among patients hospitalized with pneumonia.<sup>74</sup> Pneumonia patients with this principal diagnosis code were not included in the original MORT-30-PN and READM-30-PN measure cohorts, and including them would better capture the complete patient population of a hospital with patients receiving clinical management and treatment for pneumonia. In addition, because patients with a principal diagnosis of sepsis are not included in the original MORT-30-PN and READM-30-PN measure specifications, efforts to evaluate changes over time in pneumonia outcomes could be biased as coding practices change. Lastly, a published article<sup>75</sup> also demonstrated wide variation in the use of sepsis codes as principal discharge diagnosis for pneumonia patients across hospitals, which can potentially bias efforts to compare hospital performance on the MORT-30-PN and READM-30-PN measures.

The proposal to align the PN Payment measure cohort with those of the MORT-30-PN, READM-30-PN, and proposed PN Excess Days measures would address the changing coding patterns in which patients with pneumonia are increasingly given a principal discharge diagnosis code of sepsis in combination with a secondary discharge diagnosis of pneumonia that is POA. Moreover, expanding the PN Payment measure cohort would ensure that the measure captures the broader population of patients admitted for pneumonia that may have been excluded from the previously adopted measure. Finally, the expansion of the cohort for the PN Payment measure harmonizes the cohort of this measure with the MORT-30-PN, the READM-30-PN, and the proposed PN Excess Days measures.

The proposed PN Payment measure (MUC15-378), which includes this expanded measure cohort was included

on a publicly available document entitled “2015 Measures Under Consideration List” for December 1, 2015 (available at: <http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367>) and has been reviewed by the NQF Measure Applications Partnership (MAP) Hospital Workgroup. The revised measure was conditionally supported pending the examination of sociodemographic status (SDS) factors and NQF review and endorsement of the measure update, as referenced in the MAP 2016 Final Recommendations Report (available at: <http://www.qualityforum.org/map/>).<sup>76</sup>

In regard to MAP stakeholder concerns that the proposed PN Payment measure may need to be adjusted for SDS, we understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status, because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how

they apply to our quality programs at such time as they are available.

The refined PN Payment measure will be submitted to NQF for reendorsement as part of the next Cost and Resource Use project which is expected in the first quarter of 2017. We will work to minimize any potential confusion when publicly reporting the updated measure to ensure that the refined measure would not be confused with the originally adopted measure.

## (2) Overview of Measure Change

The proposed measure refinement expands the cohort. As the measure is currently specified, the cohort includes hospitalizations for patients with a principal discharge diagnosis of pneumonia using the ICD-9-CM, which includes viral and bacterial pneumonia (79 FR 50227 through 50231). This refinement would expand the cohort to also include hospitalizations for patients with a: (1) Principal discharge diagnosis of pneumonia, including not only viral or bacterial pneumonia, but also aspiration pneumonia; and (2) principal discharge diagnosis of sepsis (but not severe sepsis) with a secondary diagnosis of pneumonia (including viral or bacterial pneumonia and aspiration pneumonia) coded as POA.

For the ICD-9-CM and ICD-10-CM codes that define the expanded PN Payment cohort, we refer readers to the 2016 Reevaluation and Re-specifications Report of the Hospital-Level 30-Day Risk-Standardized Pneumonia Payment Measure—Pneumonia Payment Version 3.1 in the AMI, HF, PN, and Hip/Knee Arthroplasty Payment Updates zip file on our Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

The data sources, exclusion criteria, assessment of the total payment outcome, and 3 year reporting period all remain unchanged.

## (3) Risk Adjustment

The statistical modeling approach as well as the measure calculation remains unchanged from the previously adopted measure. The risk adjustment approach also remains unchanged; however, to maintain model performance, we conducted variable reselection, or reevaluation of the variables used, to ensure the model risk variables are appropriate for the discharge diagnoses included in the expanded cohort.

The previously adopted pneumonia payment risk-adjustment model

<sup>74</sup>Lindenauer PK, Lagu T, Shieh MS, Pekow PS, Rothberg MB. Association of diagnostic coding with trends in hospitalizations and mortality of patients with pneumonia, 2003–2009. *Journal of the American Medical Association*. Apr 4 2012;307(13):1405–1413.

<sup>75</sup>Rothberg MB, Pekow PS, Priya A, Lindenauer PK. Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: a cross-sectional analysis. *Annals of Internal Medicine*. Mar 18 2014;160(6):380–388.

<sup>76</sup>Spreadsheet of MAP 2016 Final Recommendations Available at: <http://www.qualityforum.org/map/>.

includes 48 variables.<sup>77</sup> As a result of the variable reselection process, the revised risk-adjustment model includes a total of 57 variables—37 of the same variables that are in the previously adopted model as well as 20 additional variables. However, there are 11 variables from the previously adopted model that are not included in the revised model. For details on variable reselection and the full measure specifications of the proposed change to the measure, we refer readers to the 2016 Reevaluation and Re-specifications Report of the Hospital-Level 30-Day Risk-Standardized Pneumonia Payment Measure—Pneumonia Payment Version 3.1 in the AMI, HF, PN, and Hip/Knee Arthroplasty Payment Updates zip file on our Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

#### (4) Estimated Effects of the Cohort Expansion

Using administrative claims data for the FY 2016 payment determination (which included discharges between July 2011 and June 2014), we simulated and analyzed the effects of the proposed cohort refinements on the PN Payment measure (NQF #2579) as if these changes had been applied for FY 2016 payment determination. We note that these statistics are for illustrative purposes only, and we are not proposing to revise measure calculations for the FY 2016 payment determination.

In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43881), we established that if a hospital has fewer than 25 eligible cases combined over a measure's reporting period, we would replace the hospital's data with a footnote indicating that the number of cases is too small to reliably determine how well the hospital is performing. These cases are still used to calculate the measure; however, for hospitals with fewer than 25 eligible cases, the hospital's Risk Standardization Payment (RSP) and RSP interval estimates are not publicly reported for the measure. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), the FY 2013 IPPS/LTCH PPS

final rule (77 FR 53537), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 24588) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years. Expanding the measure cohort to include a broader population of patients as proposed would add a large number of patients, as well as additional hospitals (which would now meet the minimum threshold of 25 eligible cases for public display), to the PN Payment measure (NQF #2579). The increase in the size of the measure cohort proposed in this rule also is estimated to change results for some hospitals as detailed below.

The previously adopted PN Payment measure cohort includes 901,764 patients and 4,685 hospitals for the FY 2016 payment determination (administrative claims from July 2011–June 2014). We noted the following effects for the PN Payment measure if the proposed expanded cohort is applied for FY 2016 payment determinations: (1) The cohort would increase to include an additional 386,143 patients across all hospitals (creating a total measure cohort size of 1,287,907 patients); (2) an additional 81 hospitals would meet the minimum 25 patient case volume threshold over the 3-year reporting period and, as a result, would be publicly reported for the measure; and (3) 31.7 percent of the refined measure cohort would consist of patients who fall into the expanded set of hospitalizations.

The expansion of the cohort leads to an overall increase in the mean national payment of \$16,116 when compared to the mean national payment of \$14,294 for the previously adopted cohort. This leads to an increase in the RSP outcome of \$1,822 or 12.7 percent due to the higher mean payments for patients added to the cohort. An individual hospital's average payment category or reclassification of outlier status of "higher than the U.S. national payment," "no different than the U.S. national payment," or "less than the U.S. national payment" may change as demonstrated in the 2016 Reevaluation and Re-specifications Report of the Hospital-Level 30-Day Risk-Standardized Pneumonia Payment Measure—Pneumonia Payment Version 3.1, which can be found in the AMI, HF, PN, and Hip/Knee Arthroplasty Payment Updates zip file on our Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

Overall, we estimate that 1.4 percent of hospitals included in the previously

adopted measure would change categorization from greater than average to average payment, 9.3 percent would change from average to greater than average payment, and 8.5 percent would change from average to less than average payment. Finally, 1.8 percent of hospitals would change from less than average to average payment. Therefore, there would be an increase in the number of hospitals considered outliers and a shift in some hospitals' outlier status classification. We reiterate that these statistics are for illustrative purposes only, and we are not proposing to revise measure calculations for the FY 2016 payment determination; our proposal would affect the FY 2018 payment determination and subsequent years.

A detailed description of the refinements to the PN Payment measure (NQF #2579) and the estimated effects of the change are available in the 2016 Reevaluation and Re-specifications Report of the Hospital-Level 30-Day Risk-Standardized Pneumonia Payment Measure—Pneumonia Payment Version 3.1 in the AMI, HF, PN, and Hip/Knee Arthroplasty Payment Updates zip file on our Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

We are inviting public comment on our proposal to refine the Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia (NQF #2579) (PN Payment) measure for the FY 2018 payment determination and subsequent years as described above.

#### b. Proposed Adoption of Modified PSI 90: Patient Safety and Adverse Events Composite Measure (NQF #0531)

##### (1) Background

We are proposing to adopt refinements to the Agency for Healthcare Research and Quality (AHRQ) Patient Safety and Adverse Events Composite (NQF #0531) for the Hospital IQR Program beginning with the FY 2018 payment determination and subsequent years. In summary, the PSI 90 measure was refined to reflect the relative importance and harm associated with each component indicator to provide a more reliable and valid signal of patient safety events. We believe refining the PSI 90 measure will provide strong incentives for hospitals to ensure that patients are not harmed by the medical care they receive, a critical consideration in quality improvement.

In the FY 2009 IPPS/LTCH PPS final rule (73 FR 48607 through 48610), we

<sup>77</sup> Kim N, Ott L, Hsieh A, et al. 2015 Condition-Specific Measure Updates and Specifications Report, Hospital-Level 30-Day Risk-Standardized Payment Measures—Acute Myocardial Infarction (Version 4.0), Heart Failure (Version 2.0), Pneumonia (Version 2.0). Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>. Accessed Date: March 16, 2016.

adopted the Complication/Patient Safety for Selected Indicators Composite Measure (NQF #0531) in the Hospital IQR Program beginning with the FY 2010 payment determination as an important measure of patient safety and adverse events. In the FY 2015 IPPS/LTCH PPS final rule, we updated the title of the measure to Patient Safety for Selected Indicators Composite Measure (NQF #0531), to be consistent with the NQF (79 FR 50211). As previously adopted, the PSI 90 measure consisted of eight component indicators: (1) PSI 3 Pressure Ulcer Rate; (2) PSI 6 Iatrogenic Pneumothorax Rate; (3) PSI 7 Central Venous Catheter-Related Blood Stream Infections Rate; (4) PSI 8 Postoperative Hip Fracture Rate; (5) PSI 12 Perioperative Pulmonary Embolism/Deep Vein Thrombosis Rate; (6) PSI 13 Postoperative Sepsis Rate; (7) PSI 14 Postoperative Wound Dehiscence Rate; and (8) PSI 15 Accidental Puncture and Laceration Rate.<sup>78</sup>

The currently adopted eight-indicator version of the measure underwent an extended NQF maintenance reendorsement in the 2014 NQF Patient Safety Committee due to concerns with the underlying component indicators and their composite weights. In the NQF-Endorsed Measures for Patient Safety, Final Report,<sup>79</sup> the NQF Patient Safety Committee deferred their final decision for the PSI 90 measure until the following measure evaluation cycle. In the meantime, AHRQ worked to address many of the NQF stakeholders' concerns about the PSI 90 measure, which subsequently completed NQF maintenance re-review and received reendorsement on December 10, 2015.

The PSI 90 measure's extended NQF reendorsement led to several changes to the measure.<sup>80</sup> First, the name of the PSI 90 measure has changed to "Patient Safety and Adverse Events Composite" (NQF #0531) (herein referred to as the "modified PSI 90"). Second, the modified PSI 90 measure includes the addition of three indicators: (1) PSI 09 Perioperative Hemorrhage or Hematoma

Rate; (2) PSI 10 Physiologic and Metabolic Derangement Rate; and (3) PSI 11 Postoperative Respiratory Failure Rate. Third, PSI 12, Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate, and PSI 15, Accidental Puncture or Laceration Rate, have been respecified in the modified PSI 90 measure. Fourth, PSI 07 Central Venous Catheter-Related Blood Stream Infection Rate has been removed in the modified PSI 90 measure. Fifth, the weighting of component indicators in the modified PSI 90 measure is based not only on the volume of each of the patient safety and adverse events, but also the harms associated with the events. We consider these changes to the modified PSI 90 measure to be substantive changes to the measure. Therefore, we are proposing to adopt refinements to the PSI 90 measure for the Hospital IQR Program beginning with the FY 2018 payment determination and subsequent years. We explain the modified PSI 90 measure more fully below, and also refer readers to the measure description on the NQF Web site at: <https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=321&print=0&entityTypeID=3>. We are also proposing to modify the reporting periods for FYs 2018 and 2019 payment determinations and subsequent years as detailed further below.

We note that the proposed modified PSI 90 measure (MUC15-604) was included on a publicly available document entitled 2015 Measures Under Consideration for December 1, 2015<sup>81</sup> in compliance with section 1890A(a)(2) of the Act, and was reviewed by the MAP. The MAP supported this measure stating that, "the PSI measures were developed to identify harmful healthcare related events that are potentially preventable. Three additional PSIs have been added to this updated version of the measure. PSIs were better linked to important changes in clinical status with 'harm weights' that are based on diagnoses that were assigned after the complication. This is intended to allow the measure to more accurately reflect the impact of the events."<sup>82</sup> The measure received support for inclusion in the Hospital IQR Program as referenced in the MAP Final Recommendations Report.<sup>83</sup>

<sup>81</sup> 2015 Measures Under Consideration List Available at: <http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367>.

<sup>82</sup> MAP Final Recommendations. Available at: <http://www.qualityforum.org/map/>.

<sup>83</sup> MAP Final Recommendations. Available at: <http://www.qualityforum.org/map/>.

(2) Overview of the Measure Changes

First, the name of the PSI 90 measure has changed from the "Patient Safety for Selected Indicators Composite Measure" to the "Patient Safety and Adverse Events Composite" (NQF #0531) to more accurately capture the indicators included in the measure.

Second, the PSI 90 measure has expanded from eight to 10 component indicators. The modified PSI 90 measure is a weighted average of the following 10 risk-adjusted and reliability-adjusted individual component PSI rates:

- PSI 03 Pressure Ulcer Rate;
- PSI 06 Iatrogenic Pneumothorax Rate;
- PSI 08 Postoperative Hip Fracture Rate;
- PSI 09 Postoperative Hemorrhage or Hematoma Rate; \*
- PSI 10 Physiologic and Metabolic Derangement Rate; \*
- PSI 11 Postoperative Respiratory Failure Rate; \*
- PSI 12 Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate;
- PSI 13 Postoperative Sepsis Rate;
- PSI 14 Postoperative Wound Dehiscence Rate; and
- PSI 15 Accidental Puncture or Laceration Rate.<sup>84</sup>

(\* Denotes new component for the modified PSI 90 measure)

As stated above, the modified PSI 90 measure also removed PSI 07 Central Venous Catheter-Related Blood Stream Infection Rate, because of potential overlap with the CLABSI measure (NQF #0139), which has been included in the Hospital IQR Program since the FY 2011 IPPS/LTCH PPS final rule (75 FR 50201 through 50202), the HAC Reduction Program since the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), and the Hospital VBP Program since the FY 2013 IPPS/LTCH PPS final rule (77 FR 53597 through 53598).

In response to stakeholder concerns, highlighted in the NQF 2014 Patient Safety Report,<sup>85</sup> the modified PSI 90 measure also respecified two component indicators, PSI 12 and PSI 15. Specifically, for PSI 12 Perioperative PE or DVT Rate, the NQF received public comments concerning the inclusion of: (1) Extracorporeal membrane oxygenation (ECMO) procedures in the denominator; and (2) intra-hospital variability in the

<sup>84</sup> <http://www.qualityforum.org/QPS/0531>.

<sup>85</sup> NQF Endorsed Measures for Patient Safety, Final Report. Available at: [http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed\\_Measures\\_for\\_Patient\\_Safety\\_Final\\_Report.aspx](http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety_Final_Report.aspx).

<sup>78</sup> NQF-Endorsed Measures for Patient Safety, Final Report. Available at: [http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed\\_Measures\\_for\\_Patient\\_Safety\\_Final\\_Report.aspx](http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety_Final_Report.aspx).

<sup>79</sup> NQF-Endorsed Measures for Patient Safety, Final Report available at: [http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed\\_Measures\\_for\\_Patient\\_Safety\\_Final\\_Report.aspx](http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety_Final_Report.aspx).

<sup>80</sup> National Quality Forum QPS Measure Description for "Patient Safety for Selected Indicators (modified version of PSI90) (Composite measure)" found at: <https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=321&print=0&entityTypeID=3>.

documentation of calf vein thrombosis (which has uncertain clinical significance). As such, the modified PSI 12 component indicator no longer includes ECMO procedures in the denominator or isolated deep vein thrombosis of the calf veins in the numerator. PSI 15 also was respecified further to focus on the most serious intraoperative injuries—those that were unrecognized until they required a subsequent reparative procedure. The modified denominator of PSI 15 now is limited to discharges with an abdominal/pelvic operation, rather than including all medical and surgical discharges. In addition, to identify events that are more likely to be clinically significant and preventable, the PSI 15 numerator was modified to require both: (1) A diagnosis of an accidental puncture and/or laceration; and (2) an abdominal/pelvic reoperation one or more days after the index surgery.

Finally, the NQF Patient Safety Review Committee raised concerns about the weighting scheme of the component indicators. In prior versions of the measure, the weights of each component PSI were based solely on volume (numerator rates). In the modified PSI 90 measure, the rates of each component PSI are weighted based on statistical and empirical analyses of volume, excess clinical harm associated with the PSI, and disutility (individual preference for a health state linked to a harm, such as death or disability). The final weight for each component indicator is the product of harm weights and volume weights (numerator weights). Harm weights are calculated by multiplying empirical estimates of excess harms associated with the patient safety event by the utility weights linked to each of the harms. Excess harms are estimated using statistical models comparing patients with a safety event to those without a safety event in a Medicare fee-for-service sample. Volume weights are calculated based on the number of safety events for the component indicators in an all-payer reference population. For more information on the modified PSI 90 measure and component indicators, we refer readers to Quality Indicator Empirical Methods available online at: [www.qualityindicators.ahrq.gov](http://www.qualityindicators.ahrq.gov).

### (3) Risk Adjustment

The risk adjustment and statistical modeling approaches of the models remain unchanged in the modified PSI 90 measure. In summary, the predicted value for each case is computed using a modeling approach that includes, but is not limited to, applying a Generalized

Estimating Equation (GEE) hierarchical model (logistic regression with hospital random effect) and covariates for gender, age, Modified MS-DRG (MDRG), Major Diagnostic Category, transfer in, point of origin not available, procedure days not available, and AHRQ comorbidity (COMORB).

The expected rate for each of the indicators is computed as the sum of the predicted value for each case divided by the number of cases for the unit of analysis of interest (that is, the hospital). The risk-adjusted rate for each of the indicators is computed using indirect standardization as the observed rate divided by the expected rate, multiplied by the reference population rate. For more details about risk adjustment, we refer readers to: [http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical\\_Methods\\_2015.pdf](http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical_Methods_2015.pdf). As stated above, we are not proposing any changes to the risk adjustment for this measure.

### (4) Proposed Reporting Periods

The PSI 90 measure is a claims-based measure that has been calculated using 24-months of data. For the FY 2018 and FY 2019 payment determinations, measure rates would be calculated using reporting periods of July 1, 2014 through June 30, 2016 and July 1, 2015 through June 30, 2017, respectively. However, because hospitals began ICD-10-CM/PCS implementation on October 1, 2015, these reporting periods for the FY 2018 and FY 2019 payment determinations would require using both ICD-9 and ICD-10 claims data to calculate measure performance.

Since the ICD-10 transition was implemented on October 1, 2015, we have been monitoring our systems, and so far, claims are processing normally. The measure steward, AHRQ, has been reviewing the measure for any potential issues related to the conversion of approximately 70,000 ICD-10 coded operating room procedures<sup>86</sup> ([https://www.cms.gov/icd10manual/fullcode\\_cms/P1616.html](https://www.cms.gov/icd10manual/fullcode_cms/P1616.html)), which could directly affect the modified PSI 90 component indicators. In addition, to meet program requirements and implementation schedules, our system would require an ICD-10 risk-adjusted version of the AHRQ QI PSI software<sup>87</sup> by December

<sup>86</sup> International Classification of Diseases, (ICD-10-CM/PCS) Transition—Background. Available at: [http://www.cdc.gov/nchs/icd/icd10cm\\_pcs\\_background.htm](http://www.cdc.gov/nchs/icd/icd10cm_pcs_background.htm).

<sup>87</sup> The AHRQ QI Software is the software used to calculate PSIs and the composite measure. More information is available at: [http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical\\_Methods\\_2015.pdf](http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical_Methods_2015.pdf).

2016 for the FY 2018 payment determination year. At this time, a risk adjusted ICD-10 version of the modified PSI 90 Patient Safety and Adverse Events Composite software is not expected to be available until late CY 2017.

To address the above issues, we are proposing to modify the reporting periods for the FYs 2018 and 2019 payment determinations and beyond. For the FY 2018 payment determination, we are proposing to use a 15-month reporting period spanning July 1, 2014 through September 30, 2015. The 15-month reporting period would only apply to the FY 2018 payment determination and would only use ICD-9 data. For the FY 2019 payment determination, we are proposing to use a 21-month reporting period spanning October 1, 2015 through June 30, 2017. The 21-month reporting period would only apply to the FY 2019 payment determination and would only use ICD-10 data. For all subsequent payment determinations after FY 2019, we are proposing to use the standard 24-month reporting period, which would only use ICD-10 data. In order to align the modified PSI 90 measure and the use of ICD-9 and ICD-10 data across CMS hospital quality programs, we are proposing similar modifications for FYs 2018 and 2019 payment determinations and beyond in the HAC Reduction Program, as set forth in section IV.I.5.b. of the preamble of this proposed rule, and similar modifications to the performance period for the Hospital VBP Program FY 2018 program year, as set forth in section IV.H.2. of the preamble of this proposed rule.

Prior to deciding to propose abbreviated reporting periods for the FY 2018 and FY 2019 payment determinations, we took several factors into consideration, including the recommendations of the measure steward, the feasibility of using a combination of ICD-9 and ICD-10 data without the availability of the appropriate measure software, minimizing provider burden, program implementation timelines, and the reliability of using shortened reporting periods, as well as the importance of continuing to publicly report this measure. We believe that using a 15-month reporting period for the FY 2018 payment determination and a 21-month reporting period for the FY 2019 payment determination best serves the need to provide important information on hospital patient safety and adverse events by allowing sufficient time to process the claims data and calculate the measures, while minimizing

reporting burden and program disruption. We will continue to test ICD–10 data that are submitted in order to ensure the accuracy of measure calculations, to monitor and assess the translation of measure specifications to ICD–10 as well as potential coding variation, and to assess any impacts on measure performance.

We note that a prior reliability analysis of the PSI 90 measure (not the modified PSI 90 measure) showed that the majority of hospitals attain a moderate or high level of reliability after a 12-month reporting period.<sup>88</sup> Although the modified PSI 90 measure has undergone substantial changes since this analysis, we believe that measure scores would continue to be reliable for the above proposed reporting periods, because the NQF, which reendorsed the modified version, found it to be reliable using 12 months of data.<sup>89</sup> In establishing the revised reporting periods for the modified PSI 90 measure, we also relied upon an analysis by Mathematica Policy Research, a CMS contractor, which found that the measure was most reliable with a 24-month reporting period and unreliable with a reporting period of less than 12 months.<sup>90</sup> Therefore, we believe that the proposed abbreviated reporting periods for the modified PSI 90 measure would produce reliable data because the reporting periods are still greater than 12 months.

#### (5) Proposed Adoption of the Modified PSI 90 Measure

In summary, the PSI 90 measure was revised to reflect the relative importance and harm associated with each component indicator to provide a more reliable and valid signal of patient safety events. We believe that adopting the modified PSI 90 measure would continue to provide strong incentives for hospitals to ensure that patients are not harmed by the medical care they receive, which is a critical consideration in quality improvement.

<sup>88</sup> 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](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf).

<sup>89</sup> “Patient Safety 2015 Final Report” is available at: [http://www.qualityforum.org/Publications/2016/02/Patient\\_Safety\\_2015\\_Final\\_Report.aspx](http://www.qualityforum.org/Publications/2016/02/Patient_Safety_2015_Final_Report.aspx).

<sup>90</sup> 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](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf).

We are inviting public comment on our proposal to adopt the modified PSI 90 measure (NQF #0531) for the Hospital IQR Program beginning with the FY 2018 payment determination. We will continue to use the currently adopted eight-indicator version of the PSI 90 measure in the Hospital IQR Program for FY 2017. We also are inviting public comment on the proposals to revise the reporting periods for this measure as described above: (1) A 15-month reporting period using only ICD–9 data for the FY 2018 payment determination; (2) a 21-month reporting period using only ICD–10 data for the FY 2019 payment determination; and (3) a 24-month reporting period using only ICD–10 data for the FY 2020 payment determination and subsequent years.

#### 7. Proposed Additional Hospital IQR Program Measures for the FY 2019 Payment Determination and Subsequent Years

We are proposing to add four new measures to the Hospital IQR Program for the FY 2019 payment determination and subsequent years. We are proposing to adopt three clinical episode-based payment measures:

- Aortic Aneurysm Procedure Clinical Episode-Based Payment (AA Payment) Measure;
- Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment (Chole and CDE Payment) Measure; and
- Spinal Fusion Clinical Episode-Based Payment (SFusion Payment) Measure.

In addition, we are proposing to adopt one required outcome measure: Excess Days in Acute Care After Hospitalization for Pneumonia.

The proposed measures were included on a publicly available document entitled “2015 Measures Under Consideration”<sup>91</sup> in compliance with section 1890A(a)(2) of the Act, and they were reviewed by the MAP as discussed in its MAP Pre-Rulemaking Report and Spreadsheet of MAP 2016 Final Recommendations.<sup>92</sup>

Below, we discuss each of the above measures in more detail.

#### a. Proposed Adoption of Three Clinical Episode-Based Payment Measures

##### (1) Background

Clinical episode-based payment measures are clinically coherent

<sup>91</sup> Measure Applications Partnership: List of Measures Under Consideration (MUC) for December 1, 2015. Available at: <http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367>.

<sup>92</sup> Spreadsheet of MAP 2016 Final Recommendations Available at: <http://www.qualityforum.org/map/>.

groupings of healthcare services that can be used to assess providers’ resource use. Combined with other clinical quality measures, they contribute to the overall picture of providers’ clinical effectiveness and efficiency. Episode-based performance measurement allows meaningful comparisons between providers based on resource use for certain clinical conditions or procedures, as noted in the NQF report for the “Episode Grouper Evaluation Criteria” project available at: [http://www.qualityforum.org/Publications/2014/09/Evaluating\\_Episode\\_Groupers\\_A\\_Report\\_from\\_the\\_National\\_Quality\\_Forum.aspx](http://www.qualityforum.org/Publications/2014/09/Evaluating_Episode_Groupers_A_Report_from_the_National_Quality_Forum.aspx) and in various peer-reviewed articles.<sup>93</sup> We are proposing three clinical episode-based payment measures for inclusion in the Hospital IQR Program beginning with the FY 2019 payment determination: (1) Aortic Aneurysm Procedure Clinical Episode-Based Payment (AA Payment) Measure; (2) Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment (Chole and CDE Payment) Measure; and (3) Spinal Fusion Clinical Episode-Based Payment (SFusion Payment) Measure. The proposed measures capture Medicare payment for services related to the episode procedure and take into account beneficiaries’ clinical complexity as well as geographic payment differences.

We are proposing these clinical episode-based measures to supplement the Hospital IQR Program’s Medicare Spending per Beneficiary (MSPB) Measure. The proposed measures also support our mission to provide better healthcare for individuals, better health for populations, and lower costs for healthcare. We note that these measures were reviewed by the MAP and did not receive support for adoption into the Hospital IQR Program, as discussed in its MAP Pre-Rulemaking Report and Spreadsheet of MAP 2016 Final Recommendations.<sup>94</sup> The result of the MAP vote for the proposed measures was as follows: (1) Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure: 8 percent support, 32 percent conditional support, and 60 percent do not support; (2) Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure: 20 percent support, 28 percent conditional support, and 52 percent do not support; and (3) Spinal

<sup>93</sup> For example: Hussey, P. S., Sorbero, M. E., Mehrotra, A., Liu, H., & Damberg, S. L.: (2009). Episode-Based Performance Measurement and Payment: Making It a Reality. *Health Affairs*, 28(5), 1406–1417. Doi:10.1377/hlthaff.28.5.1406.

<sup>94</sup> Spreadsheet of MAP 2016 Final Recommendations. Available at: <http://www.qualityforum.org/map/>.



Fusion Clinical Episode-Based Payment Measure: 16 percent support, 36 percent conditional support, and 48 percent do not support. MAP stakeholders expressed concerns that the proposed measures: (1) Overlap with the Medicare Spending per Beneficiary (MSPB) Measure;<sup>95</sup> (2) are not NQF-endorsed; (3) may need to be adjusted for sociodemographic status (SDS); and (4) fail to link outcomes to quality because they do not reflect appropriateness of care.

In response to MAP stakeholder concerns that the clinical episode-based payment measures overlap with the MSPB measure, we note that unlike the overall MSPB measure, the clinical episode-based payment measures assess payment variation at the procedure level and only include services that are clinically related to the named episode procedure (for example, the spinal fusion measure includes inpatient admissions for “medical back problems” that occur following the initial spinal fusion procedure since the admission is likely a result of complications from the initial procedure).

With respect to MAP stakeholder concerns that the clinical episode-based payment measures are not NQF-endorsed, section 1886(b)(3)(B)(IX)(bb) 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. We considered other existing measures related to payment that have been endorsed by the NQF and other consensus organizations, but we were unable to identify any NQF-endorsed (or other consensus organization endorsed) payment measures that assess the aortic aneurysm procedure, cholecystectomy and common duct exploration, or spinal fusion. However, these proposed clinical episode-based payment measures will be submitted to NQF for endorsement as part of the next Cost and Resource Use project.

In regard to MAP stakeholder concerns that the clinical episode-based payment measures may need to be

adjusted for SDS, we refer readers to section VIII.A.6.a.(1) of the preamble of this proposed rule for a discussion of our policy on SDS factors. Finally, regarding MAP stakeholder concerns that the clinical episode-based payment measures fail to link outcomes to quality because they do not reflect appropriateness of care, we believe that the proposed measures cover topics of critical importance to quality in the inpatient hospital setting. Hospitals have a significant influence on Medicare spending during the episode surrounding a hospitalization, through the provision of appropriate, high-quality care before and during inpatient hospitalization and through proper hospital discharge planning, care coordination, and care transitions. While we recognize that high or low payments to hospitals are difficult to interpret in isolation, high payments for services may implicitly be associated with poor quality of care (for example, preventable readmissions, procedure complications, or emergency room usage).

Although the MAP did not support inclusion of these clinical episode-based payment measures in the Hospital IQR Program,<sup>96</sup> stakeholders have requested to have more condition-specific and procedure-specific measures, similar to the MSPB measure included in the Hospital IQR Program, as described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51623). We believe that including condition- and procedure-specific payment measures will provide hospitals with actionable feedback that will better equip them to implement targeted improvements in comparison to an overall payment measure alone. Further, we believe that supplementing the MSPB measure with condition-specific and procedure-specific measures will provide both overall hospital-level and detailed information on high-cost and high-prevalence conditions and procedures to better inform their future spending plans. Moreover, the payment measures will help consumers and other payers and providers identify hospitals involved in the provision of efficient care for certain procedures.

The three procedures selected for the clinical episode-based payment measures were chosen based on the following criteria: (1) The condition constitutes a significant share of Medicare payments and potential savings for hospitalized patients during and surrounding a hospital stay; (2)

there was a high degree of agreement among clinical experts consulted for this project that standardized Medicare payments for services provided during this episode can be linked to the care provided during the hospitalization; (3) episodes of care for the condition are comprised of a substantial proportion of payments and potential savings for post-acute care, indicating episode payment differences are driven by utilization outside of the MS-DRG payment; (4) episodes of care for the condition reflect high variation in post discharge payments, enabling differentiation among hospitals; and (5) the medical condition is managed by general medicine physicians or hospitalists and the surgical conditions are managed by surgical subspecialists, enabling comparison between similar practitioners. These selection criteria were also used for the three clinical episode-based payment measures finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49664 through 49665).

The measures follow the general construction of episode-based measures previously adopted in the Hospital IQR Program: The NQF-endorsed MSPB measure finalized in the FY 2012 IPPS/LTCH PPS final rule for the Hospital IQR Program (76 FR 51626 through 74529); and the three clinical episode-based payment measures for kidney/UTI, cellulitis, and gastrointestinal hemorrhage finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49674). Similar to these previously adopted measures, the proposed measures include standardized payments for Medicare Part A and Part B services and are risk adjusted for individual patient characteristics and other factors (for example, the MS-DRG of the index inpatient stay). However, unlike the MSPB measure, the clinical episode-based payment measures only include Medicare Part A and Part B services that are clinically related to the named episode procedure. The clinical episode-based payment measures are price-standardized, risk-adjusted ratios that compare a provider's resource use against the resource use of other providers within a reporting period (that is, the measure calculation includes eligible episodes occurring within a 1-year timeframe). Similar to the MSPB measure though, the ratio allows for ease of comparison over time as it obviates the need to adjust for inflation.

Each clinical episode-based payment measure is calculated as the ratio of the Episode Amount for each provider divided by the episode-weighted median Episode Amount across all providers. To calculate the Episode

<sup>95</sup> MSPB measure specifications can be found in the “Medicare Spending Per Beneficiary (MSPB) Measure Overview,” available at: <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996>.

<sup>96</sup> Spreadsheet of MAP 2016 Final Recommendations. Available at: <http://www.qualityforum.org/map/>.

Amount for each provider, one calculates the average of the ratio of the observed episode payment over the expected episode payment (as predicted in risk adjustment), and then multiplies this quantity by the average observed

episode payment level across all providers nationally. The denominator for a provider's measure is the episode weighted national median<sup>97</sup> of Episode Amounts across all providers. A clinical episode-based payment measure of less

than 1 indicates that a given provider's resource use is less than that of the national median provider during a reporting period. Mathematically, this is represented in equation (A) below.

$$(A) \text{ Episode Measure}_j = \frac{\text{Episode Amount}_j}{\text{Episode-Weighted Median of All Providers' Episode Amounts}} = \frac{\frac{\sum_{i \in j} (O_{ij})}{n_j} \bar{O}_{i \in I}}{\text{Episode-Weighted Median of All Providers' Episode Amounts}}$$

Where:

$O_{ij}$  = observed episode payment for episode  $i$  in provider  $j$ ,

$E_{ij}$  = expected episode payment for episode  $i$  in provider  $j$ ,

$\bar{O}_{i \in I}$  = average observed episode payment across all episodes  $i$  nationally, and

$n_j$  = total number of episodes for provider  $j$ .

Each of the three measures we are proposing is described further below, followed by explanations of payment standardization and risk adjustment. For detailed measure specifications, we refer readers to the clinical episode-based payment measures report entitled, "Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion" available at: <http://www.qualitynet.org> > Hospital-Inpatient > Claims-Based Measures > Episode-Based Payment Measures.

(2) Proposed Aortic Aneurysm Procedure Clinical Episode-Based Payment (AA Payment) Measure

(a) Background

Inpatient hospital stays and associated services assessed by the proposed Aortic Aneurysm Procedure Clinical Episode-Based Payment (AA Payment) measure have high payments with substantial variation. In CY 2014, Medicare FFS beneficiaries experienced more than 22,000 aortic aneurysm procedure episodes triggered by related inpatient stays. Payment-standardized, risk-adjusted episode payment for these episodes (payment for the hospitalization plus payment for clinically related services in the episode window) totaled nearly \$760 million in CY 2014, with a mean episode payment of over \$33,000. There is substantial variation in aortic aneurysm procedure episode payment—ranging from approximately \$21,000 at the 5th

percentile to approximately \$62,000 at the 95th percentile—that is partially driven by variation in postdischarge payment clinically-related to the inpatient hospitalization.<sup>98</sup> These clinically-related postdischarge payments may be an indicator of the quality of care provided during the hospitalization. Specifically, higher quality hospital treatment may yield lower postdischarge payment.

(b) Overview of Measure

The proposed AA Payment measure includes the set of medical services related to a hospital admission for an aortic aneurysm procedure, including treatment, follow-up, and postacute care. The measure includes two clinical subtypes: (1) Abdominal Aortic Aneurysm Procedure; and (2) Thoracic Aortic Aneurysm Procedure. Clinical subtypes are included in the measure construction to distinguish relatively homogeneous subpopulations of patients whose health conditions significantly influence the form of treatment and the expected post-discharge outcomes and risks. The risk adjustment model is estimated separately for each clinical subtype, such that the measure compares observed spending for an episode of a given clinical subtype only to expected spending among episodes of that subtype. This measure, like the NQF-endorsed MSPB measure (NQF #2158), assesses the payment for services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the "episode window", discussed in more detail below). In contrast to the MSPB measure, however, this proposed measure includes Medicare payments for services during the episode window only if they are clinically related to the aortic aneurysm procedure that was

performed during the index hospital stay.

(c) Data Sources

The proposed AA Payment measure is a claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized for an aortic aneurysm procedure. The reporting period for the measure is 1 year (that is, the measure calculation includes eligible episodes occurring within a 1-year timeframe). For example, for the FY 2019 payment determination, the reporting period would be CY 2017.

(d) Measure Calculation

The proposed AA Payment measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during the episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without the need to adjust for inflation. The numerator is the Episode Amount, calculated as the average of the ratios of the observed episode payment over the expected episode payment (as predicted in risk adjustment), multiplied by the average observed episode payment level across all providers nationally. The denominator for a provider's measure is the episode weighted national median of Episode Amounts across all providers. An aortic aneurysm procedure episode begins 3 days prior to the initial (index) admission and extends 30 days following the discharge from the index hospital stay. For detailed measure specifications, we refer readers to the clinical episode-

<sup>97</sup> Example of episode weighted median: If there are 2 hospitals and one hospital had an measure score of 1.5 and another had one of 0.5, but the first

had 4 episodes and the second only 1, then the episode-weighted median would be 1.5 (that is, 0.5, 1.5, 1.5, 1.5, 1.5).

<sup>98</sup> Statistics based on Acumen's testing of episode definition on Medicare FFS population using Medicare Parts A and B claims.

based payment measures report entitled, “Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion” and available at: <http://www.qualitynet.org> > Hospital-Inpatient > Claims-Based Measures > Episode-Based Payment Measures.

(e) Cohort

The proposed AA Payment measure cohort includes Medicare FFS beneficiaries hospitalized for an aortic aneurysm procedure. Measure exclusions are discussed in more detail in section VIII.A.7.a.(5) of the preamble of this proposed rule.

We are inviting public comment on our proposal to adopt the Aortic Aneurysm Procedure Clinical Episode-Based Payment (AA Payment) measure to the Hospital IQR Program measure set for the FY 2019 payment determination and subsequent years as discussed in this section.

(3) Proposed Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment (Chole and CDE Payment) Measure

(a) Background

Inpatient hospital stays and associated services assessed by the proposed Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment (Chole and CDE Payment) measure have high payments with substantial variation. In CY 2014, Medicare FFS beneficiaries experienced more than 48,000 cholecystectomy and common duct exploration episodes triggered by related inpatient stays. Payment-standardized, risk-adjusted episode payment for these episodes (payment for the hospitalization plus the payment for clinically related services in the episode window) totaled nearly \$690 million in CY 2014, with a mean episode payment of over \$14,000. There is substantial variation in cholecystectomy and common duct exploration episode payment—ranging from approximately \$11,000 at the 5th percentile to approximately \$22,000 at the 95th percentile—that is partially driven by variation in postdischarge payment clinically-related to the inpatient hospitalization.<sup>99</sup> These clinically-related postdischarge payments may be an indicator of the quality of care provided during the hospitalization. Specifically, higher

<sup>99</sup> Statistics based on Acumen’s testing of episode definition on Medicare FFS population using Medicare Parts A and B claims.

quality hospital treatment may yield lower postdischarge payment.

(b) Overview of Measure

The proposed Chole and CDE Payment measure includes the set of medical services related to a hospital admission for a cholecystectomy and common duct exploration, including treatment, follow-up, and postacute care. This measure, like the NQF-endorsed MSPB measure (NQF #2158), assesses the payment for services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary’s hospital stay (the “episode window”, discussed in more detail below). In contrast to the MSPB measure, however, this measure includes Medicare payments for services during the episode window only if they are clinically related to the cholecystectomy and common duct exploration that was performed during the index hospital stay.

(c) Data Sources

The proposed Chole and CDE Payment measure is a claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized for a cholecystectomy and common duct exploration. The reporting period for the measure is 1 year (that is, the measure calculation includes eligible episodes occurring within a 1-year timeframe). For example, for the FY 2019 payment determination, the reporting period would be CY 2017.

(d) Measure Calculation

The proposed Chole and CDE Payment measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during the episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted. Similar to the MSPB measure’s construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without need to adjust for inflation. The numerator is the Episode Amount, calculated as the average of the ratios of the observed episode payment over the expected episode payment (as predicted in risk adjustment), multiplied by the average observed episode payment level across all providers nationally. The denominator for a provider’s measure is the episode weighted national median of Episode Amounts across all providers. A cholecystectomy and common duct exploration episode

begins 3 days prior to the initial (index) admission and extends 30 days following the discharge from the index hospital stay. For detailed measure specifications, we refer readers to the clinical episode-based payment measures report entitled, “Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion” and available at: <http://www.qualitynet.org> > Hospital-Inpatient > Claims-Based Measures > Episode-Based Payment Measures.

(e) Cohort

The proposed Chole and CDE Payment measure cohort includes Medicare FFS beneficiaries hospitalized for cholecystectomy and common duct exploration. Measure exclusions are discussed in more detail in section VIII.A.7.a.(5) of the preamble of this proposed rule below.

We are inviting public comment on our proposal to adopt the Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment (Chole and CDE Payment) measure to the Hospital IQR Program measure set for the FY 2019 payment determination and subsequent years as discussed in this section.

(4) Proposed Spinal Fusion Clinical Episode-Based Payment (SFusion Payment) Measure

(a) Background

Inpatient hospital stays and associated services assessed by the proposed Spinal Fusion Clinical Episode-Based Payment (SFusion Payment) measure have high payments with substantial variation. In CY 2014, Medicare FFS beneficiaries experienced nearly 60,000 spinal fusion episodes triggered by related inpatient stays. Payment-standardized, risk-adjusted episode payment for these episodes (payment for the hospitalization plus the payment for clinically related services in the episode window) totaled over \$2 billion in CY 2014, with a mean episode payment of over \$35,000. There is substantial variation in spinal fusion episode payment—ranging from approximately \$27,000 at the 5th percentile to approximately \$56,000 at the 95th percentile—that is partially driven by variation in postdischarge payment clinically-related to the inpatient hospitalization.<sup>100</sup> These clinically-related postdischarge

<sup>100</sup> Statistics based on Acumen’s testing of episode definition on Medicare FFS population using Medicare Parts A and B claims.

payments may be an indicator of the quality of care provided during the hospitalization. Specifically, higher quality hospital treatment may yield lower postdischarge payment.

#### (b) Overview of Measure

The proposed SFusion Payment measure includes the set of medical services related to a hospital admission for a spinal fusion, including treatment, follow-up, and postacute care. The measure includes five clinical subtypes: (1) Anterior Fusion—Single; (2) Anterior Fusion—2 Levels; (3) Posterior/Posterior-Lateral Approach Fusion—Single; (4) Posterior/Posterior-Lateral Approach Fusion—2 or 3 Levels; and (5) Combined Fusions. The clinical subtypes are included in the measure construction to distinguish relatively homogeneous subpopulations of patients whose health conditions significantly influence the form of treatment and the expected outcomes and risks. The risk adjustment model is estimated separately for each clinical subtype, such that the measure compares observed spending for an episode of a given clinical subtype only to expected spending among episodes of that subtype. A similar measure, the Lumbar Spinal Fusion/Refusion Clinical Episode-Based Payment Measure, was proposed for inclusion in the Hospital IQR Program in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24570–24571). Based on public comment regarding the heterogeneity of the spinal fusion patient population, we decided not to finalize the measure for the Hospital IQR Program at that time (80 FR 49668 through 49674). We have since refined the measure by including more granular subtypes of fusions of the lumbar spine to create more homogenous patient cohorts.

This proposed measure, like the NQF-endorsed MSPB measure (NQF #2158), assesses the payment for services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the "episode window", discussed in more detail below). In contrast to the MSPB measure, however, this measure includes Medicare payments for services during the episode window only if they are clinically related to the spinal fusion procedure that was performed during the index hospital stay.

#### (c) Data Sources

The proposed SFusion Payment measure is a claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized

for spinal fusion. The reporting period for the measure is 1 year (that is, the measure calculation includes eligible episodes occurring within a 1-year timeframe). For example, for the FY 2019 payment determination, the reporting period would be CY 2017.

#### (d) Measure Calculation

The proposed SFusion Payment measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during the episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without need to adjust for inflation. The numerator is the Episode Amount, calculated as the average of the ratios of the observed episode payment over the expected episode payment (as predicted in risk adjustment), multiplied by the average observed episode payment level across all providers nationally. The denominator for a provider's measure is the episode weighted national median of Episode Amounts across all providers. A spinal fusion episode begins 3 days prior to the initial (index) admission and extends 30 days following the discharge from the index hospital stay.

For detailed measure specifications, we refer readers to the clinical episode-based payment measures report entitled, "Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion" available at: <http://www.qualitynet.org> > Hospital-Inpatient > Claims-Based Measures > Episode-Based Payment Measures.

#### (e) Cohort

The proposed SFusion Payment measure cohort includes Medicare FFS beneficiaries hospitalized for spinal fusion. Measure exclusions are discussed in more detail in section VIII.A.7.a.(5) of the preamble of this proposed rule below.

We are inviting public comment on our proposal to adopt the Spinal Fusion Clinical Episode-Based Payment (SFusion Payment) measure to the Hospital IQR Program measure set for the FY 2019 payment determination and subsequent years as discussed in this section.

#### (5) Exclusion Criteria

For a full list of the MS-DRG, procedure, and diagnosis codes used to identify beneficiaries included in the final cohort for each of the proposed episode-based payment measures, we refer readers to the report entitled, "Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion" available at: <http://www.qualitynet.org> > Hospital-Inpatient > Claims-Based Measures > Episode-Based Payment Measures.

Episodes for beneficiaries that meet any of the following criteria are excluded from all three measures: (1) Lack of continuous enrollment in Medicare Part A and Part B from 90 days prior to the episode through the end of the episode with traditional Medicare fee-for-service as the primary payer; (2) Death date during episode window; or (3) Enrollment in Medicare Advantage anytime from 90 days prior to the episode through the end of the episode.

In addition, claims that meet any of the following criteria do not trigger, or open, an episode for all three measures: (1) Claims with data coding errors, including missing date of birth or death dates preceding the date of the trigger event; (2) Claims with standardized payment  $\leq 0$ ; (3) Admissions to hospitals that Medicare does not reimburse through the IPPS system (for example, cancer hospitals, critical access hospitals, hospitals in Maryland); or (4) Transfers (by which a transfer is defined based on the claim discharge code) are not considered index admissions. In other words, these cases do not generate new episodes; neither the hospital that transfers a patient to another hospital, nor the receiving hospital will have an index admission or associated admission attributed to them.

#### (6) Standardization

Standardization, or payment standardization, is the process of adjusting the allowed charge for a Medicare service to facilitate comparisons of resource use across geographic areas. Medicare payments included in these proposed episode-based measures would be standardized according to the standardization methodology previously finalized for the MSPB measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51627). The methodology removes geographic payment differences, such as wage index and geographic practice cost

index, incentive payment adjustments, and other add-on payments that support broader Medicare program goals, such as add-on payments for indirect graduate medical education (IME) and add-ons for serving a disproportionate share of uninsured patients.<sup>101</sup>

#### (7) Risk Adjustment

Risk adjustment uses patient claims history to account for case-mix variation and other factors. The steps used to calculate risk-adjusted payments align with the NQF-endorsed MSPB measure (NQF #2158) method as specified in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51624 through 51626). For more details on the specifications for the risk adjustment employed in the proposed episode-based payment measures, we refer readers to the report entitled, “Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion” available at: <http://www.qualitynet.org> > Hospital-Inpatient > Claims-Based Measures > Episode-Based Payment Measures.

We are inviting public comment on our proposals to add three clinical episode-based payment measures as stated above for the FY 2019 payment determination and subsequent years.

#### b. Proposed Adoption of Excess Days in Acute Care After Hospitalization for Pneumonia (PN Excess Days) Measure

##### (1) Background

Pneumonia is a priority area for outcomes measurement because it is a common condition associated with considerable morbidity, mortality, and healthcare spending. Pneumonia was the third most common principal discharge diagnosis among patients with Medicare in 2011.<sup>102</sup> Pneumonia also accounts for a large fraction of hospitalization costs, and it was the seventh most expensive condition billed to Medicare, accounting for 3.7 percent of the total national costs for all Medicare hospitalizations in 2011.<sup>103</sup>

Some of the costs for pneumonia can be attributed to high acute care

utilization for post-discharge pneumonia patients in the form of readmissions, observation stays, and emergency department (ED) visits. Patients admitted for pneumonia have disproportionately high readmission rates, and that readmission rates following discharge for pneumonia are highly variable across hospitals in the United States.<sup>104 105</sup>

For the previously adopted Hospital IQR Program measure, Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization (NQF #0506) (hereinafter referred to as READM–30–PN) (80 FR 49654 through 49660), publicly reported 30-day risk-standardized readmission rates for pneumonia ranged from 12.9 percent to 24.8 percent for the time period between July 2012 and June 2015.<sup>106</sup> However, during the post-discharge period, patients are not only at risk of requiring readmission. Emergency Department (ED) visits represent a significant proportion of post-discharge acute care utilization. Two recent studies conducted in patients of all ages have shown that 9.5 percent of patients return to the ED within 30 days of hospital discharge and approximately 12 percent of these patients are discharged from the ED, and thus are not captured by the READM–30–PN Measure.<sup>107 108</sup>

In addition, over the past decade, the use of observation stays has rapidly increased. Specifically, between 2001 and 2008, the use of observation services increased nearly three-fold,<sup>109</sup> and significant variation has been demonstrated in the use of observation services.

<sup>104</sup> Lindenaauer PK, Bernheim SM, Grady JN, et al. The performance of US hospitals as reflected in risk-standardized 30-day mortality and readmission rates for medicare beneficiaries with pneumonia. *J Hosp Med.* 2010;5(6):E12–18.

<sup>105</sup> Dharmarajan K, Hsieh AF, Lin Z, et al. Hospital readmission performance and patterns of readmission: retrospective cohort study of Medicare admissions. *BMJ.* 2013;347:f6571.

<sup>106</sup> Dorsey K, Grady J, Desai N, Lindenaauer P, et al. 2016 Condition-Specific Measures Updates and Specifications Report: Hospital-Level Risk-Standardized Readmission Measures for Acute Myocardial Infarction, Heart Failure, and Pneumonia. 2016.

<sup>107</sup> Rising KL, White LF, Fernandez WG, Boutwell AE. Emergency Department Visits After Hospital Discharge: A Missing Part of the Equation. *Annals of Emergency Medicine.* 2013(0).

<sup>108</sup> Vashi AA, Fox JP, Carr BG, et al.: Use of hospital-based acute care among patients recently discharged from the hospital. *JAMA: the journal of the American Medical Association.* Jan 23 2013;309(4):364–371.

<sup>109</sup> Venkatesh AK GB, Gibson Chambers JJ, Baugh CW, Bohan JS, Schuur JD. Use of Observation Care in US Emergency Departments, 2001 to 2008. *PLoS One.* September 2011;6(9):e24326.

Thus, in the context of the previously adopted and publicly reported READM–30–PN measure, the increasing use of ED visits and observation stays has raised concerns that the READM–30–PN measure does not capture the full range of unplanned acute care in the post-discharge period. In particular, some policymakers and stakeholders have expressed concern that high use of observation stays in some cases could replace readmissions, and hospitals with high rates of observation stays in the post-discharge period may therefore have low readmission rates that do not more fully reflect the quality of care.<sup>110</sup>

In response to these concerns, we improved on a previously developed measure, which is not currently part of the Hospital IQR Program measure set, titled, “30-Day Post-Hospital Pneumonia Discharge Care Transition Composite” (NQF #0707—NQF endorsement removed). The improved measure entitled Excess Days in Acute Care after Hospitalization for Pneumonia (PN Excess Days) is a risk-adjusted outcome measure for pneumonia that incorporates the full range of acute care use that patients may experience post-discharge: Hospital readmissions, observation stays, and ED visits. We are proposing this PN Excess Days measure for inclusion in the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

The proposed PN Excess Days measure assesses all-cause acute care utilization for post-discharge pneumonia patients for several reasons. First, from the patient perspective, acute care utilization for any cause is undesirable. It is costly, exposes patients to additional risks of medical care, interferes with work and family care, and imposes significant burden on caregivers. Second, limiting the measure to inpatient utilization may make it susceptible to gaming. Finally, this measure includes all-cause acute care utilization because it is often hard to exclude quality concerns and accountability based on the documented cause of a hospital visit.

Although the original measure was NQF-endorsed, this improved measure has not yet been NQF-endorsed. Section 1886(b)(3)(B)(IX)(bb) 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

<sup>110</sup> Carlson J. Readmissions are down, but observational-status patients are up and that could skew Medicare numbers. *Modern Healthcare.* 2013.

<sup>101</sup> An overview of payment standardization can be found in the “CMS Price (Payment) Standardization—Basics” document available at: <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPages%2FQnetTier4&cid=1228772057350>.

<sup>102</sup> Agency for Healthcare Research and Quality (AHRQ). *Healthcare Cost and Utilization Project (HCUP)* <http://hcupnet.ahrq.gov/>.

<sup>103</sup> Torio CM, Andrews RM. National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2011. HCUP Statistical Brief #160. 2013; <http://hcup-us.ahrq.gov/reports/statbriefs/sb160.jsp>.

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. While we considered other existing measures related to care transitions and post-discharge acute care utilization that have been endorsed by NQF or other consensus organizations, but we were unable to identify any NQF-endorsed (or other consensus organization endorsed) measures that assess the full range of post-discharge acute care use that patients may experience. Existing process measures capture many important domains of care transitions such as education, medication reconciliation, and follow-up, but all require chart review and manual abstraction. Existing outcome measures are focused entirely on readmissions or complications and do not include observation stays or ED visits. We are not aware of any other measures that assess the quality of transitional care by measuring 30-day risk-standardized days in acute care (hospital readmissions, observation stays, and ED visits) following hospitalization for pneumonia that have been endorsed or adopted by a consensus organization, and we have not found any other feasible and practical measures on this topic. However, we note that this measure has been submitted to NQF for endorsement proceedings as part of the All-Cause Admissions and Readmissions project in January 2016.

The proposed PN Excess Days measure was developed in conjunction with the previously adopted Hospital IQR Program measures, Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (AMI Excess Days) (80 FR 49690) and Hospital 30-Day Excess Days in Acute Care after Hospitalization for Heart Failure (HF Excess Days) (80 FR 49690). All three measures assess the same outcome and use the same risk-adjustment methodology. They differ only in the target population and the specific risk variables included.

When we finalized the AMI Excess Days and HF Excess Days measures for the FY 2018 payment determination and subsequent years, stakeholders expressed concern about the interaction between Medicare payment policy regarding admissions spanning two midnights and the AMI Excess Days and HF Excess Days measures (80 FR 49686 through 49687). We continue to believe that the “2-midnight” policy or any changes to such policy will not influence the outcome of Excess Days in Acute Care measures, as all postdischarge days in acute care are

captured whether they are billed as inpatient or outpatient days (80 FR 49686 through 49687).

The proposed PN Excess Days measure (MUC15–391) was included on a publicly available document entitled “2015 Measures Under Consideration List” for December 1, 2015 (available at: <http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367>) and has been reviewed by the NQF Measure Applications Partnership (MAP) Hospital Workgroup. The measure was conditionally supported pending the examination of sociodemographic status (SDS) factors and NQF review and endorsement of the measure update, as referenced in the MAP 2016 Final Recommendations Report (available at: <http://www.qualityforum.org/map/>).<sup>111</sup> We refer readers to section VIII.A.6.a.(1) of the preamble of this proposed rule for a discussion of our policy on SDS factors. As stated above, we note that this measure has been submitted to NQF for endorsement proceedings as part of the All-Cause Admissions and Readmissions project in January 2016.

#### (2) Overview of Measure

The proposed PN Excess Days measure is a risk-standardized outcome measure that compares the number of days that patients, discharged from a hospital for pneumonia, are predicted to spend in acute care across the full spectrum of possible events (hospital readmissions, observation stays, and ED visits) to the days that patients are expected to spend based on their degree of illness as defined using principal diagnosis and comorbidity data from administrative claims.

#### (3) Data Sources

The proposed PN Excess Days measure is claims-based. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized for pneumonia. To determine eligibility for inclusion in the measure, we also use Medicare enrollment data. As proposed, the measure would use 3 years of data. For example, for the FY 2019 payment determination, the reporting period would be July 2014 through June 2017.

#### (4) Outcome

The outcome of the proposed PN Excess Days measure is the excess number of days patients spend in acute care (hospital readmissions, observation stays, and ED visits) per 100 discharges

during the first 30 days after discharge from the hospital, relative to the number spent by the same patients discharged from an average hospital. The measure defines days in acute care as days spent: (1) In an ED; (2) admitted to observation status; or (3) admitted as an unplanned readmission for any cause within 30 days from the date of discharge from the index pneumonia hospitalization. Readmission days are calculated as the discharge date minus the admission date. Admissions that extend beyond the 30-day follow-up period are truncated on day 30. Observation days are calculated by the hours in observation, rounded up to the nearest half day. Based on the recommendation of our technical expert panel convened as part of developing this measure, an ED treat-and-release visit is counted as one half day. ED visits are not counted as a full day because the majority of treat-and-release visits last fewer than 12 hours.

“Planned” readmissions are those planned by providers for anticipated medical treatment or procedures that must be provided in the inpatient setting. This measure excludes planned readmissions using the planned readmission algorithm previously developed for the READM–30–PN measure (78 FR 50786 through 50787). The planned readmission algorithm is a set of criteria for classifying admissions as planned among the general Medicare population using Medicare administrative claims data. The algorithm identifies admissions that are typically planned and may occur within 30 days of discharge from the hospital. The planned readmission algorithm has three fundamental principles: (1) A few specific, limited types of care are always considered planned (transplant surgery, maintenance chemotherapy/immunotherapy, rehabilitation); (2) otherwise, a planned readmission is defined as a non-acute readmission for a scheduled procedure; and (3) admissions for acute illness or for complications of care are never planned. A more detailed discussion of exclusions follows in section VIII.A.7.b.(6) of the preamble of this proposed rule.

The measure counts all use of acute care occurring in the 30-day post-discharge period. For example, if a patient returns to the ED three times, the measure counts each ED visit as a half-day. Similarly, if a patient has two hospitalizations within 30 days, the days spent in each are counted. We take this approach to capture the full patient experience of need for acute care in the post-discharge period.

<sup>111</sup> Spreadsheet of MAP 2016 Final Recommendations Available at: <http://www.qualityforum.org/map/>.

## (5) Cohort

We defined the eligible cohort using the same criteria as the previously adopted Hospital IQR Program measure, READM-30-PN (80 FR 49654 through 49660). The READM-30-PN cohort criteria are included in a report posted on our Measure Methodology Web page, under the “Downloads” section in the “AMI, HF, PN, COPD, and Stroke Readmission Updates” zip file on our Web site at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

The cohort includes Medicare FFS patients aged 65 years or older: (1) With a principal discharge diagnosis of pneumonia, a principal discharge diagnosis of aspiration pneumonia, or a principal discharge diagnosis of sepsis (not including severe sepsis) who also have a secondary diagnosis of pneumonia present on admission; (2) enrolled in Part A and Part B Medicare for the 12 months prior to the date of admission, and enrolled in Part A during the index admission; (3) who were discharged from a non-Federal acute care hospital; (4) who were not transferred to another acute care facility; and (5) who were alive at discharge.

The measure cohort is also harmonized with the previously adopted Hospital IQR Program measure, the MORT-30-PN measure (80 FR 49837), and the proposed refined cohort for the PN Payment measure proposed in section VIII.A.6.a. of the preamble of this proposed rule.

For the ICD-9-CM and ICD-10-CM codes that define the measure development cohort, we refer readers to the “Excess Days in Acute Care after Hospitalization for Pneumonia Version 1.0” in the Pneumonia Excess Days in Acute Care zip file on our Web site at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

## (6) Exclusion Criteria

The proposed PN Excess Days measure excludes the following admissions from the measure cohort: (1) Hospitalizations without at least 30 days of post-discharge enrollment in Part A and Part B FFS Medicare, because the 30-day outcome cannot be assessed in this group since claims data are used to determine whether a patient was readmitted, was placed under observation, or visited the ED; (2) discharged against medical advice, because providers did not have the opportunity to deliver full care and

prepare the patient for discharge; and (3) hospitalizations for patients with an index admission within 30 days of a previous index admission, because additional pneumonia admissions within 30 days are part of the outcome, and we choose not to count a single admission both as an index admission and a readmission for another index admission.

## (7) Risk-Adjustment

The proposed PN Excess Days measure adjusts for variables that are clinically relevant and have strong relationships with the outcome. The measure seeks to adjust for case-mix differences among hospitals based on the clinical status of the patient at the time of the index admission. Accordingly, only comorbidities that convey information about the patient at that time or in the 12 months prior, and not complications that arise during the course of the index hospitalization, are included in the risk adjustment. The measure does not adjust for patients' admission source or their discharge disposition (for example, skilled nursing facility) because these factors are associated with the structure of the healthcare system, not solely patients' clinical comorbidities. Patients' admission source and discharge disposition may be influenced by regional differences in the availability of post-acute care providers and practice patterns. These regional differences might exert undue influence on results. In addition, patients' admission source and discharge disposition are not audited and are not as reliable as diagnosis codes. The proposed PN Excess Days measure uses the same risk-adjustment variables as the READM-30-PN (73 FR 48614).

The outcome is risk adjusted using a two-part random effects model. This statistical model, often referred to as a “hurdle” model, accounts for the structure of the data (patients clustered within hospitals) and the observed distribution of the outcome. Specifically, it models the number of acute care days for each patient as: (1) a probability that they have a non-zero number of days; and (2) a number of days, given that this number is non-zero. The first part is specified as a logit model, and the second part is specified as a Poisson model, with both parts having the same risk-adjustment variables and each part having a random effect. This is an accepted statistical method that explicitly estimates how much of the variation in acute care days is accounted for by patient risk factors, how much by the hospital where the patient is treated, and how much is

explained by neither. This model is used to calculate the predicted (including random effects) and expected (assuming random effects are zero) number of days for each patient. The average difference between the predicted and expected number of days for each patient for each hospital is used to construct the risk-standardized Excess Days in Acute Care. For more details about risk-adjustment for this proposed measure, we refer readers to the “Pneumonia Excess Days in Acute Care” zip file on our Web site at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

## (8) Calculating Excess Acute Care Days

The proposed PN Excess Days measure is calculated as the difference between the average of the predicted number of days spent in acute care for patients discharged from each hospital and the average number of days that would have been expected if those patients had been cared for at an average hospital, and then the difference is multiplied by 100 so that the measure result represents PN Excess Days per 100 discharges. We multiply the final measure by 100 to be consistent with the reporting of the previously adopted READM-30-PN measure that is reported as a rate (that is, a 25 percent rate is equivalent to 25 out of 100 discharges) (80 FR 49654 through 49660), as well as the AMI Excess Days (80 FR 49690) and HF Excess Days (80 FR 49685) measures. A positive result indicates that patients spend more days in acute care post-discharge than expected if admitted to an average performing hospital with a similar case mix; a negative result indicates that patients spend fewer days in acute care than expected if admitted to an average performing hospital with a similar case mix. A negative PN Excess Days measure score reflects better quality.

We are inviting public comment on our proposal to adopt the PN Excess Days measure for the FY 2019 payment determination and subsequent years as described above.

### c. Summary of Previously Adopted and Newly Proposed Hospital IQR Program Measures for the FY 2019 Payment Determination and Subsequent Years

The table below outlines the proposed Hospital IQR Program measure set for the FY 2019 payment determination and subsequent years, and includes both previously adopted measures and measures newly proposed in this proposed rule. Measures proposed for removal in section VIII.A.3.b. of the

preamble of this proposed rule are not included in this chart.

PROPOSED HOSPITAL IQR PROGRAM MEASURE SET FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Short name	Measure name	NQF No.
<b>NHSN</b>		
CAUTI .....	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CDI .....	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset <i>Clostridium difficile</i> Infection (CDI) Outcome Measure.	1717
CLABSI .....	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS—CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
HCP .....	Influenza Vaccination Coverage Among Healthcare Personnel .....	0431
MRSA Bacteremia .....	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) Bacteremia Outcome Measure.	1716
<b>Chart-abstracted</b>		
ED-1 * .....	Median Time from ED Arrival to ED Departure for Admitted ED Patients .....	0495
ED-2 * .....	Admit Decision Time to ED Departure Time for Admitted Patients .....	0497
Imm-2 .....	Influenza Immunization .....	1659
PC-01 * .....	Elective Delivery (Collected in aggregate, submitted via Web-based tool or electronic clinical quality measure).	0469
Sepsis .....	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure) .....	0500
VTE-6 .....	Incidence of Potentially Preventable Venous Thromboembolism .....	+
<b>Claims-based Outcome</b>		
MORT-30-AMI .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT-30-CABG .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
MORT-30-COPD .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
MORT-30-HF .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0229
MORT-30-PN .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
MORT-30-STK .....	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke	N/A
READM-30-AMI .....	Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0505
READM-30-CABG .....	Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2515
READM-30-COPD .....	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1891
READM-30-HF .....	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization.	0330
READM-30-HWR .....	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR) .....	1789
READM-30-PN .....	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization.	0506
READM-30-STK .....	30-Day Risk Standardized Readmission Rate Following Stroke Hospitalization .....	N/A
READM-30-THA/TKA .....	Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1551
AMI Excess Days .....	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction .....	N/A
HF Excess Days .....	Excess Days in Acute Care after Hospitalization for Heart Failure .....	N/A
PN Excess Days** .....	Excess Days in Acute Care after Hospitalization for Pneumonia .....	N/A
Hip/knee complications .....	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
PSI 04 .....	Death Rate among Surgical Inpatients with Serious Treatable Complications .....	0351
PSI 90 .....	Patient Safety for Selected Indicators Composite Measure, Modified PSI 90 (Updated Title: Patient Safety and Adverse Events Composite).	0531
<b>Claims-based Payment</b>		
AMI Payment .....	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	2431
HF Payment .....	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF).	2436
PN Payment .....	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia.	2579



PROPOSED HOSPITAL IQR PROGRAM MEASURE SET FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF No.
THA/TKA Payment .....	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty.	N/A
MSPB .....	Payment-Standardized Medicare Spending Per Beneficiary (MSPB) .....	2158
Cellulitis Payment .....	Cellulitis Clinical Episode-Based Payment Measure .....	N/A
GI Payment .....	Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure .....	N/A
Kidney/UTI Payment .....	Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure .....	N/A
AA Payment** .....	Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure .....	N/A
Chole and CDE Payment** .....	Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure .....	N/A
SFusion Payment** .....	Spinal Fusion Clinical Episode-Based Payment Measure .....	N/A
<b>Electronic Clinical Quality Measures (eCQMs)</b>		
AMI-8a .....	Primary PCI Received Within 90 Minutes of Hospital Arrival .....	0163
CAC-3 .....	Home Management Plan of Care Document Given to Patient/Caregiver .....	+
ED-1 * .....	Median Time from ED Arrival to ED Departure for Admitted ED Patients .....	0495
ED-2 * .....	Admit Decision Time to ED Departure Time for Admitted Patients .....	0497
EHDI-1a .....	Hearing Screening Prior to Hospital Discharge .....	1354
PC-01 * .....	Elective Delivery (Collected in aggregate, submitted via Web-based tool or electronic clinical quality measure).	0469
PC-05 .....	Exclusive Breast Milk Feeding*** .....	0480
STK-02 .....	Discharged on Antithrombotic Therapy .....	0435
STK-03 .....	Anticoagulation Therapy for Atrial Fibrillation/Flutter .....	0436
STK-05 .....	Antithrombotic Therapy by the End of Hospital Day Two .....	0438
STK-06 .....	Discharged on Statin Medication .....	0439
STK-08 .....	Stroke Education .....	+
STK-10 .....	Assessed for Rehabilitation .....	0441
VTE-1 .....	Venous Thromboembolism Prophylaxis .....	0371
VTE-2 .....	Intensive Care Unit Venous Thromboembolism Prophylaxis .....	0372
<b>Patient Survey</b>		
HCAHPS .....	HCAHPS + 3-Item Care Transition Measure (CTM-3) .....	0166 0228
<b>Structural Measures</b>		
Patient Safety Culture .....	Hospital Survey on Patient Safety Culture .....	N/A
Safe Surgery Checklist .....	Safe Surgery Checklist Use .....	N/A

\* Measure listed twice, as both chart-abstracted and electronic clinical quality measure.  
 \*\* Newly proposed measures for the FY 2019 payment determination and for subsequent years.  
 \*\*\* Measure name has been shortened. Please refer to annually updated electronically clinical quality measure specifications on the CMS eCQI Resource Center Page for further information: <https://www.healthit.gov/newsroom/ecqi-resource-center>.  
 + NQF endorsement has been removed.

8. Proposed Changes to Policies on Reporting of eCQMs

For a discussion of our previously finalized eCQMs and policies, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50807 through 50810; 50811 through 50819), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50241 through 50253; 50256 through 50259; and 50273 through 50276), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49692 through 49698; and 49704 through 49709).

We are proposing two changes to our policies with respect to eCQMs reporting to require that hospitals: (1) Submit data for an increased number of eCQMs as further detailed below; and (2) report a full year of data. These proposals are made in conjunction with our proposals in section VIII.A.3.b.(3) of

the preamble of this proposed rule to remove 13 eCQMs from the Hospital IQR Program and proposals in sections VIII.A.10.d. and VIII.E.2.b. of the preamble of this proposed rule to align requirements for the Hospital IQR and the Medicare and Medicaid EHR Incentive Programs.

In addition, we are clarifying that for three measures (ED-1, ED-2, and PC-01), our previously finalized policy that hospitals must submit a full year of chart-abstracted data regardless of whether data also are submitted electronically continues to apply.

a. Proposed Requirement That Hospitals Report on All eCQMs in the Hospital IQR Program Measure Set for the CY 2017 Reporting Period/FY 2019 Payment Determination and Subsequent Years

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49698), we finalized our policy to require hospitals to submit one quarter of data (either Q3 or Q4) for 4 self-selected eCQMs for the CY 2016 reporting period/FY 2018 payment determination by February 28, 2017. Furthermore, in that final rule (80 FR 49694), we signaled our intent to propose increasing the reporting requirement to 16 eCQMs in future rulemaking. In this proposed rule, we are proposing to require reporting of a full calendar year of data for all eCQMs in the Hospital IQR Program measure set

for the CY 2017 reporting period/FY 2019 payment determination and subsequent years.

Requiring hospitals to electronically report a greater number of eCQMs furthers our goal of expanding electronic reporting in the Hospital IQR Program, which we believe will improve patient outcomes by providing more robust data to support quality improvement efforts. As stated above, this proposal is made in conjunction with our proposals in section VIII.A.3.b.(3) of the preamble of this proposed rule to remove thirteen eCQMs from the Hospital IQR Program and proposals in sections VIII.A.10.d. and VIII.E.2.b. of the preamble of this proposed rule to align requirements for the Hospital IQR and the Medicare and Medicaid EHR Incentive Programs. In addition, as discussed in section VIII.A.3.b.(3) of the preamble of this proposed rule, we believe that removing certain eCQMs for which the chart-abstracted versions have been determined to be “topped-out” will reduce certification burden and implementation hurdles, enabling hospitals to focus efforts on successfully implementing a smaller subset of eCQMs. If our proposals to remove 13 eCQMs in section VIII.A.3.b.(3) of the preamble of this proposed rule is finalized as proposed, hospitals would be required to report on a total 15 eCQMs for the CY 2017 reporting period/FY 2019 payment determination. While the number of required eCQMs would increase as compared to that required for the CY 2016 reporting period/FY 2018 payment determination (that is, from 4 to 15 eCQMs), we believe that a coordinated reduction in the overall number of eCQMs (from 28 to 15 eCQMs) in both the Hospital IQR and Medicare and Medicaid EHR Incentive Programs will reduce certification burden on hospitals and improve the quality of reported data by enabling hospitals to focus on a smaller, more specific subset of eCQMs.

In crafting this proposal, we also considered proposing to require a lesser number of eCQMs—that hospitals submit eight of the available eCQMs (that is, in other words, 8 of the proposed 15 eCQMs as discussed above) for the CY 2017 reporting period/FY 2019 payment determination. Specifically, hospitals would submit a full calendar year of data on an annual basis for eight of the available eCQMs whether reporting only for the Hospital IQR Program or if reporting for both the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program for the CY 2017 reporting period/FY 2019 payment determination. Reporting

on all eCQMs in the Hospital IQR Program measure set would begin with the CY 2018 reporting period/FY 2020 payment determination and subsequent years.

Ultimately we chose to propose to require reporting on all the proposed eCQMs for the CY 2017 reporting period/FY 2019 payment determination, because we believe that requiring hospitals to report measures electronically is in line with our goals to move towards eCQM reporting and to align with the Medicare and Medicaid EHR Incentive Programs. We believe that the CY 2017/FY 2019 payment determination is the appropriate time to require eCQM reporting because hospitals have had several years to report data electronically for the Medicare and Medicaid EHR Incentive Programs and Hospital IQR Program (3 years of voluntary reporting and 2 years of reporting as part of a pilot). Based upon data collected by CMS, currently, 95 percent of hospitals attest to successful eCQM reporting under the Medicare and Medicaid EHR Incentive Programs.

#### b. Proposed Requirement That Hospitals Report a Full Year of eCQM Data

In the FY 2016 IPPS/LTCH PPS final rule, we finalized our policy to require hospitals to submit one quarter of data (either Q3 or Q4) for 4 self-selected eCQMs for the CY 2016 reporting period/FY 2018 payment determination by February 28, 2017 (80 FR 49698). As previously stated, we believe that the CY 2017/FY 2019 payment determination is the appropriate time to require eCQM reporting because hospitals have had several years to report data electronically for the Medicare and Medicaid EHR Incentive Programs and for the Hospital IQR Program. As such, we are proposing that for the CY 2017 reporting period/FY 2019 payment determination and subsequent years, hospitals must submit one year’s worth of eCQM data for each required eCQM. For example, for the ED–1 eCQM, hospitals would be required to submit one year of data (covering Q1, Q2, Q3, and Q4), instead of just one quarter of data (either Q3 or Q4) as previously required.

We hope to address stakeholder concerns associated with increasing the number of eCQMs for which reporting will be required proactively by reducing burden on hospitals by aligning data submission deadlines between the Hospital IQR Program and the Medicare EHR Incentive Program. We note that deadlines for the Medicaid EHR Incentive Program differ by State, and therefore our proposal to align data

submission deadlines for eCQMs applies only to the Hospital IQR Program and the Medicare EHR Incentive Program and not to the Medicaid EHR Incentive Program. For more details on Hospital IQR Program reporting requirements and eCQM submission deadlines, we refer readers to section VIII.A.10.d.(5) of the preamble of this proposed rule.

#### c. Clarification Regarding Data Submission for ED–1, ED–2, PC–01, STK–4, VTE–5, and VTE–6

In the FY 2016 IPPS/LTCH PPS final rule, we finalized our policy that hospitals must continue to submit data on ED–1, ED–2, PC–01, STK–4, VTE–5, and VTE–6 via chart abstraction as previously required and that the results would be publicly displayed (80 FR 49695–49698). We also finalized, however, that hospitals may choose to submit electronic data on any of these 6 measures in addition to the chart-abstraction requirements to meet the requirement to report 4 of 28 eCQMs (80 FR 49695–49698). As discussed in section VIII.A.3.b.(3)(a)(ii) of the preamble of this proposed rule, we are proposing to remove the electronic version of the STK–4 measure. As discussed in section VIII.A.3.b.(3)(d) of the preamble of this proposed rule, we are proposing to remove the electronic version of the VTE–5 and VTE–6 measure. Lastly, in section VIII.A.3.b.(2) of the preamble of this proposed rule, we are proposing to remove the chart-abstracted versions of the STK–4 and VTE–5 measures. If these proposals are finalized as proposed, the STK–4 and VTE–5 measures will be completely removed from the Hospital IQR Program measure set, but the VTE–6 measure would continue to be included in its chart-abstracted form.

For the FY 2019 payment determination and subsequent years, we are clarifying that requirements for the chart-abstracted versions of ED–1, ED–2, PC–01, and VTE–6 remain the same as previously finalized. Hospitals must submit a full calendar year of data (covering Q1, Q2, Q3, and Q4) via chart-abstraction regardless of whether data also are submitted electronically in accordance with the applicable submission requirements. However, we note that if our proposal that hospitals submit a full calendar year of eCQM data for each required eCQM is finalized as proposed above, data submission for the chart-abstracted version of these measures will differ from those submitted electronically (quarterly basis for chart-abstracted measures versus annual basis for electronic measures).

We are inviting public comment on our proposals to require that hospitals: (1) Submit data for all eCQMs included in the Hospital IQR Program measure set; and (2) report a full year of data for the CY 2017 reporting period/FY 2019 payment determination and subsequent years, as discussed above.

#### 9. Possible New Quality Measures and Measure Topics for Future Years

We are providing information about new quality measures and measure topics under consideration for future inclusion in the Hospital IQR Program. We are considering to propose in future rulemaking: (1) A refined version of the Stroke Scale for the Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Measure; (2) a new measure, the National Healthcare Safety Network (NHSN) Antimicrobial Use Measure (NQF #2720); and (3) one or more potential measures of behavioral health for the inpatient hospital setting, including measures previously adopted for the IPFQR Program (80 FR 46694), for adoption into the Hospital IQR Program measure set. Also, we are considering public reporting of Hospital IQR Program data stratified by race, ethnicity, sex, and disability on *Hospital Compare*. These topics are further discussed below.

#### a. Potential Inclusion of the National Institutes of Health (NIH) Stroke Scale for the Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Measure Beginning as Early as the FY 2022 Payment Determination

##### (1) Background

Mortality following stroke is an important adverse outcome that can be measured reliably and objectively and is influenced by the quality of care provided to patients during their initial hospitalization; therefore, mortality is an appropriate measure of quality of care following stroke hospitalization.<sup>112 113</sup> Specifically, post-stroke mortality rates have been shown to be influenced by critical aspects of care such as response to complications, speediness of delivery of care, organization of care, and appropriate imaging.<sup>114 115 116 117</sup> Therefore, we are

<sup>112</sup>Weir NU, Sandercock PA, Lewis SC, Signorini DF, Warlow CP. Variations between countries in outcome after stroke in the International Stroke Trial (IST). *Stroke*. Jun 2001;32(6):1370–1377.

<sup>113</sup>DesHarnais SI, Chesney JD, Wroblewski RT, Fleming ST, McMahon LF, Jr. The Risk-Adjusted Mortality Index. A new measure of hospital performance. *Med Care*. Dec 1988;26(12):1129–1148.

<sup>114</sup>Hong KS, Kang DW, Koo JS, et al. Impact of neurological and medical complications on 3-

refining the previously adopted CMS Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) following Acute Ischemic Stroke Hospitalization Measure (hereafter referred to as the Stroke 30-day Mortality Rate) (78 FR 50802) by changing the measure's risk adjustment to include stroke severity. We are considering proposing this refinement to the measure in the future.

The previously adopted Stroke 30-day Mortality Rate (78 FR 50802) includes 42 risk variables, but does not include an assessment of stroke severity. For more details on the measure as currently adopted and implemented, we refer readers to its measure methodology report and measure risk-adjustment statistical model in the AMI, HF, PN, COPD, and Stroke Mortality Update zip file on our Web site at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

In the future, we are considering proposing a refinement to the Stroke 30-day Mortality Rate for several reasons. First, the refined measure would allow for more rigorous risk adjustment by incorporating the NIH Stroke Scale (discussed in more detail below) as an assessment of stroke severity.<sup>118</sup> Second, the inclusion of the NIH Stroke Scale is aligned with and supportive of clinical guidelines, as use of the NIH Stroke Scale to assess stroke severity upon acute ischemic stroke patient presentation is Class I recommended in the American Heart Association and American Stroke Association (AHA/ASA) guidelines.<sup>119</sup> Third, clinicians

month outcomes in acute ischaemic stroke. *European journal of neurology: the official journal of the European Federation of Neurological Societies*. Dec 2008;15(12):1324–1331.

<sup>115</sup>Lingsma HF, Dippel DW, Hoeks SE, et al. Variation between hospitals in patient outcome after stroke is only partly explained by differences in quality of care: results from the Netherlands Stroke Survey. [Reprint in *Ned Tijdschr Geneeskd*. 2008 Sep 27;152(39):2126–32; PMID: 18856030]. *Journal of Neurology, Neurosurgery & Psychiatry*. 2008;79(8):888–894.

<sup>116</sup>Reeves MJ, Smith E, Fonarow G, Hernandez A, Pan W, Schwamm LH. Off-hour admission and in-hospital stroke case fatality in the get with the guidelines-stroke program. *Stroke*. Feb 2009;40(2):569–576.

<sup>117</sup>Smith MA, Liou JI, Frytak JR, Finch MD. 30-day survival and rehospitalization for stroke patients according to physician specialty. *Cerebrovascular diseases (Basel, Switzerland)*. 2006;22(1):21–26.

<sup>118</sup>NIH Stroke Scale. Available at: <http://www.nihstrokescale.org/>.

<sup>119</sup>Jauch EC, Saver JL, Adams HP, Jr., et al. Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. Mar 2013;44(3):870–947.

and stakeholders, including AHA, ASA, and other professional organizations, highlight the importance of including an assessment of stroke severity in risk-adjustment models of stroke mortality. Therefore, the refined Stroke 30-day Mortality Rate is responsive to comments received from the feedback of measure developers during measure development, the Technical Expert Panel, and the NQF endorsement process (78 FR 50802). Fourth, in addition to a modestly higher c-statistic, which evaluates the measure's ability to discriminate or differentiate between high and low performing hospitals, the refined Stroke 30-day Mortality Rate includes a more parsimonious risk model than the publicly reported stroke mortality measure, with a total of 20 risk adjustment variables including the NIH Stroke Scale, compared to the current use of 42 risk adjustment variables.

Initial stroke severity score, such as the NIH Stroke Scale score, is one of the strongest predictors of mortality in ischemic stroke patients,<sup>120 121 122</sup> and is part of the national guidelines on stroke care.<sup>123</sup> The NIH Stroke Scale is a 15-item neurologic examination stroke scale used to provide a quantitative measure of stroke-related neurologic deficit. The NIH Stroke Scale evaluates the effect of acute ischemic stroke on a patient's level of consciousness, language, neglect, visual-field loss, extra-ocular movement, motor strength, ataxia (the loss of full control of bodily movements), dysarthria (difficult or unclear articulation of speech), and sensory loss. The NIH Stroke Scale was designed to be a simple, valid, and reliable tool that can be administered at the bedside consistently by neurologists, physicians, nurses, or therapists. In October 2016, codes for the NIH Stroke Scale are expected to be added to the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD–10). The currently adopted measure covers 3 years of

<sup>120</sup>Fonarow GC, Saver JL, Smith EE, et al. Relationship of national institutes of health stroke scale to 30-day mortality in medicare beneficiaries with acute ischemic stroke. *J Am Heart Assoc*. Feb 2012;1(1):42–50.

<sup>121</sup>Nedeltchev K, Renz N, Karameshev A, et al. Predictors of early mortality after acute ischaemic stroke. *Swiss Medical Weekly*. 2010;140(17–18):254–259.

<sup>122</sup>Smith EE, Shobha N, Dai D, et al. Risk score for in-hospital ischemic stroke mortality derived and validated within the Get With the Guidelines-Stroke Program. *Circulation*. Oct 12 2010;122(15):149615041496–1504.

<sup>123</sup>Jauch EC, Saver JL, Adams HP, Jr., et al. Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. Mar 2013;44(3):870–947.

claims data using administrative claims from July 2011–June 2014. In order to give hospitals time to adjust to reporting the NIH Stroke Scale, we are considering this measure refinement for as early as the July 2017 through June 2020 reporting period (3 years of data), which would correspond to the FY 2022 payment determination in the Hospital IQR Program.

The measure refinement was developed in collaboration with the AHA/ASA. We sought to update the current publicly reported measure to include an assessment of stroke severity at this time, because it has become feasible to do so due to both the increased use of the NIH Stroke Scale related to the AHA/ASA guidelines that recommend administering the NIH Stroke Scale on all stroke patients, as well as due to the upcoming availability to obtain the scores through claims data (incorporation into ICD–10).

The Stroke 30-day Mortality Rate (MUC15–294) with the refined risk adjustment was included on a publicly available document entitled “List of Measures under Consideration for December 1, 2015” with identification number MUC15–294, (available at: <http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367>) and has been reviewed by the MAP. The MAP conditionally supported this measure pending NQF review and endorsement and asked that CMS consider a phased approach in regards to implementation to avoid multiple versions of the same measure.<sup>124</sup> The MAP also noted that mortality is not the most meaningful outcome for stroke patients and to consider cognitive or functional outcomes such as impaired capacity.<sup>125</sup> The Stroke 30-day Mortality Rate with the refined risk adjustment was submitted to NQF for endorsement in the neurology project on January 15, 2016.

## (2) Overview of Measure Change

The measure cohort for the refined measure would not be substantively different from the currently adopted, publicly reported Stroke 30-day Mortality Rate. In addition, the data sources, three-year reporting period, inclusion and exclusion criteria, as well as the assessment of the outcome of mortality would all align with the currently adopted measure.

<sup>124</sup> Spreadsheet of MAP 2016 Final Recommendations Available at: <http://www.qualityforum.org/map/>.

<sup>125</sup> Spreadsheet of MAP 2016 Final Recommendations Available at: <http://www.qualityforum.org/map/>.

## (3) Risk Adjustment

The statistical modeling, measure calculation, and risk-adjustment calculation for this refined measure would align with the currently adopted Stroke 30-day Mortality Rate. However, we reselected risk variables, resulting in a final model with 20 risk-adjustment variables including the NIH Stroke Scale as an assessment of stroke severity. For the full measure specifications of the refined measure, we refer readers to the AMI, HF, PN, COPD, and Stroke Mortality Update zip file on our Web site at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

In summary, we are considering proposing in the future a refinement of the Stroke 30-day Mortality Rate, which would change the risk adjustment to include an assessment of stroke severity, in the Hospital IQR Program for as early as the July 2017–June 2020 reporting period/FY 2022 payment determination and for subsequent years.

We are inviting comments on the possibility of a future proposal of refinements to the previously adopted Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Measure to include the NIH Stroke Scale beginning as early as the FY 2022 payment determination.

## b. Potential Inclusion of National Healthcare Safety Network (NHSN) Antimicrobial Use Measure (NQF #2720)

### (1) Background

The emergence of antibiotic drug resistance is a clinical and public health problem that threatens the effective prevention and treatment of bacterial infections. The CDC estimates that each year at least two million people become infected with bacteria that are resistant to antibiotics, and at least 23,000 people die as a direct result of these drug-resistant bacterial infections. In addition, antibiotic resistance contributes an estimated \$20 billion in excess direct healthcare costs.<sup>126</sup>

In order to promote the efficiency and coordination of efforts to detect, prevent, and control antibiotic resistance, HHS announced in 2015 the establishment of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council).<sup>127</sup> The Advisory Council

<sup>126</sup> Centers for Disease Control and Prevention. Antibiotic Resistance Threats in the United States, 2013. Available from: <http://www.cdc.gov/drugresistance/threat-report-2013/>.

<sup>127</sup> Centers for Disease Control and Prevention. Presidential Advisory Council on Combating

makes recommendations to the Secretary regarding policies to support the implementation of the National Strategy for Combating Antibiotic-Resistant Bacteria<sup>128</sup> and the National Action Plan for Combating Antibiotic-Resistant Bacteria.<sup>129</sup> Evidence is accumulating that programs dedicated to optimizing inpatient antibiotic use, known as antimicrobial stewardship programs (ASPs), may slow the emergence of antibiotic resistance and improve appropriateness of antimicrobial use and patient outcomes.<sup>130 131 132</sup> Therefore, the CDC and several professional societies have published guidelines and resources to support hospitals in implementing antimicrobial stewardship programs.<sup>133</sup>

In the future, we are considering proposing the NHSN Antimicrobial Use measure to advance national efforts to reduce the emergence of antibiotic resistance by enabling hospitals and CMS to assess national trends of antibiotic use to facilitate improved stewardship by comparing antibiotic use that hospitals report to antibiotic use that is predicted based on nationally aggregated data. The measure was included on a publicly available document entitled “List of Measures Under Consideration for December 1, 2015,”<sup>134</sup> in compliance with section 1890A(a)(2) of the Act. The measure received conditional support, pending CDC recommendation that the measure is ready for use in public reporting as referenced in the MAP 2016 Final

Antibiotic-Resistant Bacteria. Available from: <http://www.hhs.gov/ash/carb/index.html>.

<sup>128</sup> National Strategy for Combating Antibiotic-Resistant Bacteria, 2014. Available from: [https://www.whitehouse.gov/sites/default/files/docs/carb\\_national\\_strategy.pdf](https://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf).

<sup>129</sup> National Action Plan for Combating Antibiotic-Resistant Bacteria, 2015. Available from: [https://www.whitehouse.gov/sites/default/files/docs/national\\_action\\_plan\\_for\\_combating\\_antibiotic-resistant\\_bacteria.pdf](https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf).

<sup>130</sup> Davey P, Brown E, Charani E, Fenelon L, Gould IM, Holmes A, et al. Interventions to improve antibiotic prescribing practices for hospital inpatients. *Cochrane Database Syst Rev*. 2013;4:CD003543.

<sup>131</sup> Feazel LM, Malhotra A, Perencevich EN, Kaboli P, Diekema DJ, Schweizer ML. Effect of antibiotic stewardship programmes on Clostridium difficile incidence: a systematic review and meta-analysis. *J Antimicrob Chemother*. 2014;69(7):1748–54. <http://jac.oxfordjournals.org/content/69/7/1748.full.pdf>.

<sup>132</sup> Kaki R, Ellingsen M, Walker S, Simor A, Palmay L, Daneman N. Impact of antimicrobial stewardship in critical care: a systematic review. *J Antimicrob Chemother*. 2011;66(6):1223–30.

<sup>133</sup> Centers for Disease Control and Prevention. Core Elements of Hospital Antibiotic Stewardship Programs. Available from: <http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html>.

<sup>134</sup> 2015 Measures Under Consideration List Available at: <http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367>.

Recommendations.<sup>135</sup> The MAP recognized the high importance of antimicrobial stewardship and conditionally supported the inclusion of this measure in the Hospital IQR Program while acknowledging that additional testing may be necessary to address feasibility issues for public reporting, quality implications of measuring the amount of antibiotics used versus appropriate use of antibiotics, and risk-adjustment. Further, MAP noted these issues should be addressed before the measure is reported on *Hospital Compare*.<sup>136</sup> The measure received endorsement from NQF on December 10, 2015.<sup>137</sup>

## (2) Overview of Measure

The NHSN Antimicrobial Use measure assesses antibiotic use in hospitals based on medication administration data that hospitals collect electronically at the point of care. The measure compares antibiotic use that hospitals report, via electronic file submissions to the CDC's NHSN, to antibiotic use that is predicted based on nationally aggregated data. Data on administered antibiotics are required to be extracted from an electronic medication administration record (eMAR)<sup>138</sup> and/or bar coded medication administration (BCMA) system.<sup>139</sup> The antibiotic use data that are in scope for this measure include antibiotic agents administered to adult and pediatric patients in a specified set of ward and intensive care unit (ICU) locations. Locations include adult and pediatric medical, medical/surgical, and surgical wards and adult and pediatric medical, medical/surgical, and surgical ICUs as defined by the NHSN at: [http://www.cdc.gov/nhsn/PDFs/pscManual/15LocationsDescriptions\\_current.pdf](http://www.cdc.gov/nhsn/PDFs/pscManual/15LocationsDescriptions_current.pdf).

The measure is comprised of a discrete set of risk-adjusted summary ratios, known as Standardized Antimicrobial Administration Ratios (SAARS), which summarize observed-

to-predicted antibacterial use for one of sixteen antibiotic agent-patient care location combinations. The specific antibiotic agent-location combinations were selected based on extensive consultation with infectious disease physicians and pharmacists at the forefront of ASPs. The specified categories of antibiotic agents include:

- Broad spectrum agents predominantly used for hospital-onset/multi-drug resistant bacteria;
- Broad spectrum agents predominantly used for community-acquired infection;
- Anti-MRSA agents; and
- Agents predominantly used for surgical site infection prophylaxis.

The SAARS are designed to serve as high value targets or high-level indicators for hospital ASPs to assess hospital antimicrobial use. A SAAR that is not significantly different from 1.0 indicates "expected" antibiotic use. A SAAR that is above 1.0 may indicate excessive antibiotic use or a SAAR that is below 1.0 may indicate antibiotic underuse. We note that the SAARS do not provide a definitive indication of antibiotic appropriateness of use. Outlier SAAR values should prompt hospitals to do further analysis to assess overuse, underuse, or inappropriate use of antibacterial medications. In addition, the SAARS may be used by hospital ASPs to identify opportunities to improve antibiotic use and gauge the impact of stewardship efforts.

## (3) Data Sources

The data submission and reporting standard procedures for the NHSN Antimicrobial Use measure have been set forth by the CDC for NHSN participation, in general, and for submission of measure data. We refer readers to the CDC's NHSN Web site (<http://www.cdc.gov/nhsn>) for detailed data submission and reporting procedures. Although the NHSN Antimicrobial Use measure is not specified as an eCQM, manual data entry is not available. Data must be electronically extracted from an eMAR<sup>140</sup> and/or BCMA system.<sup>141</sup> The format for data submission must adhere to the data format prescribed by the CDC

HL7 Clinical Data Architecture (CDA) Implementation Guide available at: <http://www.cdc.gov/nhsn/cdaportal/toolkits/guidetocdaversions.html>.

## (4) Measure Calculation

Each SAAR is an observed to expected ratio and is calculated by dividing the numerator, or total number of observed antimicrobial days (days of therapy reported by a healthcare facility for a specified category of antimicrobial agents in a specified patient care location or group of locations), by the denominator, or expected (predicted on the basis of nationally aggregated AU data for a healthcare facility's use of a specified category of antimicrobial agents in a specified patient care location or group of locations) number of antimicrobial days, for each antibiotic agent category-patient care location combination. The total number of observed antimicrobial days for each patient care location is defined as the aggregated sum of days for which any amount of a specific antibiotic agent within an antibiotic agent category was administered as documented in the eMAR or BCMA system. The predicted number of antimicrobial days for each patient care location is determined by multiplying the observed days present by the corresponding antimicrobial use rate in the standard population obtained from the relevant regression model. Hospital patient care locations other than adult and pediatric medical, medical/surgical, and surgical wards and adult and pediatric medical, medical/surgical, and surgical ICUs are excluded from this measure. For more information regarding the specifications for the Antimicrobial Use measure, we refer readers to the NHSN Antimicrobial Use and Resistance Module (AUR): <http://www.cdc.gov/nhsn/PDFs/pscManual/11pscAURcurrent.pdf>.

We are inviting public comment on the possibility of future inclusion of the NHSN Antimicrobial Use Measure (NQF #2720).

## c. Potential Measures for Behavioral Health in the Hospital IQR Program

Although the IPFQR Program incorporates measures of inpatient psychiatric treatment (80 FR 46694), the Hospital IQR Program does not include any measures directly related to behavioral health. Based on MedPAC analyses, over a third of Medicare inpatient psychiatric admissions are treated "in acute care hospital beds not within distinct-part psychiatric units."<sup>142</sup> Thus, there may be a gap in

<sup>142</sup> Medicare Payment Advisory Commission (U.S.). (2010). MedPAC June 2010 Report to the

<sup>135</sup> Spreadsheet of MAP 2016 Final Recommendations Available at: <http://www.qualityforum.org/map/>.

<sup>136</sup> Spreadsheet of MAP 2016 Final Recommendations Available at: <http://www.qualityforum.org/map/>.

<sup>137</sup> <http://www.qualityforum.org/QPS/2720>.

<sup>138</sup> eMAR is defined as technology that automatically documents the administration of medication into CEHRT using electronic tracking sensors (for example, radio frequency identification (RFID)) or electronically readable tagging such as bar coding (77 FR 54034).

<sup>139</sup> Barcode Medication Administration (BCMA) System is defined as a system that allows users to electronically document medications at the bedside or other points-of-care using an electronically readable format. More information. Available at: <http://www.ahrq.gov/downloads/pub/advances/vol3/wideman.pdf>.

<sup>140</sup> eMAR is defined as technology that automatically documents the administration of medication into CEHRT using electronic tracking sensors (for example, radio frequency identification (RFID)) or electronically readable tagging such as bar coding (77 FR 54034).

<sup>141</sup> Barcode Medication Administration (BCMA) System is defined as a system that allows users to electronically document medications at the bedside or other points-of-care using an electronically readable format. More information available at: <http://www.ahrq.gov/downloads/pub/advances/vol3/wideman.pdf>.

understanding the quality of care given to inpatient psychiatric patients not paid for under the IPFQR Program.

To address this gap, we are inviting public comments on potential behavioral health quality measures appropriate to include in the Hospital IQR Program in future years, including the possible use of one or more measures previously adopted in the IPFQR Program (80 FR 46417).

d. Potential Public Reporting of Quality Measures Data Stratified by Race, Ethnicity, Sex, and Disability and Future Hospital Quality Measures That Incorporate Health Equity

We are seeking comment on the possibility of including Hospital IQR Program measure data stratified by race, ethnicity, sex, and disability on *Hospital Compare*, if feasible and appropriate (that is, statistically appropriate, etc.) in the future. By stratification, we mean that we would report quality measures for each group of a given category (age, race, sex, and disability status). For example, if we were to report the Hospital-Wide All-Cause Unplanned Readmission Measure (HWR) (NQF #1789) stratified by sex, we would report a hospital's measure result for females and then again separately for males, in addition to reporting a hospital's unstratified rate, as is currently displayed.

In addition, we are also seeking comment on potential hospital quality measures, including composite measures, for inclusion in the Hospital IQR Program measure set and thus, future postings on *Hospital Compare*, that could help consumers and stakeholders not only assess the measurement of the quality of care furnished by hospitals in inpatient settings, but also monitor trends in health equity.

Any data pertaining to these areas that are recommended for collection through measure reporting for the Hospital IQR Program and public disclosure on *Hospital Compare*, would be addressed through a separate and future notice-and-comment rulemaking.

We are inviting public comment on the possibility of future inclusion of stratified quality measures data on *Hospital Compare* and on stratification categories, including any categories not specified in this preamble. We are also seeking comment on potential future hospital quality measures that incorporate health equity.

10. Form, Manner, and Timing of Quality Data Submission

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (b)(3)(B)(viii)(II) of the Act state that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced 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 data required to be submitted on measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. Previously, the applicable percentage increase for FY 2007 and each subsequent fiscal year until FY 2015 was reduced by 2.0 percentage points for subsection (d) hospitals failing to submit data in accordance with the description above. In accordance with the statute, the FY 2016 payment determination began the second year that the Hospital IQR Program will reduce the applicable percentage increase by one-quarter of such applicable percentage increase.

In order to participate in the Hospital IQR Program, hospitals must meet specific procedural, data collection, submission, and validation requirements. For each Hospital IQR Program payment determination, we require that hospitals submit data on each specified 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 must register and submit quality data through the secure portion of the QualityNet Web site. There are safeguards in place in accordance with the HIPAA Security Rule to protect patient information submitted through this Web site.

b. Procedural Requirements for the FY 2019 Payment Determination and Subsequent Years

The Hospital IQR Program's procedural requirements are codified in regulation at 42 CFR 412.140. We refer readers to these codified regulations for participation requirements, as further explained by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50810 through 50811). In this proposed rule, we are not proposing any changes to these procedural requirements.

However, as discussed below in section VIII.A.11. of the preamble of this proposed rule, we are proposing to amend § 412.140(d)(2) in connection

with our proposal to modify our validation processes beginning with the FY 2020 payment determination.

c. Data Submission Requirements for Chart-Abstracted Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536 through 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures. In this proposed rule, we are not proposing any changes to the data submission requirements for chart-abstracted measures.

d. Proposed Alignment of the Hospital IQR Program With the Medicare and Medicaid EHR Incentive Programs for Eligible Hospitals and CAHs

(1) Background

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49709) for our policies aligning eCQM data reporting and submission periods on a calendar year basis for both the Medicare EHR Incentive Program for eligible hospitals and CAHs and the Hospital IQR Program for the FY 2017 payment determination and subsequent years for the Hospital IQR Program.

In this section, we are proposing the following changes to the Hospital IQR Program to further align eCQM data reporting for the Hospital IQR Program with the Medicare and Medicaid EHR Incentive Programs: (1) Maintaining the eCQM data certification process we previously adopted for the FY 2018 payment determination, including requiring hospitals to report eCQM data using either the 2014 or 2015 Edition of the Office of the National Coordinator for Health Information Technology's (ONC's) certified electronic health record technology (CEHRT) for the CY 2017 reporting period/FY 2019 payment determination; and (2) requiring the use of the 2015 Edition of CEHRT beginning with the CY 2018 reporting period/FY 2020 payment determination and subsequent years.

In addition, we are proposing to require eCQM data submission by the end of 2 months following the close of the reporting period calendar year for the CY 2017 reporting period/FY 2019 payment determination and subsequent years to further align eCQM data reporting for the Hospital IQR Program with the Medicare EHR Incentive Program. These proposals are discussed in more detail below.

(2) Proposed Continuation of eCQM Certification Processes for the FY 2019 Payment Determination and Proposals for Subsequent Years

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708), we finalized policies regarding eCQM certification for the FY 2018 payment determination. Specifically, we finalized that: (1) Hospitals can report using either the 2014 or 2015 Edition of CEHRT for the CY 2016 reporting period/FY 2018 payment determination since certification to the 2015 Edition is expected to be available in 2016; and (2) hospitals must submit eCQM data via Quality Reporting Document Architecture (QRDA) Category I file (80 FR 49707–49708). In addition, hospitals may use third parties to submit QRDA I files on their behalf (80 FR 49706) and can either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I (80 FR 49706).

We are proposing to continue these eCQM certification policies. Specifically, for the CY 2017 reporting period/FY 2019 payment determination (not subsequent years), we are proposing to require that hospitals report using either the 2014 or 2015 Edition of CEHRT as previously required. We note that we are proposing to change these policies, however, for the CY 2018 reporting period/FY 2020 payment determination as discussed in the following section.

In addition, for the CY 2017 reporting period/FY 2019 payment determination and subsequent years, we are proposing that hospitals: (1) Must submit eCQM data via QRDA I files as previously required; (2) may continue to use a third party to submit QRDA I files on their behalf; and (3) continue to either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I. This would align the Hospital IQR Program with the Medicare EHR Incentive Program. We refer readers to section VIII.E.2.c. of the preamble of this proposed rule for discussion of the proposed certification requirements for the Medicare EHR Incentive Program.

We are inviting comment on these proposals. In addition, we refer readers to section VIII.A.11.b.(4) of the preamble of this proposed rule where we encourage hospitals to take advantage of eCQM pre-submission testing tools to

help reduce submission errors related to improperly formatted QRDA I files.

(3) Proposed Required Use of EHR Technology Certified to the 2015 Edition for the FY 2020 Payment Determination and Subsequent Years

As stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705), some commenters requested that hospitals be given the opportunity to use the most recent version of the CEHRT (2015 Edition) for the CY 2016 reporting period/FY 2018 payment determination if they are able. We believe this requirement will mitigate the existing vendor issue of system comparability between hospitals and vendors and facilitate consistency regarding the version of CEHRT to which vendors are certified by establishing uniformity in the version of the product used. Therefore, we are proposing to require the use of EHR technology certified to the 2015 Edition beginning with the CY 2018 reporting period for the FY 2020 payment determination and subsequent years. This would align the Hospital IQR Program with the Medicare EHR Incentive Program. We refer readers to section VIII.E.2.c. of the preamble of this proposed rule for discussion of the proposed certification requirements for the Medicare EHR Incentive Program.

We are inviting public comment on our proposal to require the use of EHR technology certified to the 2015 Edition for the CY 2018 reporting period/FY 2020 payment determination and subsequent years as stated above.

(4) Proposed Electronic Submission Deadlines for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) for our previously adopted policies to align eCQM data reporting and submission periods for both the Medicare EHR Incentive Program for eligible hospitals and CAHs and the Hospital IQR Program for the FY 2018 payment determination.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50249 through 50252), we finalized our policy that hospitals may voluntarily report 16 electronic measures by submitting one quarter of eCQM data from CY Q1 (January 1-March 31, 2015), CY Q2 (April 1-June 30, 2015), or CY Q3 (July 1-September 30) by November 30, 2015. In the FY

2016 IPPS/LTCH PPS final rule (80 FR 49693 through 49698), for the FY 2018 payment determination, we finalized a policy that hospitals must submit one quarter of data (either Q3 or Q4 of CY 2016) for at least 4 eCQMs by the submission deadline of February 28, 2017.

In this year's proposed rule, in order to align the Hospital IQR Program eCQM data submission deadline with that of the Medicare EHR Incentive Program, which requires eCQM data submission by the end of two months following the close of the reporting period calendar year (80 FR 62896 through 62897), we are proposing to establish an eCQM submission deadline for the Hospital IQR Program which requires eCQM data submission by the end of two months following the close of the calendar year for the CY 2017 reporting period/FY 2019 payment determination and subsequent years. For example, for the CY 2017 reporting period/FY 2019 payment determination, hospitals would be required to submit eCQM data for the Hospital IQR Program by February 28, 2018, which is the end of 2 months following the close of the calendar year (December 31, 2017). This would align the Hospital IQR Program with the Medicare EHR Incentive Program deadlines. We note that deadlines for the Medicaid (not Medicare) EHR Incentive Program differ by State, and therefore our proposal to align data submission deadlines for eCQMs applies only to the Hospital IQR Program and the Medicare EHR Incentive Program and not to the Medicaid EHR Incentive Program. For more information about the Medicaid EHR Incentive Program for eligible hospitals and CAHs, we refer readers to: [https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Eligible\\_Hospital\\_Information.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Eligible_Hospital_Information.html).

We are inviting public comment on our proposal to align the Hospital IQR Program eCQM submission deadline with that of the Medicare EHR Incentive Program for the CY 2017 reporting period/FY 2019 payment determination and subsequent years as discussed above.

(5) Summary of Alignment

We are proposing to align the Hospital IQR Program with the Medicare and Medicaid EHR Incentive Programs as summarized below:

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#### Alignment of Hospital IQR Program with both the Medicare and Medicaid EHR Incentive Programs

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- Proposed removal of 13 eCQMs
- Proposed requirement for submission of all available eCQMs

## Alignment of Hospital IQR Program with both the Medicare and Medicaid EHR Incentive Programs

- Proposed requirement for annual submission of four quarters of eCQM data
- Proposed continued use of 2014 or 2015 CEHRT for CY 2017 reporting period/FY2019 payment determination
- Proposed use of 2015 CEHRT for CY 2018 reporting period/FY2020 payment determination

## Alignment of Hospital IQR Program with only the Medicare EHR Incentive Program

- Proposed submission of eCQM data 2 months following the close of the calendar year

## e. Sampling and Case Thresholds for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 24588), we revised our sampling and case thresholds policy so that, for the FY 2018 payment determination and subsequent years, hospitals will be required to submit population and sample size data only for those measures that a hospital submits as chart-abstracted measures under the Hospital IQR Program.

We are not proposing any changes to our sampling and case thresholds policy in this proposed rule.

## f. HCAHPS Requirements for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 through 50820) for details on previously-adopted HCAHPS requirements. We also refer hospitals and HCAHPS survey vendors to the official HCAHPS Web site at <http://www.hcahpsonline.org> for new information and program updates regarding the HCAHPS Survey, its administration, oversight, and data adjustments. In this proposed rule, we are not proposing any changes to the HCAHPS requirements.

## g. Data Submission Requirements for Structural Measures for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 through 51644) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53538 through 53539) for details on the data

submission requirements for structural measures. In this proposed rule, we are not proposing any changes to data submission requirements for structural measures.

## h. Data Submission and Reporting Requirements for HAI Measures Reported via NHSN

For details on the data submission and reporting requirements for HAI measures reported via the CDC's NHSN Web site, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51629 through 51633; 51644 through 51645), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50821 through 50822), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50259 through 50262). The data submission deadlines are posted on the QualityNet Web site at: <http://www.QualityNet.org/>. In this proposed rule, we are not proposing any changes to data submission and reporting requirements for HAI measures reported via the NHSN.

## 11. Proposed Modifications to the Existing Processes for Validation of Hospital IQR Program Data

## a. Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), we finalized the processes and procedures for validation of chart-abstracted measures in the Hospital IQR Program for the FY 2015 payment determination and subsequent years; the FY 2013 IPPS/LTCH PPS final rule also contains a comprehensive summary of all procedures finalized in previous years that are still in effect. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50835), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50262 through 50273), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49710 through 49712) for detailed information on the modifications to these processes finalized for the FY 2016, FY 2017, and FY 2018 payment determinations and subsequent years.

In this proposed rule, we are proposing to update the validation process in order to incorporate a process for validating eCQM data.

## b. Proposed Modifications to the Existing Processes for Validation of Hospital IQR Program Data

## (1) Background

In this proposed rule, we are proposing to update the existing process for validation of Hospital IQR Program data, which has previously included up to 600 hospitals for chart-abstracted validation, to also include eCQM validation of up to 200 hospitals, for a total of up to 800 hospitals for validation for the FY 2020 payment determination and subsequent years. Specifically, 200 hospitals would be randomly selected for eCQM validation but among those hospitals some may be granted Extraordinary Circumstances Exception (ECE) waivers or meet other exclusion criteria (discussed in additional detail below) potentially resulting in a number totaling less than 200 hospitals that actually participate in eCQM validation. Furthermore, we are proposing that hospitals would be required to submit timely and complete medical record information from the Electronic Health Records (EHR) for at least 75 percent of sampled records, but would not be scored on the basis of measure accuracy for FY 2020 payment determinations.

As we stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53555), determining the equivalence of eCQM data and chart-abstracted measures data requires extensive testing given that the data for the Hospital IQR Program support public reporting for both the Hospital IQR and the Hospital VBP Programs; in addition, for the Hospital VBP Program, the data are used to calculate hospitals' performance on a subset of measures which tie payment directly to measure performance. As described in the Hospital IQR Program discussion in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50258), we have received anecdotal comments about performance level differences between chart-abstracted and eCQM data. We stated that we did not have sufficient data to be able to confirm or refute the accuracy of those comments (79 FR 50258). In order to substantiate or refute the existence of performance-level differences between eCQM data and



chart-abstracted measure data, we believe that we must collect more eCQM data and develop a process for validating the accuracy of that data.

As a result, we conducted a validation pilot test for eCQMs (discussed below). Our findings from this pilot test have informed what we believe the initial future direction of eCQM validation in the Hospital IQR Program should be. In this proposed rule, we are proposing to adopt a validation process for eCQM data submissions beginning in spring of CY 2018, as further explained below.

(2) Validation Pilot Test

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50269 through 50273), we finalized a proposal to conduct a validation pilot test for eCQMs in FY 2015. The results of the pilot test yielded measure record matching rates (that is, the rates of medical record abstracted values as compared to the values reported in the QRDA I file) of less than 50 percent for all of the measures reported. For all measures, the inconsistencies between abstracted values and values reported in the QRDA I files appear to be mainly due to missing data rather than actual differences in reported versus abstracted values. The highest rate of accuracy was 48 percent on both the STK-04 and VTE-1 eCQM measures. In addition, all of the participating hospitals demonstrated significant difficulty in reporting the ED-1 and ED-2 eCQM measures due to the ED Admit Date/Time data element, which contributed to the ED measure mismatch rates. Specifically, hospitals systematically reported a later date and time for the decision to admit a patient to the hospital in the QRDA I file than that identified by the Clinical Data Abstraction Center (CDAC) in the review of the medical record.

Follow-up interviews conducted by CDAC revealed that low accuracy rates

and reporting difficulties were a result of a lack of targeted outreach and education efforts at the time of the pilot to adequately prepare participating hospitals for the specific reporting mechanisms. In order to improve data accuracy and diminish reporting difficulties, the CMS Outreach and Education contractor (EOC) as well as the Validation Support Contractor (VSC) plan to continue to conduct provider education follow-up and refine the validation process. We will work in conjunction with the EOC and VSC to enlarge the cohort of eligible hospitals that are able to successfully submit QRDA I files, as well as encourage hospitals that were not able to successfully submit QRDA I files to participate in follow-up interviews. These follow-up interviews will inform the eCQM validation process moving forward, and allow us to derive “best reporting practices” to consider once we begin scoring the measures.

(3) Proposal To Validate eCQMs Beginning Spring CY 2018/FY 2020 Payment Determination

In response to the findings of the pilot test and in light of our proposal to increase the number of eCQMs on which hospitals are required to submit data for the Hospital IQR Program in section VIII.A.8.a. of the preamble of this proposed rule, we believe that it is increasingly important to validate eCQM data to ensure the accuracy of future information submitted by hospitals and reported to the public. Therefore, we are proposing to adopt a validation process for eCQM data submissions beginning in spring of CY 2018, as further explained below.

(a) Number and Selection of Hospitals

We are proposing to validate eCQM data submitted by up to 200 hospitals selected via random sample. Furthermore, we are proposing that the

following hospitals be excluded from this random sample of 200 hospitals selected for eCQM validation:

- Any hospital selected for chart-abstracted measure validation; and
- Any hospital that has been granted a Hospital IQR Program “Extraordinary Circumstances Exemption” for the applicable eCQM reporting period.

We acknowledge that the burden associated with both the chart-abstracted and eCQM validation processes would be significant. We do not intend to impose an undue burden on any hospital by requiring that it be subject to more than one of these processes in a program year. Thus, if a hospital is selected for chart-abstracted targeted or random validation, we are proposing that hospital would be excluded from the eCQM validation sample.

In addition, although our targeted criteria permit that a hospital may be selected for chart-abstracted validation even if it has been granted an Extraordinary Circumstances Exemption with respect to one or more chart-abstracted measures for the applicable data collection period (77 FR 53552 through 53553), if a hospital is granted an Extraordinary Circumstances Exemption with respect to eCQM reporting for the applicable eCQM reporting period, we are proposing that the hospital would be excluded from the eCQM validation sample due to its inability to supply data for validation. We note that due to these proposed exclusions, the total number of hospitals validated for eCQMs might be less than 200.

Adding the proposed eCQM validation would result in a total of 800 hospitals in the validation process, as described in the below tables.

Current Validation Process Number of Hospitals		Proposed Validation Process Number of Hospitals	
Chart-Abstracted Random .....	400	Chart-Abstracted Random .....	400
Chart-Abstracted Targeted .....	200	Chart-Abstracted Targeted .....	200
		eCQM: random .....	200
Total .....	600	.....	800

We believe that as we expand the required reporting of eCQMs in the Hospital IQR Program, we need to validate eCQM data to ensure the accuracy of information submitted by hospitals and reported to the public, as well as for future consideration of eCQMs for potential use in the Hospital VBP Program. In addition, during the

first round of eCQM validation, we could better assess strategies to offset the resources required to conduct a scored method of eCQM validation for future rulemaking cycles.

We are inviting public comment on our proposals for the FY 2020 payment determination and subsequent years to:

- (1) Validate eCQM data submitted by up

to 200 hospitals selected via random sample; and (2) to exclude any hospital selected for chart-abstracted measure validation as well as any hospital that has been granted a Hospital IQR Program “Extraordinary Circumstances Exemption” for the applicable eCQM reporting period as discussed above.

**(b) Number of Cases**

We are proposing to randomly select 32 cases (individual patient-level reports) from the QRDA I file submitted per hospital selected for eCQM validation. Each randomly selected case (individual patient-level report) contains eCQM data elements<sup>143</sup> for one patient for one or more eCQMs available in the program's eCQM measure set. The CDAC would then request that each of the selected hospitals submit patient medical record data for each of their 32 randomly selected cases (transmitted by the hospital to the Clinical Data Warehouse) within 30 days of the medical records request date. We refer readers to our discussion in section VIII.A.11.b.(3)(c) of the preamble of this proposed rule, below, for more information on our proposed submission requirements.

Based on the statistical properties of estimates as discussed below, we believe that a sample size of 32 cases is necessary to assess hospital performance on eCQMs. More specifically, at the individual hospital level, if we assume the average agreement rate between the QRDA I file data and data abstracted from the patient medical record is around 90 percent, and we want the hospital's confidence interval to vary by no more than plus or minus 10 percentage points (80 to 100 percent), then we need to select at least 32 cases per year. Also, 32 cases aligns with the number of cases currently selected for chart-abstracted validation of clinical process of care measures. We currently select eight cases per quarter per hospital, which equates to 32 cases annually (79 FR 50264).

We are inviting public comment on our proposal to randomly select 32 cases from the QRDA I file submitted per hospital selected for eCQM validation for the FY 2020 payment determination and subsequent years as discussed above.

**(c) Submission Requirements**

We are proposing to require hospitals selected for eCQM validation to submit timely and complete medical record information to CMS on eCQMs selected for the validation sample. These are defined below.

<sup>143</sup> A data element is a representation of a clinical concept that represents a patient state or attribute. This may be a diagnosis, lab value, sex, etc., which is encoded using standardized terminologies. The e-specifications for an eCQM include the data elements, logic, and definitions for that measure, available from: [https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Electronic\\_Reporting\\_Spec.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Electronic_Reporting_Spec.html).

Consistent with the Hospital IQR Program chart-abstracted and NHSN validation submission deadline, which is 30 calendar days following the medical records request date listed on the CDAC request form (76 FR 51645), we are proposing to require eCQM validation submission by 30 calendar days following the medical records request date listed on the CDAC request form for the FY 2020 payment determination and subsequent years. Also, we are proposing to require sufficient patient level information (defined below) necessary to match the requested medical record to the original Hospital IQR Program submitted eCQM measure data record for the FY 2020 payment determination and subsequent years. Sufficient patient level information is defined as the entire medical record that sufficiently documents the eCQM measure data elements, which would include but would not be limited to, patient arrival date and time, inpatient admission date, and discharge date from inpatient episode of care. Lastly, we are proposing that, if selected as part of the random sample for eCQM validation, a hospital would be required to submit records in PDF file format through QualityNet using the Secure File Transfer (SFT) for the FY 2020 payment determination and subsequent years. The data submission deadlines and additional details about the eCQM validation procedures would be posted on the QualityNet Web site at: <http://www.QualityNet.org/>.

We are inviting public comment on our proposals regarding eCQM validation submission requirements for the FY 2020 payment determination and subsequent years as discussed above.

**(d) Scoring: Summary of Previously Adopted Chart-Abstracted Measure Validation Scoring**

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50226 through 50227), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50832 through 50833), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50268 through 50269), for a detailed description of our previously adopted scoring methodology for chart-abstracted measure data.

We note that we are not proposing any changes to our chart-abstracted measures validation. We are providing this information as background for our discussion of eCQM validation scoring. Under the current validation process for the Hospital IQR Program there are 600 hospitals (400 randomly sampled and 200 targeted) selected for validation on a yearly basis. As stated above, those

selected for chart-abstracted measure validation would not be eligible for selection to participate in eCQM validation. For chart-abstracted measure validation, the CDAC contractor requests hospitals to submit 8 randomly selected medical charts on a quarterly basis from which data were abstracted and submitted by the hospital to the Clinical Data Warehouse (for a total of 32 charts per year). Under the validation methodology, once the CDAC contractor receives the charts, it reabstracts the same data submitted by the hospitals and calculates the percentage of matching Hospital IQR Program measure numerators and denominators for each measure within each chart submitted by the hospital. Each selected case has multiple measures included in the validation score. Consistent with previous years, each quarter and clinical topic is treated as a stratum for variance estimation purposes (70 FR 47423).

As in previous years, for the FY 2020 payment determination, the overall validation score from the chart-abstracted measure validation will be used to determine a hospital's overall annual payment update. Specifically, if a hospital fails chart-abstracted validation, it would not receive the full annual payment update. If a hospital passes chart-abstracted validation, and also meets the other Hospital IQR Program requirements, it would be eligible to receive the full annual payment update. Consistent with previous years, a hospital must attain at least a 75 percent validation score (the percentage of matching Hospital IQR Program measure numerators and denominators for each measure within each chart submitted by the hospital) based upon chart-abstracted data validation to pass the validation requirement and to be eligible for a full annual payment update, if all other Hospital IQR Program requirements are met.

**(e) Scoring: Proposals for eCQM Validation Scoring**

For the FY 2020 payment determination, for hospitals selected for eCQM validation, we are proposing to require submission of at least 75 percent of sampled eCQM measure medical records in a timely and complete manner. However, unlike chart-abstracted validation, which requires a hospital to attain at least a 75 percent validation score, we are proposing that the accuracy of eCQM data (the extent to which data abstracted for validation matches the data submitted in the QRDA I file) submitted for validation would not affect a hospital's validation score for the FY 2020 payment

determination only. This is further explained below.

Public comments on the FY 2015 IPPS/LTCH PPS final rule suggested further refinements to the process for eCQM validation. Specifically, several commenters urged CMS to implement the recommendations of a March 2014 Government Accountability Office (GAO) report to develop a comprehensive data collection strategy, which includes testing for and mitigation of reliability issues arising from variance in certified EHR systems tested to different CQM specifications (79 FR 50272). Commenters in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49711) expressed concern over the barriers hospitals encounter associated with reporting eCQMs and encouraged CMS to ensure that a diverse group of hospitals and certified EHRs are represented to inform an assessment of the work required to make eCQM validation feasible, reliable, and valid. In response to these concerns, in light of operational capacity limitations, and due to the time necessary to analyze eCQM validation results, we are proposing that eCQM data would be validated, but initially (meaning for the FY 2020 payment determination only), the measure accuracy would not affect hospitals' validation scores.

In other words, although hospitals would be required to submit eCQM data in a timely and complete manner, we are proposing that hospitals would not be required to attain at least a 75 percent validation score (the percentage of matching Hospital IQR Program measure numerators and denominators for each measure within each chart submitted by the hospital) based upon QRDA I validation to pass the validation requirement and to be eligible for a full annual payment update. Hospitals that submit at least 75 percent of sampled eCQM measure medical records (even if those records do not produce a validation score of at least 75 percent) in a timely manner (that is, within 30 days of the date listed on the CDAC medical records request) would not be subject to payment reduction. However, hospitals that fail to submit timely and complete information for at least 75 percent of requested records would not meet the eCQM validation requirement and would be subject to payment reduction. For example, if a hospital submits timely and complete information for at least 75 percent of requested records, but comparison of the QRDA I file and the abstracted data results in a validation score of 28 percent, the hospital still would pass validation and be eligible for a full annual payment update.

Hospitals that pass either chart-abstracted or eCQM validation requirements would receive their full annual payment update, assuming all other Hospital IQR Program requirements are met. Hospitals that fail to attain at least a 75-percent validation score for chart-abstracted validation or fail to submit timely and complete data for 75 percent of requested records for eCQM validation, would not receive their full annual payment update.

In addition, we are proposing to update our regulations at 42 CFR 412.140(d)(2) to reflect the above proposals and to specify that the 75 percent score would only apply to chart-abstracted validation.

We are inviting public comment on our eCQM validation scoring proposals for the FY 2020 payment determination as discussed above.

#### (4) Reimbursement for eCQM Validation

To align with the chart-abstracted validation process, which reimburses hospitals at a rate of \$3.00 per chart (78 FR 50956) for submitting charts electronically via Secure File Transfer (SFT), we are proposing to similarly reimburse hospitals at a rate of \$3.00 per chart for submitting charts electronically via Secure File Transfer (SFT) for eCQM validation for the FY 2020 payment determination and subsequent years. We also refer readers to section X.B.6. of the preamble of this proposed rule for more information regarding the collection of information for eCQM validation.

We are inviting public comment on our proposal to reimburse hospitals at a rate of \$3.00 per chart for eCQM validation for the FY 2020 payment determination and subsequent years as discussed above.

#### (5) eCQM Pre-Submission Testing

We are encouraging hospitals to test their eCQM submissions prior to annual reporting using an available CMS pre-submission validation tool for electronic reporting—the Pre-submission Validation Application (PSVA), which can be downloaded from the Secure File Transfer (SFT) section of the QualityNet Secure Portal at [https://cportal.qualitynet.org/QNet/pgm\\_select.jsp](https://cportal.qualitynet.org/QNet/pgm_select.jsp). The PSVA is a downloadable tool that operates on a user's system to allow submitters to catch and correct errors prior to data submission to CMS. It provides validation feedback within the submitter's system and allows valid files to be separated and submitted while identifying invalid files for error

correction.<sup>144</sup> While the PSVA does not guarantee the accuracy of data in a hospital's QRDA I file, it helps to reduce submission errors related to improperly formatted QRDA I files. Pre-submission testing would assist in proactively identifying inconsistencies in data mapping, a process used in data warehousing by which different data models are linked to each other using a defined set of methods to characterize the data in a specific definition.<sup>145</sup>

#### 12. Data Accuracy and Completeness Acknowledgement (DACA) Requirements for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for previously-adopted details on DACA requirements. We are not proposing any changes to the DACA requirements in this proposed rule.

#### 13. Public Display Requirements for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47364), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), and the FY 2016 final rule (80 FR 49712 through 49713) for details on public display requirements. 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 <https://data.medicare.gov>. We are not proposing any changes to our public display requirements in this proposed rule.

#### 14. Reconsideration and Appeal Procedures for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), and 42 CFR 412.140(e) for details on reconsideration and appeal procedures for the FY 2017 payment determination and subsequent years. We are not

<sup>144</sup> PSVA Demonstration and eCQM Question and Answer Session. Available at: [http://www.qualityreportingcenter.com/wp-content/uploads/2016/03/3-10-16-eCQM\\_PSVA-Demonstration\\_FINAL508.pdf](http://www.qualityreportingcenter.com/wp-content/uploads/2016/03/3-10-16-eCQM_PSVA-Demonstration_FINAL508.pdf).

<sup>145</sup> Data Mapping Definition Available at: <https://www.techopedia.com/definition/6750/data-mapping>.

proposing any changes to the reconsideration and appeals procedures in this proposed rule.

#### 15. Proposed Changes to the Hospital IQR Program Extraordinary Circumstances Extensions or Exemptions (ECE) Policy

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651 through 51652), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836 through 50837), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713), and 42 CFR 412.140(c)(2) for details on the Hospital IQR Program ECE policy. We also refer readers to the QualityNet Web site at <http://www.QualityNet.org/> for our current requirements for submission of a request for an extension or exemption.

In this proposed rule, we are proposing to update our ECE policy by: (1) Extending the general ECE request deadline for non-eCQM circumstances from 30 to 90 calendar days following an extraordinary circumstance; and (2) establishing a separate submission deadline for ECE requests related to eCQM reporting circumstances to be April 1 following the end of the reporting calendar year. We are proposing that these policies would apply beginning in FY 2017 as related to extraordinary circumstance events that occur on or after October 1, 2016.

##### a. Proposal To Extend the General ECE Request Deadline for Non-eCQM Circumstances

In the past, we have allowed hospitals to submit an ECE request form for non-eCQM measures within 30 calendar days following an event that causes hardship and prevents them from providing data for non-eCQM measures (76 FR 51652). In certain circumstances, however, it may be difficult for hospitals to timely evaluate the impact of a certain extraordinary event within 30 calendar days. We believe that extending the deadline to 90 calendar days would allow hospitals more time to determine whether it is necessary and appropriate to submit an ECE request and to provide a more comprehensive account of the “event” in their ECE request form to CMS. For example, if a hospital has suffered damage due to a hurricane on January 1, it would have until March 31 to submit an ECE form via the QualityNet Secure Portal, mail, email, or secure fax as instructed on the ECE form. This proposed timeframe (90 calendar days) also aligns with the ECE request deadlines for the Hospital VBP Program (78 FR 50706), the HAC Reduction Program (80 FR 49580) and

the Hospital Readmissions Reduction Program (80 FR 49542 through 49543), all of which at least partially rely on the same data collection.

##### b. Proposal To Establish a Separate Submission Deadline for ECE Requests Related to eCQMs

In addition, we are proposing to establish a separate submission deadline for ECE requests with respect to eCQM reporting, such that hospitals must submit a request by April 1 following the end of the reporting calendar year. We are proposing that this deadline for ECE requests with respect to eCQM reporting would first apply with an April 1, 2017 deadline and apply for subsequent eCQM reporting years. For example, for data collected for the CY 2016 reporting period (through December 31, 2016), hospitals would have until April 1, 2017 to submit an ECE request. This timeframe also aligns with the Medicare and Medicaid EHR Incentive Programs’ typical annual hardship request deadline (77 FR 54104 through 54109), which we believe would help reduce burden for hospitals.

We are inviting public comment on our proposals related to the Hospital IQR Program’s ECE policy beginning FY 2017 as described above.

#### B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

##### 1. Background

Section 3005 of the Affordable Care Act added new sections 1866(a)(1)(W) and (k) to the Act. Section 1866(k) of the Act 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” or “PCHs”) that specifically applies to PCHs that meet the requirements under 42 CFR 412.23(f). Section 1866(k)(1) of the Act states that, for FY 2014 and each subsequent fiscal year, a PCH must submit data to the Secretary in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. For additional background information, including previously finalized measures and other policies for the PCHQR Program, we refer readers to the following final rules: FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50838 through 50846); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277 through 50288); and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49723).

##### 2. Proposed Criteria for Removal and Retention of PCHQR Program Measures

We have received public comments on past proposed rules asking that we clarify our policy for measure retention and removal. We generally retain measures from the previous year’s PCHQR Program measure set for subsequent years’ measure sets, except when we specifically propose to remove or replace a measure. With respect to measure removal, we believe it is important to be transparent in identifying criteria that we would use to evaluate a measure for potential removal from the PCHQR Program. We also believe that we should align these criteria between our programs whenever possible.

Therefore, we are proposing the following measure removal criteria for the PCHQR Program, which are based on criteria established in the Hospital IQR Program (80 FR 49641 through 49642):

- Measure performance among PCHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (“topped-out” measures);
- A measure does not align with current clinical guidelines or practice;
- The availability of a more broadly applicable measure (across settings or populations) or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;
- Performance or improvement on a measure does not result in better patient outcomes;
- The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;
- Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and
- It is not feasible to implement the measure specifications.

For the purposes of considering measures for removal from the program, we would consider “topped-out” to be that there is statistically indistinguishable performance at the 75th and 90th percentiles and that the truncated coefficient of variation is less than or equal to 0.10.

However, we recognize that there are times when measures may meet some of the outlined criteria for removal from the program, but continue to bring value to the program. Therefore, we are proposing the following criteria for consideration in determining whether to retain a measure in the PCHQR Program,

which also are based on criteria established in the Hospital IQR Program (80 FR 49641 through 49642):

- Measure aligns with other CMS and HHS policy goals;
- Measure aligns with other CMS programs, including other quality reporting programs; and
- Measure supports efforts to move PCHs towards reporting electronic measures.

We welcome public comments on these proposed measure removal and retention criteria.

### 3. Retention and Proposed Update to Previously Finalized Quality Measures for PCHs Beginning With the FY 2019 Program Year

#### a. Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561), we finalized five quality measures for the FY 2014 program year and subsequent years. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50837 through 50847), we finalized one new quality measure for the FY 2015 program year and subsequent years and 12 new quality measures for the FY 2016 program year and subsequent years. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278 through 50280), we finalized one new quality measure for the FY 2017 program year and subsequent years. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49719), we finalized three new CDC NHSN measures for the FY 2018 program year and subsequent years, and finalized the removal of six previously finalized measures for fourth quarter (Q4) 2015 discharges and subsequent years. We refer readers to the final rules referenced in section VIII.B.1. of the preamble of this proposed rule for more information regarding these previously finalized measures.

We are not proposing for FY 2019 to remove any of the measures previously finalized for the FY 2018 program year from the PCHQR measure set. However, we are proposing to update the Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) measure, described below.

#### b. Proposed Update of Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) Measure for FY 2019 Program Year and Subsequent Years

Beginning with the FY 2019 program year, we are proposing to update the specifications of the Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) measure. This measure was originally finalized in the

FY 2014 IPPS/LTCH PPS final rule (78 FR 50841 through 50842). In November 2014, subsequent to our adoption of the measure in the PCHQR Program, updated specifications were endorsed by the NQF.

The updated measure specifications expand the patient cohort to include patients receiving 3D conformal radiation therapy for breast or rectal cancer in addition to patients receiving 3D conformal radiation therapy for lung or pancreatic cancers (the original cohort).<sup>146</sup> For additional information about the original measure cohort, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50842), in which we introduced the measure to the PCHQR Program. In 2012, breast cancer was the most common cancer among women, and the second most common cause of cancer related deaths for women.<sup>147</sup> For 2016, the National Institutes of Health estimates that there will be approximately 135,000 new cases of colorectal cancer in the United States, with approximately 39,000 of these cases being rectal cancer.<sup>148</sup>

As these cancer types are so prevalent, we believe that the expansion of the measure cohort to include breast and rectal cancer patients is important to ensuring the delivery of high quality care in the PCH setting. In compliance with section 1890A(a)(2) of the Act, this measure update was included in a publicly available document, “List of Measures under Consideration for December 1, 2015.”<sup>149</sup> The MAP, a multi-stakeholder group convened by the NQF, reviews the measures under consideration for the PCHQR Program, among other Federal programs, and provides input on those measures to the Secretary. The MAP’s 2016 recommendations for quality measures under consideration are captured in the following document: “Process and Approach for MAP Pre-Rulemaking Deliberations 2015–2016” (<http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81599>). The MAP expressed conditional support for the update of Oncology: Radiation Dose Limits to Normal Tissues. The MAP’s conditional support was solely pending annual NQF review, and was not based on significant

<sup>146</sup> Available at: <http://www.qualityforum.org/QPS/0382>.

<sup>147</sup> CDC Breast Cancer Statistics. Available at: <http://www.cdc.gov/cancer/breast/statistics/>.

<sup>148</sup> NIH Colorectal Cancer Incidence and Mortality. Available at: <http://www.cancer.gov/types/colorectal/hp/rectal-treatment-pdq>.

<sup>149</sup> CMS List of Measures under Consideration. Available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81172>.

concerns. We considered the input and recommendations provided by the MAP, and the importance of aligning with NQF-endorsed specifications of measures whenever possible, in proposing this update for the PCHQR Program.

We welcome public comments on this proposal for the Oncology: Radiation Dose Limits to Normal Tissues measure cohort expansion for the FY 2019 program year and subsequent years.

#### 4. Proposed New Quality Measure Beginning With the FY 2019 Program Year

##### a. Considerations in the Selection of Quality Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50837 through 50838), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278), we indicated that we have taken a number of principles into consideration when developing and selecting measures for the PCHQR Program, and that many of these principles are modeled on those we use for measure development and selection under the Hospital IQR Program. In this proposed rule, we are not proposing any changes to the principles we consider when developing and selecting measures for the PCHQR Program.

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 (the NQF is the entity that currently holds this contract). Section 1866(k)(3)(B) of the Act provides an exception under which, 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.

Using the principles for measure selection in the PCHQR Program, we are proposing one new measure, described below.

##### b. Proposed Adoption of the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy Measure

We are proposing to adopt the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure for the FY 2019 program year and

subsequent years. Cancer care is a priority area for outcome measurement because cancer is an increasingly prevalent condition associated with considerable morbidity and mortality. In 2015, there were more than 1.6 million new cases of cancer in the United States.<sup>150</sup> Each year, about 22 percent of cancer patients receive chemotherapy,<sup>151</sup> with Medicare payments for cancer treatment totaling \$34.4 billion in 2011 or almost 10 percent of Medicare fee-for-service (FFS) spending.<sup>152</sup> With an increasing number of cancer patients receiving chemotherapy in a hospital outpatient department,<sup>153</sup> a growing body of peer-reviewed literature identifies unmet needs in the care provided to these patients. This gap in care may be due to reasons including: (1) Delayed onset of side effects that patients must manage at home; (2) patients assuming that little can be done and not seeking assistance; and (3) limited access to and communication with providers who can tailor care to the individual.<sup>154</sup> As a result, cancer patients that receive chemotherapy in a hospital outpatient department require more frequent acute care in the hospital setting and experience more adverse events than cancer patients that are not receiving chemotherapy.<sup>155 156 157</sup>

Unmet patient needs resulting in admissions and ED visits related to chemotherapy treatment pose a heavy financial burden and affect patients' quality of life. Based on available commercial claims data, in 2010 the national average cost of a chemotherapy-related admission was \$22,000, and the average cost of a chemotherapy-related ED visit was \$800.<sup>158</sup> Furthermore, admissions and ED visits can reduce patients' quality of life by affecting their physical and emotional well-being, disrupting their schedules, decreasing their desire to engage in work and social activities, and increasing the burden on their family.<sup>159 160</sup>

Hospital admissions and ED visits among cancer patients are often caused by manageable side effects. Chemotherapy treatment can have severe, predictable side effects. Recent studies of cancer outpatients show the most commonly cited symptoms and reasons for unplanned hospital visits following chemotherapy treatment are pain, anemia, fatigue, nausea and/or vomiting, fever and/or febrile neutropenia, shortness of breath, dehydration, diarrhea, and anxiety/depression.<sup>161</sup> These hospital visits may be due to conditions related to the cancer itself or to side effects of chemotherapy. However, treatment plans and guidelines exist to support the management of these conditions. PCHs that provide outpatient chemotherapy should implement appropriate care to minimize the need for acute hospital care for these adverse events. Guidelines from the American Society of Clinical Oncology, National Comprehensive Cancer Network, Oncology Nursing Society, Infectious Diseases Society of America, and other

professional societies recommend evidence-based interventions to prevent and treat common side effects and complications of chemotherapy. Appropriate outpatient care should reduce potentially avoidable hospital admissions and ED visits for these issues and improve cancer patients' quality of life.

This measure aims to assess the care provided to cancer patients and encourage quality improvement efforts to reduce the number of unplanned inpatient admissions and ED visits among cancer patients receiving chemotherapy in a PCH outpatient setting. Improved PCH management of these potentially preventable symptoms—including anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—could reduce unplanned admissions and ED visits for these conditions. Measuring unplanned admissions and ED visits for cancer patients receiving outpatient chemotherapy would provide PCHs with an incentive to improve the quality of care for these patients by taking steps to prevent and better manage side effects and complications from treatment. In addition, this measure meets two National Quality Strategy priorities: (1) Promoting effective communication and coordination of care; and (2) promoting the most effective prevention and treatment practices for the leading causes of mortality.

We are proposing to adopt this measure under the exception authority in section 1866(k)(3)(B) of the Act under which, 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. Existing measures that the NQF has endorsed focus on processes of care related to outpatient cancer care.

This proposed measure aligns with the intent of two process measures we adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50842 through 50843) for FY 2016 and subsequent years: (1) Clinical Process/Oncology Care—Plan of Care for Pain (NQF #0383); and (2) Clinical Process/Oncology: Medical and Radiation—Pain Intensity Quantified (NQF #0384). Process measures NQF #0383 and NQF #0384, which are not risk-adjusted, support the intent of the proposed measure by reinforcing that providers of outpatient care should

<sup>150</sup> American Cancer Society. "Cancer Facts & Figures 2015." Available at: <http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspsc-044552.pdf>.

<sup>151</sup> Klodziej, M., J.R. Hoverman, J.S. Garey, J. Espirito, S. Sheth, A. Ginsburg, M.A. Neubauer, D. Patt, B. Brooks, C. White, M. Sitarik, R. Anderson, and R. Beveridge. "Benchmarks for Value in Cancer Care: An Analysis of a Large Commercial Population." *Journal of Oncology Practice*, Vol. 7, 2011, pp. 301–306.

<sup>152</sup> Sockdale, H., K. Guillory. "Lifeline: Why Cancer Patients Depend on Medicare for Critical Coverage." Available at: <http://www.acscan.org/content/wp-content/uploads/2013/06/2013-Medicare-Chartbook-Online-Version.pdf>.

<sup>153</sup> Vandervelde, Aaron, Henry Miller, and JoAnna Younts. "Impact on Medicare Payments of Shift in Site of Care for Chemotherapy Administration." Washington, DC: Berkeley Research Group, June 2014. Available at: [http://www.communityoncology.org/UserFiles/BRG\\_340B\\_SiteofCare\\_ReportF\\_6-9-14.pdf](http://www.communityoncology.org/UserFiles/BRG_340B_SiteofCare_ReportF_6-9-14.pdf).

<sup>154</sup> McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. "Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study." *Supportive Care in Cancer*, Vol. 19, No. 7, 2011, pp. 963–969.

<sup>155</sup> Sadik, M., K. Ozlem, M. Huseyin, B. AliAyberk, S. Ahmet, and O. Ozgur. "Attributes of Cancer Patients Admitted to the Emergency Department in One Year." *World Journal of Emergency Medicine*, Vol. 5, No. 2, 2014, pp. 85–90. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4129880/#ref4>.

<sup>156</sup> Hassett, M.J., J. O'Malley, J.R. Pakes, J.P. Newhouse, and C.C. Earle. "Frequency and Cost of Chemotherapy-Related Serious Adverse Effects in a Population Sample of Women with Breast Cancer." *Journal of the National Cancer Institute*, Vol. 98, No. 16, 2006, pp. 1108–1117.

<sup>157</sup> Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, SE. Lutrino, M. Mazzer, M. Giovannoni, G.G. Cardellino, F. Puglisi, and G. Fasola. "Risk of Unplanned Visits for Colorectal Cancer Outpatients Receiving Chemotherapy: A Case-Crossover Study." *Supportive Care in Cancer*, Vol. 22, No. 9, 2014, pp. 2527–2533.

<sup>158</sup> Fitch, K., and B. Pyenson. "Cancer Patients Receiving Chemotherapy: Opportunities for Better Management." Available at: <http://us.milliman.com/uploadedFiles/insight/research/health-rr/cancer-patients-receiving-chemotherapy.pdf>.

<sup>159</sup> McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. "Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study." *Supportive Care in Cancer*, Vol. 19, No. 7, 2011, pp. 963–969.

<sup>160</sup> Hassett, M.J., J. O'Malley, J.R. Pakes, J.P. Newhouse, and C.C. Earle. "Frequency and Cost of Chemotherapy-Related Serious Adverse Effects in a Population Sample of Women with Breast Cancer." *Journal of the National Cancer Institute*, Vol. 98, No. 16, 2006, pp. 1108–1117.

<sup>161</sup> Ibid.

screen for and manage symptoms such as pain. The proposed measure improves upon these two measures in two key ways: (1) It does not target a specific symptom, but rather assesses the overall management of 10 important symptoms that studies have identified as frequent reasons for ED visits and inpatient admissions in this population; and (2) it assesses the care outcomes that matter to patients, rather than measuring processes to detect and treat these conditions. Also, we are not aware of any other measures a consensus organization has endorsed or adopted that assess the quality of outpatient cancer care by measuring unplanned inpatient admissions and ED visits.

The MAP supported this measure on the condition that it is reviewed and endorsed by NQF. We refer readers to the Spreadsheet of MAP 2016 Final Recommendations available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>. In particular, MAP members recommended considering the measure for sociodemographic status (SDS) adjustment in the ongoing NQF trial period and reviewing it to ensure that the detailed specifications meet the intent of the measure and align with current cancer care practice.

We understand the important role that SDS plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. We submitted this measure to NQF with appropriate consideration for SDS for endorsement proceedings as part of the NQF Cancer Consensus Development Project in

March 2016 and it is currently undergoing review. However, the measure we are proposing to adopt at this time for the PCHQR Program does not include this adjustment.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the effect of socioeconomic, demographic, and other characteristics on quality measures, resource use, and other measures in the Medicare program, as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

In addition, several MAP members noted the alignment of this measure concept with other national priorities, such as improving patient experience, and other national initiatives to improve cancer care, as well as the importance of this measure to raise awareness and create a feedback loop with providers.

This Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure is a risk-standardized outcome measure for patients age 18 years or older who are receiving PCH-based outpatient chemotherapy treatment for all cancer types except leukemia; it measures inpatient admissions or ED visits within 30 days of each outpatient chemotherapy encounter for any of the following qualifying diagnoses: anemia, dehydration; diarrhea; emesis; fever; nausea; neutropenia; pain; pneumonia; or sepsis, as these are associated with commonly cited reasons for hospital visits among cancer patients receiving chemotherapy.<sup>162</sup>

The proposed measure uses 1 year of Medicare FFS Part A and Part B administrative claims data with respect to beneficiaries receiving chemotherapy treatment in a PCH outpatient setting. The qualifying diagnosis on the admission or ED visit claim must be (1) the primary diagnosis or (2) a secondary diagnosis accompanied by a primary diagnosis of cancer.

We limited the window for identifying the outcomes of admissions and ED visits to 30 days after PCH outpatient chemotherapy treatment encounters, as existing literature suggests the vast majority of adverse events occur within that time

frame<sup>163 164 165</sup> and we also observed this during testing. In addition, the technical expert panel (TEP) supported this time window because: (1) It helps link patients' experiences to the facilities that provided their recent treatment while accounting for variations in time between outpatient treatment encounters; (2) it supports the idea that the admission is related to the management of side effects of treatment and ongoing care, as opposed to progression of the disease or other unrelated events; and (3) clinically, 30 days after each outpatient chemotherapy treatment is a reasonable timeframe to observe related side effects.

The measure identifies outcomes separately for the inpatient and ED measures. A patient can qualify only once for one of the two outcomes in each measurement period. If patients experience both an inpatient admission and an ED visit after outpatient chemotherapy during the measurement period, the measure counts them toward the inpatient admission outcome because this outcome represents a more significant deterioration in patient quality of life, and is more costly. Among those with no qualifying inpatient admissions, the measure counts qualifying standalone ED visits. As a result, the rates provide a comprehensive performance estimate of quality of care. We calculate the rates separately because the severity and cost of an inpatient admission differ from those of an ED visit, but both adverse events are significant quality indicators and represent outcomes of care that are important to patients.

The measure attributes the outcome to the PCH where the patient received chemotherapy treatment during the 30 days before the outcome. If a patient received outpatient chemotherapy treatment from more than one PCH in the 30 days before the outcome, the measure would attribute the outcome to all the PCHs that provided treatment. For example, if a patient received an

<sup>163</sup> Aprile, G., F.E. Pisa, A. Follador, L. Foltran, F. De Pauli, M. Mazzer, S. Lutrino, C.S. Sacco, M. Mansutti, and G. Fasola. "Unplanned Presentations of Cancer Outpatients: A Retrospective Cohort Study." *Supportive Care in Cancer*, Vol. 21, No. 2, 2013, pp. 397–404.

<sup>164</sup> Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, SE. Lutrino, M. Mazzer, M. Giovannoni, G.G. Cardellino, F. Puglisi, and G. Fasola. "Risk of Unplanned Visits for Colorectal Cancer Outpatients Receiving Chemotherapy: A Case-Crossover Study." *Supportive Care in Cancer*, Vol. 22, No. 9, 2014, pp. 2527–2533.

<sup>165</sup> McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. "Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study." *Supportive Care in Cancer*, Vol. 19, No. 7, 2011, pp. 963–969.

<sup>162</sup> Hassett, M.J., J. O'Malley, J.R. Pakes, J.P. Newhouse, and C.C. Earle. "Frequency and Cost of Chemotherapy-Related Serious Adverse Effects in a Population Sample of Women with Breast Cancer." *Journal of the National Cancer Institute*, Vol. 98, No. 16, 2006, pp. 1108–1117.

outpatient chemotherapy treatment at PCH A on January 1, a second treatment at PCH B on January 10, and then experienced a qualifying inpatient admission on January 15, the measure would count this outcome for both PCH A and PCH B because both PCHs provided outpatient chemotherapy treatment to the patient within the 30-day window. However, if a patient received an outpatient chemotherapy treatment from PCH A on January 1, and a second treatment from PCH B on March 1, and then experienced a qualifying inpatient admission on March 3, the measure would attribute this outcome only to PCH B. In measure testing, using Medicare FFS claims data from July 1, 2012, to June 30, 2013, only 5 percent of patients in the cohort received outpatient chemotherapy treatment from more than one facility during that year.

For additional methodology details, including the code sets used to identify the qualifying outcomes, we refer readers to the CMS Web site at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html> under “Hospital Outpatient Chemotherapy.”

This measure includes all adult Medicare FFS patients because this would enable us to more broadly assess the quality of care provided by the PCH.

This measure focuses on treatments in the PCH outpatient setting because of the increase in hospital-based chemotherapy, which presents an opportunity to coordinate care. From 2008 to 2012, the proportion of Medicare patients receiving hospital-based outpatient chemotherapy increased from 18 to 29 percent, and this trend is likely to continue. As currently specified, the measure identifies chemotherapy treatment using ICD-9-CM procedure and encounter codes and Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) procedure and medication procedure codes. It excludes procedure codes for oral chemotherapy because it is challenging to identify oral chemotherapy without using pharmacy claims data and, according to our TEP, most oral chemotherapies have fewer adverse reactions that result in admissions. We have developed a “coding crosswalk” between the ICD-9-CM codes and the ICD-10 codes that became effective beginning on October 1, 2015, and we will test this crosswalk prior to implementation. For detailed information on the cohort definition, including the ICD-9-CM, ICD-10, CPT, and HCPCS codes that identify

chemotherapy treatment, we refer readers to the Data Dictionary appendix to the measure Technical Report at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html> under “Hospital Outpatient Chemotherapy.”

The measure excludes three groups of patients: (1) Patients with a diagnosis of leukemia at any time during the measurement period because of the high toxicity of treatment and recurrence of disease, and because inpatient admissions and ED visits may reflect a relapse, rather than poorly managed outpatient care; (2) patients who were not enrolled in Medicare FFS Parts A and B in the year before the first outpatient chemotherapy treatment encounter during the measurement period (because the risk-adjustment model uses claims data for the year before the first chemotherapy treatment encounter during the period to identify comorbidities); and (3) patients who do not have at least one outpatient chemotherapy treatment encounter followed by continuous enrollment in Medicare FFS Parts A and B in the 30 days after the encounter (because the measure cannot assess the 30-day outcome in this group since it uses claims data to determine whether a patient had an ED visit or a hospital inpatient admission).

Risk adjustment takes into account important demographic and clinically-relevant patient characteristics that have strong relationships with the outcome. It seeks to adjust for differences in patient demographics, clinical comorbidities, and treatment exposure, which vary across patient populations and influence the outcome but do not relate to quality. Specifically, the measure adjusts for: (1) The patient’s age at the start of the measurement period; (2) sex; (3) comorbidities that convey information about the patient in the 12 months before his or her first outpatient chemotherapy treatment encounter during the measurement period; (4) cancer type; and (5) the number of outpatient chemotherapy treatments the patient received at the reporting PCH during the measurement period.

We developed two risk-adjustment models, one for each dependent variable described above—qualifying inpatient admissions and qualifying ED visits. The separate models are necessary to enable the use of the most parsimonious model with variables tailored to those that are most predictive for each of the measure’s two mutually exclusive outcomes. The measure algorithm first searches for a qualifying inpatient admission, and for those patients that

do not have a qualifying inpatient admission, searches for a qualifying ED visit. Therefore, the patient-mix and predictive risk factors for each outcome is slightly different. The statistical risk-adjustment model for inpatient admissions includes 20 clinically relevant risk-adjustment variables that are strongly associated with the risk of one or more hospital admissions within 30 days following an outpatient chemotherapy treatment encounter in a hospital outpatient setting; the statistical risk-adjustment model for ED visits includes 15 clinically relevant risk-adjustment variables that are strongly associated with risk of one or more ED visits within 30 days following an outpatient chemotherapy treatment encounter in a hospital outpatient setting (3 comorbidities and 2 cancer types significant for inpatient admissions are not significant for ED visits).

The measure uses hierarchical logistic modeling, similar to the approach used in the CMS inpatient hospital 30-day risk-standardized mortality and readmission outcome measures, such as the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.<sup>166</sup> This approach appropriately accounts for both differences in patient-mix and the clustering of observations within PCHs. The measure calculates the PCH-specific risk-adjusted rate as the ratio of the PCH’s “predicted” number of outcomes to “expected” number of outcomes multiplied by the national observed outcome rate. It estimates the expected number of outcomes for each PCH using the PCH’s patient-mix and the average PCH-specific intercept (that is, the average intercept among all PCHs in the sample). The measure estimates the predicted number of outcomes for each PCH using the same patient-mix, but an estimated PCH-specific intercept.

The measure calculates two rates, one for each mutually exclusive outcome (qualifying inpatient admissions and qualifying ED visits). It derives the two rates (also referred to as the PCH-level risk-standardized admission rate (RSAR) and risk-standardized ED visit rate (RSEDR)), from the ratio of the numerator to the denominator multiplied by the national observed rate. The numerator is the number of predicted (meaning adjusted actual) patients with the measured adverse outcome. The denominator is the

<sup>166</sup> Methodology reports for these measures are available at the following link: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.



number of patients with the measured adverse outcome the PCH is expected to have based on the national performance with the PCH’s case mix. The national observed rate is the national unadjusted number of patients who have an adverse outcome among all the qualifying patients who had at least one chemotherapy treatment encounter in a PCH. If the “predicted” number of outcomes is higher (or lower) than the “expected” number of outcomes for a given hospital, the risk-standardized rate will be higher (or lower) than the national observed rate.

For more detailed information on the calculation methodology, we refer readers to the methodology report at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html> under “Hospital Outpatient Chemotherapy.”

We would publicly report the RSAR and RSEDR for all participating PCHs with 25 or more eligible patients per measurement period to maintain a reliability of at least 0.4 (as measured by the interclass correlation coefficient, ICC). If a PCH does not meet the 25 eligible patient threshold, we would include a footnote on the *Hospital Compare* Web site indicating that the number of cases is too small to reliably measure that PCH’s rate. These patients and PCHs would still be included when calculating the national rates for both the RSAR and RSEDR.

To prepare PCHs for public reporting, we would conduct a confidential national reporting (dry run) of measure results prior to public reporting. The objectives of the dry run are to: (1) Educate PCHs and other stakeholders about the measure; (2) allow PCHs to review their measure results and data

prior to public reporting; (3) answer questions from PCHs and other stakeholders; (4) test the production and reporting process; and (5) identify potential technical changes to the measure specifications that might be needed. We have not yet determined the measurement period to use for the dry run calculations, but acknowledge the importance of including some data based on ICD–10 codes to evaluate the success of the “coding crosswalk.”

We are inviting public comment on our proposal to adopt the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure for the FY 2019 program year and subsequent years.

In summary, the previously finalized and newly proposed measures for the PCHQR Program for the FY 2019 program year and subsequent years are listed in the table below.

PREVIOUSLY FINALIZED AND PROPOSED PCHQR MEASURES FOR THE FY 2019 PROGRAM YEAR AND SUBSEQUENT YEARS

Short name	NQF No.	Measure name
<b>Safety and Healthcare-Associated Infection (HAI)</b>		
CLABSI .....	0139	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection Outcome Measure.
CAUTI .....	0138	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infections Outcome Measure.
SSI .....	0753	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery].
CDI .....	1717	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset <i>Clostridium difficile</i> Infection (CDI) Outcome Measure.
MRSA .....	1716	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant <i>Staphylococcus aureus</i> Bacteremia Outcome Measure.
HCP .....	0431	Influenza Vaccination Coverage Among Healthcare Personnel.
<b>Clinical Process/Cancer Specific Treatment</b>		
N/A .....	0223	Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis to Patients Under the Age of 80 with AJCC III (lymph node positive) Colon Cancer.
N/A .....	0559	Combination Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 with AJCC T1cN0M0, or Stage IB–III Hormone Receptor Negative Breast Cancer. ***
N/A .....	0220	Adjuvant Hormonal Therapy.
<b>Clinical Process/Oncology Care Measures</b>		
N/A .....	0382	Oncology: Radiation Dose Limits to Normal Tissues. *
N/A .....	0383	Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology.
N/A .....	0384	Oncology: Medical and Radiation—Pain Intensity Quantified.
N/A .....	0390	Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients.
N/A .....	0389	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients.
<b>Patient Engagement/Experience of Care</b>		
HCAHPS .....	0166	HCAHPS.
<b>Clinical Effectiveness Measure</b>		
EBRT .....	1822	External Beam Radiotherapy for Bone Metastases.

PREVIOUSLY FINALIZED AND PROPOSED PCHQR MEASURES FOR THE FY 2019 PROGRAM YEAR AND SUBSEQUENT YEARS—Continued

Short name	NQF No.	Measure name
<b>Claims Based Outcome Measure</b>		
N/A .....	N/A	Admissions and Emergency Department (ED) Visits for Patients Receiving Out-patient Chemotherapy. **

\* Proposed for update in FY 2019 program year.

\*\* Newly proposed for FY 2019 program year.

\*\*\* In previous final rules, this measure was titled “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 Hormones Receptor Negative Breast Cancer. This name change is consistent with NQF updates to the measure name and reflects an update in the AJCC staging, does not reflect a change in the measure inclusion criteria, and is not considered substantive.

5. Possible New Quality Measure Topics for Future Years

We discussed future quality measure topics and quality measure domain areas in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50280), and in the FY 2016 IPPS/LTCH PPS final rule (80 FR4979), we discussed public comment and specific suggestions for measure topics addressing the following CMS Quality Strategy domains: Making care affordable; communication and coordination; and working with communities to promote best practices of healthy living. We welcome public comment and specific suggestions for measure topics that we should consider for future rulemaking.

6. Maintenance of Technical Specifications for Quality Measures

We maintain technical specifications for the PCHQR Program measures, and we periodically update those specifications. The specifications may be found on the QualityNet Web site at: <https://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228774479863>.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50281), we adopted a policy under which we use a subregulatory process to make nonsubstantive updates to measures used for the PCHQR Program. We are not proposing any changes to this policy in this proposed rule.

7. Public Display Requirements

a. Background

Under section 1866(k)(4) of the Act, we are required to establish procedures for making the data submitted under the PCHQR Program available to the public. Such procedures must ensure that a PCH has the opportunity to review the data that are to be made public with respect to the PCH prior to such data being made public. Section 1866(k)(4) of the Act also provides that the Secretary must report quality measures of process, structure, outcome, patients’ perspective on care, efficiency, and costs of care that relate to services furnished in such hospitals on the CMS Web site. The measures that we have finalized for public display are shown in the table below.

PREVIOUSLY FINALIZED MEASURES FOR PUBLIC DISPLAY

Measure name	First year of public display
• Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis to Patients Under the Age of 80 with AJCC III (lymph node positive) Colon Cancer (NQF #0223).	2014
• 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).	2015 2016
• Adjuvant Hormonal Therapy (NQF #0220) .....	
• Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) .....	No Later Than 2017.
• Oncology: Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383).	
• Oncology: Oncology: Medical and Radiation—Pain Intensity Quantified (NQF #0384).	
• Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients (NQF #0390).	
• Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients (NQF #0389).	
• HCAHPS (NQF #0166).	
• CLABSI (NQF #0139) .....	
• CAUTI (NQF #0138).	

b. Proposed Additional Public Display Requirements

As we strive to publicly display data as soon as possible on a CMS Web site, we are proposing the following update to our public display polices. We believe it is best to not specify in rulemaking the exact timeframe during the year for publication as doing so may prevent earlier publication. We are proposing, then, to make these data available as soon as it is feasible during

the year, starting with the first year for which we are publishing data for each measure. We will continue to propose in rulemaking the first year for which we intend to publish data for each measure. We intend to make the data available on at least a yearly basis.

As stated above, we are required to give PCHs an opportunity to review their data before the data are made public. Because we are proposing to make the data for this program available

as soon as possible, and the timeframe for this publication may change year-to-year, we are not proposing to specify in rulemaking the exact dates for review. However, we are proposing that the time period for review would be approximately 30 days in length. We are proposing to announce the exact timeframes on a CMS Web site and/or on our applicable listservs.

We welcome public comments on these updates to our public display and preview policies.

c. Proposed Public Display of Additional PCHQR Measure

We are proposing to publicly display one additional PCHQR measure beginning with FY 2017 program year data (which is data collected during CY 2015). This proposal would mean that we would display the measure data during CY 2017, and that we would use a CMS Web site and/or our applicable listservs to announce the exact timeframe. This measure is External Beam Radiotherapy for Bone Metastases (NQF #1822), which we adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278 through 50280). We believe that it is important to share data collected under the PCHQR Program with healthcare consumers through publication on public Web sites to help inform healthcare choices. We intend to make this data publicly available at the first opportunity.

We welcome public comment on our proposal to display this measure

beginning with the FY 2017 program year data and for subsequent years.

d. Proposed Public Display of Updated Measure

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49720 through 49722), we finalized public display of the Oncology: Radiation Dose Limits to Normal Tissues measure in 2016 and subsequent years. If our proposal to update this measure (described in section VIII.B.3.b. of the preamble of this proposed rule) is finalized, we are proposing to begin displaying on *Hospital Compare* data using the updated measure cohort as soon as feasible after the updated data is collected in CY 2017. We intend to denote the cohort expansion on *Hospital Compare* to ensure that consumers are informed about the expansion.

We welcome public comment on our proposals regarding public display of this updated measure.

e. Proposed Postponement of Public Display of Two Measures

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50281 through 50282), we finalized public display of the CLABSI and CAUTI measures beginning no later than 2017 and subsequent years. However, at this time, we are proposing to defer the public reporting of these two measures' data. At present, all PCHs are reporting CLABSI and CAUTI data to the NHSN under the PCHQR Program; however, due to the low volume of data produced and reported by this small number of facilities, we need additional time to work with CDC to identify an appropriate timeframe for public reporting and collaborate on the analytic methods that will be used to summarize the CLABSI and CAUTI data for public reporting purposes.

We are inviting public comment on our proposal to defer the public reporting of the CLABSI and the CAUTI measures.

Our previously finalized and proposed public display requirements are summarized in the table below.

PREVIOUSLY FINALIZED AND PROPOSED PUBLIC DISPLAY REQUIREMENTS

Measures	Public reporting
<b>Summary of Finalized and Proposed Public Display Requirements</b>	
<ul style="list-style-type: none"> <li>• Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis to Patients Under the Age of 80 with AJCC III (lymph node positive) Colon Cancer (NQF #0223).</li> <li>• Combination Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 with AJCC T1cN0M0, or Stage IB—III Hormone Receptor Negative Breast Cancer (NQF #0559).</li> <li>• Adjuvant Hormonal Therapy (NQF #0220) .....</li> <li>• Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382).*</li> <li>• Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383).</li> <li>• Oncology: Medical and Radiation—Pain Intensity Quantified (NQF #0384) .....</li> <li>• Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients (NQF #0390).</li> <li>• Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients (NQF #0389).</li> <li>• HCAHPS (NQF #0166).</li> <li>• CLABSI (NQF #0139).**</li> <li>• CAUTI (NQF #0138)** .....</li> <li>• External Beam Radiotherapy for Bone Metastases (NQF #1822)*** .....</li> </ul>	<p>2014 and subsequent years.</p> <p>2015 and subsequent years.</p> <p>2016 and subsequent years.</p> <p>Deferred. Beginning at the first opportunity in 2017 and for subsequent years.</p>

\* Update proposed for display for the FY 2019 program year and subsequent years in this proposed rule—expanded cohort will be displayed as soon as feasible.

\*\* Deferral proposed in this proposed rule.

\*\*\* Measure newly proposed for public display in this proposed rule.

8. Form, Manner, and Timing of Data Submission

Section 1866(k)(2) of the Act requires that, beginning with the FY 2014 PCHQR program year, each PCH must submit to the Secretary data on quality measures specified under section 1866(k)(3) of the Act in a form and manner, and at a time, as specified by the Secretary.

Data submission requirements and deadlines for the PCHQR Program are generally posted on the QualityNet Web site at: <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPPage%2FQnetTier3&cid=1228772864228>.

The newly proposed measure for FY 2019 (Admissions and Emergency Department (ED) Visits for Patients

Receiving Outpatient Chemotherapy) is a claims-based measure; therefore, there are no additional data submission requirements for this measure. As this measure uses 1 year of Medicare administrative claims data, we are proposing to calculate this measure on a yearly basis, beginning with data from July 1, 2016 through June 30, 2017, and then to calculate the measure for

subsequent years using data from July 1 through June 30.

We are not proposing any changes to previously finalized data submission requirements in this proposed rule.

#### 9. Exceptions From PCHQR Program Requirements

In our experience with other quality reporting and performance programs, we have noted occasions when providers have been unable to submit required quality data due to extraordinary circumstances that are not within their control (for example, natural disasters). We do not wish to increase their burden unduly during these times. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50848), we finalized our policy that, for the FY 2014 program year and subsequent years, PCHs may request and we may grant exceptions (formerly referred to as waivers) with respect to the reporting of required quality data when extraordinary circumstances beyond the control of the PCH warrant. When exceptions are granted, we will notify the respective PCH.

We are not proposing any changes to this PCHQR exception process in this proposed rule.

#### C. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

##### 1. Background and Statutory Authority

We seek to promote higher quality and more efficient health care for Medicare beneficiaries, and our efforts are furthered by quality reporting programs coupled with public reporting of that information.

Section 3004(a) of the Affordable Care Act amended section 1886(m)(5) of the Act, requiring the Secretary to establish the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The LTCH QRP applies to all hospitals certified by Medicare as LTCHs. Beginning with the FY 2014 payment determination and subsequent years, the Secretary is required to reduce any annual update to the LTCH PPS standard Federal rate for discharges occurring during such fiscal year by 2 percentage points for any LTCH that does not comply with the requirements established by the Secretary. Section 1886(m)(5) of the Act requires that for the FY 2014 payment determination and subsequent years, each LTCH submit data on quality measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. For more information on the statutory history of the LTCH QRP, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286).

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) imposed new data reporting requirements for certain post-acute care (PAC) providers, including LTCHs. For information on the statutory background of the IMPACT Act, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723 through 49724).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723 through 49728), we reviewed and finalized the activities and the timeline and sequencing of such activities that would occur under the LTCH QRP. In addition, we established our approach for identifying cross-cutting measures and process for the adoption of measures, including the application and purpose of the Measures Application Partnership (MAP) and the notice-and-comment rulemaking process. For information on these topics, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723).

##### 2. General Considerations Used for Selection of Quality, Resource Use, and Other Measures for the LTCH QRP

For a detailed discussion of the considerations we use for the selection of LTCH QRP quality measures, such as alignment with the CMS Quality Strategy,<sup>167</sup> which incorporates the three broad aims of the National Quality Strategy,<sup>168</sup> we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286 through 50287) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49728). Overall, we strive to promote high quality and efficiency in the delivery of health care to the beneficiaries we serve. Performance improvement leading to the highest quality health care requires continuous evaluation to identify and address performance gaps and reduce the unintended consequences that may arise in treating a large, vulnerable, and aging population. Quality reporting programs, coupled with public reporting of quality information, are critical to the advancement of health care quality improvement efforts. Valid, reliable, relevant quality measures are fundamental to the effectiveness of our quality reporting programs. Therefore, selection of quality measures is a priority for CMS in all of its quality reporting programs.

In this proposed rule, we are proposing to adopt for the LTCH QRP

one measure that we are specifying under section 1899B(c)(1) of the Act to meet the Medication Reconciliation domain, that is, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP. Further, we are proposing for the LTCH QRP to adopt three measures in order to meet the resource use and other measure domains identified in section 1899B(d)(1) of the Act. These measures consist of: (1) Total Estimated Medicare Spending Per Beneficiary (MSPB); MSPB-PAC LTCH QRP; (2) Discharge to Community: Discharge to Community-PAC LTCH QRP; and (3) Measures to reflect all-condition risk-adjusted potentially preventable hospital readmission rates: Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP.

In our selection and specification of measures, we employ a transparent process in which we seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, as required by section 1890A of the Act. To meet this requirement, we provided the following opportunities for stakeholder input: Our measure development contractor convened technical expert panels (TEPs) that included stakeholder experts and patient representatives on July 29, 2015, for the Drug Regimen Review Conducted with Follow-Up for Identified Issues measures; on August 25, 2015, September 25, 2015, and October 5, 2015, for the Discharge to Community measures; on August 12 and 13, 2015, and October 14, 2015 for the Potentially Preventable 30-Day Post-Discharge Readmission Measures; and on October 29 and 30, 2015, for the Medicare Spending Per Beneficiary measures. In addition, we released draft quality measure specifications for public comment for the Drug Regimen Review Conducted with Follow-Up for Identified Issues measures from September 18, 2015, to October 6, 2015; for the Discharge to Community measures from November 9, 2015, to December 8, 2015; for the Potentially Preventable 30-Day Post-Discharge Readmission Measures from November 2, 2015 to December 1, 2015; and for the Medicare Spending Per Beneficiary measures from January 13, 2016 to February 5, 2016. We implemented a public mailbox, [PACQualityInitiative@cms.hhs.gov](mailto:PACQualityInitiative@cms.hhs.gov), for the submission of public comments. This PAC mailbox is accessible on our post-acute care quality initiatives Web site at: [<sup>167</sup> <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html>.](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-</a></p>
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<sup>168</sup> <http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm>.

*Act-of-2014-and-Cross-Setting-Measures.html.*

In addition, we sought public input from the MAP Post-Acute Care, Long-Term Care Workgroup during the annual in-person meeting held December 14 and 15, 2015. The MAP is composed of multi-stakeholder groups convened by the NQF, our current contractor under section 1890(a) of the Act, tasked to provide input on the selection of quality and efficiency measures described in section 1890(b)(7)(B) of the Act.

The MAP reviewed each IMPACT Act-related measure proposed in this proposed rule for use in the LTCH QRP. For more information on the MAP's recommendations, we refer readers to the MAP 2016 Final Recommendations to HHS and CMS public report at: [http://www.qualityforum.org/Publications/2016/02/MAP\\_2016\\_Considerations\\_for\\_Implementing\\_Measures\\_in\\_Federal\\_Programs\\_-\\_PAC-LTC.aspx](http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx).

For measures that do not have NQF endorsement, or which are not fully supported by the MAP for use in the LTCH QRP, we are proposing for the LTCH QRP for the purposes of satisfying the measure domains required under the IMPACT Act measures that closely align with the national priorities identified in the National Quality Strategy (<http://www.ahrq.gov/workingforquality/>) and for which the MAP supports the measure concept. Further, discussion as to the importance and high-priority status of these proposed measures in the LTCH setting is included under each quality measure proposal in this proposed rule.

3. Policy for Retention of LTCH QRP Measures Adopted for Previous Payment Determinations

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53615), for the purpose of streamlining the rulemaking process, we adopted a policy that, when we initially adopt a measure for the LTCH QRP for a payment determination and all subsequent years, it would remain in effect until the measure was actively removed, suspended, or replaced. For further information on how measures are considered for removal, suspension, or replacement, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53615).

We are not proposing any changes to the policy for retaining LTCH QRP measures adopted for previous payment determinations.

4. Policy for Adopting Changes to LTCH QRP Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616), we

adopted a subregulatory process to incorporate NQF updates to LTCH quality measure specifications that do not substantively change the nature of the measure. Substantive changes will be proposed and finalized through rulemaking. For further information on what constitutes a substantive versus a nonsubstantive change and the subregulatory process for nonsubstantive changes, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616). We are not proposing any changes to the policy for adopting changes to LTCH QRP measures.

5. Quality Measures Previously Finalized for and Currently Used in the LTCH QRP

A history of the LTCH QRP quality measures adopted for the FY 2014 payment determinations and subsequent years is presented in the table below. The year in which each quality measure was first adopted and implemented, and then subsequently readopted or revised, if applicable, is displayed. The initial and subsequent annual payment determination years are also shown in this table. For more information on a particular measure, we refer readers to the IPPS/LTCH PPS final rule and associated page numbers referenced in this table.

QUALITY MEASURES PREVIOUSLY FINALIZED FOR AND CURRENTLY USED IN THE LTCH QRP

Measure title	IPPS/LTCH PPS Final rule	Data collection start date	Annual payment determination: initial and subsequent APU Years
National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138).	Adopted an application of the measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51745 through 51747).	October 1, 2012 .....	FY 2014 and subsequent years.
	Adopted the NQF-endorsed version and expanded measure (with standardized infection ratio [SIR]) in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53616 through 53619).	January 1, 2013 .....	FY 2015 and subsequent years.
National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139).	Adopted an application of the measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51747 through 51748).	October 1, 2012 .....	FY 2014 and subsequent years.
	Adopted the NQF-endorsed and expanded measure (with SIR) in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53616 through 53619).	January 1, 2013 .....	FY 2015 and subsequent years.
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678).	Adopted an application of the measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51748 through 51750).	October 1, 2012 .....	FY 2014 and subsequent years.
	Adopted the NQF-endorsed version in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50861 through 50863).	January 1, 2013 .....	FY 2015 and subsequent years.
	Adopted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49731 through 49736) to fulfill IMPACT Act requirements.	January 1, 2016 .....	FY 2018 and subsequent years.

QUALITY MEASURES PREVIOUSLY FINALIZED FOR AND CURRENTLY USED IN THE LTCH QRP—Continued

Measure title	IPPS/LTCH PPS Final rule	Data collection start date	Annual payment determination: initial and subsequent APU Years
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680).	Adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627).	January 1, 2014 .....	FY 2016 and subsequent years.
	Revised data collection timeframe in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50858 through 50861).	October 1, 2014 .....	FY 2016 and subsequent years.
	Revised data collection timeframe in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50289 through 50290).	October 1, 2014 .....	FY 2016 and subsequent years.
Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431).	Adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53630 through 53631).	October 1, 2014 .....	FY 2016 and subsequent years.
	Revised data collection timeframe in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50857 through 50858).	October 1, 2014 .....	FY 2016 and subsequent years.
All-Cause Unplanned Readmission Measure for 30-Days Post-Discharge from Long-Term Care Hospitals (NQF #2512).	Adopted in FY 2014 IPPS/LTCH PPS final rule (78 FR 50868 through 50874).	N/A .....	FY 2017 and subsequent years.
	Adopted the NQF-endorsed version in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49730 through 49731).	N/A .....	FY 2018 and subsequent years.
National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716).	Adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50863 through 50865).	January 1, 2015 .....	FY 2017 and subsequent years.
National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717).	Adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50865 through 50868).	January 1, 2015 .....	FY 2017 and subsequent years.
National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure (NQF #N/A).	Adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50301 through 50305).	January 1, 2016 .....	FY 2018 and subsequent years.
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).	Adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877).	January 1, 2016 .....	FY 2018 and subsequent years.
	Revised data collection timeframe in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50290 through 50291).	April 1, 2016 .....	FY 2018 and subsequent years.
	Adopted an application of the measure in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49736 through 49739) to fulfill IMPACT Act requirements.	April 1, 2016 .....	FY 2018 and subsequent years.
Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).	Adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50291 through 50298).	April 1, 2016 .....	FY 2018 and subsequent years.
Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).	Adopted an application of the measure in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49739 through 49747) to fulfill IMPACT Act requirements.	April 1, 2016 .....	FY 2018 and subsequent years.
Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632).	Adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50298 through 50301).	April 1, 2016 .....	FY 2018 and subsequent years.

6. LTCH QRP Quality, Resource Use and Other Measures Proposed for the FY 2018 Payment Determination and Subsequent Years

For the FY 2018 payment determinations and subsequent years, in addition to the quality measures we are retaining under our policy described in section VIII.C.3. of the preamble of this

proposed rule, we are proposing three new measures. These measures were developed to meet the requirements of the IMPACT Act. They are:

- MSPB–PAC LTCH QRP;
- Discharge to Community-PAC LTCH QRP, and

- Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP.

The measures are described in more detail below.

For the risk-adjustment of the resource use and other measures, we understand the important role that sociodemographic status plays in the

care of patients. However, we continue to have concerns about holding providers to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on providers' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

We are inviting public comment on how socioeconomic and demographic factors should be used in risk adjustment for the resource use measures.

#### a. Proposal To Address the IMPACT Act Domain of Resource Use and Other Measures: Total Estimated MSPB–PAC LTCH QRP

We are proposing an MSPB–PAC LTCH QRP measure for inclusion in the LTCH QRP for the FY 2018 payment determination and subsequent years. Section 1899B(d)(1)(A) of the Act requires the Secretary to specify resource use measures, including total estimated Medicare spending per beneficiary, on which PAC providers, consisting of LTCHs, Inpatient Rehabilitation Facilities (IRFs), Skilled Nursing Facilities (SNFs), and Home Health Agencies (HHAs), are required to submit necessary data specified by the Secretary.

Rising Medicare expenditures for post-acute care as well as wide variation in spending for these services underlines the importance of measuring resource use for providers rendering these services. Between 2001 and 2013, Medicare PAC spending grew at an annual rate of 6.1 percent and doubled to \$59.4 billion, while payments to inpatient hospitals grew at an annual rate of 1.7 percent over this same period.<sup>169</sup> A study commissioned by the Institute of Medicine found that variation in PAC spending explains 73 percent of variation in total Medicare spending across the United States.<sup>170</sup>

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use measures for PAC settings. Therefore, we are proposing this MSPB–PAC LTCH QRP measure under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act. Because of the current lack of resource use measures for PAC settings, our proposed MSPB–PAC LTCH QRP measure has the potential to provide valuable information to LTCHs on their relative Medicare spending in delivering services to approximately 122,000 Medicare beneficiaries.<sup>171</sup>

The proposed MSPB–PAC LTCH QRP episode-based measure will provide actionable and transparent information to support LTCHs' efforts to promote care coordination and deliver high quality care at a lower cost to Medicare. The MSPB–PAC LTCH QRP measure holds LTCHs accountable for the Medicare payments within an "episode of care" (episode), which includes the period during which a patient is directly under the LTCH's care, as well as a defined period after the end of the LTCH treatment, which may be reflective of and influenced by the services furnished by the LTCH. MSPB–PAC LTCH QRP episodes, constructed according to the methodology described below, have high levels of Medicare spending with substantial variation. In FY 2013 and FY 2014, Medicare FFS beneficiaries experienced 178,538 MSPB–PAC LTCH QRP episodes triggered by admission to an LTCH. The mean payment-standardized, risk-adjusted episode spending for these episodes is \$67,181. There is substantial variation in the Medicare payments for

these MSPB–PAC LTCH QRP episodes—ranging from approximately \$27,502 at the 5th percentile to approximately \$115,291 at the 95th percentile. This variation is partially driven by variation in payments occurring following LTCH treatment.

Evaluating Medicare payments during an episode creates a continuum of accountability between providers and has the potential to improve post-treatment care planning and coordination. While some stakeholders throughout the measure development process supported the measures and believed that measuring Medicare spending was critical for improving efficiency, other stakeholders believed that resource use measures did not reflect quality of care in that they do not take into account patient outcomes or experience beyond those observable in claims data. However, LTCHs involved in the provision of high quality PAC care as well as appropriate discharge planning and post-discharge care coordination would be expected to perform well on this measure since beneficiaries would likely experience fewer costly adverse events (for example, avoidable hospitalizations, infections, and emergency room usage). Further, it is important that the cost of care be explicitly measured so that, in conjunction with other quality measures, we can recognize providers that are involved in the provision of high quality care at lower cost.

We have undertaken development of MSPB–PAC measures for each of the four PAC settings. We intend to propose IRF-, SNF-, and HHA-specific MSPB–PAC measures through future notice-and-comment rulemaking. The four setting-specific MSPB–PAC measures are closely aligned in terms of episode construction and measure calculation. Each of the MSPB–PAC measures assess Medicare Part A and Part B spending during an episode, and the numerator and denominator are defined similarly for each of the MSPB–PAC measures. However, developing setting-specific measures allows us to account for differences between settings in payment policy, the types of data available, and the underlying health characteristics of beneficiaries. For example, the MSPB–PAC LTCH QRP measure reflects the dual payment rate of the LTCH PPS by comparing episodes triggered by each payment rate case only with episodes of the same type, as detailed below.

The MSPB–PAC measures mirror the general construction of the Hospital IQR Program MSPB measure that was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618 through 51627). That measure was endorsed by

<sup>169</sup> MedPAC, "A Data Book: Health Care Spending and the Medicare Program," (2015). 114.

<sup>170</sup> Institute of Medicine, "Variation in Health Care Spending: Target Decision Making, Not Geography," (Washington, DC: National Academies 2013). 2.

<sup>171</sup> Figures for 2013. MedPAC, "Medicare Payment Policy," Report to the Congress (2015). xvii-xviii.

the NQF on December 6, 2013, and has been used in the Hospital VBP Program (NQF #2158) since FY 2015.<sup>172</sup> The Hospital IQR Program MSPB measure was originally established under the authority of section 1886(o)(2)(B)(ii) of the Act. The hospital MSPB measure evaluates hospitals' Medicare spending relative to the Medicare spending for the national median hospital during a hospital MSPB episode. It assesses Medicare Part A and Part B payments for services performed by hospitals and other healthcare providers during a hospital MSPB episode, which is comprised of the periods immediately prior to, during, and following a patient's hospital stay.<sup>173 174</sup>

Similarly, the MSPB-PAC measures assess all Medicare Part A and Part B payments for FFS claims with a start date during the episode window (which, as discussed below, is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB-PAC LTCH QRP episode). However, there are differences between the MSPB-PAC measures, as proposed, and the hospital MSPB measure to reflect differences in payment policies and the nature of care provided in each PAC setting. For example, the MSPB-PAC measures exclude a limited set of services (for example, for clinically unrelated services) provided to a beneficiary during the episode window while the hospital MSPB measure does not exclude any services.<sup>175</sup>

MSPB-PAC episodes may begin within 30 days of discharge from an inpatient hospital as part of a patient's trajectory from an acute to a PAC setting. An LTCH stay beginning within 30 days of discharge from an inpatient hospital will therefore be included once in the hospital's MSPB measure, and once in the LTCH's MSPB-PAC measure. Aligning the hospital MSPB and MSPB-PAC measures in this way creates continuous accountability and aligns incentives to improve care planning and coordination across inpatient and PAC settings.

We have sought and considered the input of stakeholders throughout the measure development process for the

MSPB-PAC measures. We convened a TEP consisting of 12 panelists with combined expertise in all of the PAC settings on October 29 and 30, 2015, in Baltimore, Maryland. A follow-up email survey was sent to TEP members on November 18, 2015, to which 7 responses were received by December 8, 2015. The MSPB-PAC TEP Summary Report is available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Technical-Expert-Panel-on-Medicare-Spending-Per-Beneficiary.pdf>. The measures were also presented to the NQF MAP Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup on December 15, 2015. As the MSPB-PAC measures were under development, there were three voting options for members: Encourage continued development, do not encourage further consideration, and insufficient information.<sup>176</sup> The MAP PAC/LTC Workgroup voted to "encourage continued development" for each of the MSPB-PAC measures.<sup>177</sup> The MAP PAC/LTC Workgroup's vote of "encourage continued development" was affirmed by the MAP Coordinating Committee on January 26, 2016.<sup>178</sup> The MAP's concerns about the MSPB-PAC measures, as outlined in their final report, "MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care," and Spreadsheet of Final Recommendations were taken into consideration during the measure development process and are discussed as part of our responses to public comments, described below.<sup>179 180</sup>

<sup>176</sup> National Quality Forum, Measure Applications Partnership, "Process and Approach for MAP Pre-Rulemaking Deliberations, 2015–2016" (February 2016) <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81693>.

<sup>177</sup> National Quality Forum, Measure Applications Partnership Post-Acute Care/Long-Term Care Workgroup, "Meeting Transcript—Day 2 of 2" (December 15, 2015) 104–106 <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81470>.

<sup>178</sup> National Quality Forum, Measure Applications Partnership, "Meeting Transcript—Day 1 of 2" (January 26, 2016) 231–232 <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81637>.

<sup>179</sup> National Quality Forum, Measure Applications Partnership, "MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care" Final Report, (February 2016) [http://www.qualityforum.org/Publications/2016/02/MAP\\_2016\\_Considerations\\_for\\_Implementing\\_Measures\\_in\\_Federal\\_Programs\\_-\\_PAC-LTC.aspx](http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx).

<sup>180</sup> National Quality Forum, Measure Applications Partnership, "Spreadsheet of MAP 2016 Final Recommendations" (February 1, 2016) <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>.

Since the MAP's review and recommendation of continued development, CMS has continued to refine risk adjustment models and conduct measure testing for the IMPACT Act measures in compliance with the MAP's recommendations. The proposed IMPACT Act measures are both consistent with the information submitted to the MAP and support the scientific acceptability of these measures for use in quality reporting programs.

In addition, a public comment period, accompanied by draft measures specifications, was originally open from January 13 to 27, 2016 and twice extended to January 29 and February 5. A total of 45 comments on the MSPB-PAC measures were received during this comment period. The comments received also covered each of the MAP's concerns as outlined in their Final Recommendations.<sup>181</sup> The MSPB-PAC Public Comment Summary Report is available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html> and contains the public comments (summarized and verbatim), along with our responses including statistical analyses. If finalized, the proposed MSPB-PAC LTCH QRP measure, along with the other MSPB-PAC measures, as applicable, will be submitted for NQF endorsement.

To calculate the MSPB-PAC LTCH QRP measure for each LTCH, we first define the construction of the MSPB-PAC LTCH QRP episode, including the length of the episode window as well as the services included in the episode. Next, we apply the methodology for the measure calculation. The specifications are discussed further below. More detailed specifications for the proposed MSPB-PAC measures, including the MSPB-PAC LTCH QRP measure in this proposed rule, are available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

#### (1) Episode Construction

An MSPB-PAC LTCH QRP episode begins at the episode trigger, which is defined as the patient's admission to an LTCH. This admitting facility is the attributed provider, for whom the

<sup>181</sup> National Quality Forum, Measure Applications Partnership, "Spreadsheet of MAP 2016 Final Recommendations" (February 1, 2016) <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593>.

<sup>172</sup> QualityNet, "Measure Methodology Reports: Medicare Spending Per Beneficiary (MSPB) Measure," (2015). <http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPPage%2FQnetTier3&cid=1228772053996>.

<sup>173</sup> QualityNet, "Measure Methodology Reports: Medicare Spending Per Beneficiary (MSPB) Measure," (2015). <http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPPage%2FQnetTier3&cid=1228772053996>.

<sup>174</sup> FY 2012 IPPS/LTCH PPS final rule (76 FR 51619).

<sup>175</sup> FY 2012 IPPS/LTCH PPS final rule (76 FR 51620).



MSPB–PAC LTCH QRP measure is calculated. The episode window is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB–PAC LTCH QRP episode. Because Medicare FFS claims are already reported to the Medicare program for payment purposes, LTCHs will not be required to report any additional data to CMS for calculation of this measure. Thus, there will be no additional data collection burden from the implementation of this measure.

Our proposed MSPB–PAC LTCH QRP episode construction methodology differentiates between episodes triggered by standard payment rate cases and site neutral payment rate cases, reflecting the LTCH dual-payment policy detailed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623). Standard and site neutral episodes would be compared only with standard and site neutral episodes respectively. Differences in episode construction between standard and site neutral episodes are noted below; they otherwise share the same definition.

The episode window is comprised of a treatment period and an associated services period. The treatment period begins at the trigger (that is, on the day of admission to the LTCH) and ends on the day of discharge from that LTCH. Readmissions to the same facility occurring within 7 or fewer days do not trigger a new episode, and instead are included in the treatment period of the original episode. When two sequential stays at the same LTCH occur within 7 or fewer days of one another, the treatment period ends on the day of discharge for the latest LTCH stay. The treatment period includes those services that are provided directly or reasonably managed by the LTCH that are directly related to the beneficiary's care plan. The associated services period is the time during which Medicare Part A and Part B services (with certain exclusions) are counted towards the episode. The associated services period begins at the episode trigger and ends 30 days after the end of the treatment period. The distinction between the treatment period and the associated services period is important because clinical exclusions of services may differ for each period.

Certain services are excluded from the MSPB–PAC LTCH QRP episodes because they are clinically unrelated to LTCH care, and/or because LTCHs may have limited influence over certain Medicare services delivered by other providers during the episode window. These limited service-level exclusions are not counted towards a given LTCH's

Medicare spending to ensure that beneficiaries with certain conditions and complex care needs receive the necessary care. Certain services that have been determined by clinicians to be outside of the control of an LTCH include planned hospital admissions, management of certain preexisting chronic conditions (for example, dialysis for end-stage renal disease (ESRD), and enzyme treatments for genetic conditions), treatment for preexisting cancers, organ transplants, and preventive screenings (for example, colonoscopy and mammograms). Exclusion of such services from the MSPB–PAC LTCH QRP episode ensures that facilities do not have disincentives to treat patients with certain conditions or complex care needs.

An MSPB–PAC episode may begin during the associated services period of an MSPB–PAC LTCH QRP episode in the 30 days post-treatment. One possible scenario occurs where an LTCH discharges a beneficiary who is then admitted to a HHA within 30 days. The HHA claim would be included once as an associated service for the attributed provider of the first MSPB–PAC LTCH QRP episode and once as a treatment service for the attributed provider of the second MSPB–PAC HHA episode. As in the case of overlap between hospital and PAC episodes discussed earlier, this overlap is necessary to ensure continuous accountability between providers throughout a beneficiary's trajectory of care, as both providers share incentives to deliver high quality care at a lower cost to Medicare.

Even within the LTCH setting, one MSPB–PAC LTCH QRP episode may begin in the associated services period of another MSPB–PAC LTCH QRP episode in the 30 days post-treatment. The second LTCH claim would be included once as an associated service for the attributed LTCH of the first MSPB–PAC LTCH QRP episode and once as a treatment service for the attributed LTCH of the second MSPB–PAC LTCH QRP episode. Again, this ensures that LTCHs have the same incentives throughout both MSPB–PAC LTCH QRP episodes to deliver quality care and engage in patient-focused care planning and coordination. If the second MSPB–PAC LTCH QRP episode were excluded from the second LTCH's MSPB–PAC LTCH QRP measure, that LTCH would not share the same incentives as the first LTCH of the first MSPB–PAC LTCH QRP episode. The MSPB–PAC LTCH QRP measure is designed to benchmark the resource use of each attributed provider against what their spending is expected to be as predicted through risk adjustment. As

discussed further below, the measure takes the ratio of observed spending to expected spending for each episode and then takes the average of those ratios across all of the attributed provider's episodes. The measure is not a simple sum of all costs across a provider's episodes, thus mitigating concerns about double counting.

## (2) Measure Calculation

Medicare payments for Part A and Part B claims for services included in MSPB–PAC LTCH episodes, defined according to the methodology above, are used to calculate the MSPB–PAC LTCH QRP measure. Measure calculation involves determination of the episode exclusions, the approach for standardizing payments for geographic payment differences, the methodology for risk adjustment of episode spending to account for differences in patient case mix, and the specifications for the measure numerator and denominator. The measure calculation is performed separately for MSPB–PAC LTCH QRP standard and site neutral episodes to ensure that they are compared only to other standard and site neutral episodes, respectively. The final MSPB–PAC LTCH QRP measure would combine the two ratios to construct one LTCH score as described below.

### (a) Exclusion Criteria

In addition to service-level exclusions that remove some payments from individual episodes, we exclude certain episodes in their entirety from the MSPB–PAC LTCH QRP measure to ensure that the MSPB–PAC LTCH QRP measure accurately reflects resource use and facilitates fair and meaningful comparisons between LTCHs. The proposed episode-level exclusions are as follows:

- Any episode that is triggered by an LTCH claim outside the 50 States, DC, Puerto Rico, and U.S. territories.
- Any episode where the claim(s) constituting the attributed LTCH's treatment have a standard allowed amount of zero or where the standard allowed amount cannot be calculated.
- Any episode in which a beneficiary is not enrolled in Medicare FFS for the entirety of a 90-day lookback period (that is, a 90-day period prior to the episode trigger) plus episode window (including where a beneficiary dies), or is enrolled in Part C for any part of the lookback period plus episode window.
- Any episode in which a beneficiary has a primary payer other than Medicare for any part of the 90-day lookback period plus episode window.
- Any episode where the claim(s) constituting the attributed LTCH's

treatment include at least one related condition code indicating that it is not a prospective payment system bill.

#### (b) Standardization and Risk Adjustment

Section 1899B(d)(2)(C) of the Act requires that the MSPB–PAC measures are adjusted for the factors described under section 1886(o)(2)(B)(ii) of the Act, which include adjustment for factors such as age, sex, race, severity of illness, and other factors that the Secretary determines appropriate. Medicare payments included in the proposed MSPB–PAC LTCH QRP measure are payment-standardized and risk-adjusted. Payment standardization removes sources of payment variation not directly related to clinical decisions and facilitates comparisons of resource use across geographic areas. We are proposing to use the same payment standardization methodology as that used in the NQF-endorsed hospital MSPB measure. This methodology removes geographic payment differences, such as wage index and geographic practice cost index (GPCI), incentive payment adjustments, and other add-on payments that support broader Medicare program goals including indirect graduate medical education (IME) and hospitals serving a disproportionate share of uninsured patients (DSH).<sup>182</sup>

Risk adjustment uses patient claims history to account for case-mix variation and other factors that affect resource use but are beyond the influence of the attributed LTCH. To assist with risk adjustment for MSPB–PAC LTCH QRP episodes, we create mutually exclusive and exhaustive clinical case-mix categories using the most recent institutional claim in the 60 days prior to the start of the MSPB–PAC LTCH QRP episode. The beneficiaries in these clinical case-mix categories have a greater degree of clinical similarity than the overall LTCH patient population, and allow us to more accurately estimate Medicare spending. Our proposed MSPB–PAC LTCH QRP model, adapted for the LTCH setting from the NQF-endorsed hospital MSPB measure, uses a regression framework with a 90-day hierarchical condition category (HCC) lookback period and covariates including the clinical case mix categories, MS–LTC–DRGs, HCC indicators, age brackets, indicators for originally disabled, ESRD enrollment, and long-term care status, and selected interactions of these covariates where

sample size and predictive ability make them appropriate. We sought and considered public comment regarding the treatment of hospice services occurring within the MSPB–PAC LTCH QRP episode window. After consideration of the comments received, we are proposing to include the Medicare spending for hospice services but risk adjust for them, so that MSPB–PAC LTCH QRP episodes with hospice are compared to a benchmark reflecting other MSPB–PAC LTCH QRP episodes with hospice. We believe that this strikes a balance between the measure's intent of evaluating Medicare spending and ensuring that providers do not have incentives against the appropriate use of hospice services in a patient-centered continuum of care.

We understand the important role that sociodemographic status, beyond age, plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how

they apply to our quality programs at such time as they are available.

While we conducted analyses on the impact of age by sex on the performance of the MSPB–PAC LTCH QRP risk-adjustment model, we are not proposing to adjust the MSPB–PAC LTCH measure for socioeconomic and demographic factors at this time. As this MSPB–PAC LTCH QRP measure will be submitted for NQF endorsement, we prefer to await the results of this trial and study before deciding whether to risk adjust for socioeconomic and demographic factors. We will monitor the results of the trial, studies, and recommendations. We are inviting public comment on how socioeconomic and demographic factors should be used in risk adjustment for the MSPB–PAC LTCH QRP measure.

#### (c) Measure Numerator and Denominator

The MSPB–PAC LTCH measure is a payment-standardized, risk-adjusted ratio that compares a given LTCH's Medicare spending against the Medicare spending of other LTCHs within a performance period. Similar to the hospital MSPB measure, the ratio allows for ease of comparison over time as it obviates the need to adjust for inflation or policy changes.

The MSPB–PAC LTCH QRP measure is calculated as the ratio of the MSPB–PAC Amount for each LTCH divided by the episode-weighted median MSPB–PAC Amount across all LTCHs. To calculate the MSPB–PAC Amount for each LTCH, one calculates the average of the ratio of the standardized spending for LTCH standard episodes over the expected spending (as predicted in risk adjustment) for LTCH standard episodes, and the average of the ratio of the standardized spending for LTCH site neutral episodes over the expected spending (as predicted in risk adjustment) for LTCH site neutral episodes. This quantity is then multiplied by the average episode spending level across all LTCHs nationally for standard and site neutral episodes. The denominator for an LTCH's MSPB–PAC LTCH QRP measure is the episode-weighted national median of the MSPB–PAC Amounts across all LTCHs. An MSPB–PAC LTCH QRP measure of less than 1 indicates that a given LTCH's Medicare spending is less than that of the national median LTCH during a performance period. Mathematically, this is represented in equation (A) below:

<sup>182</sup> QualityNet, "CMS Price (Payment) Standardization—Detailed Methods" (Revised May

2015) <https://qualitynet.org/dcs/>

ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350.

$$(A) \text{ MSPB-PAC LTCH Measure}_j = \frac{\text{MSPB-PAC Amount}_j}{\text{National Median MSPB-PAC Amount}}$$

$$= \frac{\left( \frac{1}{n_j} \sum_{i \in \{I_j\}} \frac{Y_{ij}}{\bar{Y}_{ij}} \right) \left( \frac{1}{n} \sum_j \sum_{i \in \{I_j\}} Y_{ij} \right)}{\text{Episode - Weighted Median of LTCH Providers' MSPB-PAC Amount}}$$

where

- $Y_{ij}$  = attributed standardized spending for episode  $i$  and provider  $j$
- $\bar{Y}_{ij}$  = expected standardized spending for episode  $i$  and provider  $j$ , as predicted from risk adjustment
- $n_j$  = number of episodes for provider  $j$
- $n$  = total number of episodes nationally
- $i \in \{I_j\}$  = all episodes  $i$  in the set of episodes attributed to provider  $j$ .

### (3) Data Sources

The MSPB-PAC LTCH QRP resource use measure is an administrative claims-based measure. It uses Medicare Part A and Part B claims from FFS beneficiaries and Medicare eligibility files.

### (4) Cohort

The measure cohort includes Medicare FFS beneficiaries with an LTCH treatment period ending during the data collection period.

### (5) Reporting

If this proposed measure is finalized, we intend to provide initial confidential feedback to providers, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2015 and CY 2016. We intend to publicly report this measure using claims data from discharges in CY 2016 and CY 2017.

We are proposing a minimum of 20 episodes for reporting and inclusion in the LTCH QRP. For the reliability calculation, as described in the measure specifications identified and for which a link has been provided above, we used two years of data (FY 2013 and FY 2014) to increase the statistical reliability of this measure. The reliability results support the 20 episode case minimum, and 98.83 percent of LTCHs had moderate or high reliability (above 0.4).

We are inviting public comment on our proposal to adopt the MSPB-PAC LTCH QRP measure for the LTCH QRP.

### b. Proposal To Address the IMPACT Act Domain of Resource Use and Other Measures: Discharge to Community-Post Acute Care (PAC) Long-Term Care Hospital Quality Reporting Program

Sections 1899B(d)(1)(B) and 1899B(a)(2)(E)(ii) of the Act require the Secretary to specify a measure to

address the domain of discharge to community by SNFs, LTCHs, and IRFs by October 1, 2016, and HHAs by January 1, 2017. We are proposing to adopt the measure, Discharge to Community-PAC LTCH QRP, for the LTCH QRP for the FY 2018 payment determination and subsequent years as a Medicare FFS claims-based measure to meet this requirement.

This proposed measure assesses successful discharge to the community from an LTCH setting, with successful discharge to the community including no unplanned rehospitalizations and no death in the 31 days following discharge from the LTCH. Specifically, this proposed measure reports an LTCH's risk-standardized rate of Medicare FFS patients who are discharged to the community following an LTCH stay, and do not have an unplanned readmission to an acute care hospital or LTCH in the 31 days following discharge to community, and who remain alive during the 31 days following discharge to community. The term "community," for this measure, is defined as home/self-care, with or without home health services, based on Patient Discharge Status Codes 01, 06, 81, and 86 on the Medicare FFS claim.<sup>183 184</sup> This measure is conceptualized uniformly across the PAC settings, in terms of the definition of the discharge to community outcome, the approach to risk adjustment, and the measure calculation.

Discharge to a community setting is an important health care outcome for many patients for whom the overall goals of post-acute care include optimizing functional improvement, returning to a previous level of independence, and avoiding institutionalization. Returning to the community is also an important

<sup>183</sup> Further description of patient discharge status codes can be found, for example, at the following Web page: <https://med.noridianmedicare.com/web/jea/topics/claim-submission/patient-status-codes>.

<sup>184</sup> This definition is not intended to suggest that board and care homes, assisted living facilities, or other settings included in the definition of "community" for the purpose of this measure are the most integrated setting for any particular individual or group of individuals under the Americans with Disabilities Act (ADA) and Section 504.

outcome for many patients who are not expected to make functional improvement during their LTCH stay, and for patients who may be expected to decline functionally due to their medical condition. The discharge to community outcome offers a multi-dimensional view of preparation for community life, including the cognitive, physical, and psychosocial elements involved in a discharge to the community.<sup>185 186</sup>

In addition to being an important outcome from a patient and family perspective, patients discharged to community settings, on average, incur lower costs over the recovery episode, compared with those discharged to institutional settings.<sup>187 188</sup> Given the high costs of care in institutional settings, encouraging LTCHs to prepare patients for discharge to community, when clinically appropriate, may have cost-saving implications for the Medicare program.<sup>189</sup> Also, providers have discovered that successful discharge to community was a major driver of their ability to achieve savings, where capitated payments for post-acute care were in place.<sup>190</sup> For patients who require long-term care due to persistent disability, discharge to community could result in lower long-term care

<sup>185</sup> El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a postacute geriatric rehabilitation unit. *Archives of physical medicine and rehabilitation*. 2000;81(10):1388-1393.

<sup>186</sup> Tanwir S, Montgomery K, Chari V, Nesathurai S. Stroke rehabilitation: availability of a family member as caregiver and discharge destination. *European journal of physical and rehabilitation medicine*. 2014;50(3):355-362.

<sup>187</sup> Dobrez D, Heinemann AW, Deutsch A, Manheim L, Mallinson T. Impact of Medicare's prospective payment system for inpatient rehabilitation facilities on stroke patient outcomes. *American journal of physical medicine & rehabilitation/Association of Academic Physiatrists*. 2010;89(3):198-204.

<sup>188</sup> Gage B, Morley M, Spain P, Ingber M. *Examining Post Acute Care Relationships in an Integrated Hospital System. Final Report*. RTI International;2009.

<sup>189</sup> *Ibid*.

<sup>190</sup> Doran JP, Zabinski SJ. Bundled payment initiatives for Medicare and non-Medicare total joint arthroplasty patients at a community hospital: bundles in the real world. *The journal of arthroplasty*. 2015;30(3):353-355.

costs for Medicaid and for patients' out-of-pocket expenditures.<sup>191</sup>

Analyses conducted for ASPE on PAC episodes, using a 5 percent sample of 2006 Medicare claims, revealed that relatively high average, unadjusted Medicare payments are associated with discharge to institutional settings from IRFs, SNFs, LTCHs or HHAs, as compared with payments associated with discharge to community settings.<sup>192</sup> Average, unadjusted Medicare payments associated with discharge to community settings ranged from \$0 to \$4,017 for IRF discharges, \$0 to \$3,544 for SNF discharges, \$0 to \$4,706 for LTCH discharges, and \$0 to \$992 for HHA discharges. In contrast, payments associated with discharge to non-community settings were considerably higher, ranging from \$11,847 to \$25,364 for IRF discharges, \$9,305 to \$29,118 for SNF discharges, \$12,465 to \$18,205 for LTCH discharges, and \$7,981 to \$35,192 for HHA discharges.<sup>193</sup>

Measuring and comparing facility-level discharge to community rates is expected to help differentiate among facilities with varying performance in this important domain, and to help avoid disparities in care across patient groups. Variation in discharge to community rates has been reported within and across post-acute settings; across a variety of facility-level characteristics, such as geographic location (for example, regional location, urban or rural location), ownership (for example, for-profit or nonprofit), and freestanding or hospital-based units; and across patient-level characteristics, such as race and gender.<sup>194 195 196 197 198 199</sup> Discharge to

community rates in the IRF setting have been reported to range from about 60 to 80 percent.<sup>200 201 202 203 204 205</sup> Longer-term studies show that rates of discharge to community from IRFs have decreased over time as IRF length of stay has decreased.<sup>206 207</sup> Greater variation in discharge to community rates is seen in the SNF setting, with rates ranging from 31 to 65 percent.<sup>208 209 210 211</sup> A multi-center

destination among older patients with traumatic brain injury. *Archives of physical medicine and rehabilitation*. 2008;89(2):231–236.

<sup>199</sup> Berges IM, Kuo YF, Ostir GV, Granger CV, Graham JE, Ottenbacher KJ. Gender and ethnic differences in rehabilitation outcomes after hip-replacement surgery. *American journal of physical medicine & rehabilitation/Association of Academic Physiatrists*. 2008;87(7):567–572.

<sup>200</sup> Galloway RV, Granger CV, Karmarkar AM, et al. The Uniform Data System for Medical Rehabilitation: report of patients with debility discharged from inpatient rehabilitation programs in 2000–2010. *American journal of physical medicine & rehabilitation/Association of Academic Physiatrists*. 2013;92(1):14–27.

<sup>201</sup> Morley MA, Coots LA, Fougues AL, Gage BJ. Inpatient rehabilitation utilization for Medicare beneficiaries with multiple sclerosis. *Archives of physical medicine and rehabilitation*. 2012;93(8):1377–1383.

<sup>202</sup> Reistetter TA, Graham JE, Deutsch A, Granger CV, Markello S, Ottenbacher KJ. Utility of functional status for classifying community versus institutional discharges after inpatient rehabilitation for stroke. *Archives of physical medicine and rehabilitation*. 2010;91(3):345–350.

<sup>203</sup> Gagnon D, Nadeau S, Tam V. Clinical and administrative outcomes during publicly-funded inpatient stroke rehabilitation based on a case-mix group classification model. *Journal of rehabilitation medicine*. 2005;37(1):45–52.

<sup>204</sup> DaVanzo J, El-Gamil A, Li J, Shimer M, Manolov N, Dobson A. *Assessment of patient outcomes of rehabilitative care provided in inpatient rehabilitation facilities (IRFs) and after discharge*. Vienna, VA: Dobson DaVanzo & Associates, LLC;2014.

<sup>205</sup> Kushner DS, Peters KM, Johnson-Greene D. Evaluating Siebens Domain Management Model for Inpatient Rehabilitation to Increase Functional Independence and Discharge Rate to Home in Geriatric Patients. *Archives of physical medicine and rehabilitation*. 2015;96(7):1310–1318.

<sup>206</sup> Galloway RV, Granger CV, Karmarkar AM, et al. The Uniform Data System for Medical Rehabilitation: report of patients with debility discharged from inpatient rehabilitation programs in 2000–2010. *American journal of physical medicine & rehabilitation/Association of Academic Physiatrists*. 2013;92(1):14–27.

<sup>207</sup> Mallinson T, Deutsch A, Bateman J, et al. Comparison of discharge functional status after rehabilitation in skilled nursing, home health, and medical rehabilitation settings for patients after hip fracture repair. *Archives of physical medicine and rehabilitation*. 2014;95(2):209–217.

<sup>208</sup> El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a postacute geriatric rehabilitation unit. *Archives of physical medicine and rehabilitation*. 2000;81(10):1388–1393.

<sup>209</sup> Hall RK, Toles M, Massing M, et al. Utilization of acute care among patients with ESRD discharged home from skilled nursing facilities. *Clinical journal of the American Society of Nephrology: CJASN*. 2015;10(3):428–434.

<sup>210</sup> Stearns SC, Dalton K, Holmes GM, Seagrave SM. Using propensity stratification to compare

study of 23 LTCHs demonstrated that 28.8 percent of 1,061 patients who were ventilator-dependent on admission were discharged to home.<sup>212</sup> A single-center study revealed that 31 percent of LTCH hemodialysis patients were discharged to home.<sup>213</sup> In the LTCH Medicare FFS population, using CY 2012–2013 national data, we found that approximately 25 percent of patients were discharged to the community. One study noted that 64 percent of beneficiaries who were discharged from the home health episode did not use any other acute or post-acute services paid by Medicare in the 30 days after discharge.<sup>214</sup> However, significant numbers of patients were admitted to hospitals (29 percent) and lesser numbers to SNFs (7.6 percent), IRFs (1.5 percent), home health (7.2 percent) or hospice (3.3 percent).<sup>215</sup>

Discharge to community is an actionable health care outcome, as targeted interventions have been shown to successfully increase discharge to community rates in a variety of post-acute settings.<sup>216 217 218 219</sup> Many of these interventions involve discharge planning or specific rehabilitation strategies, such as addressing discharge barriers and improving medical and

patient outcomes in hospital-based versus freestanding skilled-nursing facilities. *Medical care research and review: MCR*. 2006;63(5):599–622.

<sup>211</sup> Wodchis WP, Teare GF, Naglie G, et al. Skilled nursing facility rehabilitation and discharge to home after stroke. *Archives of physical medicine and rehabilitation*. 2005;86(3):442–448.

<sup>212</sup> Scheinhorn DJ, Hassenpflug MS, Votto JJ, et al. Post-ICU mechanical ventilation at 23 long-term care hospitals: a multicenter outcomes study. *Chest*. 2007;131(1):85–93.

<sup>213</sup> Thakar CV, Quate-Operacz M, Leonard AC, Eckman MH. Outcomes of hemodialysis patients in a long-term care hospital setting: a single-center study. *American journal of kidney diseases: the official journal of the National Kidney Foundation*. 2010;55(2):300–306.

<sup>214</sup> Wolff JL, Meadow A, Weiss CO, Boyd CM, Leff B. Medicare home health patients' transitions through acute and post-acute care settings. *Medical care*. 2008;46(11):1188–1193.

<sup>215</sup> *Ibid*.

<sup>216</sup> Kushner DS, Peters KM, Johnson-Greene D. Evaluating Siebens Domain Management Model for Inpatient Rehabilitation to Increase Functional Independence and Discharge Rate to Home in Geriatric Patients. *Archives of physical medicine and rehabilitation*. 2015;96(7):1310–1318.

<sup>217</sup> Wodchis WP, Teare GF, Naglie G, et al. Skilled nursing facility rehabilitation and discharge to home after stroke. *Archives of physical medicine and rehabilitation*. 2005;86(3):442–448.

<sup>218</sup> Berkowitz RE, Jones RN, Rieder R, et al. Improving disposition outcomes for patients in a geriatric skilled nursing facility. *Journal of the American Geriatrics Society*. 2011;59(6):1130–1136.

<sup>219</sup> Kushner DS, Peters KM, Johnson-Greene D. Evaluating use of the Siebens Domain Management Model during inpatient rehabilitation to increase functional independence and discharge rate to home in stroke patients. *PM & R: the journal of injury, function, and rehabilitation*. 2015;7(4):354–364.

<sup>191</sup> Newcomer RJ, Ko M, Kang T, Harrington C, Hulett D, Bindman AB. Health Care Expenditures After Initiating Long-term Services and Supports in the Community Versus in a Nursing Facility. *Medical Care*. 2016;54(3):221–228.

<sup>192</sup> Gage B, Morley M, Spain P, Ingber M. *Examining Post Acute Care Relationships in an Integrated Hospital System. Final Report*. RTI International;2009.

<sup>193</sup> *Ibid*.

<sup>194</sup> Reistetter TA, Karmarkar AM, Graham JE, et al. Regional variation in stroke rehabilitation outcomes. *Archives of physical medicine and rehabilitation*. 2014;95(1):29–38.

<sup>195</sup> El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a postacute geriatric rehabilitation unit. *Archives of physical medicine and rehabilitation*. 2000;81(10):1388–1393.

<sup>196</sup> *March 2015 Report to the Congress: Medicare Payment Policy*. Medicare Payment Advisory Commission;2015.

<sup>197</sup> Bhandari VK, Kushel M, Price L, Schillinger D. Racial disparities in outcomes of inpatient stroke rehabilitation. *Archives of physical medicine and rehabilitation*. 2005;86(11):2081–2086.

<sup>198</sup> Chang PF, Ostir GV, Kuo YF, Granger CV, Ottenbacher KJ. Ethnic differences in discharge

functional status.<sup>220 221 222 223</sup> The effectiveness of these interventions suggests that improvement in discharge to community rates among post-acute care patients is possible through modifying provider-led processes and interventions.

A TEP convened by our measure development contractor was strongly supportive of the importance of measuring discharge to community outcomes, and implementing the proposed measure, Discharge to Community-PAC LTCH QRP in the LTCH QRP. The panel provided input on the technical specifications of this proposed measure, including the feasibility of implementing the measure, as well as the overall measure reliability and validity. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 9, 2015, through December 8, 2015. Several stakeholders and organizations, including the MedPAC, among others, supported this measure for implementation. The public comment summary report for the proposed measure is available on the CMS Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The NQF-convened MAP met on December 14 and 15, 2015, and provided input on the use of this proposed Discharge to Community-PAC LTCH QRP measure in the LTCH QRP.

<sup>220</sup> Kushner DS, Peters KM, Johnson-Greene D. Evaluating Siebens Domain Management Model for Inpatient Rehabilitation to Increase Functional Independence and Discharge Rate to Home in Geriatric Patients. *Archives of physical medicine and rehabilitation*. 2015;96(7):1310–1318.

<sup>221</sup> Wodchis WP, Teare GF, Naglie G, et al. Skilled nursing facility rehabilitation and discharge to home after stroke. *Archives of physical medicine and rehabilitation*. 2005;86(3):442–448.

<sup>222</sup> Berkowitz RE, Jones RN, Rieder R, et al. Improving disposition outcomes for patients in a geriatric skilled nursing facility. *Journal of the American Geriatrics Society*. 2011;59(6):1130–1136.

<sup>223</sup> Kushner DS, Peters KM, Johnson-Greene D. Evaluating use of the Siebens Domain Management Model during inpatient rehabilitation to increase functional independence and discharge rate to home in stroke patients. *PM & R: the journal of injury, function, and rehabilitation*. 2015;7(4):354–364.

The MAP encouraged continued development of the proposed measure to meet the mandate of the IMPACT Act. The MAP supported the alignment of this proposed measure across PAC settings, using standardized claims data. More information about the MAP's recommendations for this measure is available at: [http://www.qualityforum.org/Publications/2016/02/MAP\\_2016\\_Considerations\\_for\\_Implementing\\_Measures\\_in\\_Federal\\_Programs\\_-\\_PAC-LTC.aspx](http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx).

Since the MAP's review and recommendation of continued development, we have continued to refine risk-adjustment models and conduct measure testing for this measure, as recommended by the MAP. This proposed measure is consistent with the information submitted to the MAP and is scientifically acceptable for current specification in the LTCH QRP. As discussed with the MAP, we fully anticipate that additional analyses will continue as we submit this measure to the ongoing measure maintenance process.

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use or other measures for post-acute care focused on discharge to community. In addition, we are unaware of any other post-acute care measures for discharge to community that have been endorsed or adopted by other consensus organizations. Therefore, we are proposing the measure, Discharge to Community-PAC LTCH QRP, under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act.

We are proposing to use data from the Medicare FFS claims and Medicare eligibility files to calculate this proposed measure. We are proposing to use data from the "Patient Discharge Status Code" on Medicare FFS claims to determine whether a patient was discharged to a community setting for calculation of this proposed measure. In all PAC settings, we tested the accuracy of determining discharge to a community setting using the "Patient Discharge Status Code" on the PAC claim by examining whether discharge to community coding based on PAC claim data agreed with discharge to community coding based on PAC assessment data. We found excellent agreement between the two data sources in all PAC settings, ranging from 94.6 percent to 98.8 percent. Specifically, in the LTCH setting, using 2013 data, we found 95.6 percent agreement in coding of community and non-community discharges when comparing discharge status codes on claims and the

Discharge Location (item A2100) codes on the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set Version 1.01. We further examined the accuracy of the "Patient Discharge Status Code" on the PAC claim by assessing how frequently discharges to an acute care hospital were confirmed by follow-up acute care claims. We discovered that 88 percent to 91 percent of IRF, LTCH, and SNF claims with acute care discharge status codes were followed by an acute care claim on the day of, or day after, PAC discharge. We believe these data support the use of the claims "Patient Discharge Status Code" for determining discharge to a community setting for this measure. In addition, this measure can feasibly be implemented in the LTCH QRP because all data used for measure calculation are derived from Medicare FFS claims and eligibility files, which are already available to CMS.

Based on the evidence discussed above, we are proposing to adopt the measure, Discharge to Community-PAC LTCH QRP, for the LTCH QRP for FY 2018 payment determination and subsequent years. This proposed measure is calculated using 2 years of data. We are proposing a minimum of 25 eligible stays in a given LTCH for public reporting of the proposed measure for that LTCH. Since Medicare FFS claims data are already reported to the Medicare program for payment purposes, and Medicare eligibility files are also available, LTCHs will not be required to report any additional data to CMS for calculation of this measure. The proposed measure denominator is the risk-adjusted expected number of discharges to community. The proposed measure numerator is the risk-adjusted estimate of the number of patients who are discharged to the community, do not have an unplanned readmission to an acute care hospital or LTCH in the 31-day post-discharge observation window, and who remain alive during the post-discharge observation window. The measure is risk-adjusted for variables such as age and sex, principal diagnosis, comorbidities, ventilator status, ESRD status, and dialysis, among other variables. For technical information about this proposed measure, including information about the measure calculation, risk adjustment, and denominator exclusions, we refer readers to the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 LTCH QRP NPRM, available at:

*Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html.*

If this proposed measure is finalized, we intend to provide initial confidential feedback to LTCHs, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2015 and 2016. We intend to publicly report this measure using claims data from discharges in CY 2016 and 2017. We plan to submit this proposed measure to the NQF for consideration for endorsement.

We are inviting public comment on our proposal to adopt the measure, Discharge to Community-PAC LTCH QRP, for the LTCH QRP.

c. Proposal To Address the IMPACT Act Domain of Resource Use and Other Measures: Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital Quality Reporting Program

Sections 1899B(a)(2)(E)(ii) and 1899B(d)(1)(C) of the Act require the Secretary to specify measures to address the domain of all-condition risk-adjusted potentially preventable hospital readmission rates by SNFs, LTCHs, and IRFs by October 1, 2016, and HHAs by January 1, 2017. We are proposing the measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP as a Medicare FFS claims-based measure to meet this requirement for the FY 2018 payment determination and subsequent years.

The proposed measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions for Medicare FFS beneficiaries in the 30 days post-LTCH discharge. The LTCH admission must have occurred within up to 30 days of discharge from a prior proximal hospital stay which is defined as an inpatient admission to an acute care hospital (including IPPS, CAH, or a psychiatric hospital). Hospital readmissions include readmissions to a short-stay acute care hospital or an LTCH, with a diagnosis considered to be unplanned and potentially preventable. This proposed measure is claims-based, requiring no additional data collection or submission burden for LTCHs. Because the measure denominator is based on LTCH admissions, each Medicare beneficiary may be included in the measure multiple times within the measurement period. Readmissions counted in this measure are identified by examining Medicare FFS claims data for readmissions to either acute care hospitals (IPPS or CAH) or LTCHs that occur during a 30-day window beginning two days after LTCH

discharge. This measure is conceptualized uniformly across the PAC settings, in terms of the measure definition, the approach to risk adjustment, and the measure calculation. Our approach for defining potentially preventable hospital readmissions is described in more detail below.

Hospital readmissions among the Medicare population, including beneficiaries that utilize PAC, are common, costly, and often preventable.<sup>224 225</sup> MedPAC and a study by Jencks et al. estimated that 17 to 20 percent of Medicare beneficiaries discharged from the hospital were readmitted within 30 days. MedPAC found that more than 75 percent of 30-day and 15-day readmissions and 84 percent of 7-day readmissions were considered “potentially preventable.”<sup>226</sup> In addition, MedPAC calculated that annual Medicare spending on potentially preventable readmissions would be \$12 billion for 30-day, \$8 billion for 15-day, and \$5 billion for 7-day readmissions.<sup>227</sup> For hospital readmissions from one post-acute care setting, SNFs, MedPAC deemed 76 percent of readmissions as “potentially avoidable”—associated with \$12 billion in Medicare expenditures.<sup>228</sup> Mor et al. analyzed 2006 Medicare claims and SNF assessment data (Minimum Data Set), and reported a 23.5 percent readmission rate from SNFs, associated with \$4.3B in expenditures.<sup>229</sup> Fewer studies have investigated potentially preventable readmission rates from the remaining post-acute care settings.

We have addressed the high rates of hospital readmissions in the acute care setting as well as in PAC. For example, we developed the following measure: All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512), as well as similar measures for other PAC

<sup>224</sup> Friedman, B., and Basu, J.: The rate and cost of hospital readmissions for preventable conditions. *Med. Care Res. Rev.* 61(2):225–240, 2004. doi:10.1177/1077558704263799.

<sup>225</sup> Jencks, S.F., Williams, M.V., and Coleman, E.A.: Rehospitalizations among patients in the Medicare Fee-for-Service Program. *N. Engl. J. Med.* 360(14):1418–1428, 2009. doi:10.1016/j.jvs.2009.05.045

<sup>226</sup> MedPAC: Payment policy for inpatient readmissions, in *Report to the Congress: Promoting Greater Efficiency in Medicare*. Washington, DC, pp. 103–120, 2007. Available from [http://www.medpac.gov/documents/reports/Jun07\\_EntireReport.pdf](http://www.medpac.gov/documents/reports/Jun07_EntireReport.pdf).

<sup>227</sup> Ibid.

<sup>228</sup> Ibid.

<sup>229</sup> Mor, V., Intrator, O., Feng, Z., et al.: The revolving door of rehospitalization from skilled nursing facilities. *Health Aff.* 29(1):57–64, 2010. doi:10.1377/hlthaff.2009.0629.

providers (NQF #2502 for IRFs and NQF #2510 for SNFs).<sup>230</sup> These measures are endorsed by the NQF, and the NQF-endorsed LTCH measure (NQF #2512) was adopted into the LTCH QRP in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49730 through 49731). Note that these NQF-endorsed measures assess all-cause unplanned readmissions.

Several general methods and algorithms have been developed to assess potentially avoidable or preventable hospitalizations and readmissions for the Medicare population. These include the Agency for Healthcare Research and Quality’s (AHRQ’s) Prevention Quality Indicators, approaches developed by MedPAC, and proprietary approaches, such as the 3M™ algorithm for Potentially Preventable Readmissions.<sup>231 232 233</sup> Recent work led by Kramer et al. for MedPAC identified 13 conditions for which readmissions were deemed as potentially preventable among SNF and IRF populations.<sup>234 235</sup> Although much of the existing literature addresses hospital readmissions more broadly and potentially avoidable hospitalizations for specific settings like long-term care, these findings are relevant to the development of potentially preventable readmission measures for PAC.<sup>236 237 238</sup>

<sup>230</sup> National Quality Forum: *All-Cause Admissions and Readmissions Measures*. pp. 1–319, April 2015. Available from [http://www.qualityforum.org/Publications/2015/04/All-Cause\\_Admissions\\_and\\_Readmissions\\_Measures\\_-\\_Final\\_Report.aspx](http://www.qualityforum.org/Publications/2015/04/All-Cause_Admissions_and_Readmissions_Measures_-_Final_Report.aspx).

<sup>231</sup> Goldfield, N.I., McCullough, E.C., Hughes, J.S., et al.: Identifying potentially preventable readmissions. *Health Care Finan. Rev.* 30(1):75–91, 2008. Available from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4195042/>.

<sup>232</sup> National Quality Forum: *Prevention Quality Indicators Overview*. 2008.

<sup>233</sup> MedPAC: *Online Appendix C: Medicare Ambulatory Care Indicators for the Elderly*. pp. 1–12, prepared for Chapter 4, 2011. Available from: [http://www.medpac.gov/documents/reports/Mar11\\_Ch04\\_APPENDIX.pdf?sfvrsn=0](http://www.medpac.gov/documents/reports/Mar11_Ch04_APPENDIX.pdf?sfvrsn=0).

<sup>234</sup> Kramer, A., Lin, M., Fish, R., et al.: *Development of Inpatient Rehabilitation Facility Quality Measures: Potentially Avoidable Readmissions, Community Discharge, and Functional Improvement*. pp. 1–42, 2015. Available from <http://www.medpac.gov/documents/contractor-reports/development-of-inpatient-rehabilitation-facility-quality-measures-potentially-avoidable-readmissions-community-discharge-and-functional-improvement.pdf?sfvrsn=0>.

<sup>235</sup> Kramer, A., Lin, M., Fish, R., et al.: *Development of Potentially Avoidable Readmission and Functional Outcome SNF Quality Measures*. pp. 1–75, 2014. Available from [http://www.medpac.gov/documents/contractor-reports/mar14\\_snfqualitymeasures\\_contractor.pdf?sfvrsn=0](http://www.medpac.gov/documents/contractor-reports/mar14_snfqualitymeasures_contractor.pdf?sfvrsn=0).

<sup>236</sup> Alladeen, N., Vidyarthi, A., Maselli, J., et al.: Redefining readmission risk factors for general medicine patients. *J. Hosp. Med.* 6(2):54–60, 2011. doi:10.1002/jhm.805.

<sup>237</sup> Gao, J., Moran, E., Li, Y.-F., et al.: Predicting potentially avoidable hospitalizations. *Med. Care*

*Potentially Preventable Readmission Measure Definition:* We conducted a comprehensive environmental scan, analyzed claims data, and obtained input from a TEP to develop a definition and list of conditions for which hospital readmissions are potentially preventable. The Ambulatory Care Sensitivity Conditions and Prevention Quality Indicators, developed by AHRQ, served as the starting point in this work. For patients in the 30-day post-PAC discharge period, a potentially preventable readmission (PPR) refers to a readmission for which the probability of occurrence could be minimized with adequately planned, explained, and implemented post-discharge instructions, including the establishment of appropriate follow-up ambulatory care. Our list of PPR conditions is categorized by 3 clinical rationale groupings:

- Inadequate management of chronic conditions;
- Inadequate management of infections; and
- Inadequate management of other unplanned events.

Additional details regarding the definition for potentially preventable readmissions are available in the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 LTCH QRP NPRM, available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html>.

This proposed measure focuses on readmissions that are potentially preventable and also unplanned. Similar to the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512), this proposed measure uses the current version of the CMS Planned Readmission Algorithm as the main component for identifying planned readmissions. A complete description of the CMS Planned Readmission Algorithm, which includes lists of planned diagnoses and procedures, can be found on the CMS Web site at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>. In addition to the CMS Planned Readmission

Algorithm, this proposed measure incorporates procedures that are considered planned in post-acute care settings, as identified in consultation with TEPs. Full details on the planned readmissions criteria used, including the CMS Planned Readmission Algorithm and additional procedures considered planned for post-acute care, can be found in the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 LTCH QRP NPRM, available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html>.

The proposed measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP, assesses potentially preventable readmission rates while accounting for patient demographics, principal diagnosis in the prior hospital stay, comorbidities, and other patient factors. While estimating the predictive power of patient characteristics, the model also estimates a facility-specific effect, common to patients treated in each facility. This proposed measure is calculated for each LTCH based on the ratio of the predicted number of risk-adjusted, unplanned, potentially preventable hospital readmissions that occur within 30 days after an LTCH discharge, including the estimated facility effect, to the estimated predicted number of risk-adjusted, unplanned inpatient hospital readmissions for the same patients treated at the average LTCH. A ratio above 1.0 indicates a higher than expected readmission rate (worse) while a ratio below 1.0 indicates a lower than expected readmission rate (better). This ratio is referred to as the standardized risk ratio (SRR). The SRR is then multiplied by the overall national raw rate of potentially preventable readmissions for all LTCH stays. The resulting rate is the risk-standardized readmission rate (RSRR) of potentially preventable readmissions.

An eligible LTCH stay is followed until: (1) The 30-day post-discharge period ends; or (2) the patient is readmitted to an acute care hospital (IPPS or CAH) or LTCH. If the readmission is unplanned and potentially preventable, it is counted as a readmission in the measure calculation. If the readmission is planned, the readmission is not counted in the measure rate.

This measure is risk adjusted. The risk adjustment modeling estimates the effects of patient characteristics, comorbidities, and select health care variables on the probability of

readmission. More specifically, the risk-adjustment model for LTCHs account for demographic characteristics (age, sex, original reason for Medicare entitlement), principal diagnosis during the prior proximal hospital stay, body system specific surgical indicators, prolonged mechanical ventilation indicator, comorbidities, length of stay during the patient's prior proximal hospital stay, length of stay in the intensive care and coronary care unit (ICU and CCU), and number of acute care hospitalizations in the preceding 365 days.

The proposed measure is calculated using 2 consecutive calendar years of FFS claims data, to ensure the statistical reliability of this measure for facilities. In addition, we are proposing a minimum of 25 eligible stays for public reporting of the proposed measure.

A TEP convened by our measure contractor provided recommendations on the technical specifications of this proposed measure, including the development of an approach to define potentially preventable hospital readmission for PAC. Details from the TEP meetings, including TEP members' ratings of conditions proposed as being potentially preventable, are available in the TEP summary report available on the CMS Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>. We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 2 through December 1, 2015. Comments on the measure varied, with some commenters supportive of the proposed measure, while others either were not in favor of the measure, or suggested potential modifications to the measure specifications, such as including standardized function data. A summary of the public comments is also available on the CMS Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The MAP encouraged continued development of the proposed measure. Specifically, the MAP stressed the need to promote shared accountability and ensure effective care transitions. More information about the MAP's recommendations for this measure is available at: [http://www.qualityforum.org/Publications/2016/02/MAP\\_2016\\_Considerations\\_for\\_Implementing\\_Measures\\_in\\_Federal\\_Programs\\_-\\_PAC-](http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-)

52(2):164–171, 2014. doi:10.1097/MLR.000000000000041.

<sup>238</sup> Walsh, E.G., Wiener, J.M., Haber, S., et al.: Potentially avoidable hospitalizations of dually eligible Medicare and Medicaid beneficiaries from nursing facility and home-and community-based services waiver programs. *J. Am. Geriatr. Soc.* 60(5):821–829, 2012. doi:10.1111/j.1532-5415.2012.03920.x.

*LTC.aspx*. At the time, the risk-adjustment model was still under development. Following completion of that development work, we were able to test for measure validity and reliability as identified in the measure specifications document provided above. Testing results are within range for similar outcome measures finalized in public reporting and value-based purchasing programs, including the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) adopted into the LTCH QRP.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed measures focused on potentially preventable hospital readmissions. We are unaware of any other measures for this IMPACT Act domain that have been endorsed or adopted by other consensus organizations. Therefore, we are proposing the Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP, under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act, for the LTCH QRP for the FY 2018 payment determination and subsequent years, given the evidence previously discussed above.

We plan to submit the proposed measure to the NQF for consideration of endorsement. If this proposed measure is finalized, we intend to provide initial confidential feedback to LTCHs, prior to public reporting of this proposed measure, based on 2 calendar years of data from discharges in CY 2015 and 2016. We intend to publicly report this proposed measure using data from CY 2016 and 2017.

We are inviting public comment on our proposal to adopt the measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP.

## 7. LTCH QRP Quality Measure Proposed for the FY 2020 Payment Determination and Subsequent Years

### a. Background

In addition to the measures we are retaining as described in section VIII.C.5. of the preamble of this proposed rule under our policy described in section VIII.C.3. of the preamble of this proposed rule and the new quality measures proposed in section VIII.C.6. of the preamble of this proposed rule for the FY 2018 payment determinations and subsequent years, we are also proposing one new quality measure to meet the requirements of the IMPACT Act for the FY 2020 payment

determination and subsequent years. The proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post-Acute Care (PAC) LTCH QRP, addresses the IMPACT Act quality domain of Medication Reconciliation.

### b. Quality Measure Addressing the IMPACT Act Domain of Medication Reconciliation: Drug Regimen Review Conducted With Follow-up for Identified Issues-Post Acute Care LTCH QRP

Sections 1899B(a)(2)(E)(i)(III) and 1899B(c)(1)(C) of the Act require the Secretary to specify a quality measure to address the domain of medication reconciliation by October 1, 2018 for IRFs, LTCHs, and SNFs, and by January 1, 2017 for HHAs. We are proposing to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, for the LTCH QRP as a patient-assessment based, cross-setting quality measure to meet the IMPACT Act requirements with data collection beginning April 1, 2018 for the FY 2020 payment determinations and subsequent years.

This proposed measure assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s) when such issues were identified. Specifically, the proposed quality measure reports the percentage of patient stays in which a drug regimen review was conducted at the time of admission and timely follow-up with a physician occurred each time potential clinically significant medication issues were identified throughout that stay.

For this proposed quality measure, drug regimen review is defined as the review of all medications or drugs the patient is taking to identify any potentially clinically significant medication issues. This proposed quality measure utilizes both the processes of medication reconciliation and a drug regimen review, in the event an actual or potential medication issue occurred. The proposed measure informs whether the PAC facility identified and addressed each clinically significant medication issue and if the facility responded or addressed the medication issue in a timely manner. Of note, drug regimen review in PAC settings is generally considered to include medication reconciliation and review of the patient's drug regimen to identify potential clinically significant

medication issues.<sup>239</sup> This measure is applied uniformly across the PAC settings.

Medication reconciliation is a process of reviewing an individual's complete and current medication list. Medication reconciliation is a recognized process for reducing the occurrence of medication discrepancies that may lead to Adverse Drug Events (ADEs).<sup>240</sup> Medication discrepancies occur when there is conflicting information documented in the medical records. The World Health Organization regards medication reconciliation as a standard operating protocol necessary to reduce the potential for ADEs that cause harm to patients. Medication reconciliation is an important patient safety process that addresses medication accuracy during transitions in patient care and in identifying preventable ADEs.<sup>241</sup> The Joint Commission added medication reconciliation to its list of National Patient Safety Goals (2005), suggesting that medication reconciliation is an integral component of medication safety.<sup>242</sup> The Society of Hospital Medicine published a statement in agreement of the Joint Commission's emphasis and value of medication reconciliation as a patient safety goal.<sup>243</sup> There is universal agreement that medication reconciliation directly addresses patient safety issues that can result from medication miscommunication and unavailable or incorrect information.<sup>244 245 246</sup>

The performance of timely medication reconciliation is valuable to the process of drug regimen review. Preventing and responding to ADEs is of critical importance as ADEs account for significant increases in health services

<sup>239</sup> Institute of Medicine. Preventing Medication Errors. Washington DC: National Academies Press; 2006.

<sup>240</sup> *Ibid*

<sup>241</sup> Leotsakos A., et al. Standardization in patient safety: the WHO High 5s project. *Int J Qual Health Care*. 2014;26(2):109–116.

<sup>242</sup> The Joint Commission. 2016 Long Term Care: National Patient Safety Goals Medicare/Medicaid Certification-based Option. (NPSG.03.06.01).

<sup>243</sup> Greenwald, J. L., Halasyamani, L., Greene, J., LaCivita, C., et al. (2010). Making inpatient medication reconciliation patient centered, clinically relevant and implementable: a consensus statement on key principles and necessary first steps. *Journal of Hospital Medicine*, 5(8), 477–485.

<sup>244</sup> Leotsakos A., et al. Standardization in patient safety: the WHO High 5s project. *Int J Qual Health Care*. 2014;26(2):109–116.

<sup>245</sup> The Joint Commission. 2016 Long Term Care: National Patient Safety Goals Medicare/Medicaid Certification-based Option. (NPSG.03.06.01).

<sup>246</sup> IHI. Medication Reconciliation to Prevent Adverse Drug Events [Internet]. Cambridge, MA: Institute for Healthcare Improvement; [cited 2016 Jan 11]. Available from: <http://www.ihio.org/topics/adesmedicationreconciliation/Pages/default.aspx>.



utilization and costs,<sup>247 248 249</sup> including subsequent emergency room visits and re-hospitalizations.<sup>250</sup> Annual health care costs in the United States are estimated at \$3.5 billion, resulting in 7,000 deaths annually.<sup>251 252</sup>

Medication errors include the duplication of medications, delivery of an incorrect drug, inappropriate drug omissions, or errors in the dosage, route, frequency, and duration of medications. Medication errors are one of the most common types of medical error and can occur at any point in the process of ordering and delivering a medication. Medication errors have the potential to result in an ADE,<sup>253 254 255 256 257 258</sup>

Inappropriately prescribed medications are also considered a major healthcare concern in the United States for the elderly population, with costs of roughly \$7.2 billion annually.<sup>259</sup>

There is strong evidence that medication discrepancies occur during transfers from acute care facilities to post-acute care facilities. Discrepancies

occur when there is conflicting information documented in the medical records. Almost one-third of medication discrepancies have the potential to cause patient harm.<sup>260</sup> An estimated 50 percent of patients experienced a clinically important medication error after hospital discharge in an analysis of two tertiary care academic hospitals.<sup>261</sup>

Medication reconciliation has been identified as an area for improvement during transfer from the acute care facility to the receiving post-acute care facility. PAC facilities report gaps in medication information between the acute care hospital and the receiving post-acute care setting when performing medication reconciliation.<sup>262 263</sup> Hospital discharge has been identified as a particularly high risk time point, with evidence that medication reconciliation identifies high levels of discrepancy.<sup>264 265 266 267 268 269</sup> Also, there is evidence that medication reconciliation discrepancies occur throughout the patient stay.<sup>270 271</sup> For

older patients, who may have multiple comorbid conditions and thus multiple medications, transitions between acute and post-acute care settings can be further complicated,<sup>272</sup> and medication reconciliation and patient knowledge (medication literacy) can be inadequate post-discharge.<sup>273</sup> The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, provides an important component of care coordination for PAC settings and would affect a large proportion of the Medicare population who transfer from hospitals into PAC services each year. For example, in 2013, 1.7 million Medicare FFS beneficiaries had SNF stays, 338,000 beneficiaries had IRF stays, and 122,000 beneficiaries had LTCH stays.<sup>274</sup>

A TEP convened by our measure development contractor provided input on the technical specifications of this proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, including components of reliability, validity and the feasibility of implementing the measure across PAC settings. The TEP supported the measure's implementation across PAC settings and was supportive of our plans to standardize this measure for cross-setting development. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

We solicited stakeholder feedback on the development of this measure by means of a public comment period held from September 18 through October 6, 2015. Through public comments submitted by several stakeholders and organizations, we received support for implementation of this proposed measure. The public comment summary

and potential adverse drug events. Implications for prevention. *JAMA*. 1995;274(1): 29–34.

<sup>271</sup> Himmel, W., M. Tabache, and M. M. Kochen. "What happens to long-term medication when general practice patients are referred to hospital?." *European journal of clinical pharmacology* 50.4 (1996): 253–257.

<sup>272</sup> Chhabra, P. T., et al. (2012). "Medication reconciliation during the transition to and from long-term care settings: a systematic review." *Res Social Adm Pharm* 8(1): 60–75.

<sup>273</sup> Kripalani S, Roumie CL, Dalal AK, et al. Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: A randomized controlled trial. *Ann Intern Med*. 2012;157(1):1–10.

<sup>274</sup> March 2015 Report to the Congress: Medicare Payment Policy. Medicare Payment Advisory Commission; 2015.

<sup>247</sup> Institute of Medicine. Preventing Medication Errors. Washington DC: National Academies Press; 2006.

<sup>248</sup> Jha AK, Kuperman GJ, Rittenberg E, et al. Identifying hospital admissions due to adverse drug events using a computer-based monitor. *Pharmacoepidemiol Drug Saf*. 2001;10(2):113–119.

<sup>249</sup> Hohl CM, Nosyk B, Kuramoto L, et al. Outcomes of emergency department patients presenting with adverse drug events. *Ann Emerg Med*. 2011;58:270–279.

<sup>250</sup> Kohn LT, Corrigan JM, Donaldson MS. To Err Is Human: Building a Safer Health System. Washington, DC: National Academies Press; 1999.

<sup>251</sup> Greenwald, J. L., Halasyamani, L., Greene, J., LaCivita, C., et al. (2010). Making inpatient medication reconciliation patient centered, clinically relevant and implementable: a consensus statement on key principles and necessary first steps. *Journal of Hospital Medicine*, 5(8), 477–485.

<sup>252</sup> Phillips, David P.; Christenfeld, Nicholas; and Glynn, Laura M. Increase in US Medication-Error Deaths between 1983 and 1993. *The Lancet*. 351:643–644, 1998.

<sup>253</sup> Institute of Medicine. To err is human: building a safer health system. Washington, DC: National Academies Press; 2000.

<sup>254</sup> Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing. *JAMA*. 1997;277(4): 312–317.

<sup>255</sup> Bond CA, Raehl CL, & Franke T. Clinical pharmacy services, hospital pharmacy staffing, and medication errors in United States hospitals. *Pharmacotherapy*. 2002;22(2): 134–147.

<sup>256</sup> Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. *JAMA*. 1995;274(1): 29–34.

<sup>257</sup> Barker KN, Flynn EA, Pepper GA, Bates DW, & Mikeal RL. Medication errors observed in 36 health care facilities. *JAMA*. 2002; 162(16):1897–1903.

<sup>258</sup> Bates DW, Boyle DL, Vander Vliet MB, Schneider J, & Leape L. Relationship between medication errors and adverse drug events. *J Gen Intern Med*. 1995;10(4): 199–205.

<sup>259</sup> Fu, Alex Z., et al. "Potentially inappropriate medication use and healthcare expenditures in the US community-dwelling elderly." *Medical care* 45.5 (2007): 472–476.

<sup>260</sup> Wong, Jacqueline D., et al. "Medication reconciliation at hospital discharge: evaluating discrepancies." *Annals of Pharmacotherapy* 42.10 (2008): 1373–1379.

<sup>261</sup> Kripalani S, Roumie CL, Dalal AK, et al. Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: A randomized controlled trial. *Ann Intern Med*. 2012;157(1):1–10.

<sup>262</sup> Gandara, Esteban, et al. "Communication and information deficits in patients discharged to rehabilitation facilities: an evaluation of five acute care hospitals." *Journal of Hospital Medicine* 4.8 (2009): E28–E33.

<sup>263</sup> Gandara, Esteban, et al. "Deficits in discharge documentation in patients transferred to rehabilitation facilities on anticoagulation: results of a system wide evaluation." *Joint Commission Journal on Quality and Patient Safety* 34.8 (2008): 460–463.

<sup>264</sup> Coleman EA, Smith JD, Raha D, Min SJ. Post hospital medication discrepancies: prevalence and contributing factors. *Arch Intern Med*. 2005 165(16):1842–1847.

<sup>265</sup> Wong JD, Bajcar JM, Wong GG, et al. Medication reconciliation at hospital discharge: evaluating discrepancies. *Ann Pharmacother*. 2008 42(10):1373–1379.

<sup>266</sup> Hawes EM, Maxwell WD, White SF, Mangun J, Lin FC. Impact of an outpatient pharmacist intervention on medication discrepancies and health care resource utilization in post hospitalization care transitions. *Journal of Primary Care & Community Health*. 2014; 5(1):14–18.

<sup>267</sup> Foust JB, Naylor MD, Bixby MB, Ratcliffe SJ. Medication problems occurring at hospital discharge among older adults with heart failure. *Research in Gerontological Nursing*. 2012, 5(1): 25–33.

<sup>268</sup> Pherson EC, Shermock KM, Efird LE, et al. Development and implementation of a post discharge home-based medication management service. *Am J Health Syst Pharm*. 2014; 71(18): 1576–1583.

<sup>269</sup> Pronovosta P, Weasta B, Swarza M, et al. Medication reconciliation: a practical tool to reduce the risk of medication errors. *J Crit Care*. 2003; 18(4): 201–205.

<sup>270</sup> Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, et al. Incidence of adverse drug events

report for the proposed measure is available on the CMS Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html>.

The NQF-convened MAP met on December 14 and 15, 2015 and provided input on the use of this proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP. The MAP encouraged continued development of the proposed quality measure to meet the mandate added by the IMPACT Act. The MAP agreed with the measure gaps identified by CMS including medication reconciliation, and stressed that medication reconciliation be present as an ongoing process. More information about the MAP's recommendations for this measure is available at: [http://www.qualityforum.org/Publications/2016/02/MAP\\_2016\\_Considerations\\_for\\_Implementing\\_Measures\\_in\\_Federal\\_Programs\\_-\\_PAC-LTC.aspx](http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx).

Since the MAP's review and recommendation of continued development, we have continued to refine this proposed measure in compliance with the MAP's recommendations. The proposed measure is both consistent with the information submitted to the MAP and support its scientific acceptability for use in quality reporting programs. Therefore, we are proposing this measure for implementation in the LTCH QRP as required by the IMPACT Act.

We reviewed the NQF's endorsed measures and identified one NQF-endorsed cross-setting and quality measure related to medication reconciliation, which applies to the SNF, LTCH, IRF, and HHA settings of care: Care for Older Adults (COA), (NQF #0553). The quality measure, Care for Older Adults (COA), (NQF #0553) assesses the percentage of adults 66 years and older who had a medication review. The Care for Older Adults (COA), (NQF #0553) measure requires at least one medication review conducted by a prescribing practitioner or clinical pharmacist during the measurement year and the presence of a medication list in the medical record. This is in contrast to the proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, which reports the percentage of patient stays in which a drug regimen review was conducted at the time of admission and that timely follow-up with a

physician occurred each time one or more potential clinically significant medication issues were identified throughout that stay.

After careful review of both quality measures, we have decided to propose the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP for the following reasons:

- The IMPACT Act requires the implementation of quality measures, using patient assessment data that are standardized and interoperable across PAC settings. The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, employs three standardized patient-assessment data elements for each of the four PAC settings so that data are standardized, interoperable, and comparable; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure does not contain data elements that are standardized across all four PAC settings.

- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, requires the identification of potential clinically significant medication issues at the beginning, during, and at the end of the patient's stay to capture data on each patient's complete PAC stay; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure only requires annual documentation in the form of a medication list in the medical record of the target population.

- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, includes identification of the potential clinically significant medication issues and communication with the physician (or physician designee) as well as resolution of the issue(s) within a rapid timeframe (by midnight of the next calendar day); whereas, the Care for Older Adults (COA), (NQF #0553) quality measure does not include any follow-up or timeframe in which the follow-up would need to occur.

- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, does not have age exclusions; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure limits the measure's population to patients aged 66 and older.

- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, would be reported to LTCHs quarterly to facilitate internal quality

monitoring and quality improvement in areas such as patient safety, care coordination, and patient satisfaction; whereas the Care for Older Adults (COA), (NQF #0553) quality measure would not enable quarterly quality updates, and thus data comparisons within and across PAC providers would be difficult due to the limited data and scope of the data collected.

Therefore, based on the evidence discussed above, we are proposing to adopt the quality measure entitled, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, for the LTCH QRP for FY 2020 payment determination and subsequent years. We plan to submit the quality measure to the NQF for consideration for endorsement.

The calculation of the proposed quality measure would be based on the data collection of three standardized items to be included in the LTCH CARE Data Set. The collection of data by means of the standardized items would be obtained at admission and discharge. For more information about the data submission required for this proposed measure, we refer readers to section VIII.C.9. of the preamble of this proposed rule.

The standardized items used to calculate this proposed quality measure do not duplicate existing items currently used for data collection within the LTCH CARE Data Set. The proposed measure denominator is the number of patient stays with a discharge or expired assessment during the reporting period. The proposed measure numerator is the number of stays in the denominator where the medical record contains documentation of a drug regimen review conducted at: (1) Admission; and (2) discharge with a lookback through the entire patient stay with all potential clinically significant medication issues identified during the course of care and followed up with a physician or physician designee by midnight of the next calendar day. This measure is not risk adjusted. For technical information about this proposed measure, including information about the measure calculation and discussion pertaining to the standardized items used to calculate this measure, we refer readers to the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 LTCH QRP NPRM available at: <http://www.cms.gov/Medicare/Quality-Initiative-Patient-Assessment-Instruments/LTCH-Quality-Reporting-Program-Measures-Information-.html>.

Data for the proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP,

would be collected using the Long-Term Care Hospital LTCH CARE Data Set with submission through the Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP) system.

We are inviting public comment on our proposal to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP for the LTCH QRP.

#### 8. LTCH QRP Quality Measures and Measure Concepts Under Consideration for Future Years

We are inviting comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in the table below for

future years in the LTCH QRP. We are developing a measure related to the IMPACT Act domain, “Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions.” We are considering the possibility of adding quality measures that rely on the patient’s perspective; that is, measures that include patient-reported experience of care and health status data. We recently posted a “Request for Information to Aid in the Design and Development of a Survey Regarding Patient and Family Member Experiences

with Care Received in Long-Term Care Hospitals” (80 FR 72722 through 72725).

Also, we are considering a measure focused on pain that relies on the collection of patient-reported pain data, and another that documents whether a patient has an Advance Care Plan. Finally, we are considering measures related to patient safety: Venous Thromboembolism Prophylaxis, Ventilator Weaning (Liberation) Rate, Compliance with Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay, and Patients Who Received an Antipsychotic Medication.

### LTCH QRP QUALITY MEASURES UNDER CONSIDERATION FOR FUTURE YEARS

IMPACT Act Domain: Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions

IMPACT Act Measure

Transfer of health information and care preferences when an individual transitions

NQS Priority: Patient- and Caregiver-Centered Care

Measures

- Patient Experience of Care
- Percent of Patients with Moderate to Severe Pain
- Advance Care Plan

NQS Priority: Patient Safety

Measures

- Ventilator Weaning (Liberation) Rate
- Compliance with Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay
- Patients Who Received an Antipsychotic Medication
- Venous Thromboembolism Prophylaxis

9. Proposed Form, Manner, and Timing of Quality Data Submission for the FY 2018 Payment Determination and Subsequent Years

#### a. Background

Section 1886(m)(5)(C) of the Act requires that, for the FY 2014 payment determination and subsequent years, each LTCH submit to the Secretary data on quality measures specified by the Secretary. In addition, section 1886(m)(5)(F) of the Act requires that, for the fiscal year beginning on the specified application date, as defined in section 1899B(a)(2)(E) of the Act, and each subsequent year, each LTCH submit to the Secretary data on measures specified by the Secretary under section 1899B of the Act. The data required under sections

1886(m)(5)(C) and (F) of the Act must 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 sections 1886(m)(5)(C) and (F) of the Act for a given fiscal year, the annual payment for discharges occurring during the fiscal year must be reduced by 2 percentage points.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49749 through 49752), we:

- Adopted timing for new LTCHs to begin reporting quality data under the LTCH QRP for the FY 2017 payment determination and subsequent years; and
- Adopted new deadlines that allow 4.5 months (approximately 135 days) after the end of each calendar year

quarter for quality data submission, beginning with quarter 4 of 2015 (October 2015 through December 2015). The new deadlines apply to all LTCH QRP quality measures (except Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)) for the FY 2017 and FY 2018 payment determinations and subsequent years.

#### b. Timeline for Data Submission Under the LTCH QRP for the FY 2018 Payment Determination and Subsequent Years

The table below presents the data collection period, data submission (for the LTCH CARE Data Set-assessment based and CDC measures) and data correction timelines for quality measures affecting the FY 2018 and subsequent years payment determination.

## SUMMARY DETAILS ON THE LTCH CARE DATA SET AND CDC NHSN DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED QUALITY MEASURES AFFECTING THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS\*

Quality measure	Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction period and data submission deadlines for payment determination	First APU determination affected
NQF #0678: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (76 FR 51748 through 51750).	LTCH CARE Data Set/QIES ASAP.	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018.
NQF #0138: NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (76 FR 51745 through 51747).	CDC NHSN .....	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018.
NQF #0139: NHSN Central-Line Associated Bloodstream Infection (CLABSI) Outcome Measure (76 FR 51747 through 51748).	CDC NHSN .....	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018.
NQF #1716: NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) Bacteremia Outcome Measure (78 FR 50863 through 50865).	CDC NHSN .....	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018.
NQF #1717: NHSN Facility-wide Inpatient Hospital-onset <i>Clostridium difficile</i> Infection (CDI) Outcome Measure (78 FR 50865 through 50868).	CDC NHSN .....	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018.
NHSN Ventilator-Associated Event (VAE) Outcome Measure (79 FR 50301 through 50305).	CDC NHSN .....	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018.
NQF #0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (77 FR 53624 through 53627).	LTCH CARE Data Set/QIES ASAP.	10/1/15–12/31/15, 1/1/16–3/31/16**.	5/15/16, 8/15/16** .....	FY 2018.
NQF #0431: Influenza Vaccination Coverage Among Healthcare Personnel (77 FR 53630 through 53631).	CDC NHSN .....	10/1/16–3/31/17, 10/1–3/31 for subsequent years.	5/15/17, 5/15 for subsequent years.	FY 2018.
NQF #2512: All-Cause Unplanned Readmission Measure for 30-Days Post-Discharge from Long-Term Care Hospitals (78 FR 50868 through 50874).	Medicare FFS Claims Data.	N/A .....	N/A .....	FY 2018.
NQF #0674: Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (80 FR 49736 through 49739).	LTCH CARE Data Set/QIES ASAP.	4/1/16–6/30/16, 7/1/16–9/30/16, 10/1/16–12/31/16; Quarterly for each subsequent calendar year.	11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Quarterly approximately 135 days after the end of each quarter for subsequent years.	FY 2018.
NQF #2631: Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (79 FR 50298 through 50301).	LTCH CARE Data Set/QIES ASAP.	4/1/16–6/30/16, 7/1/16–9/30/16, 10/1/16–12/31/16; Quarterly for each subsequent calendar year.	11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Quarterly approximately 135 days after the end of each quarter for subsequent years.	FY 2018.
NQF #2631: Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (80 FR 49739 through 49747).	LTCH CARE Data Set/QIES ASAP.	4/1/16–6/30/16, 7/1/16–9/30/16, 10/1/16–12/31/16; Quarterly for each subsequent calendar year.	11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Quarterly approximately 135 days after the end of each quarter for subsequent years.	FY 2018.

SUMMARY DETAILS ON THE LTCH CARE DATA SET AND CDC NHSN DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED QUALITY MEASURES AFFECTING THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS\*—Continued

Quality measure	Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction period and data submission deadlines for payment determination	First APU determination affected
NQF #2632: Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support (79 FR 50298 through 50301).	LTCH CARE Data Set/QIES ASAP.	4/1/16–6/30/16, 7/1/16–9/30/16, 10/1/16–12/31/16; Quarterly for each subsequent calendar year.	11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Quarterly approximately 135 days after the end of each quarter for subsequent years.	FY 2018.

\* We refer readers to the table below for an illustration of the CY quarterly data collection/submission quarterly reporting periods and correction and submission deadlines for all APU years.

\*\* For this measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine, we refer readers to the proposals on data submission for this measure we are making in section VIII.C.9.d. of the preamble of this proposed rule. These proposals for the FY 2019 payment determination and for FY 2020 payment determination and subsequent years are illustrated in the tables in that section.

Further, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49749 through 49752), we established that the LTCH CARE Data Set-based and CDC NHSN measures finalized for adoption into the LTCH QRP would follow a calendar year schedule with quarterly reporting

periods, followed by quarterly review and correction periods and submission deadlines. This pattern is illustrated in the table below and is in place for all APU years unless otherwise specified. We also wish to illustrate that for the measures finalized for use in the LTCH

QRP that use the LTCH CARE Data Set or CDC NHSN data sources, payment determination would subsequently use the data collection and deadlines shown below unless otherwise specified.

ANNUAL CY LTCH CARE DATA SET AND CDC NHSN DATA COLLECTION/SUBMISSION REPORTING PERIODS AND DATA SUBMISSION/CORRECTION DEADLINES FOR PAYMENT DETERMINATIONS

Proposed CY data collection quarter	Data collection/submission quarterly reporting period	Quarterly review and correction periods and data submission deadlines for payment determination	
Quarter 1 .....	January 1–March 31 *** .....	April 1–August 15* .....	Deadline: August 15.**
Quarter 2 .....	April 1–June 30 .....	July 1–November 15 .....	Deadline: November 15.
Quarter 3 .....	July 1–September 30 .....	October 1–February 15 .....	Deadline: February 15.
Quarter 4 .....	October 1–December 31 *** .....	January 1–May 15* .....	Deadline: May 15.**

\* The annual data submission time frame for the measure, Influenza Vaccination Coverage among Healthcare Personnel, is October 1 through March 31 of the subsequent year with a reporting deadline of May 15 in that subsequent year.

\*\* For the measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine, we refer readers to the proposals on data submission for this measure we are making in section VIII.C.9.d. of the preamble of this proposed rule. These proposals for the FY 2019 payment determination and for FY 2020 payment determination and subsequent years are illustrated in the tables in that section.

c. Proposed Timeline and Data Submission Mechanisms for the FY 2018 Payment Determination and Subsequent Years for Proposed New LTCH QRP Resource Use and Other Measures—Claims-Based Measures

The MSPB–PAC LTCH QRP measure; Discharge to Community–PAC LTCH QRP measure and Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP, which we have proposed in this proposed rule, are Medicare FFS claims-based measures. Because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, no additional information collection would be required from LTCHs. As discussed in section VIII.C.6. of the preamble of this proposed rule, these measures would use 2 years of

claims-based data beginning with CY 2015 and CY 2016 claims to inform confidential feedback reports for LTCHs, and CYs 2016 and 2017 claims data for public reporting.

We are inviting public comments on this proposal.

d. Proposal To Revise the Previously Adopted Data Collection Period and Submission Deadlines for Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) for the FY 2019 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627), we adopted the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure for the FY 2016

payment determination and subsequent years. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50858 through 50861), we finalized the data submission timelines and submission deadlines for the measures for FY 2016 and FY 2017 payment determinations. We refer readers to the FY 2013 and FY 2014 IPPS/LTCH PPS final rules for a more detailed discussion of the measure, timelines and deadlines.

In these previous rules, we finalized that LTCHs were required to perform data collection in alignment with the influenza vaccination season (IVS); that is, obtaining the vaccination status of patients who are in an LTCH for one or more days between the dates of October 1 of a given year through March 31 of the subsequent year, or what the CDC terms the Influenza Vaccination Season (IVS), but for only those patients whose

corresponding admissions and discharges occurred during the IVS. Through analysis of the quality data submitted for this measure, we discovered that only requiring LTCH providers to submit patient Influenza vaccination data during the IVS (October 1 of a given year through March 31 of the subsequent year) inadvertently limits the data collection to only a subset of patients whose stays at an LTCH qualify for inclusion in the measure calculation. This measure is structured in such a way that all patients in an LTCH for one or more days during the IVS are included in the measure. For those patients, an LTCH should have the opportunity to demonstrate the Influenza vaccination status of these patients on either their LTCH CARE Data Set (LCDS) admission assessment or on their discharge assessment (planned, unplanned, or expired). By limiting data collection to only those assessments obtained during the IVS, per our previously finalized policy, CMS inadvertently excluded the collection of Influenza vaccination status data on those patients who were in an LTCH for at least one day during the IVS, but for whom the associated LCDS admission and/or discharge assessments occurred outside of the IVS (prior to October 1 or after March 31).

For these reasons, we are proposing that beginning with the FY 2019 payment determination and subsequent years, which includes the CY 2016/2017 IVS, data collection and submission for the measure Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) will be required year-round, thus including all patients in the LTCH one or more days during the IVS (October 1 of any given CY through March 31 of the subsequent CY), regardless of the associated LCDS admission and discharge dates. This includes, for example, a patient that is admitted September 15 of a given year, and discharged April 1 of the subsequent year (thus, in the LTCH during the IVS). This proposal would enable the important data collection necessary to indicate that a patient who had an admission or a discharge outside of the IVS, but was in the facility during the vaccination season, ensuring that the data collected and submitted to CMS is representative of the status of all patients within the IVS, rather than only

a subset of those who had both admissions and discharges within the IVS.

Further, our proposal effectively changes the data collection and submission timeline for this measure to include 4 calendar quarters, that is based on the influenza *season* (July 1 of any given year through June 30 of the subsequent year), rather than on the calendar year. For the purposes of APU determination and for public reporting, data calculation and analysis uses data from an influenza vaccination season which takes place within the *influenza season* itself. While the influenza vaccination season is October 1 of a given year (or when the vaccine becomes available) through March 31 of the subsequent year, this timeframe rests within a greater time period of the *influenza season*, which spans 12 months—that is, July 1 of a given year through June 30 of the subsequent year, as defined by the CDC. Thus, for this measure, we utilize data from a timeframe of 12 months that mirrors the influenza season which is July 1 of a given year through June 30 of the subsequent year. In addition, for the APU determination, we review data submitted beginning on July 1 of the calendar year 2 years prior to the calendar year of the APU effective date and ending June 30 of the subsequent calendar year, one year prior to the calendar year of the APU effective date. For example, and as provided in the below for the FY 2020 (October 1, 2019) APU determination, we review data submission beginning July 1, 2017 through June 30, 2018 for the 2017/2018 influenza vaccination season (October 1, 2017 [or when the vaccine becomes available] through March 31, 2018), so as to capture all data that an LTCH will have submitted with regard to the 2017/2018 influenza vaccination season itself which resides within the associated influenza season. We will use assessment data from the influenza season so as to ensure full capture of vaccination status in the IVS that resides within the influenza season period, as well for public reporting. Further, because we enable the opportunity to review and correct data for all assessment based LCDS measures within the LTCH QRP, we continue to follow quarterly calendar data collection/submission quarterly reporting period(s) and their subsequent quarterly review and correction periods

with data submission deadlines for public reporting and payment determinations. However, rather than using a standard CY timeframe, these quarterly data collection/submission periods and their subsequent quarterly review and correction periods and submission deadlines begin with CY quarter 3, July 1, of a given year and end CY quarter 2, June 30, of the following year.

The proposed revisions to the data collection period for the measure Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), will ultimately have the effect of helping LTCHs capture Influenza vaccination data on any LTCH patients that were in their hospital for one or more days during the IVS, by ensuring that such patient's admission and discharge assessments, regardless of the date of those assessments, capture potential influenza vaccination data, and allow the appropriate inclusion of patients and thus the accurate calculation of data for this measure. Lastly, this clarification will also remove any ambiguity and ensure that LTCHs are receiving credit for recording the vaccination status of all patients that were in their hospital for at least one day during any given IVS, regardless of the date(s) of their admission and/or discharge.

We would like to note that in order to implement the newly proposed revision to the data collection timeframes and submission deadlines for this measure, the FY 2019 payment determination will only be based on three CY quarters, as this policy will not go into effect until October 1, 2016, which is the start of the 2016/2017 IVS. Because of this, we are not requiring LTCHs to respond to the Influenza vaccination items on the LCDS admission or discharge assessments that take place during Q3 2016 (7/1/16–9/30/16), as this quarter will occur prior to the effective date of this policy, if finalized. This is illustrated in the table for the FY 2019 payment determination, below. All subsequent payment determinations will be based on four CY quarters, as discussed above, beginning with Q3 of CY 2017 for the FY 2020 payment determination. This is illustrated in table for the FY 2020 payment determination and subsequent years, below.

**FY 2019 PAYMENT DETERMINATION: \* SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED QUALITY MEASURE, NQF #0680 PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE**

Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction periods data submission deadlines for payment determination *	APU determination affected
Finalized Measure: NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (77 FR 53624 through 53627)			
LTCH CARE Data Set/QIES ASAP System.	CY 16 ..... 10/1/16–12/31/16 CY 17 Q1 ..... 1/1/17–3/31/17 CY 17 Q2 ..... 4/1/17–6/30/17	1/1/2017–5/15/17 deadline ..... 4/1/2017–8/15/17 deadline. 7/1/17–11/15/17 deadline.	FY 2019.

\* This table refers to the FY 2019 payment determination only. We refer readers to the table below for all subsequent FY payment determinations for this measure.

**FY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS: SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED QUALITY MEASURE, NQF #0680 PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE**

Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction periods data submission deadlines for payment determination *	APU determination affected
Finalized Measure: NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (77 FR 53624 through 53627)			
LTCH CARE Data Set/QIES ASAP System.	CY 17 Q3 ..... 7/1/17–9/30/17 Q3 (7/1–9/30) CY 17 Q4 ..... 10/1/17–12/31/17 Q4 (10/1–12/31) CY 18 Q1 ..... 1/1/18–3/31/18 Q1 (1/1–3/31) CY 18 Q2 ..... 4/1/18–6/30/18 Q2 (4/1–6/30)	10/1/17–2/15/18 deadline ..... 10/1–2/15 1/1/2018–5/15/18 deadline 1/1–5/15 4/1/2018–8/15/18 deadline 4/1–8/15 7/1/18–11/15/18 deadline 7/1–11/15	FY 2020  Subsequent Years

We are inviting comment on our proposal to revise the data collection and submission timeframe for the measure Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), beginning with the FY 2019 payment determination and subsequent years.

e. Proposed Timeline and Data Submission Mechanisms for the Proposed LTCH QRP Quality Measure for the FY 2020 Payment Determination and Subsequent Years

As discussed in section VIII.C.7. of the preamble of this proposed rule, we are proposing that the data for the proposed quality measure, Drug Regimen Review Conducted with

Follow-Up for Identified Issues-PAC LTCH QRP, affecting the FY 2020 payment determination and subsequent years be collected by completing data elements that would be added to the LTCH CARE Data Set with submission through the QIES ASAP system. Data collection would begin on April 1, 2018. More information on LTCH reporting using the QIES ASAP system is located at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Technical-Information.html>.

For the FY 2020 payment determination, we are proposing to collect CY 2018 Q2 through Q4 data, that is, beginning with admissions on April 1, 2018 through discharges on December 31, 2018, to remain consistent

with the usual April release schedule for the LTCH CARE Data Set, to give LTCHs sufficient time to update their systems so that they can comply with the new data reporting requirements, and to give CMS sufficient time to determine compliance for the FY 2020 payment determination. The proposed use of 3 quarters of data for the initial year of assessment data reporting in the LTCH QRP is consistent with the approach we used previously for the SNF, IRF, and Hospice QRPs.

The table below presents the proposed data collection period and data submission timelines for the new proposed LTCH QRP quality measure for the FY 2020 payment determination. We are inviting public comments on this proposal.

DETAILS ON THE PROPOSED DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR RESOURCE USE AND OTHER MEASURES AFFECTING THE FY 2020 PAYMENT DETERMINATION

Quality measure	Submission method	Data collection/submission quarterly reporting period	Quarterly review and correction periods and data submission deadlines for payment determination	APU determination affected
Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP.	LTCH CARE Data Set/QIES ASAP.	4/1/18–6/30/18 (Q2), 7/1/18–9/30/18 (Q3), 10/1/18–12/31/18 (Q4).	11/15/18 (Q2), 2/15/19 (Q3), 5/15/19 (Q4).	FY 2020.

Following the close of the reporting quarters for the FY 2020 payment determination, LTCHs would have the already established additional 4.5 months to correct their quality data and that the final deadline for correcting

data for the FY 2020 payment determination would be May 15, 2019 for these measures. We are also proposing that for the FY 2021 payment determination and subsequent years, we would collect data using the calendar

year reporting cycle as described in section VIII.C.9.c. of the preamble of this proposed rule, and illustrated in the table below. We are inviting public comments on this proposal.

PROPOSED DATA COLLECTION PERIOD AND DATA CORRECTION DEADLINES AFFECTING THE FY 2021 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Quality measure	Submission method	Proposed CY data collection quarter	Proposed data collection/submission quarterly reporting period	Proposed quarterly review and correction periods and data submission deadlines for payment determination
Drug regimen review conducted with follow-up for identified issues PAC LTCH QRP.	LTCH CARE Data Set/QIES ASAP.	Quarter 1 .....	January 1–March 31 .....	April 1–August 15.
		Quarter 2 .....	April 1–June 30 .....	July 1–November 15.
		Quarter 3 .....	July 1–September 30 .....	October 1–February 15.
		Quarter 4 .....	October 1–December 31 .....	January 1–May 15.

10. LTCH QRP Data Completion Thresholds for the FY 2016 Payment Determination and Subsequent Years

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50311 through 50314), we finalized LTCH QRP thresholds for completeness of LTCH data submissions. To ensure that LTCHs are meeting an acceptable standard for completeness of submitted data, we finalized the policy that, beginning with the FY 2016 payment determination and for each subsequent year, LTCHs must meet or exceed two separate data completeness thresholds: One threshold set at 80 percent for completion of quality measures data collected using the LTCH CARE Data Set submitted through the QIES and a second threshold set at 100 percent for quality measures data collected and submitted using the CDC’s NHSN.

In addition, we stated that we would apply the same thresholds to all measures adopted as the LTCH QRP expands and LTCHs begin reporting data on previously finalized measure sets. That is, as we finalize new measures through the regulatory process, LTCHs will be held accountable for meeting the previously finalized data completion threshold requirements for each measure until such time that updated threshold requirements are proposed and finalized through a subsequent regulatory cycle.

Further, we finalized the requirement that an LTCH must meet or exceed both thresholds to avoid receiving a 2 percentage point reduction to their annual payment update for a given fiscal year, beginning with FY 2016 and for all subsequent payment updates. For a detailed discussion of the finalized LTCH QRP data completion requirements, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50311 through 50314). We are not proposing any changes to these policies.

11. LTCH QRP Data Validation Process for the FY 2016 Payment Determination and Subsequent Years

Validation is intended to provide added assurance of the accuracy of the data that will be reported to the public as required by sections 1886(m)(5)(E) and 1899B(g) of the Act. In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28275 through 28276), we proposed, for the FY 2016 payment determination and subsequent years, a process to validate the data submitted for quality purposes. However, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50314 through 50316), we did not finalize the proposal; instead we decided to further explore suggestions from commenters before finalizing the LTCH data validation process that we proposed. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49752 through 49753), we did not

propose any new policies related to data accuracy validation. In this proposed rule, we are not proposing a data validation policy because we are developing a policy that could be applied to several PAC quality reporting programs. We intend to propose a data validation policy through future rulemaking.

12. Proposed Change to Previously Codified LTCH QRP Submission Exception and Extension Policies

We refer readers to § 412.560(c) for requirements pertaining to submission exception and extension for the FY 2017 payment determination and subsequent years. At this time, we are proposing to revise § 412.560(c) to change the timing for submission of these exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an LTCH from submitting their quality data for the LTCH QRP. We are proposing the increased time allotted for the submission of the requests from 30 to 90 days to be consistent with other quality reporting programs; for example, the Hospital Inpatient Quality Reporting (IQR) Program is also proposing to extend the deadline to 90 days in section VIII.C.15.a. of the preamble of this proposed rule. We believe that this increased time will assist providers experiencing an event in having the



time needed to submit such a request. With the exception of this one change, we are not proposing any additional changes to the exception and extension policies for the LTCH QRP at this time.

We are inviting public comments on the proposal to revise § 412.560(c) to change the timing for submission of these exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an LTCH from submitting their quality data for the LTCH QRP.

### 13. Previously Finalized LTCH QRP Reconsideration and Appeals Procedures

We refer readers to § 412.560(d) for a summary of our finalized reconsideration and appeals procedures for the LTCH QRP for FY 2017 payment determination and subsequent years. We are not proposing any changes to this policy. However, we wish to clarify that in order to notify LTCHs found to be non-compliant with the reporting requirements set forth for a given payment determination, we may include the QIES mechanism in addition to U.S. mail, and we may elect to utilize the MACs to administer such notifications.

### 14. Proposals and Policies Regarding Public Display of Measure Data for the LTCH QRP and Procedures for the Opportunity To Review and Correct Data and Information

#### a. Public Display of Measures

Section 1886(m)(5)(E) of the Act requires the Secretary to establish procedures for making the LTCH QRP data available to the public. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755), we finalized our proposals to display performance data for the LTCH QRP quality measures by fall 2016 on a CMS Web site, such as the *Hospital Compare*, after a 30-day preview period, and to give providers an opportunity to review and correct data submitted to the QIES ASAP system or to the CDC NHSN. The procedures for the opportunity to review and correct data are provided in the following section. In addition, we finalized the proposal to publish a list of LTCHs that successfully meet the reporting requirements for the applicable payment determination on the LTCH QRP Web site at: <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/ltch-quality-reporting/>. In the FY 2016 IPPS/LTCH PPS final rule, we also finalized that we would update the list after the reconsideration requests are processed on an annual basis.

Also, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755), we finalized that the display of information for fall 2016 contains performance data on four quality measures:

- Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678);
- NHSN CAUTI Outcome Measure (NQF #0138);
- NHSN CLABSI Outcome Measure (NQF #0139); and
- All-Cause Unplanned Readmission Measure for 30-Days Post-Discharge from LTCHs (NQF #2512).

The measures Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), NHSN CAUTI Outcome Measure (NQF #0138), and NHSN CLABSI Outcome Measure (NQF #0139) are based on data collected beginning with the first quarter of 2015 or discharges beginning on January 1, 2015. With the exception of the All-Cause Unplanned Readmission Measure for 30-Days Post-Discharge from LTCHs (NQF #2512), rates are displayed based on 4 rolling quarters of data and would initially use discharges from January 1, 2015 through December 31, 2015 (CY 2015) for Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and data collected from January 1, 2015 through December 31, 2015 for NHSN CAUTI Outcome Measure (NQF #0138) and NHSN CLABSI Outcome Measure (NQF #0139). For the readmissions measure, data will be publicly reported beginning with data collected for discharges beginning January 1, 2013, and rates would be displayed based on 2 consecutive years of data. For LTCHs with fewer than 25 eligible cases, we are proposing to assign the LTCH to a separate category: “The number of cases is too small (fewer than 25) to reliably tell how well the LTCH is performing.” If an LTCH has fewer than 25 eligible cases, the LTCH’s readmission rates and interval estimates would not be publicly reported for the measure.

Calculations for all four measures are discussed in detail in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755).

Pending the availability of data, we are proposing to publicly report data in CY 2017 on 4 additional measures beginning with data collected on these measures for the first quarter of 2015, or discharges beginning on January 1, 2015: (1) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF

#1716); (2) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717); and beginning with the 2015–16 influenza vaccination season these two measures; (3) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431); and (4) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680).

Standardized infection ratios (SIRs) for the Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) and Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) would be displayed based on 4 rolling quarters of data and would initially use MRSA Bacteremia and CDI events that occurred from January 1, 2015 through December 31, 2015 (CY 2015), for calculations. We are proposing that the display of these ratios would be updated quarterly.

Rates for the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) would be displayed for personnel working in the reporting facility October 1, 2015 through March 31, 2016. Rates for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) would be displayed for patients in the LTCH during the influenza vaccination season, from October 1, 2015, through March 31, 2016. We are proposing that the display of these rates would be updated annually for subsequent influenza vaccination seasons.

Calculations for the MRSA Bacteremia and CDI Healthcare Associated Infection (HAI) measures adjust for differences in the characteristics of hospitals and patients using a Standardized Infection Ratio (SIR). The SIR is a summary measure that takes into account differences in the types of patients that a hospital treats. For a more detailed discussion about SIR, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753). The MRSA Bacteremia and CDI SIRs may take into account the laboratory methods, bed size of the hospital, and other facility-level factors. It compares the actual number of HAIs in a facility or State to a national benchmark based on previous years of reported data and adjusts the data based on several factors. A confidence interval with a lower and upper limit is displayed around each SIR to indicate that there is a high degree of confidence that the true value of the SIR lies within

that interval. A SIR with a lower limit that is greater than 1.0 means that there were more HAIs in a facility or State than were predicted, and the facility is classified as “Worse than the U.S. National Benchmark.” If the SIR has an upper limit that is less than 1, the facility had fewer HAIs than were predicted and is classified as “Better than the U.S. National Benchmark.” If the confidence interval includes the value of 1, there is no statistical difference between the actual number of HAIs and the number predicted, and the facility is classified as “No Different than U.S. National Benchmark.” If the number of predicted infections is less than 1.0, the SIR and confidence interval are not calculated by CDC.

Calculations for the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) are based on reported numbers of personnel who received an influenza vaccine at the reporting facility or who provided written documentation of influenza vaccination outside the reporting facility. The sum of these two numbers is divided by the total number of personnel working at the facility for at least 1 day from October 1 through March 31 of the following year, and the result is multiplied by 100 to produce a compliance percentage (vaccination coverage). No risk adjustment is applicable to these calculations. More information on these calculations and measure specifications is available at: <http://www.cdc.gov/nhsn/pdfs/hps-manual/vaccination/4-hcp-vaccination-module.pdf>. We are proposing that this data would be displayed on an annual basis and would include data submitted by LTCHs for a specific, annual influenza vaccination season. A single compliance (vaccination coverage) percentage for all eligible healthcare personnel would be displayed for each facility.

We are inviting public comment on our proposal to begin publicly reporting in CY 2017 pending the availability of data on Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717); and Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).

For the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) we are proposing to display rates annually based on the influenza season to avoid reporting for more than one

influenza vaccination within a CY. For example, in 2017 we would display rates for the patient vaccination measure based on discharges starting on July 1, 2015, to June 30, 2016. We are proposing this approach because it includes the entire influenza vaccination season (October 1, 2015, to March 31, 2016).

Calculations for Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) would be based on patients meeting any one of the following criteria: Patients who received the influenza vaccine during the influenza season; patients who were offered and declined the influenza vaccine; and patients who were ineligible for the influenza vaccine due to contraindication(s). The facility’s summary observed score would be calculated by combining the observed counts of all the criteria. This is consistent with the publicly reported patient influenza vaccination measure for *Nursing Home Compare*. In addition, for the patient influenza measure, we would exclude LTCHs with fewer than 20 stays in the measure denominator. For additional information on the specifications for this measure, we refer readers to the LTCH Quality Reporting Measures Information Web page at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html>.

We are inviting public comments on our proposal to begin publicly reporting the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure on discharges from July 1 of the previous calendar year to June 30 of the current calendar year. We are inviting comments on the public display of the measure Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680) in 2017 pending the availability of data.

In addition, we are requesting public comments on whether to include in the future, public display comparison rates based on CMS regions or U.S. census regions for Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678); All-Cause Unplanned Readmission Measure for 30-Days Post-Discharge from LTCHs (NQF #2512); and Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine

(Short Stay) (NQF #0680) for CY 2017 public display.

b. Procedures for the Opportunity To Review and Correct Data and Information

Section 1899B(g) of the Act requires the Secretary to establish procedures for public reporting of LTCHs’ performance, including the performance of individual LTCHs, on quality measures specified under section 1899B(c)(1) of the Act and resource use and other measures specified under section 1899B(d)(1) of the Act (collectively, IMPACT Act measures) beginning not later than 2 years after the applicable specified application date under section 1899B(a)(2)(E) of the Act. Under section 1899B(g)(2) of the Act, the procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act, which refers to public display and review requirements in the Hospital IQR Program, that each LTCH has the opportunity to review and submit corrections to its data and information that are to be made public prior to the information being made public.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49754), and as illustrated in the second table in section VIII.C.9.e. of the preamble of this proposed rule, we finalized that once the provider has an opportunity to review and correct quarterly data related to measures submitted via the QIES ASAP system or CDC NHSN, we would consider the provider to have been given the opportunity to review and correct this data. We wish to clarify that although the correction of data (including claims) can occur after the submission deadline, if such corrections are made after a particular quarter’s submission and correction deadline, such corrections will not be captured in the file that contains data for calculation of measures for public reporting purposes. To have publicly displayed performance data that is based on accurate underlying data, it will be necessary for LTCHs to review and correct this data before the quarterly submission and correction deadline.

In this proposed rule, we are restating and proposing additional details surrounding procedures that would allow individual LTCHs to review and correct their data and information on measures that are to be made public before those measure data are made public.

For assessment-based measures, we are proposing a process by which we would provide each LTCH with a confidential feedback report that would

allow the LTCH to review its performance on such measures and, during a review and correction period, to review and correct the data the LTCH submitted to CMS via the CMS QIES ASAP system for each such measure. In addition, during the review and correction period, the LTCH would be able to request correction of any errors in the assessment-based measure rate calculations.

We are proposing that these confidential feedback reports would be available to each LTCH using the CASPER system. We refer to these reports as the LTCH Quality Measure (QM) Reports. We are proposing to provide monthly updates to the data contained in these reports as data become available. We are proposing to provide the reports so that providers would be able to view their data and information at both the facility and patient level for its quality measures. The CASPER facility level QM Reports may contain information such as the numerator, denominator, facility rate, and national rate. The CASPER patient-level QM Reports may contain individual patient information which would provide information related to which patients were included in the quality measures to identify any potential errors for those measures in which we receive patient-level data. Currently, we do not receive patient-level data on the CDC measure data received via the NHSN system. In addition, we would make other reports available in the CASPER system, such as LTCH CARE Data Set assessment data submission reports and provider validation reports, which would disclose the LTCH's data submission status providing details on all items submitted for a selected assessment and the status of records submitted.

We refer providers to the CDC NHSN system Web site for information on obtaining reports specific to NHSN submitted data at: <http://www.cdc.gov/nhsn/ltach/index.html>. Additional information regarding the content and availability of these confidential feedback reports would be provided on an ongoing basis on our Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html>.

As previously finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49750 through 49752) and illustrated in the second table in section VIII.C.9.c. of the preamble of this proposed rule, LTCHs would have approximately 4.5 months after the reporting quarter to correct any errors of their assessment-based data (that appear on the CASPER-

generated QM reports) and NHSN data used to calculate the measures. During the time of data submission for a given quarterly reporting period and up until the quarterly submission deadline, LTCHs could review and perform corrections to errors in the assessment data used to calculate the measures and could request correction of measure calculations. However, as already established, once the quarterly submission deadline occurs, the data is "frozen" and calculated for public reporting and providers can no longer submit any corrections. We would encourage LTCHs to submit timely assessment data during a given quarterly reporting period and review their data and information early during the review and correction period so that they can identify errors and resubmit data before the data submission deadline.

As noted above, the assessment data would be populated into the confidential feedback reports and we intend to update the reports monthly with all data that have been submitted and are available. We believe that the data collection/submission quarterly reporting periods plus 4.5 months to review and correct the data is sufficient time for LTCHs to submit, review and, where necessary, correct their data and information. These timeframes and deadlines for review and correction of such measures and data satisfy the statutory requirement that LTCHs be provided the opportunity to review and correct their data and information and are consistent with the informal process hospitals follow in the Hospital IQR Program.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755) we finalized the data submission/correction and review period. Also, we afford LTCHs a 30-day preview period prior to public display during which LTCHs may preview the performance information on their measures that will be made public. We would like to clarify that we will provide the *preview* report using the CASPER system, with which LTCHs are familiar. The CASPER preview reports inform providers of their performance on each measure which will be publicly reported. Please note that the CASPER *preview* reports for the reporting quarter will be available after the 4.5 month correction period and the applicable data submission/correction deadline have passed and are refreshed on a quarterly basis for those measures publicly reported quarterly, and annually for those measure publicly reported annually. We are proposing to give LTCHs 30 days to review the preview

report beginning from the date on which they can access the report.

As already finalized, corrections to the underlying data would not be permitted during this time; however, LTCHs may ask for a correction to their measure calculations during the 30-day preview period. We are proposing that if CMS determines that the measure, as it is displayed in the preview report, contains a calculation error, we could suppress the data on the public reporting Web site, recalculate the measure and publish it at the time of the next scheduled public display date. This process would be consistent with informal processes used in the Hospital IQR Program. If finalized, we intend to utilize a subregulatory mechanism, such as our LTCH QRP Web site, to provide more information about the preview reports, such as when they will be made available and explain the process for how and when providers may ask for a correction to their measure calculations. We are inviting public comment on these proposals to provide preview reports using the CASPER system, giving LTCHs 30 days review the preview report and ask for a correction, and to use a subregulatory mechanism to explain the process for how and when providers may ask for a correction.

In addition to assessment-based measures and CDC measure data received via the NHSN system, we have also proposed claims-based measures for the LTCH QRP. The claims-based measures include those proposed to meet the requirements of the IMPACT Act as well as the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) which was finalized for public display in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755). As noted in above, section 1899B(g)(2) of the Act requires prepublication provider review and correction procedures that are consistent with those followed in the Hospital IQR Program. Under the Hospital IQR Program's informal procedures, for claims-based measures, we provide hospitals 30 days to preview their claims-based measures and data in a preview report containing aggregate hospital-level data. We are proposing to adopt a similar process for the LTCH QRP.

Prior to the public display of our claims-based measures, in alignment with the Hospital IQR, HAC Reduction and Hospital VBP Programs, we are proposing to make available through the CASPER system, a confidential preview report that will contain information pertaining to claims-based measure rate calculations, for example, facility and

national rates. The data and information would be for feedback purposes only and could not be corrected. This information would be accompanied by additional confidential information based on the most recent administrative data available at the time we extract the claims data for purposes of calculating the measures. Because the claims-based measures are recalculated on an annual basis, these confidential CASPER QM reports for claims-based measures will be refreshed annually. As previously finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755), LTCHs will have 30 days from the date the preview report is made available in which to review this information.

The 30-day preview period is the only time when LTCHs would be able to see claims-based measures before they are publicly displayed. LTCHs would not be able to make corrections to underlying claims data during this preview period, nor would they be able to add new claims to the data extract. However, LTCHs may request that we correct our measure calculation if the LTCH believes it is incorrect during the 30-day preview period. We are proposing that if we agree that the measure, as it is displayed in the preview report, contains a calculation error, we could suppress the data on the public reporting Web site, recalculate the measure, and publish it at the time of the next scheduled public display date. This process would be consistent with informal policies followed in the Hospital IQR Program. If finalized, we intend to utilize a subregulatory mechanism, such as our LTCH QRP Web site, to explain the process for how and when providers may contest their measure calculations.

The proposed claims-based measures—The MSPB–PAC LTCH QRP; Discharge to Community—PAC LTCH QRP and Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP—use Medicare administrative data from hospitalizations for Medicare FFS beneficiaries. Public reporting of data would be based on 2 consecutive calendar years (CY) of data, which is consistent with the specifications of the proposed measures. We are proposing to create data extracts using claims data for the proposed claims based measures—The MSPB–PAC LTCH measure; Discharge to Community—PAC LTCH QRP and Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP—at least 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 December 31, 2017 for data collection January 1, 2016 through December 31, 2017, we would create the data extract on approximately March 31, 2018 at the earliest, and use that data to calculate the claims-based measures for that applicable period. Since LTCHs would not be able to submit corrections to the underlying claims snapshot nor add claims (for those measures that use LTCH claims) to this data set at the conclusion of the at least 90-day period following the last date of discharge used in the applicable period, at that time we would consider LTCH claims data to be complete for purposes of calculating the claims-based measures.

We are proposing that beginning with data that will be publicly displayed in 2018, claims-based measures will be calculated using claims data at least 90 days after the last discharge date in the applicable period, at which time we would create a data extract or snapshot of the available claims data to use for the measures calculation. This timeframe allows us to balance the need to provide timely program information to LTCHs with the need to calculate the claims-based measures using as complete a data set as possible. As noted, under this proposed procedure, during the 30-day preview period, LTCHs would not be able to submit corrections to the underlying claims data or to add new claims to the data extract. This is for two reasons: first, for certain measures, the claims data used to calculate the measures may not be derived from the LTCH's claims, but are from the claims of another provider. For example, the proposed measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP uses claims data submitted by the hospital to which the patient was readmitted, which may not be the LTCH. For the claims that are not those of the LTCH, the LTCH could not make corrections to them. Second, even where the claims used to calculate the measures are those of the LTCH, it would not be possible to correct the data after it is extracted for the measures calculation. This is because it is necessary to take a static “snapshot” of the claims in order to perform the necessary measure calculations.

We seek to have as complete a data set as possible. We recognize that the proposed at least 90 day “run-out” period when we would take the data extract to calculate the claims-based measures, is less than the Medicare program's current timely claims filing policy under which providers have up to 1 year from the date of discharge to submit claims. We considered a number

of factors in determining that the proposed at least 90 day run-out period is appropriate to calculate the claims-based measures. 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 or episode-based measures). We then need to generate and check the calculations. Because several months lead time is necessary after acquiring the data to generate the 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 LTCHs sooner than 18 to 24 months after the last discharge. We believe this would create an unacceptably long delay both for LTCHs and for us to deliver timely calculations to LTCHs for quality improvement.

We are inviting public comment on these proposals.

#### 15. Proposed Mechanism for Providing Feedback Reports to LTCHs

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback reports to PAC providers on their performance to the measures specified under sections 1899B(c)(1) and (d)(1) of the Act, beginning 1 year after the specified application date that applies to such measures and PAC providers. As discussed earlier, the reports we are proposing to provide for use by LTCHs to review their data and information would be confidential feedback reports that would enable LTCHs to review their performance on the measures required under the LTCH QRP. We are proposing that these confidential feedback reports would be available to each LTCH using the CASPER system. Data contained within these CASPER reports would be updated as previously described, on a monthly basis as the data become available except for our claims-based measures which are only updated on an annual basis.

We intend to provide detailed procedures to LTCHs on how to obtain their confidential feedback CASPER reports on the LTCH QRP Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html>.

We are proposing to use the CMS QIES ASAP system to provide quality measure reports in a manner consistent with how providers obtain various reports to date. The QIES ASAP system is a confidential and secure system with access granted to providers, or their designees.

We seek public comment on this proposal to satisfy the requirement to provide confidential feedback reports to LTCHs.

#### *D. Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program*

##### 1. Background

###### a. 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 FY 2014<sup>275</sup> and each subsequent fiscal year, the Secretary must reduce any annual update to a standard federal rate for discharges occurring during the 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.

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 the 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 may not take into account the reduction in computing the payment amount under the system

<sup>275</sup> The statute uses the term “rate year” (RY). However, 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, effective on October 1 of each year. This change allowed 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, promoting administrative efficiency. 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 RY update period would be the 12-month period from October 1 through September 30, which we refer to as a “fiscal year” (FY) (76 FR 26435). Therefore, with respect to the IPFQR Program, the terms “rate year,” as used in the statute, and “fiscal year” as used in the regulation, both refer to the period from October 1 through September 30. 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).

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 must submit to the Secretary data on quality measures as specified by the Secretary. The data must 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, unless the exception of subclause (ii) applies, 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.

Section 1886(s)(4)(D)(ii) of the Act provides an exception to the requirement for NQF endorsement of measures: 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.

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. These procedures must ensure that a facility has the opportunity to review its data prior to the data being made public. The Secretary must report quality measures that relate to services furnished by the psychiatric hospitals and units on the CMS Web site.

###### b. 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 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. Consistent with prior rules, we continue to use the term “inpatient psychiatric facility” (IPF) to refer to both inpatient psychiatric hospitals and psychiatric units. This usage follows the terminology in our IPF PPS regulations at 42 CFR 412.402. For more information on covered entities, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645).

###### c. Considerations in Selecting Quality Measures

Our objective in selecting quality measures is to balance the need for information on the full spectrum of care delivery and the need to minimize the burden of data collection and reporting. We have focused on measures that evaluate critical processes of care that have significant impact on patient outcomes and support CMS and HHS priorities for improved quality and efficiency of care provided by IPFs. We refer readers to section VIII.F.4.a. of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645 through 53646) for a detailed discussion of the considerations taken into account in selecting quality measures.

Before being proposed for inclusion in the IPFQR Program, measures are placed on a list of measures under consideration, which is published annually by December 1 on behalf of CMS by the NQF. In compliance with section 1890A(a)(2) of the Act, measures that we are proposing for the IPFQR Program in this proposed rule were included in a publicly available document: “List of Measures under Consideration for December 1, 2015” (<http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81172>). The Measure Applications Partnership (MAP), a multi-stakeholder group convened by the NQF, reviews the measures under consideration for the IPFQR Program, among other Federal programs, and provides input on those measures to the Secretary. The MAP’s 2016 recommendations for quality measures under consideration are captured in the following document: “Process and Approach for MAP Pre-Rulemaking Deliberations 2015–2016—Final Report, February 2016” (<http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81599>). We considered the input and recommendations provided by the MAP in selecting all measures for the IPFQR Program, including those discussed below.

###### 2. Retention of IPFQR Program Measures Adopted in Previous Payment Determinations

The current IPFQR Program includes 16 mandatory measures. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53646 through 53652), we adopted 6 measures for the FY 2014 payment determination and subsequent years. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50889 through 50895), we added 2 measures for the FY 2016 payment determination and subsequent years. In the FY 2015

IPF PPS final rule (79 FR 45963 through 45974), we adopted another 2 measures for the FY 2016 payment determination and subsequent years, and finalized 4 quality measures for the FY 2017 payment determination and subsequent years. In the FY 2016 IPF PPS final rule (80 FR 46694 through 46714), we removed 1 measure beginning with the FY 2017 payment determination; we also adopted 5 measures and removed 2 measures beginning with the FY 2018 payment determination. We are retaining 15 of these previously adopted measures and proposing to update one measure, as discussed below.

### 3. Proposed Update to Previously Finalized Measure: Screening for Metabolic Disorders

In the FY 2016 IPF PPS final rule (80 FR 46709 through 46713), we finalized our proposal to include the Screening for Metabolic Disorders measure in the IPFQR Program for the FY 2018 payment determination and subsequent years. In that final rule, we described the denominator as IPF patients discharged with one or more routinely scheduled antipsychotic medications during the measurement period. We also listed the following denominator exclusions: (1) Patients for whom a screening could not be completed within the stay due to the patient's enduring unstable medical or psychological condition; and (2) patients with a length of stay equal to or greater than 365 days, or less than 3 days.

In the FY 2016 IPF PPS final rule (80 FR 46717 through 46718), we finalized the CMS global sample methodology for 10 IPFQR Program measures eligible for sampling, including the Screening for Metabolic Disorders measure. Seven of these 10 measures have denominator exclusions for patients with short length of stay within an IPF. Of these 7 measures, the Screening for Metabolic Disorders measure is the only one with an exclusion for less than 3 days; the other 6 all have denominator exclusions for length of stay less than or equal to 3 days. Therefore, we are proposing to update the length of stay exclusion for the Screening for Metabolic Disorders measure to exclude patients with a length of stay equal to or greater than 365 days, or less than or equal to 3 days. We anticipate that this update would reduce burden on IPFs, if it is finalized, because it would support the intent of the global sample to allow IPFs to use the same sample for as many measures as possible, by aligning the denominator exclusions.

We welcome public comments on this proposed denominator exclusion.

### 4. Proposed New Quality Measures for the FY 2019 Payment Determination and Subsequent Years

We are proposing two new measures for the FY 2019 payment determination and subsequent years:

- SUB-3 Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and the subset measure SUB-3a Alcohol & Other Drug Use Disorder Treatment at Discharge (NQF #1664) (SUB3 and SUB-3a); and
- Thirty-day all-cause unplanned readmission following psychiatric hospitalization in an IPF.

The sections below outline our rationale for proposing these measures.

#### a. SUB-3 Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and the Subset Measure SUB-3a Alcohol & Other Drug Use Disorder Treatment at Discharge (NQF #1664) (SUB-3 and SUB3a)

Individuals with mental illness experience substance use disorders (SUDs) at a much higher rate than the general population.<sup>276</sup> Nearly 18 percent of the 43.6 million adults aged 18 years and older who had a mental illness in 2013 met the criteria for a SUD. Of those who met the criteria for a SUD, 26.7 percent used illicit drugs.<sup>277</sup> Illicit drug use is particularly high among adults with serious mental illnesses.<sup>278</sup> Misuse and abuse of prescription drugs among individuals with mental illnesses, in particular opioids, are also of growing concern.

Individuals with co-occurring mental disorders and SUDs, the combination of one or more mental disorders and one or more SUDs, experience far more physical illnesses and episodes of care than individuals with a single diagnosis.<sup>279</sup> These co-occurring disorders tend to go undetected and untreated, especially among the elderly population, which experiences more adverse effects than the young adult population.<sup>280</sup> Treatment of only one disorder for individuals who have two or more mental and SUDs often leads to poor functioning and poor treatment compliance that inhibits full recovery, increases the risk of relapse, and can lead to other high-risk illnesses, such as

coronary heart disease, diabetes, infections, and respiratory disease.<sup>281 282</sup> Furthermore, individuals with undetected, untreated or undertreated co-occurring disorders are more likely to experience homelessness, incarceration, additional medical illness, suicide, and early death.<sup>283</sup>

Due to the prevalence of substance abuse among individuals with mental illness, and the negative effects therefrom, we believe it is imperative to assess IPFs' efforts to offer treatment options for patients who screen positive for drug and alcohol use. As described under the Measure Description section of the NQF Web page regarding this measure, the SUB-3 measure includes hospitalized patients age 18 years and older "who are identified with an alcohol or drug use disorder who receive or refuse at discharge a prescription for FDA-approved medications for alcohol or drug use disorder, OR who receive or refuse a referral for addictions treatment."<sup>284</sup> The SUB-3a subset measure includes hospitalized patients age 18 years and older "who receive a prescription for FDA-approved medications for alcohol or drug use disorder OR a referral for addictions treatment."<sup>285</sup> The numerator of the SUB-3 measure includes "patients who received or refused at discharge a prescription for medication for treatment of alcohol or drug use disorder OR received or refused a referral for addictions treatment."<sup>286</sup> The numerator of the SUB-3a subset measure includes "patients who received a prescription at discharge for medication for treatment of alcohol or drug use disorder OR a referral for addictions treatment."<sup>287</sup> The denominators of both the SUB-3 measure and SUB-3a subset measure include "hospitalized inpatients 18 years of age and older identified with an alcohol or drug use disorder" subject to a list of exclusions.<sup>288</sup> Further information on this measure, including the denominator exclusions, can be found in the measure detail sheet on the NQF's Web site (<http://www.qualityforum.org/QPS/1664>) or in the section of the Specifications Manual

<sup>281</sup> SAMHSA. "Mental and Substance Use Disorders."

<sup>282</sup> Mental Health Foundation. "Physical Health and Mental Health."

<sup>283</sup> SAMHSA. "Mental and Substance Use Disorders."

<sup>284</sup> NQF SUB-3 and SUB-3a Measure Specifications. Available at: <http://www.qualityforum.org/QPS/1664>.

<sup>285</sup> Ibid.

<sup>286</sup> Ibid.

<sup>287</sup> Ibid.

<sup>288</sup> Ibid.

<sup>276</sup> National Institute on Drug Abuse (NIDA). "Comorbidity: Addiction and Other Mental Illnesses."

<sup>277</sup> SAMHSA. *Results from the 2014 National Survey on Drug Use and Health: Mental Health Findings*.

<sup>278</sup> Ibid.

<sup>279</sup> SAMHSA. "Mental and Substance Use Disorders."

<sup>280</sup> Robert Drake. "Dual Diagnosis and Integrated Treatment of Mental Illness and Substance Abuse Disorder."

for National Hospital Inpatient Quality Measures on Substance Use Measures at: [http://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890516540&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D2.6.2\\_SUB\\_v5\\_1.pdf&blobcol=urldata&blobtable=MungoBlobs](http://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890516540&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D2.6.2_SUB_v5_1.pdf&blobcol=urldata&blobtable=MungoBlobs).

We previously adopted the SUB-1 measure (Alcohol Use Screening (NQF #1661)) (78 FR 50890 through 50892) and the SUB-2 (Alcohol Use Brief Intervention Provided or Offered) and the subset measure SUB-2a (Alcohol Use Brief Intervention (NQF #1663) (SUB-2 and SUB-2a)) measure (80 FR 46699 through 46701). While the SUB-1 measure assesses “hospitalized patients 18 years of age and older who are screened during the hospital stay using a validated screening questionnaire for unhealthy alcohol use,”<sup>289</sup> the SUB-2 and SUB-2a measure assesses “hospitalized patients who screened positive for unhealthy alcohol use who received or refused a brief intervention during the hospital stay”<sup>290</sup> and “hospitalized patients 18 years and older who received the brief intervention during the hospital stay,”<sup>291</sup> respectively. The SUB-1 measure and the SUB-2 and SUB-2a measure combined provide a greater understanding of the rate at which patients are screened for potential alcohol abuse and the rate at which those who screen positive accept the offered interventions.

Despite the value created by the inclusion of the SUB-1 measure and the SUB-2 and SUB-2a measure in the IPFQR Program measure set, neither fully captures hospitalized patients 18 years of age and older with other SUDs because these measures focus on alcohol use only. In the past, commenters have urged CMS to include illicit and opioid drug screening in our measure set (80 FR 46701) stating that co-occurring substance use disorders are prevalent in many patients with psychiatric diagnoses and the SUB-3 and SUB-3a measure will ensure that patients continue to receive treatment after discharge.<sup>292</sup> While the SUB-3 and SUB-3a measure does not guarantee that patients would continue to receive treatment for substance use disorders after discharge, the addition of the SUB-

3 and SUB-3a measure to the existing measure set would encourage IPFs to offer and provide FDA-approved medication OR a referral for addictions treatment to patients with co-occurring drug or alcohol use disorders at discharge. This measure would also provide information regarding the rate at which these treatment options are accepted by patients. The SUB-3 and SUB-3a measure also provides a fuller picture of the entire episode of care. In addition, aggregated data from the SUB-1 measure, SUB-2 and SUB-2a measure, and the SUB-3 and SUB-3a measure from each IPF would help provide patients with adequate consumer information to guide their decision-making process in selecting a treatment facility, specifically for patients that are diagnosed with a substance use disorder.

Furthermore, we believe that this measure set promotes the National Quality Strategy priority of Effective Prevention and Treatment for leading causes of mortality, starting with cardiovascular disease. It is notable that the high prevalence of SUDs among adults age 65 years and older contributes to serious medical conditions, including cardiovascular disease and liver disease. The proposed measure also supports HHS’ Opioid Abuse Reduction Initiative to reduce prescription opioid and heroin related overdose, death, and dependence.<sup>293</sup> We also note that the addition of SUB-3 and SUB-3a in the measure set could encourage interventions and promote prevention of conditions that are associated with alcohol and drug use disorders.

For these reasons, we included the SUB-3 and SUB-3a measure in our “List of Measures under Consideration for December 1, 2015” (<http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81172>). The MAP provided input on the measure and supported its inclusion in the IPFQR Program in its report “Process and Approach for MAP Pre-Rulemaking Deliberations 2015–2016—Final Report, February 2016” available at: <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81599>. Moreover, this measure is NQF-endorsed for the IPF setting, in conformity with the statutory criteria for measure selection under section 1886(s)(4)(D)(i) of the Act.

Therefore, we are proposing to adopt the SUB-3 and SUB-3a measure for the

FY 2019 payment determination and subsequent years. We welcome public comment on this proposal.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53657 through 53658) and FY 2014 IPPS/LTCH PPS final rule (78 FR 50901 through 50902), we finalized policies for population, sampling, and minimum case thresholds. In the FY 2016 IPF PPS final rule, we made one change to these requirements (80 FR 46717 through 46719) in finalizing a policy in which IPFs may take one, global sample for all measures for which sampling is permitted. This policy was adopted to decrease burden on IPFs and streamline policies and procedures. We are proposing to allow sampling for the SUB-3 and SUB-3a measure. Therefore, we are proposing to include the SUB3 and SUB-3a measure in the list of measures covered by the global sample. We welcome public comment on this proposal.

b. Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF

The MAP, composed of national stakeholders, identified readmissions as a key gap area in the IPFQR Program in a January 2015 report.<sup>294</sup> A goal of the CMS Quality Strategy is to “promote effective communication and coordination of care” across different care settings and providers. In addition, readmission following discharge from IPFs is undesirable for patients because readmissions represent a deterioration in patients’ mental and/or physical health status. Furthermore, an analysis of Medicare claims data for calendar years 2012 and 2013 showed that among the 716,174 IPF admissions for Medicare beneficiaries, more than 20 percent resulted in readmission to an IPF or a short-stay acute care hospital within 30 days of discharge.<sup>295</sup> Risk-standardized readmission rates ranged from 11 percent to 35 percent, indicating wide variation across IPFs and clear opportunity for improvement. Finally, MedPAC estimates of Medicare payments to IPFs in 2012 indicated that the average payment per discharge was

<sup>294</sup> Process and Approach for MAP Pre-Rulemaking Deliberations. *Measure Applications Partnership*. 2015. Available at: [http://www.qualityforum.org/Setting\\_Priorities/Partnership/MAP\\_Final\\_Reports.aspx](http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx).

<sup>295</sup> Inpatient Psychiatric Facility All-Cause Unplanned Readmission Measure: Draft Technical Report, November 23, 2015. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html#17>. (On this page, the file is listed as “Inpatient Psychiatric Facility (IPF) Outcome and Process Measure Development and Maintenance” under downloads.)

<sup>289</sup> NQF SUB-1 Measure Specifications.

<sup>290</sup> NQF SUB-2 and SUB-2a Measure Specifications.

<sup>291</sup> Ibid.

<sup>292</sup> 80 FR 46701.

<sup>293</sup> ASPE. “Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths.”

nearly \$10,000.<sup>296</sup> Therefore, reducing readmissions would substantially reduce costs. For these reasons, we developed a facility-level outcome measure of all-cause, unplanned readmissions following discharge from a qualifying IPF admission. This measure would provide an important indicator of the quality of care patients receive in the IPF setting.

Although not all readmissions are preventable, there is evidence that improvements in the quality of care for patients in the IPF setting can reduce readmission rates which, in turn, would reduce costs to Medicare and the burden to patients and their caregivers. For example, a study of 30-day behavioral health readmissions using a multistate Medicaid database found that connecting patients to services they will need post-discharge can help prevent readmissions. A 1-percent increase in the percentage of patients receiving follow-up care within 7 days of discharge was associated with a 5 percent reduction in the probability of being readmitted.<sup>297</sup> Other studies have also found that transitional interventions such as pre- and post-discharge patient education, structured needs assessments, medication reconciliation/education, transition managers, and inpatient/outpatient provider communication have been effective in reducing early psychiatric readmissions. A systematic review of such interventions observed reductions of 13.6 percent to 37.0 percent of readmissions.<sup>298</sup>

The proposed readmission measure would complement the portfolio of facility-level, risk-standardized readmission measures in the acute care setting that CMS quality reporting and pay-for-performance programs currently use. These programs include, among others, the Hospital IQR Program, which requires facilities to report on condition-specific risk-standardized readmission measures (including Acute Myocardial Infarction (AMI), Heart Failure (HF), Pneumonia, and elective Hip/Knee replacements, among others).<sup>299</sup> In

<sup>296</sup> Inpatient Psychiatric Facility Services Payment System. *MedPAC*. 2014. Available at: <http://www.medpac.gov/documents/payment-basics/inpatient-psychiatric-facility-services-payment-system-14.pdf>.

<sup>297</sup> Mark TL, Mark T, Tomic KS, et al. Hospital readmission among medicaid patients with an index hospitalization for mental and/or substance use disorder. *J Behav Health Serv Res*. 2013; 40(2):207–221.

<sup>298</sup> Vigod SN, Kurdyak PA, Dennis CL, et al. Transitional interventions to reduce early psychiatric readmissions in adults: Systematic review. *Br J Psychiatry*. 2013; 202(3):187–194.

<sup>299</sup> <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/OutcomeMeasures.html>.

addition, the Hospital IQR Program requires reporting on a Hospital-Wide All-Cause Unplanned Readmissions measure (READM–30–HWR) as finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53521 through 53528). The Hospital Readmissions Reduction Program, a pay-for-performance program for subsection (d) hospitals or hospitals paid under section 1814(b)(3) of the Act, also uses risk-standardized condition-specific readmission measures (including AMI, HF, and Pneumonia, among others).<sup>300</sup>

The proposed IPF readmission measure, 30-day all-cause unplanned readmission following psychiatric hospitalization in an IPF, estimates a facility-level, risk-standardized readmission rate for unplanned, all-cause readmissions within 30 days of discharge from an IPF. Detailed information about the development of this measure as well as final measure specifications can be downloaded from the CMS Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html#17> (on this page, the file is listed as “Inpatient Psychiatric Facility (IPF) Outcome and Process Measure Development and Maintenance” under downloads.). The denominator for this measure includes Medicare FFS beneficiaries aged 18 years and older who are admitted to and discharged alive from an IPF with a principal diagnosis of a psychiatric disorder. Admissions to IPFs for nonpsychiatric disorders, which account for only 1.1 percent of admissions, were not included in the measure cohort because IPFs are expected to admit patients who need inpatient care for psychiatric causes.<sup>301</sup> Therefore, nonpsychiatric admissions could represent either admissions that were initiated for presumed or preliminary psychiatric diagnoses but later were changed to nonpsychiatric primary diagnoses during the admission or admissions with unreliable data.

Eligible index admissions require enrollment in Medicare Parts A and B for 12 months prior to the index admission, the month of admission, and at least 30 days post-discharge. Admissions to IPFs are excluded from the denominator if any of the following apply:

- Subsequent admission on day of discharge (Day 0) or within 2 days post-discharge (Day 1-Day 2) due to transfers

<sup>300</sup> 76 FR 51660 through 51676.

<sup>301</sup> Prospective Payment System for Inpatient Hospital Services. In: Services DoHaH, Ed. 42, Vol. 412. U.S. Government Publishing Office 2011:535–537.

to another inpatient facility on Day 0 or 1 or billing procedures for interrupted stays, which do not allow for identification of readmissions to the same IPF within 3 days;

- Patient discharged against medical advice (AMA) because the provider would not have an opportunity to provide optimal care; and
- Unreliable patient data (for example, has a death date but also admission afterwards).

The numerator for the IPF readmission measure is defined as any admission to an IPF or acute care hospital that occurs on or between days 3 and 30 post-discharge, except those considered planned by the CMS Planned Readmission Algorithm, Version 3.0.<sup>302</sup> The all-cause, unplanned, 30-day readmission rate is harmonized with other readmission measures that are endorsed by NQF and in use by CMS programs. For the timeframe for measurement, literature supports the connection between 30-day readmissions and the quality of care provided during the index admission.<sup>303 304 305 306 307</sup> This timeframe also supports interventions that have been developed on a wide range of patient populations that focus on reducing 30-day readmission rates.<sup>308 309 310 311 312</sup> Finally, a

<sup>302</sup> Horwitz LI, Grady JN, Zhang W, et al. 2015 Measure Updates and Specifications Report: Hospital-Wide All-Cause Unplanned Readmission Measure—Version 4.0. Centers for Medicare & Medicaid Services; 2015. Available in the Hospital Wide All Cause Readmission Updates folder at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

<sup>303</sup> Hyland M. National Mental Health Benchmarking Project. In: Wendy Hoey, Whitecross MFaF, eds. Reducing 28 Day Readmission. Australian Mental Health Outcomes and Classification Network 2008:38.

<sup>304</sup> Boaz TL, Becker MA, Ansel R, Van Dorn RA, Choi J, Sikirica M. Risk factors for early readmission to acute care for persons with schizophrenia taking antipsychotic medications. *Psychiatric services (Washington, DC)*. 2013; 64(12):1225–1229.

<sup>305</sup> Zilber N, Hornik-Lurie T, Lerner Y. Predictors of early psychiatric rehospitalization: A national case register study. *Isr J Psychiatry Relat Sci*. 2011; 48(1):49–53.

<sup>306</sup> Lutterman T, Ganju V, Schacht L, Shaw R, Monihan K, et al. Sixteen State Study on Mental Health Performance Measures. 2003.

<sup>307</sup> Carr VJ, Lewin TJ, Sly KA, et al. Adverse incidents in acute psychiatric inpatient units: rates, correlates and pressures. *Aust N Z J Psychiatry*. 2008; 42(4):267–282.

<sup>308</sup> Naylor M, Brooten D, Jones R, Lavizzo-Mourey R, Mezey M, Pauly M. Comprehensive discharge planning for the hospitalized elderly. A randomized clinical trial. *Annals of internal medicine*. 1994; 120(12):999–1006.

<sup>309</sup> Naylor MD, Brooten D, Campbell R, et al. Comprehensive discharge planning and home follow-up of hospitalized elders: A randomized clinical trial. *JAMA*. 1999; 281(7):613–620.

<sup>310</sup> van Walraven C, Seth R, Austin PC, Laupacis A. Effect of discharge summary availability during



workgroup of relevant clinical experts agreed that the 30-day time period captures complications that may be attributable to the IPF.

An all-cause readmission rate was selected because it promotes a holistic approach to the treatment of patients with psychiatric disorders, who often have comorbid medical conditions. From the patient and caregiver perspective, these readmissions indicate a deterioration in the patient's condition. In addition, the relationship between principal discharge diagnosis of the index admission and the principal discharge diagnosis of the readmission may be complex and difficult to determine based only on principal diagnosis codes. For example, a patient discharged with bipolar disorder may be readmitted because of a suicide attempt or self-harm due to poorly controlled symptoms of bipolar disorder. A measure that looks only for readmissions with principal discharge diagnoses of bipolar disorder would miss these readmissions.

The IPF readmission measure uses Medicare FFS claims and enrollment data over a 24-month measurement period to calculate the measure results. Twenty-four months was determined to provide an adequate number of cases and reliable results. Because this measure is not limited to a single diagnosis, a 24-month measurement period gives sufficient sample size. The IPF measure had 4.2 percent of IPFs with fewer than 25 cases in the 24-month measurement period from January 2012 to December 2013. For comparison, the HWR measure had 3.8 percent of hospitals with fewer than 25 cases in the 12-month measurement period from July 2013 to June 2014.

We recognize that the risk of readmission is influenced by patient factors, so the measure is risk-adjusted to account for differences in the patients served across IPFs. Hierarchical logistic regression is used to estimate a risk standardized readmission rate for each facility. Factors considered in the risk-adjustment model include patient demographics, principal discharge diagnoses of the index admission, comorbidities in claims during the 12 months prior to the index admission or during the index admission with the

exception of complications of care, and several risk variables specific to the IPF patient population. Risk factors were selected for inclusion in the final risk model if they were positively selected at least 70 percent of the time in a stepwise backward elimination process. The final risk model includes age, gender, 13 principal discharge diagnosis Agency for Healthcare Research and Quality (AHRQ) Clinical Classification Software (CCS) categories, 38 comorbidity CMS Hierarchical Condition Categories (CC), history of discharge against medical advice, history of suicide or self-harm, history of aggression, and the hospital as a random effect. For more information about factors used in calculating the risk-standardized readmission rate, we refer readers to the CMS Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html#17>. (On this page, the file is listed as "Inpatient Psychiatric Facility (IPF) Outcome and Process Measure Development and Maintenance" under downloads.)

We understand the importance of the role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. When this measure was submitted to NQF on January 29, 2016, this information was included.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the effect of sociodemographic status on quality measures, resource use, and other measures under the Medicare program, as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

As part of the measure development process for this measure, we solicited public comments on the measure via the CMS Public Comment Web page. As part of our comment solicitation, we provided the Measure Information Form (MIF), Data Dictionary, and the Measure Technical Report to the public to inform their review of the measure. We accepted public comments from November 25, 2015 through December 11, 2015. The significant majority of stakeholders who provided comments on the measure design supported this measure because of the importance of measuring readmissions in this population. Commenters who provided input on the methodology agreed that it appears to be scientifically acceptable, and those who provided input on the feasibility agreed with our belief that the measure is feasible as designed. After review and evaluation of all the public comments received, we did not identify any areas in which the measure needed to be modified. For specific information regarding the comments we received, we refer readers to the CMS Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html#17>. (On this page, the file is listed as "Inpatient Psychiatric Facility (IPF) Outcome and Process Measure Development and Maintenance" under downloads.)

While section 1886(s)(4)(D)(ii) of the Act authorizes the Secretary to specify a measure that is not endorsed by NQF, the proposed IPF readmission measure was submitted to NQF for endorsement on January 29, 2016, and we anticipate the measure will receive endorsement prior to the release of the final rule. However, the exception to the requirement to specify an endorsed measure 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

post-discharge visits on hospital readmission. *J Gen Intern Med.* 2002; 17(3):186–192.

<sup>311</sup> Zhang J, Harvey C, Andrew C. Factors associated with length of stay and the risk of readmission in an acute psychiatric inpatient facility: a retrospective study. *Aust N Z J Psychiatry.* 2011; 45(7):578–585.

<sup>312</sup> Silva NC, Bassani DG, Palazzo LS. A case-control study of factors associated with multiple psychiatric readmissions. *Psychiatric services (Washington, DC).* 2009; 60(6):786–791.

endorsed or adopted by a consensus organization. We have reviewed NQF-endorsed and other consensus-endorsed measures related to all-cause unplanned readmissions and believe that none are appropriate to the inpatient psychiatric setting. Therefore, no equivalent readmission measure that is endorsed

by a consensus organization is available for use in the IPFQR Program.

For the reasons stated above, we are proposing the IPF readmission measure described in this section for the FY 2019 payment determination and subsequent years. We welcome public comment on this proposal.

5. Summary of Proposed Measures for the FY 2019 Payment Determination and Subsequent Years

The measures that we are proposing to adopt for the IPFQR Program for the FY 2019 payment determination and subsequent years are set forth in the table below.

PROPOSED NEW IPFQR PROGRAM MEASURES FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

National quality strategy priority	NQF No.	Measure ID	Measure
Effective Treatment and Prevention.	1664 .....	SUB-3 and SUB-3a .....	SUB-3 Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol & Other Drug Use Disorder Treatment at Discharge.
Communication/Care Coordination.	N/A (Under review for endorsement).	N/A .....	Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF.

If these measures are adopted, the number of measures for the FY 2019 IPFQR Program and subsequent years

will total 18, as set forth in the table below.

PROPOSED AND FINALIZED MEASURES FOR FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure ID	Measure
0640 .....	HBIPS-2 .....	Hours of physical restraint use.
0641 .....	HBIPS-3 .....	Hours of seclusion use.
0560 .....	HBIPS-5 .....	Patients discharged on multiple antipsychotic medications with appropriate justification.
0576 .....	FUH .....	Follow-Up After Hospitalization for Mental Illness.
1661 .....	SUB-1 .....	Alcohol Use Screening.
1663 .....	SUB-2 and SUB-2a .....	Alcohol Use Brief Intervention Provided or Offered and the subset measure Alcohol Use Brief Intervention.*
1651 .....	TOB-1 .....	Tobacco Use Screening.
1654 .....	TOB-2 and TOB-2a .....	Tobacco Use Treatment Provided or Offered and the subset measure Tobacco Use Treatment.
1656 .....	TOB-3 and TOB-3a .....	Tobacco Use Treatment Provided or Offered at Discharge and the subset measure Tobacco Use Treatment at Discharge.
1659 .....	IMM-2 .....	Influenza Immunization.
0647 .....	N/A .....	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).
0648 .....	N/A .....	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).
N/A .....	N/A .....	Screening for Metabolic Disorders.
N/A .....	N/A .....	Influenza Vaccination Coverage Among Healthcare Personnel.
N/A .....	N/A .....	Assessment of Patient Experience of Care.
N/A .....	N/A .....	Use of an Electronic Health Record.
1664 .....	SUB-3 and SUB-3a .....	Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and the subset measure Alcohol & Other Drug Use Disorder Treatment at Discharge.*
N/A (Under review for endorsement).	N/A .....	Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF.*

\* New measures proposed for the FY 2019 payment determination and future years.

6. Possible IPFQR Program Measures and Topics for Future Consideration

As we have indicated in prior rulemaking (79 FR 45974 through 45975), 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 IPF setting. Therefore, through future rulemaking,

we intend to propose new measures for adoption that will help further our goals of achieving better health care and improved health for Medicare beneficiaries who obtain inpatient psychiatric services through the widespread dissemination and use of quality information.

We welcome public comments on possible new measures.

7. Public Display and Review Requirements

We are proposing to change to how we specify the timeframes for public display of data and the associated preview period for IPFs to review the data that will be made public.

Under section 1886(s)(4)(E) of the Act, we are required to establish procedures for making the data submitted under the

IPFQR Program available to the public. Such procedures must ensure that an IPF has the opportunity to review its data that are to be made public prior to such data being made public. Section 1866(s)(4)(E) of the Act also provides that the Secretary must report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospitals on the CMS Web site.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50897 through 50898), we stated that we would publicly display the data submitted by IPFs for the IPFQR Program on a CMS Web site in April of each calendar year following the start of the respective payment determination year. For example, we publicly displayed the data for the FY 2015 payment determination in April 2015. We strive to publicly display data as soon as possible on a CMS Web site, as this provides consumers with healthcare information and furthers our goal of transparency. Therefore, we believe it is best to not specify in rulemaking the exact timeframe for publication, as doing so may prevent earlier publication. We are proposing, then, to make these data available as soon as it is feasible. We intend to make the data available on *Hospital Compare* on at least a yearly basis.

We also are required to give each IPF an opportunity to review its data before the data are made public. This purpose of this preview period is to ensure that each IPF is informed of the IPF level data that the public will be able to see for its facility, and to submit measure rate errors resulting from MS calculations of IPF submitted patient level claims and Web-based measure numerator and denominator data. It is not for the purpose of correcting an IPF's possible submission errors. As finalized in the 2015 IPF PPS final rule (79 FR 45976), IPFs have the entire data submission period to review and correct claims data element and Web-based measure numerator and denominator count data they have submitted to CMS. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50897 through 50898), we stated that the preview period would be 30 days and would begin approximately 12 weeks prior to the public display of the data.

Because we are proposing to make the data for the IPFQR Program available as soon as possible, and the timeframe for publication may change from year-to-year, we are proposing to no longer specify the dates for review in rulemaking, nor to specify in rulemaking that the preview period will begin approximately 12 weeks prior to

publicly displaying the data. Instead, we are proposing to announce the exact timeframes through subregulatory guidance, including on a CMS Web site and/or on our applicable listservs. We also are proposing to continue our policy that the time period for review will be approximately 30 days in length.

As noted earlier, we wish to publicly display data as early as possible. For the FY 2017 payment determination, it may be technically feasible for us to display the data as early as December 2016. We previously finalized that the preview period would be 30 days and would be approximately 12 weeks prior to the public display date. However, in this case, 12 weeks prior to December 1, 2016 is in mid-September, which is 2 weeks before the usual effective date of the IPPS/LTCH PPS final rule. Therefore, for FY 2017 only, if it is technically feasible to display the data as early as December 2016, we are proposing a 2-week preview period that would start on October 1, 2016. However, as a courtesy, and to give IPFs 30 days for review if they so choose, we are proposing to provide IPFs with their data in mid-September. We believe that this proposal complies with prior policies while still allowing us to display data as soon as possible for the FY 2017 payment determination.

We are inviting public comment on these proposals.

#### 8. Form, Manner, and Timing of Quality Data Submission

##### a. Procedural and Submission Requirements

We are not proposing any changes to the procedural and submission requirements for the FY 2019 payment determination and subsequent years, and we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50898 through 50899) for more information on these previously finalized requirements.

##### b. Proposed Change to the Reporting Periods and Submission Timeframes

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50901), we finalized requirements for reporting periods and submission timeframes for the IPFQR Program measures. In the FY 2016 IPF PPS final rule, we made one change to these requirements (80 FR 46715 and 46716). We refer readers to these rules for further information.

##### c. Population and Sampling

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53657 through 53658) and FY 2014 IPPS/LTCH PPS final rule (78 FR 50901 through 50902), we finalized policies for population, sampling, and minimum case thresholds. In the FY

2016 IPF PPS final rule, we made one change to these requirements (80 FR 46717 through 46719). We refer readers to these rules for further information.

##### d. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

We are not proposing any changes to the DACA requirements and we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658) for more information on these requirements.

#### 9. Reconsideration and Appeals Procedures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658 through 53660), we adopted a reconsideration and appeals process, later codified at 42 CFR 412.434, by which an IPF can request a reconsideration of its payment update reduction if an IPF believes that its annual payment update has been incorrectly reduced for failure to meet all IPFQR Program requirements and, if dissatisfied with a decision made by CMS on its reconsideration request, may file an appeal with the Provider Reimbursement Review Board. We are not proposing any changes to the Reconsideration and Appeals Procedure and refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658 through 53660) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50953) for further details on the reconsideration process.

#### 10. Exceptions to Quality Reporting Requirements

We are not proposing any changes to the exceptions to quality reporting requirements. For more information, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53659 through 53660), where we initially finalized the policy as "Waivers from Quality Reporting," and the FY 2015 IPF PPS final rule (79 FR 45978), where we renamed the policy as "Exceptions to Quality Reporting Requirements."

#### *E. Clinical Quality Measurement for Eligible Hospitals and Critical Access Hospitals (CAHs) Participating in the EHR Incentive Programs in 2017*

##### 1. Background

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified electronic health record (EHR) technology (CEHRT). Eligible hospitals and CAHs may qualify for these incentive payments under Medicare (as authorized under sections 1886(n) and

1814(l) of the Act, respectively) if they successfully demonstrate meaningful use of CEHRT, which includes reporting on clinical quality measures (CQMs) using CEHRT.

Sections 1886(b)(3)(B) and 1814(l) of the Act also establish downward payment adjustments under Medicare, beginning with FY 2015, for eligible hospitals and CAHs that are not meaningful users of CEHRT for certain associated reporting periods. Section 1903(a)(3)(F)(i) of the Act establishes 100 percent Federal financial participation (FFP) to States for providing incentive payments to eligible Medicaid providers (described in section 1903(t)(2) of the Act) to adopt, implement, upgrade and meaningfully use CEHRT.

Under sections 1886(n)(3)(A) and 1814(l)(3)(A) of the Act and the definition of “meaningful EHR user” under 42 CFR 495.4, eligible hospitals and CAHs must report on CQMs selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare EHR Incentive Program. 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).

In order to further align CMS quality reporting programs for eligible hospitals and CAHs and avoid redundant or duplicative reporting among hospital programs, the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 (hereinafter referred to as the 2015 EHR Incentive Programs Final Rule)<sup>313</sup> (80 FR 62890) indicated our intent to address CQM reporting requirements for the Medicare and Medicaid EHR Incentive Programs for eligible hospitals and CAHs for 2016, 2017, and future years in the IPPS rulemaking. We believe that receiving and reviewing public comments for various CMS quality programs at one time while simultaneously finalizing the requirements for these programs would provide us with an opportunity to better align these programs for eligible hospitals and CAHs, allow more flexibility within the Medicare and Medicaid EHR Incentive Programs, and add overall value and consistency. To further achieve this goal, the 2015 Edition final rule (80 FR 62652) published by ONC indicated that it

<sup>313</sup> Medicare and Medicaid Programs: Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017; final rule (80 FR 62761 through 62955) (“2015 EHR Incentive Programs Final Rule”).

would address certification policy regarding the reporting of CQMs for eligible hospitals and CAHs in or in conjunction with the annual IPPS rulemaking to better align with the reporting goals of other CMS programs.

## 2. CQM Reporting for the Medicare and Medicaid EHR Incentive Programs in 2017

### a. Background

In the EHR Incentive Program Stage 2 final rule, we outlined the CQMs available for use in the EHR Incentive Programs beginning in 2014 for eligible hospitals and CAHs in Table 10 at 77 FR 54083 through 54087. For the FY 2017 IPPS/LTCH PPS proposed rule, we are proposing to maintain the existing requirements established in earlier rulemaking for the reporting of CQMs under the EHR Incentive Programs in 2017, unless otherwise indicated in this proposed rule. These requirements include reporting on 16 CQMs covering at least 3 NQS domains for eligible hospitals and CAHs (77 FR 54079). For this section of the preamble of this proposed rule, the following proposed policies regarding the EHR Incentive Programs apply to both the Medicare and Medicaid EHR Incentive Programs with the exception of the submission period proposed policy.

As we expect to expand the current measures to align with the National Quality Strategy and the CMS Quality Strategy<sup>314</sup> and incorporate updated standards and terminology in current CQMs, including updating the electronic specifications for these CQMs, and creating de novo CQMs, we plan to expand the set of CQMs available for reporting under the EHR Incentive Programs in future years. We will continue to engage stakeholders to provide input on future proposals for CQMs as well as request comment on future electronic specifications for new and updated CQMs.

In addition, we are transitioning from the quality data model (QDM) expression language to the clinical quality language (CQL) specification, which defines a representation for the expression of clinical knowledge that can be used within both the clinical decision support (CDS) and CQM domains. The QDM logic is based on capabilities of the health level 7 (HL7) reference information model (RIM), which does not have significant ability to express mathematical logic such as addition, subtraction, division, and

<sup>314</sup> Available at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html>.

multiplication. The QDM requires multiple, often repetitious lines of logic to compare relationships among different activities, usually by indicating the time of one activity with the time of the other activity. Also, EHR software cannot easily interpret QDM logic to perform calculations without significant human interaction and interpretation. In general, the CQL is a mathematical expression language that can be parsed by software to calculate results. The CQL includes basic math and allows description of relationship among activities in a simple, direct manner, which significantly reduces the lines of logic. With a modest effort, it represents a change that is straightforward to learn and interpret compared to the existing QDM logic statements.

The CQL specification defines two components: CQL—author-friendly domain specific language; and expression logical model—computable extensible markup language (XML). The CQL leverages best practices and lessons learned from the quality data model, health e-decisions, and electronic CQM and clinical decision support (CDS) communities. The CQL is designed to work with any data model, more expressive and robust than the QDM logic, and is a HL7 draft standard for trial use (DSTU). The CQL includes: Datatypes; data retrieval and queries; timing phrases and operators; variable and function declaration; input parameters with default values; conditional logic, Boolean logic, and value comparison; simple arithmetic and aggregate functions; operations on valuesets, lists, intervals, sets and dates/times; and shared libraries. We anticipate the incorporation of the CQL into the CQM electronic specifications as we support the development and testing of this standard. We anticipate starting this work effort in 2016 with the expectation that extensive development and testing will continue, at minimum, through the fall of 2017. We will not implement CQL until the development and testing phases show success for utilization with the CQMs. We are engaging the participation of hospitals and other providers, health IT developer, measure developer, and other stakeholder communities as we undertake this effort at all stages of development and testing.

### b. CQM Reporting Period for the Medicare and Medicaid EHR Incentive Programs in CY 2017

In the 2015 EHR Incentive Programs Final Rule (80 FR 62892 through 62893), beginning in CY 2017 and for subsequent years, we established a CQM reporting period of one full calendar

year (consisting of four quarterly data reporting periods) for CQM reporting for eligible hospitals and CAHs participating in the Medicare and Medicaid EHR Incentive Programs, with a limited exception for providers demonstrating meaningful use for the first time under the Medicaid EHR Incentive Program, for whom the CQM reporting period is any continuous 90-day period within the calendar year. We believe that one full calendar year of data will result in more complete and accurate data. Providers will be able to submit one full calendar year of data for both the EHR Incentive Program and the Hospital IQR Program, thereby reducing the reporting burden. We continue to assess electronically submitted data for accuracy and reliability. If data are determined to be flawed, such data will be identified by CMS in order to preserve the integrity of data used for differentiating performance.

We also established a reporting period for CQMs of any continuous 90-day period within CY 2017 for eligible hospitals and CAHs that are demonstrating meaningful use for the first time in either the Medicare or Medicaid EHR Incentive Programs (80 FR 62892 through 62893). In summary, the following CQM reporting periods apply for eligible hospitals and CAHs participating in the Medicare and Medicaid EHR Incentive Programs in CY 2017. We are proposing the following submission periods for the Medicare EHR Incentive Program, as well as requirements for eligible hospitals and CAHs reporting CQMs electronically.

- Eligible hospitals and CAHs

Reporting CQMs by Attestation:  
 ++ For eligible hospitals and CAHs demonstrating meaningful use for the first time in 2017, the reporting period is any continuous 90-day period within CY 2017. The submission period for attestation is the 2 months following the close of the calendar year, ending February 28, 2018.

++ For eligible hospitals and CAHs that demonstrated meaningful use in any year prior to 2017, the reporting period is the full CY 2017 (consisting of four quarterly data reporting periods). The submission period for attestation is the 2 months following the close of the calendar year, ending February 28, 2018.

- Eligible hospitals and CAHs Reporting CQMs Electronically: For eligible hospitals and CAHs demonstrating meaningful use for the first time in 2017 or that have demonstrated meaningful use in any year prior to 2017, the reporting period is the full CY 2017 (consisting of four quarterly data reporting periods). The

submission period for reporting CQMs electronically is the 2 months following the close of the calendar year, ending February 28, 2018.

In regard to the Medicaid EHR Incentive Program, we provide States with the flexibility to determine the submission periods for reporting CQMs.

For the reporting period in CY 2017, we are not proposing new CQMs. However, section 1886(n)(3)(B)(iii) of the Act requires that, in selecting measures for eligible hospitals and CAHs for the Medicare EHR Incentive Program, and establishing the form and manner for reporting measures, the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required, including reporting under section 1886(b)(3)(B)(viii) of the Act, the Hospital IQR Program. In the interest of avoiding redundant or duplicative reporting with the Hospital IQR Program, we are proposing to remove 13 CQMs from the set of CQMs available for eligible hospitals and CAHs to report for the EHR Incentive Programs, beginning with the reporting periods in CY 2017. We are proposing to remove such measures for both the Medicare and Medicaid EHR Incentive Programs.

We believe that a coordinated reduction in the overall number of CQMs reported electronically in both the Hospital IQR and the Medicare and Medicaid EHR Incentive Programs would reduce burdens and challenges associated with electronic reporting for hospitals and improve the quality of reported data by enabling hospitals to focus on a smaller, more specific subset of electronic CQMs. For the list of measures we are proposing to remove from the Hospital IQR Program and the Medicare and Medicaid EHR Incentive Programs, as well as the rationale in support of our proposals to remove these measures, we refer readers to section XVIII.A.3.b.(3) of the preamble of this proposed rule. All of the remaining measures listed in Table 10 of the EHR Incentive Program Stage 2 final rule (77 FR 54083 through 54087) would be available for eligible hospitals and CAHs to report for the Medicare and Medicaid EHR Incentive Programs. From that available set of measures, we are proposing the following reporting criteria for eligible hospitals and CAHs beginning with the reporting periods in CY 2017:

- For attestation: If only participating in the EHR Incentive Program, report on all 16 available CQMs.

- For electronic reporting—  
 ++ If only participating in the EHR Incentive Program, report on 15 of the 16 available CQMs (the Outpatient

Quality Reporting (OQR) Program CQM (Emergency Department (ED)-3, NQF 0496) among the 16 available CQMs is not required to be reported on for electronic reporting, in which 15 of the 16 available CQMs can be selected to meet this reporting requirement); or

++ If participating in the EHR Incentive Program and the Hospital IQR Program, report on all 15 available CQMs (the electronic reporting of the Outpatient Quality Reporting (OQR) Program CQM (ED-3, NQF 0496) is not applicable when reporting on CQMs for both programs, which results in the reporting of 15 available CQMs).

We also considered an alternative proposal to require eligible hospitals and CAHs to select and report electronically on 8 CQMs for the reporting periods in CY 2017 and all available CQMs beginning with the reporting periods in CY 2018. Section VIII.A.8.a. of the preamble of this proposed rule further outlines this considered alternative proposal. Our intent is to align, to the extent possible, the EHR Incentive Program reporting requirements with the Hospital IQR Program reporting requirements established in the final rule. We believe that the alignment of these programs will serve to reduce hospital reporting burden and encourage the adoption and meaningful use of CEHRT by eligible hospitals and CAHs. We are inviting public comment on these proposals.

c. CQM Reporting Form and Method for the Medicare EHR Incentive Program in 2017

As finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49759 through 40760), we removed the QRDA-III as an option for reporting under the Medicare EHR Incentive Program for eligible hospitals and CAHs. For the reporting periods in 2016 and future years, we are requiring QRDA-I for CQM electronic submissions for the Medicare EHR Incentive Program. As noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 40760), States would continue to have the option, subject to our prior approval, to allow or require QRDA-III for CQM reporting.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49578 through 49579), we established the following options for CQM submission for eligible hospitals and CAHs in the Medicare EHR Incentive Program for the reporting periods in 2017:

- Eligible hospital and CAH options for Medicare EHR Incentive Program participation (*single program participation*)—

++ Option 1: Attest to CQMs through the EHR Registration & Attestation System; or

++ Option 2: Electronically report CQMs through QualityNet Portal.

- Eligible hospital and CAH options for electronic reporting for multiple programs (for example, EHR Incentive Program plus Hospital IQR Program participation)—electronically report through QualityNet Portal.

As stated in the 2015 EHR Incentive Programs Final Rule (80 FR 62894), in 2017, eligible hospitals and CAHs have two options to report CQM data, either through attestation or use of established methods for electronic reporting where feasible. However, starting in 2018, eligible hospitals, and CAHs participating in the Medicare EHR Incentive Program must electronically report CQMs using CEHRT where feasible; and attestation to CQMs will no longer be an option except in certain circumstances where electronic reporting is not feasible. Therefore, we encourage eligible hospitals and CAHs to begin electronically reporting CQMs as soon as feasible.

For the Medicaid EHR Incentive Program, States will continue to be responsible for determining whether and how electronic reporting of CQMs would occur, or if they wish to allow reporting through attestation. Any changes that States make to their CQM reporting methods must be submitted through the State Medicaid Health IT Plan (SMHP) process for CMS review and approval prior to being implemented.

We are proposing to continue our policy that electronic submission of CQMs will require the use of the most recent version of the CQM electronic specification for each CQM to which the EHR is certified. In the event that an eligible hospital or CAH has certified EHR technology that is certified to the 2014 Edition and not certified to all 16 CQMs that would be available for reporting in 2017 under our proposals, we are proposing to require that an eligible hospital or CAH would need to have its EHR technology certified to all such CQMs in order to meet the reporting requirements for 2017. For electronic reporting in 2017, this means eligible hospitals and CAHs would be required to use the Spring 2017 version of the CQM electronic specifications available on the eCQI Resource Center Web page (<https://ecqi.healthit.gov/>). We are seeking public comment on this proposal.

As noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49759), an EHR certified for CQMs under the 2014 Edition certification criteria does not

need to be recertified each time it is updated to a more recent version of the CQMs. We are proposing to accept the use of CEHRT certified to ONC’s 2014 or 2015 Edition for CQM reporting in 2017. Certification to the 2015 Edition is expected to be available in 2016. (For further information on CQM reporting, we refer readers to the EHR Incentive Program Web site where guides and tip sheets are available for each reporting option (<http://www.cms.gov/ehrincentiveprograms>.) As noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49759), we encourage health IT developers to test any updates, including any updates to the CQMs and CMS reporting requirements based on the CMS Implementation Guide for Quality Reporting Document Architecture (QRDA) Category I and Category III (CMS Implementation Guide for QRDA) for Eligible Professional Programs and Hospital Quality Reporting (HQR), on an annual basis.

The form and method of electronic submission are further explained in subregulatory guidance and the certification process. For example, the following documents are updated annually to reflect the most recent CQM electronic specifications: The CMS Implementation Guide for QRDA; program specific performance calculation guidance; and CQM electronic specifications and guidance documents. These documents are located on the eCQI Resource Center Web page: (<https://ecqi.healthit.gov/>).

We are inviting public comments on these proposals.

**IX. 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 2016 “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 2017 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>.

**X. Other Required Information**

*A. Requests for Data From the Public*

In order to respond promptly to public requests for data related to the prospective payment system, we have established a process under which commenters can gain access to raw data on an expedited basis. Generally, the data are now available on compact disc (CD) format. However, many of the files are available on the Internet at: <http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>. Data files and the cost for each file, if applicable, are listed later in this section. Anyone wishing to purchase data tapes, cartridges, or diskettes should submit a written request along with a company check or money order (payable to CMS-PUF) to cover the cost to the following address: Centers for Medicare & Medicaid Services, Public Use Files, Accounting Division, P.O. Box 7520, Baltimore, MD 21207-0520, (410) 786-3691. Files on the Internet may be downloaded without charge.

1. CMS Wage Data Public Use File

This file contains the hospital hours and salaries from Worksheet S-3, Parts II and III from FY 2013 Medicare cost reports used to create the proposed FY 2017 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.M. of the preamble of this proposed rule.

Processing year	Wage data year	PPS fiscal year
2016 .....	2013	2017
2015 .....	2012	2016
2014 .....	2011	2015
2013 .....	2010	2014
2012 .....	2009	2013
2011 .....	2008	2012
2010 .....	2007	2011
2009 .....	2006	2010
2008 .....	2005	2009
2007 .....	2004	2008

*Media:* Internet at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html>.

*Periods Available:* FY 2007 through FY 2017 IPPS Update.

2. CMS Occupational Mix Data Public Use File

This file contains the CY 2013 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 II.M. of the preamble of this proposed rule.

*Media:* Internet at: <https://www.cms.gov/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html>.

*Period Available:* FY 2017 IPPS Update.

### 3. Provider Occupational Mix Adjustment Factors for Each Occupational Category Public Use File

This file contains each hospital's occupational mix adjustment factors by occupational category. Two versions of these files are created each year to support the rulemaking.

*Media:* Internet at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html>.

*Period Available:* FY 2017 IPPS Update.

### 4. Other Wage Index Files

CMS releases other wage index analysis files after each proposed and final rule.

*Media:* Internet at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html>.

*Periods Available:* FY 2005 through FY 2017 IPPS Update.

### 5. FY 2017 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 list of Core-Based Statistical Areas (CBSAs).

*Media:* Internet at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html>.

*Period Available:* FY 2017 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](http://www.cms.hhs.gov/CostReports/02_HospitalCostReport.asp).

(We note that data are no longer offered on a CD. All of the data collected are now available free for download from the cited Web site.)

### 7. Provider-Specific File

This file is a component of the PRICER program used in the MAC's system to compute DRG/MS-DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

*Media:* Internet at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspMedicareFeeSvcPmtGen/Index.html>.

*Period Available:* Quarterly Update.

### 8. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number as published in each year's update of the Medicare hospital inpatient prospective payment system. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG/MS-DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year to support the rulemaking.

*Media:* Internet at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html>.

*Periods Available:* FY 1985 through FY 2017.

### 9. MS-DRG Relative Weights (Also Table 5—MS-DRGs)

This file contains a listing of MS-DRGs, MS-DRG narrative descriptions, relative weights, and geometric and arithmetic mean lengths of stay for each fiscal year. Two versions of this file are created each year to support the rulemaking.

*Media:* Internet at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html>.

*Periods Available:* FY 2005 through FY 2017 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, MedPAR Limited Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis

of the changes to the prospective payment systems published in the **Federal Register**. Two versions of this file are created each year to support the rulemaking.

*Media:* Internet at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Historical-Impact-Files-for-FY-1994-through-Present.html>.

*Periods Available:* FY 1994 through FY 2017 IPPS Update.

### 11. AOR/BOR Tables

This file contains data used to develop the MS-DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by MS-DRG for length of stay and standardized charges. The BOR tables are "Before Outliers Removed" and the AOR is "After Outliers Removed." (Outliers refer to statistical outliers, not payment outliers.)

Two versions of this file are created each year to support the rulemaking.

*Media:* Internet at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html>.

*Periods Available:* FY 2005 through FY 2017 IPPS Update.

### 12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the hospital inpatient operating and capital prospective payment systems. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, indirect medical education (IME) adjustment, disproportionate share, and the Core-Based Statistical Area (CBSA). The file supports the rulemaking.

*Media:* Internet at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html>.

*Period Available:* FY 2017 IPPS Update.

### 13. Hospital Readmissions Reduction Program Supplemental File

This file contains information on the calculation of the Hospital Readmissions Reduction Program (HRRP) payment adjustment. Variables include the proxy excess readmission ratios for acute myocardial infarction (AMI), pneumonia (PN) and heart failure (HF), coronary obstruction pulmonary disease (COPD), total hip arthroplasty (THA)/total knee arthroplasty (TKA), and coronary artery bypass grafting (CABG) and the proxy

readmissions payment adjustment for each provider included in the program. In addition, the file contains information on the number of cases for each of the applicable conditions excluded in the calculation of the readmission payment adjustment factors. It also contains MS-DRG relative weight information to estimate the payment adjustment factors. The file supports the rulemaking.

*Media:* Internet at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/AcuteInpatient-Files-for-Download.html>.

*Period Available:* FY 2017 IPPS Update.

#### 14. Medicare Disproportionate Share Hospital (DSH) Supplemental File

This file contains information on the calculation of the uncompensated care payments for FY 2017. Variables include a hospital's SSI days and Medicaid days used to determine a hospital's share of uncompensated care payments, total uncompensated care payments and estimated per claim uncompensated care payment amounts. The file supports the rulemaking.

*Media:* Internet at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/AcuteInpatient-Files-for-Download.html>.

*Period Available:* FY 2017 IPPS Update.

#### 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.H.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 2018 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. For FYs 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, and 2017, we received 1, 4, 5, 3, 3, 5, 5, 7, 9, and 9 applications, respectively.

##### 3. ICRs for the Occupational Mix Adjustment to the Proposed FY 2017 Wage Index (Hospital Wage Index Occupational Mix Survey)

Section III.E. of the preamble of this proposed rule discusses the occupational mix adjustment to the proposed FY 2017 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 Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require us 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 OMB control number 0938–0907.

##### 4. Hospital Applications for Geographic Reclassifications by the MGCRB

Section III.J.2. of the preamble of this proposed rule discusses proposed changes to the wage index based on hospital reclassifications. As stated in that section, under section 1886(d)(10) of the Act, the MGCRB has the authority to accept short-term IPPS hospital applications requesting geographic reclassification for wage index and to issue decisions on these requests by hospitals for geographic reclassification for purposes of payment under the IPPS.

The burden associated with this application process is the time and effort necessary for an IPPS hospital to complete and submit an application for reclassification to the MGCRB. The burden associated with this requirement is subject to the PRA. It is currently approved under OMB control number 0938–0573.

##### 5. ICRs for the Notice of Observation Treatment by Hospitals and CAHs

In section IV.L. of the preamble of this proposed rule, we discuss our proposed implementation of the NOTICE Act (Pub. L. 114–42), which amended section 1866(a)(1) of the Act to require hospitals and CAHs to provide written and oral notification to Medicare beneficiaries receiving observation services as outpatients for more than 24 hours. We have developed a standardized format for the notice (the MOON), which would be disseminated during the normal course of related business activities. The proposed standardized notice discussed in this proposed rule is simultaneously being subject to public review and comment through the Office of Management and Budget (OMB) Paperwork Reduction Act process before implementation.

We estimate that it will take hospitals and CAHs 5 minutes (0.0833 hour) to complete and deliver each notice. In 2014, there were approximately 977,000 claims for Medicare outpatient observation services lasting greater than 24 hours furnished by 6,142 hospitals and CAHs.<sup>315</sup> The annual hour burden is estimated to be 81,384 (977,000 responses × 0.0833 hour). To derive average cost, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)). In this regard, we used the mean hourly wage of \$33.55 and the

<sup>315</sup> Source: CMS Office of Enterprise and Data Analytics.



cost of fringe benefits, \$33.55 (calculated at 100 percent of salary), to determine an adjusted hourly wage of \$67.10. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonable accurate estimation method. The cost per response is approximately \$5.59 based on an hourly salary rate of \$67.10 (U.S. Bureau of Labor Statistics' May 2013 National Occupational Employment and Wage Estimates for nursing) and the 5-minute response estimate. By multiplying the annual responses by \$5.59, the annual cost burden estimate is \$5,461,430 (977,000 responses × \$5.59) or approximately \$889.19 per hospital or CAH (\$5,461,430/6,142).

#### 6. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

The Hospital IQR Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment (RHQDAPU) Program) was originally established to implement section 501(b) of the MMA, Public Law 108–173. This program expanded our voluntary Hospital Quality Initiative. The Hospital IQR Program originally consisted of a “starter set” of 10 quality measures. The collection of information associated with the original starter set of quality measures was previously approved under OMB control number 0938–0918. All of the information collection requirements previously approved under OMB control number 0938–0918 have been combined with the information collection request currently approved under OMB control number 0938–1022. We no longer use OMB control number 0938–0918.

We added additional quality measures to the Hospital IQR Program and submitted the information collection request to OMB for approval. This expansion of the Hospital IQR Program measures was part of our implementation of section 5001(a) of the Deficit Reduction Act of 2005 (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 is currently approved under OMB control number 0938–1022.

In section VIII.A.3.b. of the preamble of this proposed rule, we are proposing to remove 13 eCQM versions of measures, 2 “topped out” chart-abstracted measures, and 2 structural measures, beginning with the FY 2019 payment determination. However, we note that the total number of measures proposed for removal is 15 because the STK–4 and VTE–5 measures are being proposed for removal twice—once in the chart-abstracted form and again in electronic form.

The 13 eCQM versions of measures we are proposing to remove are: (1) AMI–2: Aspirin Prescribed at Discharge for AMI (NQF #0142); (2) AMI–7a: Fibrinolytic Therapy Received Within 30 minutes of Hospital Arrival; (3) AMI–10: Statin Prescribed at Discharge; (4) HTN: Healthy Term Newborn (NQF #0716); (5) PN–6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF #0147); (6) SCIP-Inf-1a: Prophylactic Antibiotic Received within 1 Hour Prior to Surgical Incision (NQF #0527); (7) SCIP-Inf-2a: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528); (8) SCIP Inf-9: Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero; (9) STK–4: Thrombolytic Therapy (NQF #0437); (10) VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373); (11) VTE–4: Venous Thromboembolism Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram); (12) VTE–5: Venous Thromboembolism Discharge Instructions; and (13) VTE–6: Incidence of Potentially Preventable Venous Thromboembolism.

The two chart-abstracted measures we are proposing to remove are: (1) STK–4: Thrombolytic Therapy (NQF #0437); and (2) VTE–5: Venous Thromboembolism Discharge Instructions. The two structural measures we are proposing to remove are: (1) Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care; and (2) Participation in a Systematic Clinical Database Registry for General Surgery.

We believe that removing 13 eCQMs will reduce burden for hospitals, as they would have a smaller number of eCQMs to select from. As finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49698), hospitals are required to select 4 out of 28 available eCQMs on which to report data beginning with the FY 2018 payment determination. Since the

measures proposed for removal are among the list of measures available, reducing the number of eCQMs from which hospitals choose would decrease the burden associated with selecting and reporting data for 4 eCQMs because hospitals would have only 15 eCQMs from which to select instead of 28 eCQMs. However, if our proposal to require hospitals to submit data on all of the available eCQMs included in the Hospital IQR Program measure set is finalized as proposed, this modest reduction in burden would be offset by the increased burden associated with submitting data on 15 eCQMs instead of 4 eCQMs. We discuss the burden associated with our proposal to require the submission of all available eCQMs included in the Hospital IQR Program measure set below.

We believe that there would be a reduction in burden for hospitals as a result of the removal of the two chart-abstracted measures listed above (STK–4 and VTE–5). Due to the burden associated with the collection of chart-abstracted data (based on updated measure record abstraction time estimates from the third quarter in 2014 through the second quarter in 2015 provided by CDAC, the number of reporting periods in a calendar year, and the number of IPPS hospitals reporting), we estimate that the removal of STK–4 would result in a burden reduction of approximately 303,534 hours and approximately \$9.9 million across all 3,300 IPPS hospitals participating in the Hospital IQR Program for the FY 2019 payment determination. In addition, we estimate that the removal of VTE–5 would result in a burden reduction of approximately 653,565 hours and approximately \$21.4 million across all 3,300 IPPS hospitals participating in the Hospital IQR Program for the FY 2019 payment determination. More specifically, for both the STK and VTE measure sets, we calculated the burden hours by taking the difference in the burden estimates from this FY 2017 IPPS/LTCH PPS proposed rule and the burden estimates from the FY 2016 IPPS/LTCH PPS final rule. With regard to STK–4, because it is the only STK measure left in the Hospital IQR Program, and we are proposing in this FY 2017 IPPS/LTCH PPS proposed rule to remove it, we calculated the total burden hours as follows: 0 hours (time required to report in CY 2017) – 303,534 hours (time required to report in CY 2016) = – 303,534 hours for the STK measure set. With regard to the VTE measure set, we used an updated estimate from CDAC that the time per record (that is, to report all of the VTE

measures in the Hospital IQR Program) is 28 minutes, and in the FY 2016 IPPS/LTCH PPS final rule, we estimated a burden reduction of 10 minutes for removing 3 VTE measures (or approximately 3 minutes per measure). As such, we deducted 3 minutes from the 28 minute estimate to account for the proposed removal of VTE-5, for a total of 25 minutes to report on the remaining VTE measure in the Hospital IQR Program. We then calculated the estimated total burden hours per hospital for reporting the remaining VTE measure as follows: 25 minutes per record/60 minutes per hour  $\times$  4 reporting quarters per year  $\times$  198.05 records per hospital per quarter = 330 burden hours per hospital. Because there are 3,300 IPPS hospitals, we then multiplied 330 hours per hospital  $\times$  3,300 hospitals to get a total annual burden estimate of 1,089,275 hours to report the remaining measure in the VTE measure set. To demonstrate the reduction in the total burden hours for VTE from this FY 2017 IPPS/LTCH PPS proposed rule and the FY 2016 IPPS/LTCH PPS final rule, we calculated as follows: 1,089,275 (FY 2017 total annual estimate) – 1,742,840 (FY 2016 total annual estimate) = –653,565 hours for the VTE measure set.

We believe that there will be a negligible burden reduction due to the removal of two structural measures. Consistent with previous years (80 FR 49762), we estimate a burden of 15 minutes per hospital to report all four previously finalized structural measures and to complete other forms (such as the Extraordinary Circumstances Extension/Exemption Request Form). Therefore, our burden estimate of 15 minutes per hospital remains unchanged because we believe the reduction in burden associated with removing these two structural measures will be sufficiently minimal that it will not substantially impact this estimate.

In addition, in section VIII.A.6. of the preamble of this proposed rule, we are proposing refinements to two previously adopted measures: (1) Expanding the cohort for the Hospital-Level, Risk-standardized Payment Associated with a 30-Day Episode-of-Care for Pneumonia (NQF #2579); and (2) adopting the modified Patient Safety and Adverse Events Composite (NQF #0531). Because these claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe no additional burden on hospitals will result from the proposed refinements to these two claims-based measures.

Also, in section VIII.A.7. of the preamble of this proposed rule, we are

proposing to add four claims-based measures to the Hospital IQR Program measure set beginning with the FY 2019 payment determination: (1) Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure; (2) Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure; (3) Spinal Fusion Clinical Episode-Based Payment Measure; and (4) Excess Days in Acute Care after Hospitalization for Pneumonia. Because these claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe no additional burden on hospitals will result from the addition of these four proposed claims-based measures.

For the FY 2019 payment determination and subsequent years, in section VIII.A.8. of the preamble of this proposed rule, we also are proposing to require hospitals to submit data for all eCQMs included in the Hospital IQR Program measure set in a manner that will permit eligible hospitals to align Hospital IQR Program requirements with some requirements under the Medicare and Medicaid EHR Incentive Programs. Specifically, hospitals would be required to submit a full calendar year of data on all eCQMs in the Hospital IQR Program measure set, on an annual basis, beginning with CY 2017 reporting. We believe that the total burden associated with the eCQM reporting proposal would be similar to that previously outlined in the Medicare EHR Incentive Program Stage 2 final rule (77 FR 54126 through 54133). In that final rule, the burden estimate for a hospital to report all 16 eCQMs is 2 hours and 40 minutes (160 total minutes or 10 minutes per measure) per submission for a 3-month period (77 FR 54127). We believe that this estimate is accurate and appropriate to apply to the Hospital IQR Program because we are proposing to align the eCQM reporting requirements between both programs. As such, using the estimate of 10 minutes per measure, we anticipate that if our proposals to: (1) Require reporting on all of the available eCQMs (15 eCQMs for the CY 2017 reporting period/FY 2019 payment determination); and (2) submit one year of eCQM data (covering Q1, Q2, Q3, and Q4), both are finalized as proposed, it would take a hospital 150 minutes per quarter to report one medical record containing information on all the required eCQMs. In total, for the FY 2019 payment determination, we expect our proposal to require hospitals to report data on 15 eCQMs for 4 quarters

(as compared to our previously finalized requirement to report data on 4 eCQMs for 1 quarter) would represent a burden increase of 30,800 hours across all 3,300 IPPS hospitals participating in the Hospital IQR Program. This figure was derived by calculating the difference between the FY 2017 burden estimate of 33,000 hours (150 minutes per record/60 minutes per hour  $\times$  4 reporting quarters per year  $\times$  1 record per hospital per quarter  $\times$  3,300 hospitals) and the FY 2016 burden estimate of 2,200 hours (20 minutes per record/60 minutes per hour  $\times$  1 reporting quarter per year  $\times$  1 record per hospital per quarter  $\times$  3,300 hospitals) (80 FR 49763), for an incremental increase of 30,800 hours.

Furthermore, we estimate that reporting these eCQMs can be accomplished by staff with a mean hourly wage of \$16.42 per hour.<sup>316</sup> However, obtaining data on other overhead costs is challenging. Overhead costs vary greatly across industries and firm sizes. In addition, the precise cost elements assigned as “indirect” or “overhead” costs, as opposed to direct costs or employee wages, are subject to some interpretation at the firm level. Therefore, we have chosen to calculate the cost of overhead at 100 percent of the mean hourly wage. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method. This is a change from how we have accounted for the cost of overhead in our previous rules regarding the Hospital IQR Program. In calculating labor cost, we estimate an hourly labor cost of \$32.84 (\$16.42 base salary + \$16.42 fringe) and a cost increase of \$1,011,472.00 (30,800 additional burden hours  $\times$  \$32.84 per hour) across approximately 3,300 hospitals participating in the Hospital IQR Program to report a full calendar year of data for 15 eCQMs, on an annual basis.

We are not proposing any changes to our validation requirements related to chart-abstracted measures, but are providing some background information as basis for our eCQM validation proposals. As noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49762 and 49763), for validation of chart-abstracted data for the FY 2018 payment

<sup>316</sup>Occupational Outlook Handbook. Available at: <http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.html>.

determination and subsequent years, we require hospitals to provide 72 charts per hospital per year (with an average page length of 1,500), including 40 charts for HAI validation and 32 charts for clinical process of care validation, for a total of 108,000 pages per hospital per year. We reimburse hospitals at 12 cents per photocopied page (79 FR 50346) for a total per hospital cost of \$12,960. For hospitals providing charts digitally via a re-writable disc, such as encrypted CD-ROMs, DVDs, or flash drives, we will reimburse hospitals at a rate of 40 cents per digital media (80 FR 49837), and additionally hospitals will be reimbursed \$3.00 per record (78 FR 50956). For hospitals providing charts via secure file transfer, we will reimburse hospitals at a rate of \$3.00 per record (78 FR 50835).

In section VIII.A.11. of the preamble of this proposed rule, beginning in spring 2018 for the FY 2020 payment determination, we are proposing to modify the existing validation process for the Hospital IQR Program data to include a random sample of up to 200 hospitals for validation of eCQMs in the Hospital IQR Program. In previous years (79 FR 50347), we estimated a total burden of 16 hours (960 minutes) for the submission of 12 records, which would equal 1 hour and 20 minutes per record (960 minutes/12 records). Applying the time per individual submission of 1 hour and 20 minutes (or 80 minutes) for the 32 records we are proposing hospitals submit beginning with the FY 2020 payment determination, we estimate a total burden of approximately 43 hours (1 hour and 20 minutes  $\times$  32 records) for each hospital selected for participation in eCQM validation. We estimate that approximately 43 hours of work for up to 200 hospitals would increase the eCQM validation burden hours from 0 hours (as this is the first instance where eCQM validation is being proposed as a requirement) to 8,533 labor hours.

As previously stated, with respect to eCQMs, the labor performed can be accomplished by staff, with a mean hourly wage of \$16.42.<sup>317</sup> Further, in calculating labor costs, we have chosen to calculate the cost of overhead at 100 percent of the mean hourly wage. As such, we estimate a fully burdened labor rate of \$32.84 (\$16.42 base salary + \$16.42 fringe) per hour. Therefore, using these assumptions, we estimate an hourly labor cost of \$32.84 and a cost increase of \$280,224 (8,533 additional burden hours  $\times$  \$32.84 per hour) across

the (up to) 200 hospitals selected for eCQM validation, on an annual basis. Consistent with the chart-abstraction validation process, we will reimburse hospitals providing records via secure file transfer, at a rate of \$3.00 per record.

Lastly, in section VIII.A.15. of the preamble of this proposed rule, we are proposing to update our Extraordinary Circumstances Extensions or Exemptions (ECE) policy by: (1) Extending the general ECE request deadline for non-eCQM circumstances from 30 to 90 calendar days following an extraordinary circumstance; and (2) establishing a separate submission deadline for ECE requests with respect to eCQM reporting circumstances of April 1 following the end of the reporting calendar year. Consistent with previous years, we estimate a burden of 15 minutes per hospital to report all forms (including the ECE request form) and structural measures. We believe that the proposed updates to the ECE deadlines will have no effect on burden for hospitals, because we are not making any changes that will increase the amount of time necessary to complete the form. In addition, the burden associated with the completion of this form is included in the 15 minutes allocated for all forms and structural measures.

In summary, under OMB number 0938-1022, we estimate a total burden decrease of approximately 917,766 hours, for a total cost decrease of approximately \$30 million across approximately 3,300 hospitals participating in the Hospital IQR Program as a result of the policies proposed in this proposed rule.

The estimate excludes the burden associated with the NHSN and HCAHPS measures, both of which are submitted under separate information collection requests and are approved under OMB control numbers 0920-0666 and 0938-0981, respectively. The burden estimates in this proposed rule are the estimates for which we are requesting OMB approval.

#### 7. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

As discussed in sections VIII.B. of the preamble of this proposed rule, section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year.

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 28124), the FY 2014 IPPS/LTCH PPS final rule (78

FR 50957 through 50959), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50347 through 50348), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49764) for a detailed discussion of the burden for the program requirements that we have previously adopted. Below we discuss only any changes in burden that would result from the proposals in this proposed rule.

In section VIII.B.3.b. of the preamble of this proposed rule, we are proposing that PCHs submit data on Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) measure for an expanded cohort of patients. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50285) we finalized a sampling methodology for Clinical Process/Oncology Care Measures, which includes the Oncology: Radiation Dose Limits to Normal Tissues measure. Because our previous burden estimates were based on the maximum sample for this measure, the expansion of the patient cohort would not raise the burden for this measure beyond that which we described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50347 through 50348).

In section VIII.B.4.b. of the preamble of this proposed rule, we are proposing to adopt the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure beginning with the FY 2019 program year. This is a claims-based measure, and therefore, does not require PCHs to submit any new data. Thus, this measure would not pose any new burden on PCHs.

In summary, as a result of our proposals, we do not anticipate any changes to previously finalized burden estimates.

#### 8. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section IV.H. of the preamble of this proposed rule, we discuss proposed requirements for the Hospital VBP Program. Specifically, in this proposed rule, with respect to quality measures, we are proposing to: Include selected ward non-Intensive Care Unit (ICU) locations in certain NHSN measures beginning with the FY 2019 program year; adopt the Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI) and the Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure (HF) measures for the FY 2021 program year; update the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia (PN) Hospitalization (Updated Cohort)

<sup>317</sup>Occupational Outlook Handbook. Available at: <http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.html>.

measure for the FY 2021 program year; and adopt the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery measure for the FY 2022 program year.

As required under section 1886(o)(2)(A) of the Act, the additional

and updated 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 Program (LTCH QRP)

As discussed in section VIII.C.5 of the preamble of this proposed rule, we are retaining the following 13 previously finalized quality measures for use in the LTCH QRP:

LTCH QRP QUALITY MEASURES PREVIOUSLY ADOPTED FOR THE FY 2014 PAYMENT DETERMINATIONS AND SUBSEQUENT YEARS

Measure title	IPPS/LTCH PPS final rule	Annual payment determination: Initial and subsequent APU years
National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138).	Adopted an application of the measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51745 through 51747); Adopted the NQF-endorsed version and expanded measure (with standardized infection ratio [SIR]) in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53616 through 53619)	FY 2014 payment determination and subsequent years.
National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139).	Adopted an application of the measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51747 through 51748); Adopted the NQF-endorsed and expanded measure (with SIR) in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53616 through 53619).	FY 2014 payment determination and subsequent years.
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678).	Adopted an application of the measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51748 through 51750); Adopted the NQF-endorsed version in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50861 through 50863); Adopted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49731 through 49736) to fulfill IMPACT Act requirements.	FY 2014 payment determination and subsequent years.
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680).	Adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627); Revised data collection timeframe in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50858 through 50861); Revised data collection timeframe in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50289 through 50290).	FY 2016 payment determination and subsequent years.
Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431).	Adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53630 through 53631); Revised data collection timeframe in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50857 through 50858).	FY 2016 payment determination and subsequent years.
National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) Bacteremia Outcome Measure (NQF #1716).	Adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50863 through 50865).	FY 2017 payment determination and subsequent years.
National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset <i>Clostridium difficile</i> Infection (CDI) Outcome Measure (NQF #1717).	Adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50865 through 50868).	FY 2017 payment determination and subsequent years.
All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals (NQF #2512).	Adopted in FY 2014 IPPS/LTCH PPS final rule (78 FR 50868 through 50874); Adopted the NQF-endorsed version in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49730 through 49731).	FY 2017 payment determination and subsequent years.
National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure.	Adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50301 through 50305).	FY 2018 payment determination and subsequent years.

LTCH QRP QUALITY MEASURES PREVIOUSLY ADOPTED FOR THE FY 2014 PAYMENT DETERMINATIONS AND SUBSEQUENT YEARS—Continued

Measure title	IPPS/LTCH PPS final rule	Annual payment determination: Initial and subsequent APU years
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).	Adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877); Revised data collection timeframe in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50290 through 50291); Adopted an application of the measure in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49736 through 49739) to fulfill IMPACT Act requirements.	FY 2018 payment determination and subsequent years.
Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).	Adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50291 through 50298).	FY 2018 payment determination and subsequent years.
Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632).	Adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50298 through 50301).	FY 2018 payment determination and subsequent years.
Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).	Adopted an application of the measure in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49739 through 49747) to fulfill IMPACT Act requirements.	FY 2018 payment determination and subsequent years.

As discussed in section VIII.C.6 and VIII.C.7 of the preamble of this proposed rule, we are proposing the following four measures for use in the LTCH QRP:

LTCH QRP QUALITY MEASURES PROPOSED FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Measure title	Annual payment determination: Initial and subsequent APU years
Potentially Preventable 30-Day Post-Discharge Readmission Measure for the LTCH QRP*.	FY 2018 payment determination and subsequent years.
Discharge to Community-PAC LTCH QRP* .....	FY 2018 payment determination and subsequent years.
MSPB—PAC LTCH QRP* .....	FY 2018 payment determination and subsequent years.
Drug Regimen Review Conducted with Follow-Up for Identified Issues- PAC LTCH QRP**.	FY 2020 payment determination and subsequent years.

\* Proposed in this FY 2017 IPPS/LTCH PPS proposed rule for the FY 2018 payment determination and subsequent years.

\*\* Proposed in this FY 2017 IPPS/LTCH PPS proposed rule for the FY 2020 payment determination and subsequent years.

Currently, LTCHs use two separate data collection mechanisms to report quality data to CMS. Six of the 13 measures being retained in this FY 2017 IPPS/LTCH PPS proposed rule are currently collected via the CDC’s NHSN. The NHSN is a secure, Internet-based HAI tracking system maintained and managed by the CDC. The NHSN enables health care facilities to collect and use data about HAIs, adherence to clinical practices known to prevent HAIs, and other adverse events within their organizations. NHSN data collection occurs via a Web-based tool hosted by the CDC and is provided free of charge to facilities. In this proposed rule, we are not proposing any new quality measures that would be collected via the CDC’s NHSN. Therefore, at this time, there would be no additional burden related to this submission method. Any burden related to NHSN-based quality measures we

have retained in this proposed rule has been previously discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50443 through 50445) and FY 2016 IPPS/LTCH PPS final rule (80 FR 49766) and has been previously approved under OMB control number 0920–0666, with an expiration date of November, 31, 2016.

In addition to the previously finalized All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge From LTCHs (NQF #2512), we are proposing three additional Medicare FFS claims-based measures in this proposed rule: Potentially Preventable 30 Day Post-Discharge Readmission Measure for LTCH QRP; Discharge to Community—PAC LTCH QRP; and MSPB—PAC LTCH QRP. Because these proposed claims-based measures would be calculated based on data that are already reported to the Medicare program for payment purposes, we

believe no additional information collection would be required from the LTCHs. We are not proposing new assessment-based quality measures in the LTCH QRP in this proposed rule for the FY 2018 payment determination and subsequent years.

The remaining assessment-based quality measure data are reported to CMS by LTCHs using the LTCH CARE Data Set. In section VIII.C.9.d. of the preamble of this of this proposed rule, we are proposing to expand the data collection timeframe for the measure NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (77 FR 53624 through 53627), beginning with the FY 2019 payment determination. The data collection time frame and associated data submission deadlines are currently aligned with the Influenza Vaccination Season (IVS) (October 1 of a given year

through March 31 of the subsequent year), and only require data collection during the 2 calendar year quarters that align with the IVS. We are proposing to expand the data collection timeframe from just 2 quarters (covering the IVS) to a full four quarters or 12 months. We refer readers to section VIII.C.9.d. of the preamble of this this proposed rule for further details on the proposed expansion of data collection for this measures (NQF #0680), including data collection timeframes and associated submission deadlines. We originally finalized this measure for use in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627). Although we finalized data collection for this measure to coincide with the IVS, we originally proposed year-round data collection. The associated PRA package, which was approved under OMB control number 0938–1163, included burden calculations that aligned with our original proposal for year-round data collection. All subsequent PRA packages, and the PRA package that is currently under review, included burden calculations reflecting year-round (12 month) data collection for this measure. Because of this, the proposed change in the data collection timeframe for this measure, and any associated burden related to increased data collection, has already been accounted for in the total burden figures included in this section of the preamble of this proposed rule.

For the FY 2020 payment determination and subsequent years, we are proposing the use of one new assessment based quality measure in the LTCH QRP: Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP. This is a cross-setting measure that satisfies the required addition of a quality measure under the domain of medication reconciliation, as mandated by section 1899B of the Act, as added by the IMPACT Act. In addition to the proposed Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP quality measure, the remaining six measures, outlined below, will continue to be collected utilizing the LTCH CARE Data Set.

The LTCH CARE Data Set Version 2.01 has been approved under OMB control number 0938–1163. The LTCH CARE Data Set Version 2.01 contains data elements related to patient demographic data, various voluntary questions, as well as data elements related to the following quality measures:

- Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678);
- Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680).

We have submitted a revision to the PRA package that addressed the changes from LTCH CARE Data Set Version 2.01 to Version 3.00. The LTCH CARE Data Set Version 3.00, which is to be implemented April 1, 2016, contains those data elements included in Version 2.01, as well as additional data elements in order to allow for the collection of data associated with the following quality measures:

- Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) (previously finalized in the FY 2016 IPPS/LTCH PPS final rule);
- Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) (previously finalized in the FY 2015 IPPS/LTCH PPS final rule);
- Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632) (previously finalized in the FY 2015 IPPS/LTCH PPS final rule); and
- Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) (previously finalized in the FY 2016 IPPS/LTCH PPS final rule).

The LTCH CARE Data Set Version 4.00, effective April 1, 2018, will contain those data elements included in Version 3.00, as well as additional data elements in order to allow for the collection of data associated with the proposed quality measure: Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, proposed in this proposed rule.

Each time we add new data elements to the LTCH CARE Data Set related to newly proposed or finalized LTCH QRP quality measures, we are required by the PRA to submit the expanded data collection instrument to OMB for review and approval. Section 1899B(m) of the Act, as added by IMPACT Act, provides that the PRA requirements do not apply to section 1899B of the Act and the sections referenced in section 1899B(a)(2)(B) of the Act that require modifications in order to achieve the standardization of patient assessment data. We believe that the LTCH CARE Data Set Version 3.00 falls under the

PRA provisions in 1899B(m) of the Act. We believe that all additional data elements added to the LTCH CARE Data Set Version 3.00 are for the purpose of standardizing patient assessment data, as required under section 1899B(a)(2)(B) of the Act. As noted above, the LTCH CARE Data Set Version 3.00 would be updated to Version 4.0, effective April 1, 2018, to include data elements for the Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP proposed quality measure, if the measure is finalized. For the reasons discussed above, we believe that the LTCH CARE Data Set Version 4.00 also falls under the PRA provisions in section 1899B(m) of the Act.

A comprehensive list of all data elements included in the LTCH CARE Data Set Version 3.00 is available in the LTCH QRP Manual which is accessible on the LTCH QRP Web site at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html>. For a discussion of burden related to LTCH CARE Data Set Version 3.00, we refer readers to section I.M. of Appendix A of this proposed rule.

#### 10. ICRs for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

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. We refer to this program as the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program.

In section VIII.D. of the preamble of this proposed rule, we are proposing the following measure-related changes: To update a previously finalized measure (Screening for Metabolic Disorders); and to adopt two new measures beginning with the FY 2019 payment determination (SUB–3 Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and subset measure SUB–3a Alcohol & Other Drug Use Disorder Treatment at Discharge (NQF #1664), and Thirty-day all-cause unplanned readmission following psychiatric hospitalization in an IPF). We also are proposing to no longer specify in rulemaking when measure data will be publicly available, when the preview period will occur or that the preview period will begin approximately 12 weeks before the public display date, but rather to announce the timeframes using subregulatory guidance.

We refer readers to the FY 2015 IPF PPS final rule (79 FR 45978 through

45980) and the FY 2016 IPF PPS final rule (80 FR 46720 through 46721) for a detailed discussion of the burden for the IPFQR Program requirements that we have previously adopted. Below we discuss only the changes in burden resulting from the proposals in this proposed rule. Although we are proposing provisions that impact policies beginning in both the FY 2017 and FY 2019 payment determinations, IPFs must take steps to comply with all of these policies beginning in FY 2017. For example, data collection for the measures begins in FY 2017, and the changes to the public display dates take effect beginning in FY 2017. For purposes of calculating burden, we will attribute the costs to the year in which these costs begin; for the purposes of all of the proposals in this proposed rule, that year is FY 2017.

We believe that approximately 1,684<sup>318</sup> IPFs will participate in the IPFQR Program for requirements occurring in FY 2017 and subsequent years. Based on program data, we

believe that each IPF will submit measure data on approximately 848<sup>319</sup> cases per year. In prior rulemaking, we estimated that the time required to chart-abstract data for chart-abstracted measures is 12 minutes per case per measure.<sup>320</sup> Based on the experience of other quality reporting programs, such as the Hospital IQR Program, we are updating this estimate to 15 minutes per case per measure. We are only proposing one chart-abstracted measure this year: SUB-3 and subset SUB-3a. The other measure that we are proposing, Thirty-day all-cause unplanned readmission following Psychiatric hospitalization in an IPF, is claims-based and, therefore, does not require IPFs to report any additional data.

We estimate that reporting data for the IPFQR Program measures can be accomplished by staff with a mean hourly wage of \$16.42.<sup>321</sup> However, obtaining data on other overhead costs is challenging. Overhead costs vary greatly across industries and firm sizes.

In addition, the precise cost elements assigned as “indirect” or “overhead” costs, as opposed to direct costs or employee wages, are subject to some interpretation at the firm level. Therefore, we have chosen to calculate the cost of overhead at 100 percent of the mean hourly wage. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method. In calculating the labor cost, we estimate an hourly labor cost of \$32.84 (\$16.42 base salary + \$16.42 fringe). The following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage (\$/hr)	Fringe benefit (at 36.25% in \$/hr)	Adjusted hourly wage (\$/hr)
Medical Records and Health Information Technician .....	29-2071	16.42	16.42	32.84

We do not believe that our proposal to update a previously finalized measure will affect our previous burden estimate for that measure. As noted above, one of our proposed measures is claims-based and would not result in increased burden. Therefore, increased burden would occur primarily as a result of our proposed new chart-abstracted measure. We estimate that this proposal would result in an increase in burden of 212 hours per IPF (1 measure × (848 cases/measure × 0.25 hours/case)) or 357,008 hours across all IPFs (212 hours/IPF × 1,684 IPFs). The increase in costs would be approximately \$6,962 per IPF (212 hours × \$32.84/hour) or \$11,724,143 across all IPFs (357,008 hours × 32.84/hour).

Consistent with our estimates in the FY 2015 IPF PPS final rule (79 FR

45979), we believe the estimated burden for training personnel on the revised data collection and submission requirements would be 2 hours per IPF or 3,368 hours (2 hours/IPF × 1,684 IPFs) across all IPFs. Therefore, we estimate the cost for this training would be \$65.68 (\$32.84/hour × 2 hours) for each IPF or \$110,605 (\$32.84/hour × 3,368 hours) for all IPFs.

Finally, IPFs must submit to CMS aggregate population counts for Medicare and non-Medicare discharges by age group and diagnostic group, and sample size counts for measures for which sampling is performed. Because the population for the SUB-3 and SUB-3a measure is nearly identical to the population for both the SUB-1 measure and the SUB-2 and SUB-2a measure, we believe that the addition of 1 chart-abstracted measure would lead to a

negligible change in burden associated with nonmeasure data collection.

In section VIII.D.7. of the preamble of this proposed rule, we are proposing to no longer specify in rulemaking, but rather in subregulatory guidance, when measure data will be publicly available, when the preview period will occur, or that the preview period will begin approximately 12 weeks before the public display date. We do not believe this proposal will result in any change in burden because it does not require IPFs to report any more or less data. Rather, if finalized, the timeline for public display of that data is simply shifting.

In the table below, we set out a summary of annual burden estimates.

<sup>318</sup>In the FY 2016 IPF PPS final rule, we estimated 1,617 IPFs and are adjusting that estimate by +67 to account for more recent data.

<sup>319</sup>In the FY 2016 IPF PPS final rule, we estimated 431 cases per year and are adjusting that estimate by +417 to account for more recent data.

<sup>320</sup>80 FR 46720.

<sup>321</sup><http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.html>.

ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS UNDER OMB CONTROL NUMBER 0938–1171 (CMS–10432)

Proposed action [preamble section]	Respondents	Responses per respondent	Burden per response (hours) *	Total annual burden (hours)	Labor cost (\$/hr)	Total cost (\$)
Add NQF #1664 [VIII.D.4.a.] .....	1,684	848	0.25	357,008	32.84	11,724,143
Add Readmissions Measure [VIII.D.4.b.]	1,684	0	0	0	32.84	0
Training .....	1,684	1	2	3,368	32.84	110,605
Shift Public Display Timeline [VIII.D.7.] ...	1,684	0	0	0	32.84	0
	1,684	.....	.....	360,376	32.84	11,834,748

11. ICRs for the Electronic Health Record (EHR) Incentive Program and Meaningful Use

In section VIII.E. of the preamble of this proposed rule, we discuss our proposals to align the Medicare and Medicaid EHR Incentive Programs reporting and submission timelines for electronically submitted clinical quality measures for eligible hospitals and CAHs with the Hospital IQR Program’s reporting and submission timelines for the FY 2019 payment determination. Because these proposals for data collection in this proposed rule will align with the reporting requirements in place for the Hospital IQR Program, and eligible hospitals and CAHs still have the option to submit their clinical quality measures via attestation for the Medicare and Medicaid EHR Incentive Programs for CY 2017 reporting, we do not believe there is any additional burden for this collection of information. However, starting with CY 2018 reporting, eligible hospitals and CAHs participating in the Medicare EHR Incentive Programs must electronically report CQMs using CEHRT where feasible; and attestation to CQMs will no longer be an option except in certain circumstances where electronic reporting is not feasible (80 FR 62894).

We are requesting public comments on these information collection and recordkeeping requirements.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section of this proposed rule; or
2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS–1655–P

Fax: (202) 395–6974; or

Email: OIRA\_submission@omb.eop.gov.

C. Response to Public Comments

Because of the large number of public comments we normally receive on Federal Register documents, we are not able to acknowledge or respond to them individually. We will consider all public comments we receive by the date and time specified in the DATES section of this preamble, and, when we proceed with a subsequent document, we will respond to the public comments in the preamble of that document.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 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 set forth below:

**PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED**

- 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

- 2. Section 405.926 is amended by adding paragraph (u) to read as follows:

**§ 405.926 Actions that are not initial determinations.**

\* \* \* \* \*

(u) Issuance of notice to an individual entitled to Medicare benefits under Title XVIII of the Act when such individual received observation services as an outpatient for more than 24 hours, as specified under § 489.20(y) of this chapter.

**PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES**

- 3. The authority citation for part 412 is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332), sec. 1206 of Pub. L. 113–67, and sec. 112 of Pub. L. 113–93.

- 4. Section 412.64 is amended by adding paragraph (d)(1)(vii) and revising paragraphs (h)(4) introductory text and (h)(4)(vi) introductory text to read as follows:

**§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.**

\* \* \* \* \*

(d) \* \* \*  
(1) \* \* \*

(vii) For fiscal year 2017, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraphs (d)(2) and (3) of this section, less a multifactor productivity adjustment (as determined by CMS) and less 0.75 percentage point.

\* \* \* \* \*

(h) \* \* \*

(4) For discharges on or after October 1, 2004 and before October 1, 2017, CMS establishes a minimum wage index for each all-urban State, as defined in paragraph (h)(5) of this section. This minimum wage index value is computed using the following methodology:

\* \* \* \* \*

(vi) For discharges on or after October 1, 2012 and before October 1, 2017, the



minimum wage index value for the State is the higher of the value determined under paragraph (h)(4)(iv) of this section or the value computed using the following alternative methodology:

\* \* \* \* \*

■ 5. Section 412.103 is amended by adding paragraph (b)(6) to read as follows:

**§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.**

\* \* \* \* \*

(b) \* \* \*

(6) *Lock-in date for the wage index calculation and budget neutrality.* In order for a hospital to be treated as rural in the wage index and budget neutrality calculations under §§ 412.64(e)(1)(ii), (e)(2) and (4), and (h) for the payment rates for the next Federal fiscal year, the hospital's filing date must be no later than 70 days prior to the second Monday in June of the current Federal fiscal year and the application must be approved by the CMS Regional Office in accordance with the requirements of this section.

\* \* \* \* \*

■ 6. Section 412.106 is amended by revising paragraph (g)(1)(iii)(C) to read as follows:

**§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.**

\* \* \* \* \*

(g) \* \* \*

(1) \* \* \*

(iii) \* \* \*

(C)(1) For fiscal years 2014 and 2015, CMS will base its estimates of the amount of hospital uncompensated care on the most recent available data on utilization for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section.

(2) For fiscal year 2016, CMS will base its estimates of the amount of hospital uncompensated care on utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid utilization from 2012 or 2011 cost reports from the most recent HCRIS database extract, the 2012 cost report data submitted to CMS by IHS hospitals, and the most recent available data on Medicare SSI utilization.

(3) For fiscal year 2017, CMS will base its estimates of the amount of hospital uncompensated care on utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid

utilization from 2011, 2012, and 2013 cost reports from the most recent HCRIS database extract, the 2011 and 2012 cost report data submitted to CMS by IHS hospitals, and the most recent available 3 years of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data).

(4) For fiscal year 2018, CMS will base its estimates of the amount of hospital uncompensated care determined in part from utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid utilization from 2012 and 2013 cost reports from the most recent HCRIS database extract, the 2012 cost report data submitted to CMS by IHS hospitals, and the most recent available 2 years of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data), and determined in part on uncompensated care costs, defined as charity care costs plus non-Medicare bad debt costs, from 2014 cost reports also from the most recent HCRIS database extract.

(5) For fiscal year 2019, CMS will base its estimates of the amount of hospital uncompensated care determined in part from utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid utilization from 2013 cost reports from the most recent HCRIS database extract and the most recent available year of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare utilization data), and determined in part on uncompensated care costs, defined as charity care costs plus non-Medicare bad debt costs, from 2014 and 2015 cost reports also from the most recent HCRIS database extract.

(6) For fiscal year 2020, CMS will base its estimates of the amount of hospital uncompensated care on uncompensated care costs, defined as charity care costs plus non-Medicare bad debt costs, from 2014, 2015, and 2016 cost reports from the most recent HCRIS database extract.

(7) For fiscal years 2021 and subsequent years, CMS will base its estimates of the amount of hospital uncompensated care on uncompensated care costs, defined as charity care costs plus non-Medicare bad debt costs, using three cost reporting periods from the most recently available HCRIS database extract. For each fiscal year, the cost reporting periods will be advanced forward by one year (for example, for FY

2021, FYs 2016, 2017, and 2018 cost reports will be used).

\* \* \* \* \*

■ 7. Section 412.140 is amended by revising paragraph (d)(2) to read as follows:

**§ 412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Reporting (IQR) Program.**

\* \* \* \* \*

(d) \* \* \*

(2) A hospital meets the chart-abstracted validation requirement with respect to a fiscal year if it achieves a 75-percent score, as determined by CMS.

\* \* \* \* \*

■ 8. Section 412.160 is amended by revising the definitions of "Achievement threshold (or achievement performance standard)", "Benchmark", and "Cited for deficiencies that pose immediate jeopardy" 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 measures in the Efficiency and Cost Reduction domain, and the median (50th percentile) of hospital performance on a measure during the performance period with respect to a fiscal year, for the measures in the Efficiency and Cost Reduction domain.

\* \* \* \* \*

*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 measures in the Efficiency and Cost Reduction domain, 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 measures in the Efficiency and Cost Reduction domain.

*Cited for deficiencies that pose immediate jeopardy* means that, during the applicable performance period, the Secretary cited the hospital for immediate jeopardy on at least three surveys using the Form CMS-2567, Statement of Deficiencies and Plan of Correction. CMS assigns an immediate jeopardy citation to a performance period as follows:

(1) If the Form CMS–2567 only contains one or more EMTALA-related immediate jeopardy citations, CMS uses the date that the Form CMS–2567 is issued to the hospital;

(2) If the Form CMS–2567 only contains one or more Medicare conditions of participation immediate jeopardy citations, CMS uses the survey end date generated in ASPEN; and

(3) If the Form CMS–2567 contains both one or more EMTALA-related immediate jeopardy citations and one or more Medicare conditions of participation immediate jeopardy citations, CMS uses the survey end date generated in ASPEN.

\* \* \* \* \*

■ 9. Section 412.170 is amended by revising the definition of “Applicable period” to read as follows:

**§ 412.170 Definitions for the Hospital-Acquired Condition Reduction Program.**

\* \* \* \* \*

*Applicable period* is, unless otherwise specified by the Secretary, 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.

\* \* \* \* \*

■ 10. Section 412.204 is amended by revising paragraph (d) introductory text and adding paragraph (e) to read as follows:

**§ 412.204 Payment to hospitals located in Puerto Rico.**

\* \* \* \* \*

(d) *FY 2005 through December 31, 2015.* For discharges occurring on or after October 1, 2004 and before January 1, 2016, payments for inpatient operating costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of—

\* \* \* \* \*

(e) *January 1, 2016 and thereafter.* For discharges occurring on or after January 1, 2016, payments for inpatient operating costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to 100 percent of a national prospective payment rate for inpatient operating costs, as determined under § 412.212.

■ 11. Section 412.256 is amended by revising paragraph (a)(1) to read as follows:

**§ 412.256 Application requirements.**

(a) \* \* \*

(1) An application must be submitted to the MGCRB according to the method prescribed by the MGCRB, with an

electronic copy of the application sent to CMS.

\* \* \* \* \*

■ 12. Section 412.374 is amended by revising paragraph (b) introductory text and adding paragraph (e) to read as follows:

**§ 412.374 Payments to hospitals located in Puerto Rico.**

\* \* \* \* \*

(b) *FY 2005 through FY 2016.* For discharges occurring on or after October 1, 2004 and on or before September 30, 2016, payments for capital-related costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of the following:

\* \* \* \* \*

(e) *FY 2016 and FYs thereafter.* For discharges occurring on or after October 1, 2016, payments for capital-related costs to hospitals located in Puerto Rico that are paid under the prospective payment system are based on 100 percent of the Federal rate, as determined under § 412.308.

■ 13. Section 412.503 is amended by adding in alphabetical order definitions of “MSA”, “MSA-dominant area”, and “MSA-dominant hospital” and revising the definitions of “Outlier payment” and “Subsection (d) hospital” to read as follows:

**§ 412.503 Definitions.**

\* \* \* \* \*

*MSA* means a Metropolitan Statistical Area, as defined by the Executive Office of Management and Budget.

*MSA-dominant area* means an MSA in which an MSA-dominant hospital is located.

*MSA-dominant hospital* means a hospital that has discharged more than 25 percent of the total hospital Medicare discharges in the MSA (subject to the provisions of § 412.538(d)(2)(ii)) in which such subsection (d) hospital is located.

\* \* \* \* \*

*Outlier payment* means an additional payment beyond the long-term care hospital standard Federal payment rate or the site neutral payment rate (including, when applicable, the blended payment rate), as applicable, for cases with unusually high costs.

\* \* \* \* \*

*Subsection (d) hospital* means, for purposes of § 412.522, a hospital defined in section 1886(d)(1)(B) of the Social Security Act and includes any hospital that is located in Puerto Rico and that would be a subsection (d) hospital as defined in section

1886(d)(1)(B) of the Social Security Act if it were located in one of the 50 States.

\* \* \* \* \*

■ 14. Section 412.507 is amended by revising paragraph (a) and adding paragraph (b)(3) to read as follows:

**§ 412.507 Limitation on charges to beneficiaries.**

(a) *Prohibited charges.* Except as provided in paragraph (b) of this section, a long-term care hospital may not charge a beneficiary for any covered services for which payment is made by Medicare, even if the hospital’s costs of furnishing services to that beneficiary are greater than the amount the hospital is paid under the prospective payment system.

(1) If Medicare has paid at the full LTCH prospective payment system standard Federal payment rate, that payment applies to the hospital’s costs for services furnished until the high-cost outlier threshold is met.

(2) If Medicare pays less than the full LTCH prospective payment system standard Federal payment rate and payment was not made at the site neutral payment rate (including, when applicable, the blended payment rate), that payment only applies to the hospital’s costs for those costs or days used to calculate the Medicare payment.

(3) For cost reporting periods beginning on or after October 1, 2016, for Medicare payments to a long-term care hospital described in § 412.23(e)(2)(ii), that payment only applies to the hospital’s costs for those costs or days used to calculate the Medicare payment.

(4) If Medicare has paid at the full site neutral payment rate, that payment applies to the hospital’s costs for services furnished until the high-cost outlier is met.

(b) \* \* \*

(3) For cost reporting periods beginning on or after October 1, 2016, a long-term care hospital described in § 412.23(e)(2)(ii) may only charge the Medicare beneficiary for the applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of this chapter, for items and services as specified under § 489.20(a) of this chapter, and for services provided during the stay for which benefit days were not available and that were not the basis for adjusted LTCH prospective payment system payment amount under § 412.526.

■ 15. Section 412.522 is amended by adding paragraph (c)(2)(v) to read as follows:

**§ 412.522 Application of site neutral payment rate.**

\* \* \* \* \*

- (c) \* \* \*
- (2) \* \* \*

(v) The limitation on long-term care hospital admissions from referring hospitals specified in § 412.538.

\* \* \* \* \*

■ 16. Section 412.523 is amended by adding paragraph (c)(3)(xiii) to read as follows:

**§ 412.523 Methodology for calculating the Federal prospective payment rates.**

\* \* \* \* \*

- (c) \* \* \*
- (3) \* \* \*

(xiii) For long-term care hospital prospective payment system fiscal year beginning October 1, 2016, and ending September 30, 2017. The LTCH PPS standard Federal payment rate for the long-term care hospital prospective payment system beginning October 1, 2016, and ending September 30, 2017, is the standard Federal payment rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.45 percent and further adjusted, as appropriate, as described in paragraph (d) of this section.

\* \* \* \* \*

■ 17. Section 412.525 is amended by adding paragraph (d)(6) to read as follows:

**§ 412.525 Adjustments to the Federal prospective payment.**

\* \* \* \* \*

- (d) \* \* \*

(6) The limitation on long-term care hospital admissions from referring hospitals specified in § 412.538.

■ 18. The section heading of § 412.534 is revised to read as follows:

**§ 412.534 Special payment provisions for long-term care hospitals-within-hospitals and satellites of long-term care hospitals, effective for discharges occurring on or before September 30, 2016.**

\* \* \* \* \*

■ 19. The section heading of § 412.536 is revised to read as follows:

**§ 412.536 Special payment provisions for long-term care hospitals and satellites of long-term care hospitals that discharge Medicare patients admitted from a hospital not located in the same building or on the same campus as the long-term care hospital or satellite of the long-term care hospital, effective for discharges occurring on or before September 30, 2016.**

\* \* \* \* \*

■ 20. Add § 412.538 to read as follows:

**§ 412.538 Limitation on long-term care hospital admissions from referring hospitals.**

(a) *Scope.* (1) The provisions of this section apply to all long-term care hospitals excluded from the hospital inpatient prospective payment system under § 412.23(e), effective for discharges occurring on or after October 1, 2016, except as specified in paragraphs (a)(2) and (3) of this section.

(2) The provisions of this section do not apply to a long-term care hospital described in § 412.23(e)(2)(ii).

(3) The provisions of this section do not apply to a long-term care hospital described in § 412.23(e)(2)(i) that meets the criteria in § 412.22(f).

(b) *Discharges at or below the applicable percent threshold.* For any cost reporting period which includes discharges occurring on or after October 1, 2016, in which a long-term care hospital has a population of Medicare discharges occurring on or after October 1, 2016 of whom no more than the applicable percent threshold were admitted to the long-term care hospital from a single referring hospital as identified by the CCN, payments are made under the rules at §§ 412.500 through 412.541 with no adjustment under this section.

(c) *Discharges in excess of the applicable percent threshold.* For any cost reporting period which includes discharges occurring on or after October 1, 2016, in which a long-term care hospital has a population of Medicare discharges occurring on or after October 1, 2016 of whom more than the applicable percentage threshold (as defined in paragraph (e) of this section) were admitted to the long-term care hospital from a single referring hospital as identified by the CNN, payments for the Medicare discharges who are admitted from that referring hospital and who cause the long-term care hospital to exceed the applicable percentage threshold (as defined in paragraph (e) of this section) are to be paid at the lesser of the amount otherwise payable under this subpart or the amount equivalent to the hospital inpatient prospective payment system amount as defined in paragraph (f) of this section. Payments for discharges not in excess of the applicable percentage threshold (as defined in paragraph (e) of this section) are made under the rules at §§ 412.500 through 412.541 with no adjustment under this section.

(d) *Determination of exceeding the applicable percentage threshold.*—(1) *General.* The determination of whether a long-term care hospital has exceeded its applicable percentage threshold (as

defined in paragraph (e) of this section) in regard to admissions from a single referring hospital as identified by the CNN is made by comparing the hospital's percentage of Medicare discharges occurring on or after October 1, 2016 admitted to the long-term care hospital (as calculated under paragraph (d)(2) of this section) to the long-term care hospital's applicable percentage threshold in paragraph (e) of this section.

(2) *Percentage of Medicare discharges.* For each individual referring hospital, the percentage of Medicare discharges admitted to the long-term care hospital is calculated by dividing the amount in paragraph (d)(2)(i) of this section by the amount in paragraph (d)(2)(ii) of this paragraph.

(i) The number of the long-term care hospital's Medicare discharges in the cost reporting period that were admitted from a single referring hospital as identified by the CNN on whose behalf an outlier payment was not made to that hospital and for whom payment was not made by a Medicare Advantage plan.

(ii) The long-term care hospital's total number of Medicare discharges in the long-term care hospital's cost reporting period for whom payment was not made by a Medicare Advantage plan.

(e) *Applicable percentage threshold*—(1) *General.* For the purposes of this section, except as provided for in paragraphs (f)(2) and (3) of this section, "applicable percentage threshold" means 25 percent.

(2) *Special treatment of exclusively rural long-term care hospitals.* In the case of a long-term care hospital that is located in a rural area as defined in § 412.503, the applicable percentage threshold means 50 percent. If an LTCH has multiple locations, all locations of the LTCH must be in a rural area (as defined in § 412.503) in order to be treated as rural under this section.

(3) *Special treatment for long-term care hospitals located in an MSA with an MSA-dominant hospital.* In the case of a long-term care hospital that admits Medicare patients from a referring MSA-dominant hospital (as defined in paragraph (h)(3)(ii) of this section), the applicable percentage threshold means the percentage of total subsection (d) hospital Medicare discharges in the MSA in which the long-term care hospital is located for the cost reporting period for which the adjustment under this section is made, but in no case is less than 25 percent or more than 50 percent. The determination of the applicable percentage threshold in this paragraph is subject to the provisions of paragraph (d)(2) of this section. If an LTCH has multiple locations payable

under this subpart, all locations of the LTCH must be in an MSA with an MSA-dominant hospital in order to be treated as such under this section.

(f) *Determining the amount equivalent to the hospital inpatient prospective payment system amount.* (1) As specified in paragraphs (b) and (c) of this section, CMS calculates an amount payable under subpart O that is equivalent to an amount that would be paid for the services provided if such services had been provided in an inpatient prospective payment system hospital (that is, the amount that would be determined under the rules at § 412.1(a)). This amount is based on the sum of the applicable hospital inpatient prospective payment system operating standardized amount and capital Federal rate in effect (as set forth in section § 412.529(d)(4)) at the time of the long-term care hospital discharge.

(2) In addition to the payment amount under paragraph (f)(1) of this section, an additional payment for high-cost outlier cases is based on the applicable fixed-loss amount established for the hospital inpatient prospective payment system in effect at the time of the long-term care hospital discharge.

■ 21. Section 412.560 is amended by revising paragraph (c)(1) to read as follows:

**§ 412.560 Participation, data submission, and other requirements under the Long-Term Care Hospital Quality Reporting (LTCHQR) Program.**

\* \* \* \* \*

(c) \* \* \*

(1) A long-term care hospital that wishes to request an exception or extension with respect to quality data reporting requirements must submit its request to CMS within 90 days of the date that the extraordinary circumstances occurred.

\* \* \* \* \*

**PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES**

■ 22. The authority for part 413 is revised to read as follows:

**Authority:** Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883 and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332), sec. 3201 of Pub. L. 112–96 (126 Stat. 156), sec. 632 of Pub. L. 112–240 (126 Stat.

2354), sec. 217 of Pub. L. 113–93 (129 Stat. 1040), and sec. 204 of Pub. L. 113–295 (128 Stat. 4010).

■ 23. Section 413.17 is amended by revising paragraph (d)(1) introductory text to read as follows:

**§ 413.17 Cost to related organizations.**

\* \* \* \* \*

(d) \* \* \*

(1) An exception is provided to this general principle if the provider demonstrates by convincing evidence to the satisfaction of the contractor, that—

\* \* \* \* \*

■ 24. Section 413.24 is amended by revising paragraphs (f)(4)(i), (ii), and (iv) to read as follows:

**§ 413.24 Adequate cost data and cost finding.**

\* \* \* \* \*

(f) \* \* \*

(4) \* \* \*

(i) As used in this paragraph, “provider” means a hospital, skilled nursing facility, home health agency, hospice, organ procurement organization, histocompatibility laboratory, rural health clinic, Federally qualified health center, community mental health center, or end-stage renal disease facility.

(ii) Effective for cost reporting periods beginning on or after October 1, 1989 for hospitals, cost reporting periods ending on or after February 1, 1997 for skilled nursing facilities and home health agencies, cost reporting periods ending on or after December 31, 2004 for hospices, and end-stage renal disease facilities, and cost reporting periods ending on or after March 31, 2005 for organ procurement organizations, histocompatibility laboratories, rural health clinics, Federally qualified health centers, and community mental health centers, a provider is required to submit cost reports in a standardized electronic format. The provider’s electronic program must be capable of producing the CMS standardized output file in a form that can be read by the contractor’s automated system. This electronic file, which must contain the input data required to complete the cost report and to pass specified edits, must be forwarded to the contractor for processing through its system.

\* \* \* \* \*

(iv) Effective for cost reporting periods ending on or after September 30, 1994 for hospitals, cost reporting periods ending on or after February 1, 1997 for skilled nursing facilities and home health agencies, cost reporting periods ending on or after December 31, 2004 for hospices and end-stage renal disease facilities, and cost reporting

periods ending on or after March 31, 2005 for organ procurement organizations, histocompatibility laboratories, rural health clinics, Federally qualified health centers, and community mental health centers, a provider must submit a hard copy of a settlement summary, a statement of certain worksheet totals found within the electronic file, and a statement signed by its administrator or chief financial officer certifying the accuracy of the electronic file or the manually prepared cost report. During a transition period (first two cost-reporting periods on or after December 31, 2004 for hospices and end-stage renal disease facilities, and the first two cost-reporting periods on or after March 31, 2005 for organ procurement organizations, histocompatibility laboratories, rural health clinics, Federally qualified health centers, community mental health centers), providers must submit a hard copy of the completed cost report forms in addition to the electronic file. The following statement must immediately precede the dated signature of the provider’s administrator or chief financial officer:

I hereby certify that I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by \_\_\_\_\_ (Provider Name(s) and Number(s)) for the cost reporting period beginning \_\_\_ and ending \_\_\_ and that to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

\* \* \* \* \*

■ 25. Section 413.79 is amended by revising paragraphs (k)(1)(i) and (ii), (k)(2)(i) and (ii), (k)(3) and (4), and (k)(7)(ii) and (iii) to read as follows:

**§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.**

\* \* \* \* \*

(k) \* \* \*

(1) \* \* \*

(i) For rural track programs started prior to October 1, 2012, for the first 3 years of the rural track’s existence, the rural track FTE limitation for each urban hospital will be the actual number of

FTE residents, subject to the rolling average at paragraph (d)(7) of this section, training in the rural track at the urban hospital. For rural track programs started on or after October 1, 2012, prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average at paragraph (d)(7) of this section, training in the rural track at the urban hospital.

(ii) For rural track programs started prior to October 1, 2012, beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of the highest number of residents, in any program year, who during the third year of the rural track's existence are training in the rural track at the urban hospital or the rural hospital(s) and are designated at the beginning of their training to be rotated to the rural hospital(s) for at least two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2002, or for more than one-half of the duration of the program effective for cost reporting periods beginning on or after October 1, 2003, and the number of years those residents are training at the urban hospital. For rural track programs started on or after October 1, 2012, beginning with the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is equal to the product of the highest number of residents, in any program year, who during the fifth year of the rural track's existence are training in the rural track at the urban hospital or the rural hospital(s) and are designated at the beginning of their training to be rotated to the rural hospital(s) for more than one-half of the duration of the program, and the number of years those residents are training at the urban hospital.

(2) \* \* \*

(i) For rural track programs started prior to October 1, 2012, for the first 3 years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonhospital site(s). For rural track programs started on or after October 1, 2012, prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the

sixth program year of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonhospital site(s).

(ii)(A) For rural track programs started prior to October 1, 2012, beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(1) The highest number of residents in any program year who, during the third year of the rural track's existence, are training in the rural track at—

(i) The urban hospital and are designated at the beginning of their training to be rotated to a rural nonhospital site(s) for at least two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000 and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003; and

(ii) The rural nonhospital site(s); and

(2) The number of years in which the residents are expected to complete each program based on the minimum accredited length for the type of program.

(B) For rural track programs started on or after to October 1, 2012, beginning with the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(1) The highest number of residents in any program year who, during the fifth year of the rural track's existence, are training in the rural track at—

(i) The urban hospital and are designated at the beginning of their training to be rotated to a rural nonhospital site(s) for more than one-half of the duration of the program; and

(ii) The rural nonhospital site(s); and

(2) The number of years in which the residents are expected to complete each program based on the minimum accredited length for the type of program.

(3) For rural track programs started prior to October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural hospital(s) for less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the rural hospital may not include those

residents in its FTE count (if the rural track is not a new program under paragraph (e)(3) of this section, or if the rural hospital's FTE count exceeds that hospital's FTE cap), nor may the urban hospital include those residents when calculating its rural track FTE limitation. For rural track programs started on or after October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural hospital(s) for one-half or less than one-half of the duration of the program, the rural hospital may not include those residents in its FTE count (if the rural track is not a new program under paragraph (e)(3) of this section, or if the rural hospital's FTE count exceeds that hospital's FTE cap), nor may the urban hospital include those residents when calculating its rural track FTE limitation.

(4)(i) For rural track programs started prior to October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural nonhospital site(s) for less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000 and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(d). The urban hospital may include in its FTE count those residents in the rural track, not to exceed its rural track limitation, determined as follows:

(A) For the first 3 years of the rural track's existence, the rural track FTE limitation for the urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the rural nonhospital site(s).

(B) Beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(1) The highest number of residents in any program year who, during the third year of the rural track's existence, are training in the rural track at the rural nonhospital site(s) or are designated at the beginning of their training to be rotated to the rural nonhospital site(s) for a period that is less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2002, and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003; and

(2) The length of time in which the residents are training at the rural nonhospital site(s) only.

(ii) For rural track programs started on or after October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural nonhospital site(s) for one-half or less than one-half of the duration of the program, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(d). The urban hospital may include in its FTE count those residents in the rural track, not to exceed its rural track limitation, determined as follows:

(A) Prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for the urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the rural nonhospital site(s).

(B) Beginning with the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(1) The highest number of residents in any program year who, during the fifth year of the rural track's existence, are training in the rural track at the rural nonhospital site(s) or are designated at the beginning of their training to be rotated to the rural nonhospital site(s) for a period that is for one-half or less than one-half of the duration of the program; and

(2) The length of time in which the residents are training at the rural nonhospital site(s) only.

\* \* \* \* \*

(7) \* \* \*

(ii)(A) For rural track programs started prior to October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and, during the 3-year period that is used to calculate the urban hospital's rural track FTE limit, that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) and subject to paragraph (k)(7)(iii) of this section for the rural track programs started prior to the adoption of such new OMB standards for delineating statistical areas.

(B) For rural track programs started on or after October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and, during the 5-year period that is used to calculate the urban hospital's rural track FTE limit, that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) and subject to paragraph (k)(7)(iii) of this section for the rural track programs started prior to the adoption of such new OMB standards for delineating statistical areas.

(iii)(A) For rural track programs started prior to October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, regardless of whether the redesignation of the rural hospital occurs during the 3-year period that is used to calculate the urban hospital's rural track FTE limit, or after the 3-year period used to calculate the urban hospital's rural track FTE limit, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) based on the rural track programs started prior to the change in the hospital's geographic designation. In order for the urban hospital to receive or use the adjustment to its FTE resident cap for training FTE residents in the rural track residency program that was started prior to the most recent OMB standards for delineating statistical areas adopted by CMS, one of the following two conditions must be met by the end of a period that begins when the most recent OMB standards for delineating statistical areas are adopted by CMS and continues through the end of the second residency training year following the date the most recent OMB delineations are adopted by CMS: the hospital that has been redesignated from rural to urban must reclassify as rural under § 412.103 of this chapter, for purposes of IME only; or the urban hospital must find a new site that is geographically rural consistent with the most recent geographical location delineations adopted by CMS. In order to receive an

adjustment to its FTE resident cap for an additional new rural track residency program, the urban hospital must participate in a rural track program with sites that are geographically rural based on the most recent geographical location delineations adopted by CMS.

(B) For rural track programs started on or after October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, regardless of whether the redesignation of the rural hospital occurs during the 5-year period that is used to calculate the urban hospital's rural track FTE limit, or after the 5-year period used to calculate the urban hospital's rural track FTE limit, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) based on the rural track programs started prior to the change in the hospital's geographic designation. In order for the urban hospital to receive or use the adjustment to its FTE resident cap for training FTE residents in the rural track residency program that was started prior to the most recent OMB standards for delineating statistical areas adopted by CMS, one of the following two conditions must be met by the end of a period that begins when the most recent OMB standards for delineating statistical areas are adopted by CMS and continues through the end of the second residency training year following the date the most recent OMB delineations are adopted by CMS: The hospital that has been redesignated from rural to urban must reclassify as rural under § 412.103 of this chapter, for purposes of IME only; or the urban hospital must find a new site that is geographically rural consistent with the most recent geographical location delineations adopted by CMS. In order to receive an adjustment to its FTE resident cap for an additional new rural track residency program, the urban hospital must participate in a rural track program with sites that are geographically rural based on the most recent geographical location delineations adopted by CMS.

\* \* \* \* \*

#### § 413.200 [Amended]

■ 26. In § 413.200, paragraph (c)(1)(i), remove the phrase “three months” and add in its place the phrase “5 months”.

## PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 27. The authority citation for part 489 is revised 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)).

■ 28. Section 489.20 is amended by adding paragraph (y) to read as follows:

### § 489.20 Basic commitments.

\* \* \* \* \*

(y) In the case of a hospital or critical access hospital, to provide notice, as specified in paragraphs (y)(1) and (2) of this section, to each individual entitled to Medicare benefits under Title XVIII of the Act when such individual receives observation services as an outpatient for more than 24 hours. Notice must be provided to the individual not later than 36 hours after observation services are initiated or sooner if the individual is transferred, discharged, or admitted.

(1) *Written notice.* Hospitals and critical access hospitals must use a standardized written notice, as specified by the Secretary, which includes the following information:

(i) An explanation of the status of the individual as an outpatient receiving observation services and not as an inpatient of the hospital or critical access hospital and the reason for status as an outpatient receiving observation services; and

(ii) An explanation of the implications of such status as an outpatient on services furnished by the hospital or critical access hospital (including services furnished on an inpatient basis), such as Medicare cost-sharing requirements, and subsequent eligibility for Medicare coverage for skilled nursing facility services.

(2) *Oral notice.* The hospital must give an oral explanation of the written notification described in paragraph (y)(1) of this section.

(3) *Signature requirements.* The written notice specified in paragraph (y)(1) of this section must either—

(i) Be signed by the individual who receives observation services as an outpatient or a person acting on the individual's behalf to acknowledge receipt of such notification; or

(ii) If the individual who receives observation services as an outpatient or the person acting on behalf of the individual refuses to provide the signature described in paragraph (y)(1) of this section, is signed by the staff member of the hospital or critical access hospital who presented the written notification and includes the name and title of the staff member, a certification

that the notification was presented, and the date and time the notification was presented.

Dated: April 1, 2016.

**Andrew M. Slavitt,**  
*Administrator, Centers for Medicare & Medicaid Services.*

Dated: April 14, 2016.

**Sylvia M. Burwell,**  
*Secretary, Department of Health and Human Services.*

**Note:** The following Addendum and Appendixes will not appear in the Code of Federal Regulations.

### Addendum—Proposed Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2016, and Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2016

#### 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 2017 for acute care hospitals. We also are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS for FY 2017. 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 proposed figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this proposed rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that will be effective for cost reporting periods beginning on or after October 1, 2016.

In addition, we are setting forth a description of the methods and data we used to determine the proposed standard Federal payment rate that would be applicable to Medicare LTCHs for FY 2017.

In general, except for SCHs and MDHs, for FY 2017, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate (including, as discussed in section IV.F. of the preamble of this proposed rule, uncompensated care payments under section 1886(r)(2) of the Act); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated

hospital-specific rate based on FY 2006 costs per discharge.

We note that section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) extended the MDH program (which, under previous law, was to be in effect for discharges on or before March 31, 2015 only) for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017).

Under section 1886(d)(5)(G) of the Act, MDHs historically were paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever was higher. However, section 5003(a)(1) of Public Law 109–171 extended and modified the MDH special payment provision that was previously set to expire on October 1, 2006, to include discharges occurring on or after October 1, 2006, but before October 1, 2011. Under section 5003(b) of Public Law 109–171, if the change results in an increase to an MDH's target amount, we must rebase an MDH's hospital-specific rates based on its FY 2002 cost report. Section 5003(c) of Public Law 109–171 further required that MDHs be paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital-specific rate. Further, based on the provisions of section 5003(d) of Public Law 109–171, MDHs are no longer subject to the 12-percent cap on their DSH payment adjustment factor.

As discussed in section IV.A. of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, CMS calculated the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to calculate a Puerto Rico-specific standardized amount. For operating costs for inpatient hospital discharges occurring in FY 2017 and subsequent fiscal years, consistent with the provisions of section 1886(d)(9)(E) of the Act as amended by section 601 of Public Law 114–113, subsection (d) Puerto Rico hospitals will continue to be paid based on 100 percent of the national standardized amount. Because Puerto Rico hospitals are now paid 100 percent of the national standardized amount and are subject to the same national standardized amount as subsection (d) hospitals that receive the full update, our discussion below does not

include references to the Puerto Rico standardized amount or the Puerto Rico-specific wage index.

As discussed 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 2017. 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 2017. In section IV. of this Addendum, we are setting forth the rate-of-increase percentage for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2017. In section V. of this Addendum, we discuss proposed policy changes for determining the standard Federal rate for LTCHs paid under the LTCH PPS for FY 2017. 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 on the CMS Web site.

**II. Proposed Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2017**

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 proposing to use for determining the proposed prospective payment rates for FY 2017.

In summary, the proposed standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site) 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 to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act. For FY 2017, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount. We refer readers to section IV.B. of the preamble of this proposed rule for a complete discussion on the proposed FY 2017 inpatient hospital update. Below is a table with these four options:

FY 2017	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Proposed Market Basket Rate-of-Increase .....	2.8	2.8	2.8	2.8
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act .....	0.0	0.0	-0.7	-0.7
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act .....	0.0	-2.1	0.0	-2.1
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act .....	-0.6	-0.5	-0.5	-0.5
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act .....	-0.75	-0.75	-0.75	-0.75
Proposed Applicable Percentage Increase Applied to Standardized Amount	1.55	-0.55	0.85	-1.25

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for “subsection (d)” hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. Accordingly, because the provisions of section 1886(b)(3)(B)(ix) of the Act are not applicable to hospitals located in Puerto Rico until FY 2022, the adjustments under this provision are not applicable for FY 2017.

- 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 2016 budget neutrality factor and applying a revised factor.

- As discussed below and in section III.G. of the preamble of this proposed rule, an adjustment to offset the cost of the 3-year hold harmless transitional wage index provisions provided by CMS as a result of the implementation of the new OMB labor market area delineations (beginning with FY 2015).

- An adjustment to remove the FY 2016 outlier offset and apply an offset for FY 2017, 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 recoupment to meet the requirements of section 631 of ATRA to adjust the standardized amount to offset the estimated amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013.

- As discussed below and in section IV.O. of the preamble of this proposed rule, we are

proposing a (1/0.998) adjustment to the standardized amount using our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to permanently prospectively remove the 0.2 percent reduction to the rate put in place in FY 2014 to offset the estimated increase in IPPS expenditures associated with the projected increase in inpatient encounters that was expected to result from the new inpatient admission guidelines under the 2-midnight policy.

- As discussed below and in section IV.O. of the preamble of this proposed rule, we are proposing a temporary one-time prospective increase to the FY 2017 rates of 0.6 percent or a factor of 1.006 using our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to address the effects of the 0.2 percent reduction to the rate for the 2-midnight policy in effect for FY 2014, FY 2015, and FY 2016.

For FY 2017, consistent with current law, we are applying the rural floor budget neutrality adjustment to hospital wage indexes. 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 applying a uniform, national budget neutrality adjustment to the FY 2017 wage index for the rural floor. We note that, in section III.H.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 FY 2017. Therefore, for FY 2017, in 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 would be reflected in the FY 2017 wage index.

In prior fiscal years, CMS made an adjustment to ensure the effects of the rural community hospital demonstration program required under section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, which extended the demonstration program for an additional 5 years (FYs 2011 through 2016), were budget neutral as required under section 410A(c)(2) of Public Law 108–173. As discussed in section IV.K.3. of the preamble to this proposed rule, given the small number of participating hospitals and the limited time of participation during FY 2017, we are proposing to forego the process of estimating the costs attributable to the demonstration for FY 2017 and to instead analyze the set of finalized cost reports for reporting periods beginning in FY 2016 when they become available. In addition, we discuss how we would reconcile the budget neutrality offset amounts identified in the IPPS final rules for FYs 2011 through 2016 with the actual costs of the demonstration for those years, considering the fact that the demonstration will end December 31, 2016. We stated that we believe it would be appropriate to conduct this analysis for FYs 2011 through 2016 at one time, when all of the finalized cost reports for cost reporting periods beginning in FYs 2011 through 2016 are available. Such an aggregate analysis encompassing the cost experience through the end of the period of performance of the demonstration represents an administratively streamlined method, allowing for the determination of any appropriate final adjustment to the IPPS rates and obviating the need for multiple fiscal-year-specific calculations and regulatory actions. Given the general lag of 3 years in finalizing cost reports, we expect any such analysis to be conducted in FY 2020. Therefore, for FY 2017 we are not proposing to make any adjustment to the standardized amounts for the rural community hospital demonstration program. We refer the reader to section IV.K. of the preamble of this proposed rule for a complete discussion on the rural community hospital demonstration program.

#### 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. 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.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act requires 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.

For FY 2017, we are proposing to continue to use the national labor-related and nonlabor-related shares (which are based on the FY 2010-based hospital market basket) that was used in FY 2016. 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 and adjusts 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 2017, as discussed in section III. of the preamble of this proposed rule, we are proposing to continue to use a labor-related share of 69.6 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000.

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 on the CMS Web site.

##### 2. Computing the National 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. Accordingly, we are proposing to calculate the FY 2017 national average standardized amount irrespective of whether a hospital is located in an urban or rural location.

##### 3. Updating the National 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 use the revised and rebased FY 2010-based IPPS operating and capital market baskets for FY 2017 (which replaced the FY 2006-based IPPS operating and capital market baskets in FY 2014). As discussed in section IV.B. of the preamble of this proposed

rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing to reduce the FY 2017 applicable percentage increase (which is based on IHS Global Insight, Inc.'s (IGI's) first quarter 2016 forecast of the FY 2010-based IPPS market basket) by the MFP adjustment (the 10-year moving average of MFP for the period ending FY 2017) of 0.5 percentage point, which is calculated based on IGI's first quarter 2016 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 2017 by the estimated market basket percentage increase less 0.75 percentage point for hospitals in all areas. Sections 1886(b)(3)(B)(xi) and (xii) of the 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 2016 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 2017 is 2.8 percent. As discussed earlier, for FY 2017, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that could be applied to the standardized amount. We refer readers to section IV.B. of the preamble of this proposed rule for a complete discussion on the proposed FY 2017 inpatient hospital update to the standardized amount. We also refer readers to the table above for the four possible applicable percentage increases that would be applied to update the national standardized amount. The proposed standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the Internet on the CMS Web site reflect these differential amounts.

Although the update factors for FY 2017 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 2017 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. Methodology for Calculation of the Average Standardized Amount

The methodology we used to calculate the proposed FY 2017 standardized amount is as follows:

- To ensure we are only including hospitals paid under the IPPS in the

calculation of the standardized amount, we apply the following inclusion and exclusion criteria: include hospitals whose last four digits fall between 0001 and 0879 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS Web site at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf>); exclude critical access hospitals at the time of this proposed rule; exclude hospitals in Maryland (because these hospitals are paid under an all payer model under section 1115A of the Act); and remove PPS-excluded cancer hospitals that have a “V” in the fifth position of their provider number or a “E” or “F” in the sixth position.

- As in the past, we are proposing to adjust the FY 2017 standardized amount to remove the effects of the FY 2016 geographic reclassifications and outlier payments before applying the FY 2017 updates. We then apply budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on proposed FY 2017 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.

- 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.

- 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 an FFS claim).

- In order to further ensure that we capture only FFS claims, we are proposing to exclude claims with a “GHOPAID” indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).

- Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examine the MedPAR file and remove 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 remove 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 first set of health care organizations selected to participate in the BPCI initiative. Additional organizations were selected in 2014. For additional information on the BPCI initiative, we refer readers to the CMS Center for Medicare and Medicaid Innovation’s Web site at: <http://innovation.cms.gov/initiatives/Bundled-Payments/index.html>.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343), for FY 2013 and subsequent fiscal years, we finalized a methodology to treat hospitals that participate in the BPCI initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process (which includes recalibration of the MS–DRG relative weights, ratesetting, calculation of the budget neutrality factors, and the impact analysis) without regard to a hospital’s participation within these bundled payment models (that is, as if they are not participating in those models under the BPCI initiative). For FY 2017, 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.

- Consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for the Hospital Readmissions Reduction Program and the Hospital VBP Program (established under the Affordable Care Act) within our budget neutrality calculations.

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.

In order to properly determine aggregate payments on each side of the comparison, as we have done for the last 3 fiscal years, for FY 2017 and subsequent years, we are proposing to continue to apply the hospital readmissions payment adjustment and the hospital VBP payment adjustment on each side of the comparison, consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). That is, we are proposing to apply the proposed readmissions payment adjustment factor and the proposed 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 2017 readmissions payment adjustment factors, we are proposing to use excess readmission ratios and aggregate payments for excess readmissions based on admissions from the prior fiscal year’s applicable period because hospitals have had the opportunity to review and correct these data before the data were made public under the policy we adopted regarding the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act. For FY 2017, in this proposed rule, we are proposing to calculate the readmissions payment adjustment factors using excess readmission ratios and aggregate payments for excess readmissions based on admissions from the finalized applicable period for FY 2017 as hospitals have had the opportunity to review and correct these data under our policy regarding the reporting of hospital-specific readmission rates consistent with section 1886(q)(6) of the Act. We discuss our proposed policy regarding the reporting of hospital-specific readmission rates for FY 2017 in section IV.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 FY 2017, in this proposed rule, for the purpose of modeling aggregate payments when determining all budget neutrality factors, we are proposing to use proxy hospital VBP payment adjustment factors for FY 2017 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 2017 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 established section 1886(t) of the Act, which modifies

the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments will receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under age 65 who are uninsured and an additional statutory adjustment, 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 FY 2014, 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 2017 (as we did for the last 3 fiscal years), we are proposing to include estimated empirically justified Medicare DSH payments that will be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we are proposing to consider estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

- When calculating total payments for budget neutrality, to determine total payments for SCHs, we model total hospital-specific rate payments and total Federal rate payments and then include whichever one of the total payments is greater. As discussed in section IV.F. of the preamble to this proposed rule and below, we are proposing to continue the FY 2014 finalized methodology under which we would take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we are proposing to include estimated uncompensated care payments in this comparison.

Similarly, for MDHs, as discussed in section IV. of the preamble to this proposed rule, when computing payments under the Federal national rate plus 75 percent of the difference between the payments under the Federal national rate and the payments under the updated hospital-specific rate, we are continuing to take into consideration uncompensated care payments in the

computation of payments under the Federal rate and the hospital-specific rate for MDHs.

- We are proposing to include an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2017. Similar to FY 2016, we are including this adjustment based on data on the prior year's performance. Payments for hospitals would be estimated based on the proposed applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2017.

#### a. Proposed Recalibration of MS-DRG Relative Weights

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.G. 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.

For FY 2017, to comply with the requirement that MS-DRG reclassification and recalibration of the relative weights be budget neutral for the standardized amount and the hospital-specific rates, we used FY 2015 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2016 labor-related share percentages, the FY 2016 relative weights, and the FY 2016 pre-reclassified wage data, and applied the proposed FY 2017 hospital readmissions payment adjustments and estimated FY 2017 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2016 labor-related share percentages, the proposed FY 2017 relative weights, and the FY 2016 pre-reclassified wage data, and applied the same proposed FY 2017 hospital readmissions payment adjustments and estimated FY 2017 hospital VBP payment adjustments applied above.

Based on this comparison, we computed a proposed budget neutrality adjustment factor equal to 0.999006 and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we also are proposing to apply the MS-DRG reclassification and recalibration budget neutrality factor of 0.999006 to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2016.

#### b. Updated Wage Index—Budget Neutrality Adjustment

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an

annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0000, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0000 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2017, we are proposing to adjust 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.E. of the preamble of this proposed rule.

To compute a proposed budget neutrality adjustment factor for wage index and labor-related share percentage changes, we used FY 2015 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2017 relative weights and the FY 2016 pre-reclassified wage indexes, applied the FY 2016 labor-related share of 69.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the proposed FY 2017 hospital readmissions payment adjustment and the estimated FY 2017 hospital VBP payment adjustment; and

- Aggregate payments using the proposed FY 2017 relative weights and the proposed FY 2017 pre-reclassified wage indexes, applied the proposed labor-related share for FY 2017 of 69.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same proposed FY 2017 hospital readmissions payment adjustments and estimated FY 2017 hospital VBP payment adjustments applied above.

In addition, we applied the proposed MS-DRG reclassification and recalibration budget neutrality adjustment factor (derived in the first step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2016 to FY 2017. By applying this methodology, we determined a proposed budget neutrality adjustment factor of 0.999785 for proposed changes to the wage index.

We note that, in prior fiscal years, we used a three-step process and combined the

recalibration and wage index budget neutrality factors into one factor by multiplying the recalibration adjustment factor by the wage index adjustment factor. Because these two adjustments are required under two different sections of the Act (sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E)(i) of the Act) and the law requires that the wage index budget neutrality adjustment not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent for FY 2017, we are proposing to separate these two adjustments and apply them individually to the standardized amount. Applying these factors individually rather than as a combined factor has no effect mathematically on adjusting the standardized amount.

#### c. Reclassified Hospitals—Proposed 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 MGRCB. 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 adjustment factor for FY 2017, we used FY 2015 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2017 labor-related share percentages, proposed FY 2017 relative weights and proposed FY 2017 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 2017 hospital readmissions payment adjustments and the estimated FY 2017 hospital VBP payment adjustments; and
- Aggregate payments using the proposed FY 2017 labor-related share percentages, proposed FY 2017 relative weights, and proposed FY 2017 wage data after such reclassifications, and applied the same proposed FY 2017 hospital readmissions payment adjustments and the estimated FY 2017 hospital VBP payment adjustments applied above.

We note that the reclassifications applied under the second simulation and comparison are those listed in Table 2 associated with this proposed rule, which is available via the Internet on the CMS Web site. This table reflects reclassification crosswalks proposed

for FY 2017, and apply the proposed policies explained in section III. of the preamble to this proposed rule. Based on these simulations, we calculated a proposed budget neutrality adjustment factor of 0.988816 to ensure that the effects of these provisions are budget neutral, consistent with the statute.

The proposed FY 2017 budget neutrality adjustment factor was applied to the standardized amount after removing the effects of the FY 2016 budget neutrality adjustment factor. We note that the proposed FY 2017 budget neutrality adjustment reflects FY 2017 wage index reclassifications approved by the MGRCB or the Administrator at the time of development of the proposed rule.

#### d. Proposed Rural Floor Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) and the imputed floor under § 412.64(h)(4) are equal to the aggregate prospective payments that would have been made in the absence of such provisions. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.H. of the preamble of this proposed rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural floor and the imputed floor is a national adjustment to the wage index.

As noted above and as discussed in section III.H.2. of the preamble of this proposed rule, we are proposing to extend the imputed floor policy (both the original methodology and alternative methodology) for FY 2017. Therefore, in order to ensure that aggregate payments to hospitals are not affected, similar to prior years, for FY 2017, we would follow our policy of including the proposed imputed floor (calculated under the original and alternative methodologies) in the proposed national rural floor budget neutrality adjustment to the wage index.

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2017, we are proposing to calculate a national rural Puerto Rico wage index. Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the proposed FY 2017 rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). That is, we will use the unweighted average of the wage indexes from all CBSAs (urban areas) that are contiguous (share a border with) to the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Under the new OMB labor market area delineations, except for Arecibo, Puerto Rico (CBSA 11640), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the proposed FY 2017 rural Puerto Rico wage index is calculated based on the average of the proposed FY 2017 wage indexes for the following urban areas: Aguadilla-Isabela, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660), San German, PR (CBSA 41900) and San Juan-Carolina-Caguas, PR (CBSA 41980).

To calculate the national rural floor and imputed floor budget neutrality adjustment factor, we are proposing to use FY 2015 discharge data to simulate payments and the proposed post-reclassified national wage indexes and compared the following:

- National simulated payments without the proposed national rural floor and imputed floor; and
- National simulated payments with the proposed national rural floor and imputed floor.

Based on this comparison, we determined a proposed national rural floor and imputed floor budget neutrality adjustment factor of 0.993806. The national adjustment was applied to the national wage indexes to produce a proposed national rural floor and imputed floor budget neutral wage index.

#### e. Wage Index Transition Budget Neutrality

As discussed in section III.G. of the preamble of this proposed rule, in the past, we have provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts.

Similar to FY 2005, for FY 2015, we determined that the transition to using the new OMB labor market area delineations would have the largest impact on hospitals that were located in an urban county that became rural under the new OMB delineations or hospitals deemed urban where the urban area became rural under the new OMB delineations. To alleviate the decreased payments associated with having a rural wage index, in calculating the area wage index, similar to the transition provided in the FY 2005 IPPS final rule, we finalized a policy to generally assign the hospitals in these counties the urban wage index value of the CBSA where they are physically located in for FY 2014 for FYs 2015, 2016, and 2017. FY 2017 will be the final year of this 3-year transition policy. We note that the 1-year blended wage index transitional policy for all hospitals that would experience any decrease in their wage index value expired in FY 2015.

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50372 through 50373), in the past, CMS has budget neutralized transitional wage indexes. We stated that because we established a policy that allows for the application of a transitional wage index only when it benefits the hospital, we believe that it would be appropriate to ensure that such a transitional policy does not increase aggregate Medicare payments beyond the payments that would be made had we simply adopted the OMB delineations without any transitional provisions. Therefore, as we did for FYs 2015 and 2016, for FY 2017, we are proposing to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to make an adjustment to the national standardized amounts to ensure that total payments for the effect of the 3-year transitional wage index provisions would equal what payments would have been if we had fully adopted the new OMB delineations without providing these transitional provisions. To calculate the proposed transitional wage index budget neutrality factor for FY 2017, we used FY 2015

discharge data to simulate payments and compared the following:

- Aggregate payments using the OMB delineations for FY 2017, the proposed FY 2017 relative weights, proposed FY 2017 wage data after such reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, application of the proposed rural floor budget neutrality adjustment factor to the wage index, and application of the proposed FY 2017 hospital readmissions payment adjustments and the estimated FY 2017 hospital VBP payment adjustments; and

- Aggregate payments using the OMB delineations for FY 2017, the proposed FY 2017 relative weights, proposed FY 2017 wage data after such reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, application of the proposed rural floor budget neutrality adjustment factor to the wage index, application of the 3-year transitional wage indexes, and application of the same proposed FY 2017 hospital readmissions payment adjustments and the estimated FY 2017 hospital VBP payment adjustments applied above.

Based on these simulations, we calculated a proposed budget neutrality adjustment factor of 0.999999. Therefore, for FY 2017, we are proposing to apply a transitional wage index budget neutrality adjustment factor of 0.999999 to the national average standardized amounts to ensure that the effects of these proposed transitional wage indexes are budget neutral.

We note that the proposed budget neutrality adjustment factor calculated above is based on the increase in payments in FY 2017 that would result from the final year of the 3-year transitional wage index policies. Therefore, we are proposing to apply this proposed budget neutrality adjustment factor as a one-time adjustment to the FY 2017 national standardized amounts in order to offset the increase in payments in FY 2017 as a result of this final year of the 3-year transitional wage index. For FY 2017, we did not take into consideration the adjustment factor applied to the national standardized amounts in the previous fiscal year's update when calculating the current fiscal year transitional wage index budget neutrality adjustment factor (that is, this adjustment is not applied cumulatively).

#### f. Proposed Case-Mix Budget Neutrality Adjustment

##### (1) Background

Below we summarize the proposed recoupment adjustment to the FY 2017 payment rates, as required by section 631 of ATRA, to account for the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. We refer readers to section II.D. of the preamble of this proposed rule for a complete discussion regarding our proposed policies for FY 2017 in this proposed rule and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case-mix.

(2) Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA) to the National Standardized Amount

Section 631 of the ATRA amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment totaling \$11 billion by FY 2017. Our actuaries estimated that if CMS were to fully account for the \$11 billion recoupment required by section 631 of ATRA in FY 2014, a one-time –9.3 percent adjustment to the standardized amount would be necessary. It is often our practice to delay or phase-in payment rate adjustments over more than 1 year, in order to moderate the effect on payment rates in any 1 year. Therefore, consistent with the policies that we have adopted in many similar cases, for FY 2014, FY 2015 and FY 2016, we applied a –0.8 percent adjustment to the standardized amount. For FY 2017, we are proposing to apply a –1.5 percent adjustment to the standardized amount. We refer the reader to section II. D. 6 of the preamble to this proposed rule for a complete discussion on this adjustment. We note that, as section 631 of the ATRA instructs the Secretary to make a recoupment adjustment only to the standardized amount, this adjustment would not apply to the hospital-specific payment rates.

#### g. Proposed Adjustment to IPPS Rates Resulting From 2-Midnight Policy

As discussed in section IV. O of the preamble to this proposed rule, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50906 through 50954), we adopted the 2-midnight policy effective for dates of admission on or after October 1, 2013. We used our 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, and we used our authority under section 1886(g) of the Act to make a reduction of 0.2 percent to the national capital Federal rate and the Puerto Rico-specific capital rate, in order to offset the estimated increase of \$220 million in IPPS expenditures in FY 2014 as a result of the 2-midnight policy.

In *Shands Jacksonville Medical Center, Inc. v. Burwell*, No. 14–263 (D.D.C.) and consolidated cases, hospitals challenged the 0.2 percent reduction in IPPS rates to account for the estimated \$220 million in additional FY 2014 expenditures resulting from the 2-midnight policy. In its Memorandum Opinion, issued September 21, 2015, the Court found that the “Secretary’s interpretation of the exceptions and adjustments provision is a reasonable one” for this purpose. However, the Court also ordered the 0.2 percent reduction remanded back to the Secretary, without vacating the rule, to correct certain procedural deficiencies in the promulgation of the 0.2 percent reduction and reconsider the adjustment. In accordance with the Court’s order, we published a notice with comment period that appeared in the December 1, 2015 **Federal Register** (80 FR 75107), which discussed the basis for the 0.2 percent reduction and its underlying assumptions and invited comments on the same in order

to facilitate our further consideration of the FY 2014 reduction.

We still believe the assumptions underlying the 0.2 percent reduction to the rates put in place beginning in FY 2014 were reasonable at the time we made them in 2013. Nevertheless, taking all the factors discussed in section IV. O of the preamble to this proposed rule into account and in the context of the litigation, we believe it would be appropriate to use our authority under section 1886(d)(5)(I)(i) to prospectively remove, beginning in FY 2017, the 0.2 percent reduction to the standardized amount and hospital-specific rates put in place beginning in FY 2014. The 0.2 percent reduction was implemented by including a factor of 0.998 in the calculation of the FY 2014 standardized amount and hospital-specific rates, permanently reducing the standardized amount and hospital-specific rates for FY 2014 and future years until the 0.998 is removed. We are proposing to permanently remove the 0.998 reduction beginning in FY 2017 by including a factor of (1/0.998) in the calculation of the FY 2017 standardized amount and hospital specific rate.

In addition, for the reasons discussed in section IV.O. of the preamble of this proposed rule, we believe it would be appropriate to use our authority under section 1886(d)(5)(I)(i) to temporarily increase the standardized amount and hospital-specific rates, only for FY 2017, to address the effect of the 0.2 percent reduction to the standardized amount and hospital-specific rates in effect for FY 2014, the 0.2 percent reduction to the standardized amount and hospital-specific rates in effect for FY 2015 (recall the 0.998 factor included in the calculation of the FY 2014 rates permanently reduced the rates for FY 2014 and future years until it is removed), and the 0.2 percent reduction to the standardized amount and hospital-specific rates in effect for FY 2016. We believe that the most transparent, expedient, and administratively feasible method to accomplish this is a temporary one-time prospective increase to the FY 2017 standardized amount and hospital-specific rates of 0.6 percent (= 0.2 percent + 0.2 percent + 0.2 percent). Specifically, we are proposing to include a factor of 1.006 in the calculation of the standardized amount and the hospital-specific rates in FY 2017 and then remove this temporary one-time prospective increase by including a factor of (1/1.006) in the calculation of the standardized amount and hospital-specific rates for FY 2018.

We refer the reader to section IV.O. of the preamble to this proposed rule for a complete discussion.

#### h. 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 MS–DRG, any IME and DSH payments, uncompensated care 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 MS-DRG, any IME and DSH payments, uncompensated care 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 2017 is 80 percent, or 90 percent for burn MS-DRGs 927, 928, 929, 933, 934 and 935. We have used a marginal cost factor of 90 percent since FY 1989 (54 FR 36479 through 36480) for designated burn DRGs as well as a marginal cost factor of 80 percent for all other DRGs 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. 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.htm>.

(1) Proposed FY 2017 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977 through 50983), in response to public comments on the FY 2013 IPPS/LTCH

PPS proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for detailed discussion of the changes.

As we have done in the past, to calculate the proposed FY 2017 outlier threshold, we simulated payments by applying proposed FY 2017 payment rates and policies using cases from the FY 2015 MedPAR file. Therefore, in order to determine the proposed FY 2017 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2015 to FY 2017. As discussed in the FY 2015 IPPS/LTCH PPS final rule, we believe a methodology that is based on 1-year of charge data will provide a more stable measure to project the average charge per case because our prior methodology used a 6-month measure, which inherently uses fewer claims than a 1-year measure and makes it more susceptible to fluctuations in the average charge per case as a result of any significant charge increases or decreases by hospitals. The methodology we are proposing to calculate the charge inflation factor for FY 2017 and subsequent fiscal years is as follows:

- To produce the most stable measure of charge inflation, we applied the following inclusion and exclusion criteria of hospitals claims in our measure of charge inflation: include hospitals whose last four digits fall between 0001 and 0899 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS Web site at <https://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/som107c02.pdf>); include CAHs that were IPPS hospitals for the time period of the MedPAR data being used to calculate the charge inflation factor; include hospitals in Maryland; and remove PPS excluded cancer hospitals who have a “V” in the fifth position of their provider number or a “E” or “F” in the sixth position.
- We excluded Medicare Advantage IME claims for the reasons described in section I.A.4. of this Addendum. 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.
- In order to ensure that we capture only FFS claims, we included claims with a

“Claim Type” of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).

- In order to further ensure that we capture only FFS claims, we excluded claims with a “GHOPAID” indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).

- 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. We also removed organ acquisition charges from the covered charge field because organ acquisition is a pass-through payment not paid under the IPPS.

In the FY 2016 IPPS/LTCH final rule (80 FR 49779–49780), we stated that commenters were concerned that they were unable to replicate the calculation of the charge inflation factor that CMS used in the proposed rule. In response to those comments, we stated that we continue to believe that it is optimal to use the most recent period of charge data available to measure charge inflation. In response to those comments, similar to FY 2016, for FY 2017 we grouped claims data by quarter in the table below in order that the public would be able to replicate the claims summary for the claims with discharge dates through September 30, 2015, that are available under the current LDS structure. In order to provide even more information in response to the commenters’ request, similar to FY 2016, for FY 2017 we have made available on the CMS Web site at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html> (click on the link on the left titled “FY 2017 IPPS Proposed Rule Home Page” and then click the link “FY 2017 Proposed Rule Data Files”) a more detailed summary table by provider with the monthly charges that were used to compute the charge inflation factor. We continue to work with our systems teams and privacy office to explore expanding the information available in the current LDS, perhaps through the provision of a supplemental data file for future rulemaking.

Quarter	Covered charges (January 1, 2014, through December 31, 2014)	Cases (January 1, 2014, through December 31, 2014)	Covered charges (January 1, 2015, through December 31, 2015)	Cases (January 1, 2015, through December 31, 2015)
1 .....	\$126,156,195,005	2,479,295	\$134,250,323,661	2,546,078
2 .....	122,171,248,575	2,445,370	126,880,227,174	2,416,569
3 .....	119,364,629,662	2,364,553	122,165,668,615	2,308,537
4 .....	124,733,843,923	2,436,787	90,677,073,204	1,696,180
Total	492,425,917,165	9,726,005	473,973,292,654	8,967,364

Under this methodology, to compute the 1-year average annualized rate-of-change in charges per case for FY 2017, we are proposing to compare the average covered charge per case of \$50,360 (\$492,425,917,165/9,726,005) from the second quarter of FY 2014 through the first quarter of FY 2015 (January 1, 2014, through

December 31, 2014) to the average covered charge per case of \$52,855 (\$473,973,292,654/8,967,364) from the second quarter of FY 2015 through the first quarter of FY 2016 (January 1, 2015, through December 31, 2015). This rate-of-change is 4.4 percent (1.043957) or 9.8 percent (1.089846) over 2 years. The billed charges

are obtained from the claim from the MedPAR file and inflated by the inflation factor specified above.

As we have done in the past, in this proposed rule, we are proposing to establish the proposed FY 2017 outlier threshold using hospital CCRs from the December 2015 update to the Provider-Specific File (PSF)—

the most recent available data at the time of the development of this proposed rule. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we apply the following edits to providers' CCRs in the PSF. We believe these edits are appropriate in order to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replace these CCRs with the statewide average CCR for the upcoming fiscal year. We also assign the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF. We do not apply the adjustment factors described below to hospitals assigned the statewide average CCR.

For FY 2017, we also are proposing to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below). We are proposing that, if more recent data become available, we would use that data to calculate the final FY 2017 outlier threshold.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital CCR from the most recent update of the PSF to the national average case-weighted operating and capital CCR from the same period of the prior year.

Therefore, as we did for the last 3 fiscal years, we are proposing to adjust the CCRs from the December 2015 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the December 2014 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2015 update of the PSF. We note that we used total transfer-adjusted cases from FY 2015 to determine the national average case-weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison because 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 proposed December 2014 operating national average case-weighted CCR of 0.280907 and a proposed December 2015 operating national average case-weighted CCR of 0.272363. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the December 2014 operating national average case-weighted CCR from the December 2015 operating national average case-weighted CCR and then dividing the result by the December 2014 national operating average case-weighted CCR. This resulted in a proposed national operating CCR adjustment factor of 0.969585.

We used the same methodology proposed above to adjust the capital CCRs. Specifically, we calculated a December 2014 capital

national average case-weighted CCR of 0.024615 and a December 2015 capital national average case-weighted CCR of 0.024008. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the December 2014 capital national average case-weighted CCR from the December 2015 capital national average case-weighted CCR and then dividing the result by the December 2014 capital national average case-weighted CCR. This resulted in a proposed national capital CCR adjustment factor of 0.975335.

As discussed above, for FY 2017, we are proposing to apply the final year of the 3-year transitional wage index because of the adoption of the new OMB labor market area delineations. Also, as discussed in section III.B.3. of the preamble to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 and 50161) and in section III.H.3. of the preamble of this proposed rule, in accordance with section 10324(a) of the Affordable Care Act, we created a wage index floor of 1.0000 for all hospitals located in States determined to be frontier States. We note that the frontier State floor adjustments would 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 would receive a wage index less than 1.0000 due to the proposed 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 2017, it was necessary to apply the proposed 3-year transitional wage indexes and adjust the proposed wage index of those eligible hospitals in a frontier State when calculating the proposed outlier threshold that results in outlier payments being 5.1 percent of total payments for FY 2017. If we did not take the above into account, our estimate of total FY 2017 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 2017 outlier payments, we are proposing not to make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. We continue to believe that, due to the policy implemented in the June 9, 2003 Outlier Final Rule (68 FR 34494), CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year. We note that we have instructed MACs to identify for CMS any instances where (1) a hospital's actual CCR for the cost reporting period fluctuates plus or minus 10 percentage points compared to the interim CCR used to calculate outlier payments when a bill is processed; and (2)

the total outlier payments for the hospital exceeded \$500,000.00 for that period. 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 regarding the effects of reconciliation on the outlier threshold calculation.

As described in sections IV.G. and IV.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 that it is appropriate to include the hospital VBP payment adjustments and the hospital readmissions payment adjustments in the proposed outlier threshold calculation or the proposed 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 proposed outlier fixed-loss cost threshold.

We note that, to the extent section 1886(r) of the Act modifies the DSH payment methodology under section 1886(d)(5)(F) of the Act, the new uncompensated care payment under section 1886(r)(2) of the Act, like the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act, may be considered an amount payable under section 1886(d)(5)(F) of the Act such that it would be reasonable to include the payment in the outlier determination under section 1886(d)(5)(A) of the Act. As we have done since the implementation of uncompensated care payments in FY 2014, we also are proposing for FY 2017 to allocate an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally. Furthermore, we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in

the calculation of outlier payments. Therefore, consistent with the methodology used since FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2017, we are proposing to include estimated FY 2017 uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we are proposing to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1 of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. We used a threshold of \$23,681 and calculated total operating Federal payments of \$82,727,323,366 and total outlier payments of \$4,445,892,903. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold met the 5.1 percent target. As a result, we are proposing an outlier fixed-loss cost threshold for FY 2017 equal to the prospective payment rate for the MS-DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus \$23,681.

(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 2017 will result in outlier payments that will equal 5.1 percent of operating DRG payments and 6.26 percent of capital payments based on the Federal rate.

In accordance with section 1886(d)(3)(B) of the Act, we are proposing to reduce the FY 2017 standardized amount by the same percentage to account for the projected proportion of payments paid as outliers.

The proposed outlier adjustment factors that would be applied to the standardized amount based on the proposed FY 2017 outlier threshold are as follows:

	Operating standardized amounts	Capital Federal rate
National .....	0.948999	0.937400

We are proposing to apply the outlier adjustment factors to the proposed FY 2017 payment rates after removing the effects of the FY 2016 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 MAC computes operating CCRs greater than 1.19 or capital CCRs greater than 0.171, or hospitals for which the 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 on the CMS Web site) contains the proposed statewide average operating CCRs for urban hospitals and for rural hospitals for which the MAC is unable to compute a hospital-specific CCR within the above range. Effective for discharges occurring on or after October 1, 2016, these statewide average ratios would replace the ratios posted on our Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY-2014-IPPS-Final-Rule-Home-Page-Items/FY-2014-IPPS-Final-Rule-CMS-1599-F-Tables.html>. Table 8B listed in section VI. of this Addendum (and available via the Internet on the CMS Web site) contains the comparable proposed statewide average capital CCRs. As previously stated, the proposed CCRs in Tables 8A and 8B would be used during FY 2017 when hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted above. Table 8C listed in section VI. of this Addendum (and available via the Internet on the CMS Web site) 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 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 MAC can avoid possible overpayments or underpayments at cost report settlement, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR ratio at any time as long as the guidelines of Change Request 3966 are followed. In addition, as mentioned above, we published an additional manual update (Change Request 7192) to our outlier policy on December 3, 2010, which also updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update outlines the outlier

reconciliation process for hospitals and Medicare contractors. To download and view the manual instructions on outlier reconciliation, we refer readers to the CMS Web site: <http://www.cms.hhs.gov/manuals/downloads/clm104c03.pdf>.

(3) FY 2015 Outlier Payments

Our current estimate, using available FY 2015 claims data, is that actual outlier payments for FY 2015 were approximately 4.68 percent of actual total MS-DRG payments. Therefore, the data indicate that, for FY 2015, the percentage of actual outlier payments relative to actual total payments is lower than we projected for FY 2015. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2015 are equal to 5.1 percent of total MS-DRG payments. As explained in the FY 2003 Outlier Final Rule (68 FR 34502), if we were to make retroactive adjustments to all outlier payments to ensure total payments are 5.1 percent of MS-DRG payments (by retroactively adjusting outlier payments), we would be removing the important aspect of the prospective nature of the IPPS. Because such an across-the-board adjustment would either lead to more or less outlier payments for all hospitals, hospitals would no longer be able to reliably approximate their payment for a patient while the patient is still hospitalized. We believe it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment. Furthermore, we believe it is consistent with the intent of the language at section 1886(d)(5)(A)(iv) of the Act not to make retroactive adjustments to outlier payments. This section calls for the Secretary to ensure that outlier payments are equal to or greater than 5 percent and less than or equal to 6 percent of projected or estimated (not actual) MS-DRG payments. We believe this language reflects the intent of Congress regarding the prospectivity of the IPPS. We believe that an important goal of a PPS is predictability. Therefore, we believe that the fixed-loss outlier threshold should be projected based on the best available historical data and should not be adjusted retroactively. A retroactive change to the fixed-loss outlier threshold would affect all hospitals subject to the IPPS, thereby undercutting the predictability of the system as a whole.

We note that because the MedPAR claims data for the entire FY 2016 will not be available until after September 30, 2016, we are unable to provide an estimate of actual outlier payments for FY 2016 based on FY 2016 claims data in this proposed rule. We will provide an estimate of actual FY 2016 outlier payments in the FY 2018 IPPS/LTCH PPS proposed rule.

5. Proposed FY 2017 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 on the CMS Web site) contain the national standardized amounts that we are proposing to apply to all hospitals, except hospitals located in Puerto



Rico, for FY 2017. The proposed standardized amount for hospitals in Puerto Rico is shown in Table 1C listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site). The proposed amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 69.6 percent, and the labor-related share applied to the standardized amounts in Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are proposing to apply a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we will apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the proposed standardized amounts reflecting

the proposed applicable percentage increases for FY 2017.

The proposed labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2017 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site). Similar to above, section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.

The following table illustrates the changes from the FY 2016 national standardized amount to the proposed FY 2017 national standardized amount. The second through fifth columns display the proposed changes from the FY 2016 standardized amounts for each applicable FY 2017 standardized

amount. The first row of the table shows the updated (through FY 2016) average standardized amount after restoring the FY 2016 offsets for outlier payments, demonstration budget neutrality, geographic reclassification budget neutrality, new labor market delineation wage index transition budget neutrality, retrospective documentation and coding adjustment under section 7(b)(1)(B) of Public Law 110–90 and an adjustment to the standardized amount using our authority under section 1886(d)(5)(I)(i) of the Act to permanently prospectively remove the 0.2 percent reduction to the rate put in place in FY 2014 to offset the estimated increase in IPPS expenditures as a result of the 2-midnight policy. The MS–DRG reclassification and recalibration and wage index budget neutrality adjustment factors are cumulative. Therefore, those FY 2016 adjustment factors are not removed from this table.

COMPARISON OF FY 2016 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2017 STANDARDIZED AMOUNTS

	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
FY 2016 Base Rate after removing:	If Wage Index is Greater Than 1.0000: Labor (69.6%): \$4,394.09. Nonlabor (30.4%): \$1,919.26. If Wage Index is less Than or Equal to 1.0000: Labor (62%): \$3,914.28. Nonlabor (38%): \$2,399.07.	If Wage Index is Greater Than 1.0000: Labor (69.6%): \$4,394.09. Nonlabor (30.4%): \$1,919.26. If Wage Index is less Than or Equal to 1.0000: Labor (62%): \$3,914.28. Nonlabor (38%): \$2,399.07.	If Wage Index is Greater Than 1.0000: Labor (69.6%): \$4,394.09. Nonlabor (30.4%): \$1,919.26. If Wage Index is less Than or Equal to 1.0000: Labor (62%): \$3,914.28. Nonlabor (38%): \$2,399.07.	If Wage Index is Greater Than 1.0000: Labor (69.6%): \$4,394.09. Nonlabor (30.4%): \$1,919.26. If Wage Index is less Than or Equal to 1.0000: Labor (62%): \$3,914.28. Nonlabor (38%): \$2,399.07.
1. FY 2016 Geographic Reclassification Budget Neutrality (0.988169).				
2. FY 2016 Rural Community Hospital Demonstration Program Budget Neutrality (0.999837).				
3. Cumulative FY 2008, FY 2009, FY 2012, FY 2013, FY 2014, FY 2015 and FY 2016 Documentation and Coding Adjustments as Required under Sections 7(b)(1)(A) and 7(b)(1)(B) of Pub. L. 110–90 and Documentation and Coding Recoupment Adjustment as required under Section 631 of the American Taxpayer Relief Act of 2012 (0.9255).				
4. FY 2016 Operating Outlier Offset (0.948998).				
5. FY 2016 New Labor Market Delineation Wage Index Transition Budget Neutrality Factor (0.999998).				
6. FY 2017 Proposed 2-Midnight Rule Permanent Adjustment (1/0.998).				
Proposed FY 2017 Update Factor .....	1.0155 .....	0.9945 .....	1.0085 .....	0.9875
Proposed FY 2017 MS–DRG Recalibration Budget Neutrality Factor.	0.999006 .....	0.999006 .....	0.999006 .....	0.999006
Proposed FY 2017 Wage Index Budget Neutrality Factor.	0.999785 .....	0.999785 .....	0.999785 .....	0.999785
Proposed FY 2017 Reclassification Budget Neutrality Factor.	0.988816 .....	0.988816 .....	0.988816 .....	0.988816
Proposed FY 2017 Operating Outlier Factor	0.948999 .....	0.948999 .....	0.948999 .....	0.98999

COMPARISON OF FY 2016 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2017 STANDARDIZED AMOUNTS—Continued

	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Cumulative Factor: FY 2008, FY 2009, FY 2012, FY 2013, FY 2014, FY 2015, FY 2016 and FY 2017 Documentation and Coding Adjustment as Required under Sections 7(b)(1)(A) and 7(b)(1)(B) of Pub. L. 110-90 and Documentation and Coding Recoupment Adjustment as required under Section 631 of the American Taxpayer Relief Act of 2012.	0.9118 .....	0.9118 .....	0.9118 .....	0.9118
Proposed FY 2017 New Labor Market Delimitation Wage Index 3-Year Hold Harmless Transition Budget Neutrality Factor.	0.999999 .....	0.999999 .....	0.999999 .....	0.999999
Proposed FY 2017 2-Midnight Rule One-Time Prospective Increase.	1.006 .....	1.006 .....	1.006 .....	1.006
Proposed National Standardized Amount for FY 2017 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (69.6/30.4).	Labor: \$3,836.20 ..... Nonlabor: \$1,675.59 ..	Labor: \$3,756.87 ..... Nonlabor: \$1,640.94 ..	Labor: \$3,809.76 ..... Nonlabor: \$1,664.04 ..	Labor: \$3,730.43 Nonlabor: \$1,629.39
Proposed National Standardized Amount for FY 2017 if Wage Index is less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38).	Labor: \$3,417.31 ..... Nonlabor: \$2,094.48 ..	Labor: \$3,346.64 ..... Nonlabor: \$2,051.17 ..	Labor: \$3,393.76 ..... Nonlabor: \$2,080.04 ..	Labor: \$3,323.09 Nonlabor: \$2,036.73

*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 on the CMS Web site), contain the proposed labor-related and nonlabor-related shares that we are proposing to use to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2017. This section addresses two types of adjustments to the standardized amounts that are made in determining the proposed prospective payment rates as described in this Addendum.

1. Proposed Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national prospective payment rate 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 2017 wage index.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make such adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described above. To account for higher nonlabor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii by an adjustment factor.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by the U.S. Office of

Personnel Management (OPM) every 4 years (at the same time as the update to the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively).

For FY 2014, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50985 through 50987), we updated the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule.

Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, we are proposing to continue to use the same COLA factors in FY 2017 that were used in FY 2016 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. Below is a table listing the proposed COLA factors for FY 2017.

PROPOSED FY 2017 COST-OF-LIVING ADJUSTMENT FACTORS: ALASKA AND HAWAII HOSPITALS

Area	Cost of living adjustment factor
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road .....	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road .....	1.23
City of Juneau and 80-kilometer (50-mile) radius by road .....	1.23
Rest of Alaska .....	1.25
Hawaii:	
City and County of Honolulu .....	1.25
County of Hawaii .....	1.19
County of Kauai .....	1.25
County of Maui and County of Kalawao .....	1.25

Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, the next update to the COLA factors for Alaska and Hawaii would occur in FY 2018.

### C. Calculation of the Proposed Prospective Payment Rates

#### General Formula for Calculation of the Prospective Payment Rates for FY 2017

In general, the operating prospective payment rate for all hospitals (including hospitals in Puerto Rico) paid under the IPPS, except SCHs and MDHs, for FY 2017 equals the Federal rate (which includes uncompensated care payments).

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (which, as discussed in section IV.F. of the preamble of this proposed rule, includes uncompensated care payments); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2017 equals the higher of the applicable Federal rate, or the hospital-specific rate as described below. The prospective payment rate for MDHs for FY 2017 equals the higher of the Federal rate, or the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate as described below. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987 or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

#### 1. Operating and Capital Federal Payment Rate and Outlier Payment Calculation

Note: The formula below is used for actual claim payment and is also used by CMS to project the outlier threshold for the upcoming FY. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described above) to project the threshold for the upcoming FY. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described above).

Step 1—Determine the MS-DRG and MS-DRG relative weight for each claim based on the ICD-10-CM procedure and diagnosis codes on the claim.

Step 2—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data and is a meaningful EHR user, as described above.

Step 3—Compute the operating and capital Federal payment rate:

—Federal Payment Rate for Operating Costs = MS-DRG Relative Weight × [(Labor-Related Applicable Standardized Amount × Applicable CBSA Wage Index) + (Nonlabor-Related Applicable Standardized Amount × Cost of Living Adjustment)] × (1 + IME + (DSH \* 0.25))

—Federal Payment for Capital Costs = MS-DRG Relative Weight × Federal Capital Rate × Geographic Adjustment Fact × (1 + IME + DSH)

Step 4—Determine operating and capital costs:

—Operating Costs = (Billed Charges × Operating cost-to-charge ratio)

—Capital Costs = (Billed Charges × Capital cost-to-charge ratio).

Step 5—Compute operating and capital outlier threshold (CMS applies a geographic adjustment to the operating and capital outlier threshold to account for local cost variation):

—Operating Cost-to-Charge Ratio to Total Cost-to-Charge Ratio = (Operating Cost-to-Charge Ratio)/(Operating Cost-to-Charge Ratio + Capital Cost-to-Charge Ratio)

—Operating Outlier Threshold = [Fixed Loss Threshold × ((Labor-Related Portion × CBSA Wage Index) + Nonlabor-Related portion)] × Operating Cost-to-Charge Ratio to Total Cost-to-Charge Ratio + Federal Payment with IME, DSH + Uncompensated Care Payment + New Technology Add-On Payment Amount

—Capital Cost-to-Charge Ratio to Total Cost-to-Charge Ratio = (Capital Cost-to-Charge Ratio)/(Operating Cost-to-Charge Ratio + Capital Cost-to-Charge Ratio)

—Capital Outlier Threshold = (Fixed Loss Threshold × Geographic Adjustment Factor × Capital CCR to Total CCR) + Federal Payment with IME and DSH

Step 6: Compute operating and capital outlier payments:

—Marginal Cost Factor = 0.80 or 0.90 (depending on the MS-DRG)

—Operating Outlier Payment = (Operating Costs—Operating Outlier Threshold) × Marginal Cost Factor

—Capital Outlier Payment = (Capital Costs—Capital Outlier Threshold) × Marginal Cost Factor

The payment rate may then be further adjusted 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 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. Payments also may be reduced by the 1-percent adjustment under the HAC Reduction Program as described in section 1886(p) of the Act. We also make new technology add-on payments

in accordance with section 1886(d)(5)(K) and (L) of the Act. Finally, we add the uncompensated care payment to the total claim payment amount. As noted in the formula above, we take uncompensated care payments and new technology add-on payments into consideration when calculating outlier payments.

#### 2. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

##### a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

As noted above, section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10) extended the MDH program through FY 2017 (that is, for discharges occurring on or before September 30, 2017). Currently MDHs are paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the greater of the updated hospital-specific rates based on either FY 1982, FY 1987 or FY 2002 costs per discharge.

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

##### b. Updating the FY 1982, FY 1987, FY 1996, FY 2002 and FY 2006 Hospital-Specific Rate for FY 2017

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the proposed applicable percentage increases to the hospital-specific rates applicable to SCHs and MDHs are the following:

FY 2017	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Proposed Market Basket Rate-of-Increase .....	2.8	2.8	2.8	2.8
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act .....	0.0	0.0	-0.7	-0.7
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act .....	0.0	-2.1	0.0	-2.1
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act .....	-0.5	-0.5	-0.5	-0.5
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act .....	-0.75	-0.75	-0.75	-0.75
Proposed Applicable Percentage Increase Applied to Hospital-Specific Rate	1.55	-0.55	0.85	-1.25

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs and MDHs, we refer readers to section IV.B. of the preamble of this proposed rule.

In addition, because SCHs and MDHs use the same MS-DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS-DRG classifications and the recalibration of the MS-DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, the hospital-specific rate for an SCH or an MDH is adjusted by the proposed MS-DRG reclassification and recalibration budget neutrality factor of 0.999006, as discussed in section III. of this Addendum. The resulting rate is used in determining the payment rate that an SCH or MDH will receive for its discharges beginning on or after October 1, 2016. We note that, in this proposed rule, for FY 2017, we are not proposing to make a documentation and coding adjustment to the hospital-specific rate. We refer readers to section II.D. of the preamble of this proposed rule for a complete discussion regarding our proposed policies and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case-mix. Also, as discussed above and in section IV.O. of the preamble of this proposed rule, we are proposing an adjustment to the hospital-specific rates using our authority under section 1886(d)(5)(I)(i) of the Act to permanently prospectively remove the 0.2 percent reduction to the rates put in place in FY 2014 to offset the estimated increase in IPPS expenditures as a result of the 2-midnight policy. In addition, as discussed above and in section IV.O. of the preamble of this proposed rule, we are proposing a temporary one-time prospective increase to the FY 2017 hospital-specific rates of 0.6 percent by including a temporary one-time factor of 1.006 in the calculation of the hospital-specific rates, using our authority under section 1886(d)(5)(I)(i) of the Act, to address the effects of the 0.2 percent reduction to the rates for the 2-midnight policy in effect for FY 2014, FY 2015, and FY 2016.

### III. Proposed Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2017

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 §§ 412.308 through 412.352. In this section, we discuss the factors that we used to determine the proposed capital Federal rate for FY 2017, which would be effective for discharges occurring on or after October 1, 2016.

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, historically, under the capital PPS, we have computed 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. Effective with discharges occurring on or after October 1, 2004, in conjunction with the change to the operating payment methodology, we adopted a methodology for computing capital payments made to hospitals located in Puerto Rico 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). Effective with discharges on or after January 1, 2016, operating IPPS payments to hospitals located in Puerto Rico are now based on 100 percent of the Federal rate—the operating payment methodology is no longer a blend of 75 percent of the Federal rate and 25 percent of the Puerto Rico rate. Consistent with historical practice and under the authority of section 1886(g) of the Act, as discussed in section V.B.3. of the preamble of this proposed rule, we are proposing that the capital IPPS payments to hospitals located in Puerto Rico would be based on 100 percent of the capital Federal rate, effective with discharges on or after October 1, 2016, and would no longer be based on the current 75/25 blended rate.

#### A. Determination of the Proposed Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update

In the discussion that follows, we explain the factors that we used to determine the proposed capital Federal rate for FY 2017. In particular, we explain why the proposed FY 2017 capital Federal rate increases approximately 1.7 percent, compared to the FY 2016 capital Federal rate. As discussed in the impact analysis in Appendix A to this proposed rule, we estimate that capital payments per discharge will increase approximately 2.0 percent during that same period. Because capital payments constitute approximately 10 percent of hospital

payments, a percent change in the capital Federal rate yields only approximately 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 2017 under that framework is 0.9 percent based on the best data available at the time of development of this proposed rule. The proposed update factor under that framework is based on a projected 1.2 percent increase in the FY 2010-based CIPI, a 0.0 percentage point adjustment for intensity, a 0.0 percentage point adjustment for case-mix, a 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a forecast error correction of -0.3 percentage point. As discussed 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 2017 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 2017.

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 patient 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 2017, we are projecting a 0.5 percent total increase in the case-mix index.

We estimated that the real case-mix increase will equal 0.5 percent for FY 2017. The 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, we are proposing the net adjustment for case-mix change in FY 2017 of 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 2015 DRG reclassification and recalibration as part of our update for FY 2017. We estimate that FY 2015 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 a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2017.

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. Historically, when a forecast error of the CIPI is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended under this framework. A forecast error of -0.3 percentage point was calculated for the FY 2015 update, for which there are historical data. That is, current historical data indicate that the forecasted FY 2015 CIPI (1.5 percent) used in calculating the FY 2015 update factor was 0.3 percentage points higher than actual realized price increases (1.2 percent). This over-prediction was primarily due to prices from municipal bond yields declining in 2015 whereas the forecast projected an increase. Therefore, we are proposing to make a -0.3 percentage point adjustment for forecast error in the update for FY 2017.

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 CPI 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 continuing to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2017 (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 2017, we are using an intensity measure that is based on an average of cost per discharge data from the 5-year period beginning with FY 2010 and extending through FY 2014. Based on these data, we estimated that case-mix constant intensity declined during FYs 2010 through 2014. 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 continue to apply a zero intensity adjustment for FY 2017. Therefore, we are proposing to make a 0.0 percentage point adjustment for intensity in the update for FY 2017.

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 2017 as shown in the following table.

**PROPOSED CMS FY 2017 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 2015 Reclassification and Recalibration .....	0.0
Forecast Error Correction .....	-0.3
<b>Total Update .....</b>	<b>0.9</b>

\* The capital input price index represents the FY 2010-based CIPI.

#### b. Comparison of CMS and MedPAC Update Recommendation

In its March 2016 Report to Congress, MedPAC did not make a specific update recommendation for capital IPPS payments for FY 2017. (We refer readers to MedPAC's Report to the Congress: Medicare Payment Policy, March 2016, Chapter 3, available on the Web site at: <http://www.medpac.gov>.)

#### 2. Proposed 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 2016, we estimated that outlier payments for capital would equal 6.35 percent of inpatient capital-related payments based on the capital Federal rate in FY 2016. Based on the proposed thresholds as set forth in section II.A. of this Addendum, we estimate that outlier payments for capital-related costs will equal 6.26 percent for inpatient capital-related payments based on the proposed capital Federal rate in FY 2017. Therefore, we are proposing to apply an outlier adjustment factor of 0.9374 in determining the capital Federal rate for FY 2017. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2017 will be lower than the percentage for FY 2016.

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 2017 outlier adjustment of 0.9374 is a 0.10 percent change from the FY 2016 outlier adjustment of 0.9365. Therefore, the net change in the outlier adjustment to the proposed capital Federal rate for FY 2017 is 1.0010 (0.9374/0.9365). Thus, the proposed outlier adjustment will increase the FY 2017 capital Federal rate by 0.10 percent compared to the FY 2016 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 are proposing to determine capital IPPS payments to hospitals located in Puerto Rico based on 100 percent of the capital Federal rate beginning in FY 2017, we have not calculated a separate GAF for Puerto Rico, and therefore, we are not applying a separate budget neutrality

adjustment for the Puerto Rico GAF. Similarly, the budget neutrality factor for DRG reclassifications and recalibration nationally is applied in determining the capital IPPS Federal rate, and is applicable for all hospitals, including those hospitals located in Puerto Rico.

To determine the proposed national capital rate factors for FY 2017, we compared estimated aggregate capital Federal rate payments based on the FY 2016 MS-DRG classifications and relative weights and the FY 2016 GAF to estimated aggregate capital Federal rate payments based on the FY 2016 MS-DRG classifications and relative weights and the proposed FY 2017 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 0.9997 for FY 2017 to the previous cumulative FY 2016 adjustment factor of 0.9860, yielding an adjustment factor of 0.9857 through FY 2017.

We then compared estimated aggregate capital Federal rate payments based on the FY 2016 MS-DRG relative weights and the proposed FY 2017 GAFs to estimated aggregate capital Federal rate payments based on the cumulative effects of the proposed FY 2017 MS-DRG classifications and relative weights and the proposed FY 2017 GAFs. The proposed incremental adjustment factor for DRG classifications and changes in relative weights is 0.9996. The proposed cumulative adjustment factor for MS-DRG classifications and proposed changes in relative weights and for proposed changes in the GAFs through FY 2017 is 0.9853. (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 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 of 0.9993 (the product of the proposed incremental national GAF budget neutrality adjustment factor of 0.9997 and the proposed

incremental DRG budget neutrality adjustment factor of 0.9996) accounts for the MS-DRG reclassifications and recalibration and for changes in the GAFs. It also incorporates the effects on the GAFs of FY 2017 geographic reclassification decisions made by the MGCRB compared to FY 2016 decisions. However, it does not account for changes in payments due to changes in the DSH and IME adjustment factors.

As discussed in section V.C. of the preamble of this proposed rule, we are proposing to make an adjustment of (1/0.998) to the proposed national capital Federal rate to remove the 0.2 percent reduction (an adjustment factor of 0.998) to the national capital Federal rate to offset the estimated increase in capital IPPS expenditures associated with the 2-midnight policy. This is consistent with the proposed adjustment to the operating IPPS standardized amount and the hospital-specific payment rates. In addition, consistent with the approach proposed for the operating IPPS standardized amount and hospital-specific payment rates and for the reasons discussed in sections IV.O. and V.C. of the preamble of this proposed rule, we are proposing a one-time prospective adjustment of 1.006 in FY 2017 to the proposed national capital Federal rate to address the effect of the 0.2 percent reduction to the national capital Federal rates in effect for FY 2014, FY 2015, and FY 2016. We also are proposing to remove this one-time prospective adjustment through an adjustment of (1/1.006) to the national capital Federal rate in FY 2018, consistent with the approach proposed for the operating IPPS standardized amount and hospital-specific payment rates (as discussed in section IV.O. of the preamble of this proposed rule). We refer readers to sections IV.O. and V.C. of the preamble of this proposed rule for a complete discussion of these proposals.

#### 4. Proposed Capital Federal Rate for FY 2017

For FY 2016, we established a capital Federal rate of \$438.75 (as revised, in the FY 2016 IPPS/LTCH PPS correction notice CMS-1632-CN2 (80 FR 60060 and 60061)). We are proposing to establish an update of 0.9 percent in determining the FY 2017 capital Federal rate for all hospitals. As a result of this proposed update, the proposed budget neutrality factors discussed earlier, and the proposed adjustments to remove the 0.2 percent reductions (both the (1/0.998) adjustment to permanently remove the 0.2 percent reduction and the one-time 0.6 percent adjustment) resulting from the 2-midnight policy, we are proposing to establish a national capital Federal rate of \$446.35 for FY 2017. The proposed national capital Federal rate for FY 2017 was calculated as follows:

- The proposed FY 2017 update factor is 1.009, that is, the proposed update is 0.9 percent.
- The proposed FY 2017 budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the MS-DRG classifications and relative weights and changes in the GAFs is 0.9993.
- The proposed FY 2017 outlier adjustment factor is 0.9374.

- The proposed 2-midnight policy adjustment to permanently remove the 0.2 percent reduction is (1/0.998).
- The proposed 2-midnight one-time policy adjustment is 1.006.

(We note that, as discussed in section V.C. of the preamble of this proposed rule, we are not making an additional MS-DRG documentation and coding adjustment to the proposed capital IPPS Federal rate for FY 2017.)

Because the proposed FY 2017 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 budget neutrality factor for changes in the MS-DRG classifications and relative weights and for changes in the GAFs.

We are providing the following chart that shows how each of the proposed factors and adjustments for FY 2017 affects the computation of the proposed FY 2017 national capital Federal rate in comparison to the FY 2016 national capital Federal rate. The proposed FY 2017 update factor has the effect of increasing the capital Federal rate by 0.9 percent compared to the FY 2016 capital Federal rate. The proposed GAF/DRG budget neutrality adjustment factor has the effect of

decreasing the proposed capital Federal rate by 0.07 percent. The proposed FY 2017 outlier adjustment factor has the effect of increasing the proposed capital Federal rate by 0.10 percent compared to the FY 2016 capital Federal rate. The proposed permanent 2-midnight policy adjustment has the effect of increasing the proposed capital Federal rate by 0.2 percent and the proposed temporary 2-midnight policy adjustment has the effect of increasing the proposed capital Federal rate by 0.6 percent. The combined effect of all the proposed changes would increase the proposed national capital Federal rate by approximately 1.7 percent compared to the FY 2016 national capital Federal rate.

**COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2016 CAPITAL FEDERAL RATE AND PROPOSED FY 2017 CAPITAL FEDERAL RATE**

	FY 2016	Proposed FY 2017	Change	Percent change
Update Factor <sup>1</sup> .....	1.0130	1.009	1.009	0.9
GAF/DRG Adjustment Factor <sup>1</sup> .....	0.9976	0.9993	0.9993	-0.07
Outlier Adjustment Factor <sup>2</sup> .....	0.9365	0.9374	1.0010	0.10
Permanent 2-midnight Policy Adjustment Factor .....	N/A	1.002	1.002	0.2
One-Time 2-midnight Policy Adjustment Factor .....	N/A	1.006	1.006	0.6
Capital Federal Rate .....	\$438.75	\$446.35	1.0173	1.73

<sup>1</sup> The proposed update factor and the proposed GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rates. Thus, for example, the incremental change from FY 2016 to FY 2017 resulting from the application of the proposed 0.9993 GAF/DRG budget neutrality adjustment factor for FY 2017 is a net change of 0.9993 (or -0.07 percent).

<sup>2</sup> The proposed outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the proposed FY 2017 outlier adjustment factor is 0.9374/0.9365, or 1.0010 (or 0.10 percent).

**B. Calculation of the Proposed Inpatient Capital-Related Prospective Payments for FY 2017**

For purposes of calculating payments for each discharge during FY 2017, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year. Section 412.312(c) provides for a single set of thresholds to identify outlier cases for both inpatient operating and inpatient capital-related payments. The proposed outlier thresholds for FY 2017 are in section II.A. of this Addendum. For FY 2017, a case would qualify as a cost outlier if the cost for the case plus the (operating) IME and DSH payments (including both the empirically justified Medicare DSH payment and the estimated uncompensated care payment, as discussed in section II.A.4.g.(1) of this Addendum) is greater than the prospective payment rate for the MS-DRG plus the proposed fixed-loss amount of \$23,681.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the

same methodology used to pay all other hospitals subject to the capital PPS).

**C. Capital Input Price Index**

**1. Background**

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50603 through 50607), we rebased and revised the CIPI to a FY 2010 base year to reflect the more current structure of capital costs in hospitals. For a complete discussion of this rebasing, we refer readers to the FY 2014 IPPS/LTCH PPS final rule.

**2. Forecast of the CIPI for FY 2017**

Based on the latest forecast by IHS Global Insight, Inc. (first quarter of 2016), we are forecasting the FY 2010-based CIPI to increase 1.2 percent in FY 2017. This reflects a projected 1.6 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 2.6 percent increase in other capital expense prices in FY 2017, partially offset by a projected 1.5 percent decline in vintage-weighted interest expense prices in FY 2017. The weighted average of these three factors produces the forecasted 1.2 percent increase for the FY 2010-based CIPI as a whole in FY 2017.

**IV. Proposed Changes to Payment Rates for Excluded Hospitals: Proposed Rate-of-Increase Percentages for FY 2017**

Payments for services furnished in children’s hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are made on the basis of reasonable costs based on the hospital’s own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital’s own cost experience in its base year, and updated annually by a rate-of-increase percentage. (We note that, in accordance with § 403.752(a), RNHCIs are also subject to the

rate-of-increase limits established under § 413.40 of the regulations.)

In this proposed rule, the FY 2017 rate-of-increase percentage for updating the target amounts for the 11 cancer hospitals, children's hospitals, the short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNHCIs is the estimated percentage increase in the IPPS operating market basket for FY 2017, in accordance with applicable regulations at § 413.40. Based on IHS Global Insight, Inc.'s 2016 first quarter forecast, we estimated that the FY 2010-based IPPS operating market basket update for FY 2017 would be 2.8 percent (that is, the estimate of the market basket rate-of-increase). However, we proposed 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 2017. Therefore, based on IHS Global Insight, Inc.'s 2016 first quarter forecast, with historical data through 2015 fourth quarter, we estimate that the FY 2010-based IPPS operating market basket update for FY 2017 is 2.8 percent (that is, the estimate of the market basket rate-of-increase). For children's hospitals, the 11 cancer hospitals, hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and RNHCIs, the proposed FY 2017 rate-of-increase percentage that would be applied to the FY 2016 target amounts in order to determine the proposed FY 2017 target amounts is 2.8 percent.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule for the proposed update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2017. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

## V. Proposed Changes to the Payment Rates for the LTCH PPS for FY 2017

### A. Proposed LTCH PPS Standard Federal Payment Rate for FY 2017

#### 1. Background

In section VII. of the preamble of this proposed rule, we discuss our proposed annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2017.

Under § 412.523(c)(3)(ii) of the regulations, for LTCH PPS rate years beginning RY 2004 through RY 2006, we updated the standard Federal rate annually by a factor to adjust for the most recent estimate of the increases in prices of an appropriate market basket of goods and services for LTCHs. We established this policy of annually updating the standard Federal rate because, at that time, we believed that was the most appropriate method for updating the LTCH PPS standard Federal rate for years after the initial implementation of the LTCH PPS in FY 2003. Therefore, under § 412.523(c)(3)(ii),

for RYs 2004 through 2006, the annual update to the LTCH PPS standard Federal rate was equal to the previous rate year's Federal rate updated by the most recent estimate of increases in the appropriate market basket of goods and services included in covered inpatient LTCH services.

In determining the annual update to the standard Federal rate for RY 2007, based on our ongoing monitoring activity, we believed that, rather than solely using the most recent estimate of the LTCH PPS market basket update as the basis of the annual update factor, it was appropriate to adjust the standard Federal rate to account for the effect of documentation and coding in a prior period that was unrelated to patients' severity of illness (71 FR 27818). Accordingly, we established under § 412.523(c)(3)(iii) that the annual update to the standard Federal rate for RY 2007 was zero percent based on the most recent estimate of the LTCH PPS market basket at that time, offset by an adjustment to account for changes in case-mix in prior periods due to the effect of documentation and coding that were unrelated to patients' severity of illness. For RY 2008 through FY 2011, we also made an adjustment to account 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 through 2016, we updated the standard Federal rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by section 1886(m)(3)(A) of the Act as set forth in the regulations at §§ 412.523(c)(3)(viii) through (c)(3)(ix).

Section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year, any annual update to the standard Federal rate shall be reduced:

- For rate year 2010 through 2019, by the other adjustment specified in section 1886(m)(3)(A)(ii) and (m)(4) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (which we refer to as "the multifactor productivity (MFP) adjustment") as discussed in section VII.E.2. of the preamble of this proposed rule.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VII.E.2.a. of the preamble of this proposed rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term "fiscal year" (FY) rather than "rate year" (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term "fiscal year" rather than "rate year" for 2011 and subsequent years.)

For FY 2016, consistent with our historical practice, we established an update to the

LTCH PPS standard Federal payment rate based on the full estimated LTCH PPS market basket increase of 2.4 percent and the 0.7 percentage point reductions required by sections 1886(m)(3)(A)(i) and 1886(m)(3)(A)(ii) with 1886(m)(4)(E) of the Act. Accordingly, at § 412.523(c)(3)(xii) of the regulations, we established an annual update of 1.7 percent to the standard Federal payment rate for FY 2016 (80 FR 49636 through 49637). In addition, as discussed in that same final rule, the annual update for FY 2016 was further reduced by 2.0 percentage points for LTCHs that failed to submit quality reporting data in accordance with the requirements of the LTCH QRP under section 1886(m)(5) of the Act.

For FY 2017, in this proposed rule, based on the best available data, we are proposing an annual update to the LTCH PPS standard Federal payment rate of 1.45 percent, which is based on the full estimated increase in the LTCH PPS market basket of 2.7 percent, less the MFP adjustment of 0.5 percentage point consistent with section 1886(m)(3)(A)(i) of the Act, and less the 0.75 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(F) of the Act. (As discussed in section VII.E. of the preamble of this proposed rule, we are proposing to rebase and revise the 2009-based LTCH-specific market basket to reflect a 2013 base year.) For LTCHs that fail to submit the required quality reporting data for FY 2017 in accordance with the LTCH QRP, the annual update is further reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act (as discussed in greater detail in section VII.E.2.c. of the preamble of this proposed rule). Accordingly, we are proposing an annual update to the LTCH PPS standard Federal payment rate of -0.55 percent for LTCHs that fail to submit the required quality reporting data for FY 2017. This proposed -0.55 percent update was calculated based on the full estimated increase in the LTCH PPS market basket of 2.7 percent, less a MFP adjustment of 0.5 percentage point, less an additional adjustment of 0.75 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 2017 LTCH PPS Standard Federal Payment Rate

We continue to believe that the annual update to the LTCH PPS standard Federal payment 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 2017, we are proposing to apply the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the LTCH PPS standard Federal payment rate for FY 2017, we also are proposing to make certain regulatory adjustments, consistent with past practices. Specifically, in determining the proposed FY 2017 LTCH PPS standard Federal payment rate, we are proposing to apply a budget neutrality adjustment factor for the proposed 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). We also are proposing to use more recent data to



determine the update to the LTCH PPS standard Federal payment rate for FY 2017 in the final rule.

For FY 2016, we established an annual update to the LTCH PPS standard Federal payment rate of 1.7 percent based on the full estimated LTCH PPS market basket increase of 2.4 percent, less the MFP adjustment of 0.5 percentage point consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.2 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(E) of the Act. Accordingly, at § 412.523(c)(3)(xii), we established an annual update to the LTCH PPS standard Federal payment rate for FY 2015 of 1.7 percent. That is, we applied an update factor of 1.017 to the FY 2015 Federal rate of \$41,043.71 to determine the FY 2016 LTCH PPS standard Federal payment rate. We also applied an area wage level budget neutrality factor for FY 2016 of 1.000513 to the LTCH PPS standard Federal payment rate to ensure that any changes to the area wage level adjustment would not result in any change in estimated aggregate LTCH PPS payments. Consequently, we established a LTCH PPS standard Federal payment rate for FY 2016 of \$41,762.85 (calculated as  $\$41,043.71 \times 1.017 \times 1.000513$ ) (80 FR 49797).

In this proposed rule, we are proposing an annual update to the LTCH PPS standard Federal payment rate of 1.45 percent, which was determined using the methodology previously described. Accordingly, under § 412.523(c)(3)(xiii), we are proposing to apply a factor of 1.0145 to the FY 2017 LTCH PPS standard Federal payment rate of \$41,762.85 to determine the proposed FY 2017 LTCH PPS standard Federal payment rate. These factors are based on IGI's first quarter 2016 forecast, which are the best available data at this time. For LTCHs that fail to submit quality reporting data for FY 2017 under the LTCH QRP, under proposed § 412.523(c)(3)(xiii), applied in conjunction with the provisions of § 412.523(c)(4), we are proposing to reduce the annual update to the LTCH PPS standard Federal payment rate by an additional 2.0 percentage points, consistent with section 1886(m)(5) of the Act. In those cases, the LTCH PPS standard Federal payment rate is updated by -0.55 percent (that is, a proposed update factor of 0.9945) for FY 2017 for LTCHs that fail to submit the required quality reporting data for FY 2017 as required under the LTCH QRP. Consistent with § 412.523(d)(4), we also are proposing to apply an area wage level budget neutrality factor to the FY 2017 LTCH PPS standard Federal payment rate of 0.998723, which was determined using the methodology described below in section V.B.4. of this Addendum. We are proposing to apply this area wage level budget neutrality factor to the FY 2017 LTCH PPS standard Federal payment 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) will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Accordingly, we are proposing a LTCH PPS standard Federal payment rate of \$42,314.31 (calculated as  $\$41,762.85 \times 1.0145$

$\times 0.998723$ ) for FY 2017. For LTCHs that fail to submit quality reporting data for FY 2017 in accordance with the requirements of the LTCHQRP under section 1886(m)(5) of the Act, we are proposing a LTCH PPS standard Federal payment rate of \$41,480.12 (calculated as  $\$41,762.85 \times 0.9945 \times 0.998723$ ) for FY 2017. We note, as discussed in section VII.B. of the preamble of this proposed rule, under our application of the site neutral payment rate required under section 1886(m)(6) of the Act, this LTCH PPS standard Federal payment rate will only be used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate).

#### *B. Proposed Adjustment for Area Wage Levels Under the LTCH PPS for FY 2017*

##### 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 payment rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related share of the LTCH PPS standard Federal payment rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

When we implemented the LTCH PPS, we established a 5-year transition to the full area wage level adjustment. The area wage level adjustment was completely phased-in for cost reporting periods beginning in FY 2007. Therefore, for cost reporting periods beginning on or after October 1, 2006, the applicable LTCH area wage index values are the full LTCH PPS area wage index values calculated based on acute care hospital inpatient wage index data without taking into account geographic reclassification under section 1886(d)(8) and section 1886(d)(10) of the Act. For additional information on the phase-in of the area wage level adjustment under the LTCH PPS, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56015 through 56019) and the RY 2008 LTCH PPS final rule (72 FR 26891).

##### 2. Proposed Geographic Classifications (Labor Market Areas) for the LTCH PPS Standard Federal Payment Rate

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an “urban area,” or a “rural area,” as defined in § 412.503. Under § 412.503, an “urban area” is defined as a Metropolitan Statistical Area (MSA) (which includes a Metropolitan division, where applicable), as defined by the Executive OMB and a “rural

area” is defined as any area outside of an urban area. (Information on OMB's MSA delineations based on the 2010 standards can be found at: [http://www.whitehouse.gov/sites/default/files/omb/assets/jedreg\\_2010/06282010\\_metro\\_standards-Complete.pdf](http://www.whitehouse.gov/sites/default/files/omb/assets/jedreg_2010/06282010_metro_standards-Complete.pdf)).

The CBSA-based geographic classifications (labor market area definitions) currently used under the LTCH PPS, effective for discharges occurring on or after October 1, 2014, are based on the OMB labor market area delineations based on the 2010 Decennial Census data. The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. We adopted these labor market area delineations because they are based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas. We also believe that these OMB delineations will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We noted that this policy was consistent with the IPPS policy adopted in FY 2015 under § 412.64(b)(1)(ii)(D) of the regulations (79 FR 49951 through 49963). (For additional information on the CBSA-based labor market area (geographic classification) delineations currently used under the LTCH PPS and the history of the labor market area definitions used under the LTCH PPS, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).)

In general, it is our historical practice to update the CBSA-based labor market area delineations annually based on the most recent updates issued by OMB. Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. As discussed in section III.A.2. of the preamble of this proposed rule, the updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. A copy of this bulletin may be obtained on the Web site at: <https://www.whitehouse.gov/omb/bulletins/>.

OMB Bulletin No. 15–01 made the following changes that are relevant to the LTCH PPS CBSA-based labor market area (geographic classification) delineations:

- Garfield County, OK, with principal city Enid, OK, which was a Micropolitan (geographically rural) area, now qualifies as an urban area under new CBSA 21420 entitled Enid, OK.
- The county of Bedford City, VA, a component of the Lynchburg, VA CBSA

31340, changed to town status and is added to Bedford County. Therefore, the county of Bedford City is now part of the county of Bedford, VA. The CBSA remains Lynchburg, VA, 31340.

- The name of Macon, GA, CBSA 31420, as well as a principal city of the Macon-Warner Robins, GA combined statistical area, is now Macon-Bibb County, GA. The CBSA code remains as 31420.

We believe that these revisions to the CBSA-based labor market area delineations will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas and, therefore, we are proposing to adopt them under the LTCH PPS, effective October 1, 2016. Accordingly, the proposed FY 2017 LTCH PPS wage index values in Tables 12A and 12B listed in section VI. of the Addendum of this proposed rule (which are available via the Internet on the CMS Web site) reflect the revisions to the CBSA-based labor market area delineations described above. We note that, as discussed in section III.C.2. of the preamble of this proposed rule, the revisions to the CBSA-based delineations also are proposed for adoption under the IPPS, effective beginning October 1, 2016.

### 3. Proposed Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's standard Federal payment rate 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 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, beginning in FY 2013, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2009-based LTCH-specific market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479).) As noted previously, we are proposing to rebase and revise the 2009-based LTCH-specific market basket to reflect a 2013 base year. In conjunction with that

proposal, as discussed in section VII.D.4.e. of the preamble of this proposed rule, we are proposing that the LTCH PPS labor-related share for FY 2017 would be the sum of the FY 2017 relative importance of each labor-related cost category in the proposed 2013-based LTCH market basket using the most recent available data. Specifically, we are proposing that the labor related share for FY 2017 would include the sum of the labor-related portion of operating costs from the proposed 2013-based LTCH market basket (that is, the sum of the FY 2017 relative importance share of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services) and a portion of the Capital-Related cost weight from the proposed 2013-based LTCH PPS market basket. Based on IGI's first quarter 2016 forecast of the proposed 2013-based LTCH market basket, we are proposing a labor-related share under the LTCH PPS for FY 2017 of 66.6 percent. This proposed labor-related share is determined using the same methodology as employed in calculating all previous LTCH PPS labor-related shares. Consistent with our historical practice, we are proposing to use more recent data to determine the final FY 2017 labor-related share in the final rule.

Table VII-9 in section VII.D.4.e. of the preamble of this proposed rule shows the proposed FY 2017 relative importance labor-related share using the proposed 2013-based LTCH market basket and the FY 2016 relative importance labor-related share using the 2009-based LTCH-specific market basket. The proposed labor-related share for FY 2017 is the sum of the proposed FY 2017 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 (2013) and FY 2017. The sum of the proposed relative importance for FY 2017 for operating costs (Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services) is 62.3 percent. We are proposing that the portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent (the same percentage applied to the 2009-based LTCH-specific market basket). Because the relative importance for capital-related costs under our proposals would be 9.4 percent of the proposed 2013-based LTCH market basket in FY 2017, we are proposing to take 46 percent of 9.4 percent to determine the proposed labor-related share of capital-related costs for FY 2017 (0.46 x 9.4). The result is 4.3 percent, which we are proposing to add to 62.3 percent for the operating cost amount to determine the total proposed labor-related share for FY 2017. Therefore, the proposed labor-related share under the LTCH PPS for FY 2017 is 66.6 percent. We note that the proposed FY 2017 labor-related share using the proposed 2013-based LTCH market basket is 4.6 percentage points higher than the FY 2016 labor-related share using the 2009-based LTCH-specific market basket. This is primarily due to, as discussed in

greater detail in section VII.D.4.e. of the preamble of this proposed rule, the change in the quantity of labor, particularly for professional services, outpacing the change in quantity of products (which are not included in the labor-related share) between 2009 and 2013, which more than offsets the faster relative growth in prices for products.

### 4. Proposed Wage Index for FY 2017 for the LTCH PPS Standard Federal Payment Rate

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the "urban" or "rural" designation of any related or affiliated provider.

In the FY 2016 LTCH PPS final rule (80 FR 49798 through 49799), we calculated the FY 2016 LTCH PPS area wage index values using the same data used for the FY 2016 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2012), 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 2016 LTCH PPS area wage index values, consistent with the urban and rural geographic classifications (labor market areas) that were in place at that time and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments under the LTCH PPS). As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also continued to use our existing policy for determining area wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable area wage index values for the FY 2017 LTCH PPS standard Federal payment rate, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to use wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2013, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act, because these data are the most recent complete data available. We also note that these are the same data we are using to compute the proposed FY 2017 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this proposed rule. We are computing the proposed FY 2017 LTCH PPS standard Federal payment rate area wage index values consistent with the "urban" and "rural" geographic classifications (that is, labor market area delineations, including the proposed updates, as previously discussed in section V.B.2. of this Addendum) and 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. We also are proposing to continue to apportion wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, consistent with our existing methodology for determining the LTCH PPS wage index values, for FY 2017 we are proposing to continue to use our existing policy for determining area wage index values for areas where there are no IPPS wage data.

Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data would be 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 would be 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 2013 IPPS wage data that we are using to determine the proposed FY 2017 LTCH PPS standard Federal payment rate area wage index values in this proposed rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with the methodology discussed above, we calculated the proposed FY 2017 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 the FY 2013 IPPS wage data that we are using to determine the proposed FY 2017 LTCH PPS standard Federal payment rate area 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 proposed LTCH PPS standard Federal payment rate wage index value for rural areas with no IPPS wage data for FY 2017. We note that, as IPPS wage data are dynamic, it is possible that the number of rural areas without IPPS wage data will vary in the future. The proposed FY 2017 LTCH PPS standard Federal payment rate wage index values that would be applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2016, through September 30, 2017, 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 LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage-level adjustment budget neutrality factor that will be applied to the standard Federal payment rate to ensure that any changes to the area wage level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we apply an area wage level adjustment budget neutrality factor in determining the standard Federal payment 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).)

In this proposed rule, for FY 2017 LTCH PPS standard Federal payment rate cases, in accordance with § 412.523(d)(4), we are proposing to apply an area wage level adjustment budget neutrality factor to adjust the LTCH PPS standard Federal payment rate to account for the estimated effect of the proposed adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments using a methodology that is consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). Specifically, we are proposing to determine an area wage level adjustment budget neutrality factor that would be applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2017 using the following methodology:

*Step 1*—We simulated estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2016 wage index values and the FY 2016 labor-related share of 62.0 percent (as established in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49798 and 49799)).

*Step 2*—We simulated estimated aggregate LTCH PPS standard Federal payment rate payments using the proposed FY 2017 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 2017 labor-related share of 66.6 percent (based on the latest available data as previously discussed previously in this Addendum).

*Step 3*—We calculated the ratio of these estimated total LTCH PPS standard Federal payment rate payments by dividing the estimated total LTCH PPS standard Federal

payment rate payments using the FY 2016 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the proposed FY 2017 area wage level adjustments (calculated in Step 2) to determine the proposed area wage level adjustment budget neutrality factor for FY 2017 LTCH PPS standard Federal payment rate payments.

*Step 4*—We then applied the proposed FY 2017 area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2017 LTCH PPS standard Federal payment rate after the application of the proposed FY 2017 annual update (discussed previously in section V.A.2. of this Addendum).

We note that, with the exception of cases subject to the transitional blend payment rate provisions in the first 2 years, under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. Because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, we only used data from claims that would have qualified for payment at the LTCH PPS standard Federal payment rate if such rate were in effect at the time of discharge to calculate the FY 2017 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor described above.

For this proposed rule, using the steps in the methodology previously described, we determined a proposed FY 2017 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 0.998723. Accordingly, in section V.A.2. of the Addendum to this proposed rule, to determine the proposed FY 2017 LTCH PPS standard Federal payment rate, we are applying a proposed area wage level adjustment budget neutrality factor of 0.998723, in accordance with § 412.523(d)(4). The proposed FY 2017 LTCH PPS standard Federal payment rate shown in Table 1E of the Addendum to this proposed rule reflects this adjustment factor.

#### C. Proposed Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels previously described.

Under our current methodology, we 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) (77 FR 53712 through 53713). This

methodology is based on a comparison of the growth in the Consumer Price Indexes (CPIs) for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). It also includes a 25-percent cap on the CPI-updated COLA factors. (For additional details on our current methodology for updating the COLA factors for Alaska and Hawaii, we refer readers to section VII.D.3. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53481 through 53482).)

We continue to believe that determining updated COLA factors using this methodology would appropriately adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii. Under our current policy, we update the COLA factors using the methodology described above every 4 years; the first year began in FY 2014 (77 FR 53482). Therefore, in this proposed rule for FY 2017, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of the BIPA, to determine appropriate payment adjustments under the LTCH PPS, we are proposing to continue to use the COLA factors based on the 2009 OPM COLA factors updated through 2012 by the comparison of the growth in the CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as established in the FY 2014 IPPS/LTCH PPS final rule. (We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50998) for a discussion of the FY 2014 COLA factors.) Consistent with our historical practice, we are proposing to establish that the COLA factors shown in the following table will be used to adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii under § 412.525(b).

**PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII HOSPITALS UNDER THE LTCH PPS FOR FY 2017**

<b>Alaska:</b>	
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
<b>Hawaii:</b>	
City and County of Honolulu .....	1.25
County of Hawaii .....	1.19
County of Kauai .....	1.25
County of Maui and County of Kalawao .....	1.25

*D. Proposed Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases*

1. HCO Background

From the beginning of the LTCH PPS, we have included an adjustment to account for

cases in which there are extraordinarily high costs relative to the costs of most discharges. Under this policy, additional payments are made based on the degree to which the estimated cost of a case (which is calculated by multiplying the Medicare allowable covered charge by the hospital's overall hospital CCR) exceeds a fixed-loss amount. This policy results in greater payment accuracy under the LTCH PPS and the Medicare program, and the LTCH sharing the financial risk for the treatment of extraordinarily high-cost cases.

We retained the basic tenets of our HCO policy in FY 2016 when we implemented the dual rate LTCH PPS payment structure under section 1206 of Public Law 113-67. LTCH discharges that meet the criteria for exclusion from site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid at the LTCH PPS standard Federal payment rate, which includes, as applicable, HCO payments under § 412.523(e). LTCH discharges that do not meet the criteria for exclusion are paid at the site neutral payment rate, which includes, as applicable, HCO payments under § 412.522(c)(2)(i). In the same rule, we established separate fixed-loss amounts and targets for the two different LTCH PPS payment rates. Under this bifurcated policy, the historic 8 percent HCO target was retained for LTCH PPS standard Federal payment rate cases, with the fixed-loss amount calculated using only data from LTCH cases which would have been paid at the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of those discharges. For site neutral payment rate cases, we adopted the operating IPPS HCO target (currently 5.1 percent) and set the fixed-loss amount for site neutral payment rate cases at the value of the IPPS fixed-loss amount. Under the HCO policy for both payment rates, an LTCH receives 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold, which is the sum of the LTCH PPS payment for the case and the applicable fixed-loss amount for such case. In order to maintain budget neutrality, consistent with the budget neutrality requirement for HCO payments to LTCH PPS standard Federal rate payment cases, we also adopted a budget neutrality requirement for HCO payments to site neutral payment rate cases by applying a budget neutrality factor to the LTCH PPS payment for those site neutral payment rate cases. (We refer readers to § 412.522(c)(2)(i) of the regulation for further details). We note during the 2-year transitional period, the site neutral payment rate HCO budget neutrality factor does not apply to the LTCH PPS standard Federal payment rate portion of the blended rate at § 412.522(c)(3) payable to site neutral payment rate cases. (For additional details on the HCO policy adopted for site neutral payment rate cases under the dual rate LTCH PPS payment structure, including the budget neutrality adjustment for HCO payments to site neutral payment rate cases, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49617 through 49623).)

2. Determining LTCH CCRs under the LTCH PPS

a. Background

As noted above, CCRs are used to determine payments for HCO adjustments for both payment rates under the LTCH PPS, and are also used to determine payments for SSO cases under § 412.529 as well as payments for site neutral payment rate cases. (We note that the provisions of § 412.529 are only applicable to LTCH PPS standard Federal payment rate cases.) Therefore, this discussion is relevant to all HCO, SSO, and site neutral payment rate calculations.

As noted earlier, in determining HCO, SSO, and the site neutral payment rate (regardless of whether the case is also an HCO) payments, we generally calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. An overall CCR is used because the LTCH PPS uses a single prospective payment per discharge that covers both inpatient operating and capital-related costs. The LTCH's overall CCR is generally computed 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 Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges), with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in certain instances, we use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or one that is requested by the hospital. (We refer readers to § 412.525(a)(4)(iv) of the regulations for further details regarding HCO adjustments for either LTCH PPS payment rate, § 412.529(f)(4) for SSO adjustments, and § 412.522(c)(1)(ii) for the site neutral payment rate, respectively.)

The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling. Under our established policy, an LTCH with a calculated CCR in excess of the applicable maximum CCR threshold (that is, the LTCH total CCR ceiling, which is calculated as 3 standard deviations from the national geometric average CCR) is generally assigned the applicable statewide CCR. This policy is premised on a belief that calculated CCRs above the LTCH total CCR ceiling are most likely due to faulty data reporting or entry, and CCRs based on erroneous data should not be used to identify and make payments for outlier cases.

b. LTCH Total CCR Ceiling

In this proposed rule, using our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the December 2015 update of the Provider Specific File (PSF), we are proposing a LTCH total CCR ceiling of 1.302 under the LTCH PPS for FY 2017 in accordance with § 412.525(a)(4)(iv)(C)(2) for HCO cases under either payment rate, § 412.529(f)(4)(iii)(B) for SSOs, and § 412.522(c)(1)(ii) for the site neutral payment rate. Consistent with our historical practice, we also are proposing to use more

recent data to determine the LTCH total CCR ceiling for the FY 2017 final rule. (For additional information on our methodology for determining the LTCH total CCR ceiling, we refer readers to the FY 2007 IPPS final rule (71 FR 48118 through 48119).)

c. LTCH Statewide Average CCRs

Our general methodology for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling because it is based on “total” IPPS CCR data. (For additional information on our methodology for determining statewide average CCRs under the LTCH PPS, we refer readers to the FY 2007 IPPS final rule (71 FR 48119 through 48120).) Under the LTCH PPS HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(C), the SSO policy at § 412.529(f)(4)(iii), and the site neutral payment rate at § 412.522(c)(1)(ii), the MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report, 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 calculated CCR is in excess of the LTCH total CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the MAC may consider in determining an LTCH’s CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data, in this proposed rule, using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS “total CCR” data from the December 2015 update of the PSF, we are proposing LTCH PPS statewide average total CCRs for urban and rural hospitals that would be effective for discharges occurring on or after October 1, 2016 through September 30, 2017, in Table 8C listed in section VI. of the Addendum to this proposed rule (and available via the Internet on the CMS Web site). Consistent with our historical practice, we are proposing to use more recent data to determine the LTCH PPS statewide average total CCRs for FY 2017 in the final rule.

Under the current LTCH PPS labor market areas, all areas in Delaware, 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 and North Dakota have areas that are designated as rural, in our calculation of the LTCH statewide average CCRs, there was no data available from short-term, acute care IPPS hospitals to compute a rural statewide average CCR or there were no short-term, acute care IPPS hospitals or LTCHs located in those areas as of December 2015. Therefore, consistent with our existing methodology, we are proposing to use the national average total CCR for rural IPPS hospitals for rural Connecticut and North Dakota in Table 8C listed in section VI. of the Addendum to this proposed rule (and available via the Internet on the CMS Web site). Furthermore, 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 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 HCO and SSO Payments

Under the HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(D) and the SSO policy at § 412.529(f)(4)(iv), the payments for HCO and SSO cases are subject to reconciliation. Specifically, any such payments are reconciled at settlement based on the CCR that is calculated based on the cost report coinciding with the discharge. (We note the existing reconciliation process for HCO payments is also applicable to LTCH PPS payments for site neutral payment rate cases (80 FR 49610).) For additional information on the reconciliation policy, 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).

e. Proposed Technical Change to the Definition of “Outlier Payment”

The existing regulations at § 412.503 includes a definition of “outlier payment,” which was adopted when the LTCH PPS was implemented (67 FR 56049). This definition does not account for the dual rate LTCH PPS payment structure that began in FY 2016. Therefore, in this proposed rule, to account for our HCO policy for LTCH cases paid under either payment rate, we are proposing to revise the definition of “outlier payment” at § 412.503 to mean an additional payment beyond the LTCH PPS standard Federal payment rate or the site neutral payment rate (including, when applicable, the transitional blended rate), as applicable, for cases with unusually high costs.

3. Proposed High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

a. Establishment of the Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2017

When we implemented the LTCH PPS, 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 (67 FR 56022 through 56026). When we implemented the dual rate LTCH PPS payment structure beginning in FY 2016, we established that, in general, that the historical LTCH PPS HCO policy will continue to apply to LTCH PPS standard Federal payment rate cases. That is, the fixed-loss amount and target for LTCH PPS standard Federal payment rate cases is determined using the LTCH PPS HCO policy adopted when the LTCH PPS was first implemented, but we limited the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges.

To determine the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases, we estimate outlier payments and total LTCH PPS payments for each LTCH PPS standard Federal payment rate case (or for each case that would have been a LTCH PPS standard Federal payment rate case if the statutory changes had been in effect at the time of the discharge) using claims data from the MedPAR files. The applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases results in estimated total outlier payments being projected to be equal to 8 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. We use MedPAR claims data and CCRs based on data from the most recent PSF (or from the applicable statewide average CCR if an LTCH’s CCR data are faulty or unavailable) to establish an applicable fixed-loss threshold amount for LTCH PPS standard Federal payment rate cases.

For FY 2017, we are not proposing to make any modifications to the current LTCH PPS HCO payment methodology for LTCH PPS standard Federal payment rate cases. Therefore, for FY 2017, we are proposing to determine an applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases using data from LTCH PPS standard Federal payment rate cases (or cases that would have been LTCH PPS standard Federal payment rate cases had the dual rate LTCH PPS payment structure been in effect at the time of those discharges). The proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases would continue to be determined so that estimated HCO payments would be projected to equal 8 percent of estimated total LTCH PPS standard Federal payment rate cases. Furthermore, in accordance with § 412.523(d)(1), a budget neutrality factor would continue to be applied to LTCH PPS standard Federal payment rate cases to offset that 8 percent so that HCO payments for LTCH PPS standard Federal payment rate

cases will be budget neutral. Below we present our calculation of the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017, which is consistent with the methodology used to establish the FY 2016 LTCH PPS fixed-loss amount.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49803 through 49804), we presented our policies regarding the methodology and data we used to establish a fixed-loss amount of \$16,432 for FY 2016 for LTCH PPS standard Federal payment rate cases, which was calculated based on the data and the rates and policies presented in that final rule in order to maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments. Consistent with our historical practice of using the best data available, in determining the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017, we used the most recent available LTCH claims data and CCR data, that is, LTCH claims data from the December 2015 update of the FY 2015 MedPAR file and CCRs from the December 2015 update of the PSF, as these data were the most recent complete LTCH data available at that time.

For FY 2017, we are proposing to continue to use our current methodology to calculate an applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017 using the best available data that would maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the rates and policies for these cases presented in this proposed rule). Specifically, based on the most recent complete LTCH data available (that is, LTCH claims data from the December 2015 update of the FY 2015 MedPAR file and CCRs from the December 2015 update of the PSF), we determined a proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017 that will result in estimated outlier payments projected to be equal to 8 percent of estimated FY 2017 payments for such cases. Under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we are proposing a fixed-loss amount of \$22,728 for LTCH PPS standard Federal payment rate cases for FY 2017. Under our proposal, we would continue to make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount 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 LTCH PPS standard Federal payment rate payment and the fixed-loss amount for LTCH PPS standard Federal payment rate cases of \$22,728).

We note that the proposed fixed-loss amount of \$22,728 for FY 2017 for LTCH PPS standard Federal payment rate cases is notably higher than the FY 2016 fixed-loss amount for LTCH PPS standard Federal payment rate cases of \$16,423. The FY 2016 fixed-loss amount for LTCH PPS standard Federal payment rate cases was determined using LTCH claims data from the March 2015 update of the FY 2014 MedPAR file and

CCRs from the March 2015 update of the PSF. Based on that data, the estimated outlier payments were projected to be equal to 8 percent of estimated FY 2016 payments for such cases (80 FR 49803). Using the more recent LTCH claims data (that is, FY 2015 LTCH discharges from the December 2015 update of the MedPAR file and CCRs from the December 2015 update of the PSF), we currently estimate that the FY 2016 fixed-loss amount of \$16,423 results in estimated HCO payments for LTCH PPS standard Federal payment rate cases of approximately 9.1 percent of total estimated FY 2016 LTCH PPS payments to those cases, which exceeds the 8 percent target. While many factors contribute to this increase, we found that the rate-of-change in the Medicare allowable charges on the claims data in the MedPAR is a significant contributing factor. In the payment modeling used to estimate LTCH PPS payments for the FY 2016 IPPS/LTCH PPS final rule, for SSO and HCO cases paid as LTCH PPS standard Federal payment rate cases, we applied an inflation factor of 4.6 percent (determined by the Office of the Actuary) to update the 2014 costs of each case to 2016 (80 FR 49833). Upon examining the FY 2014 LTCH discharge data and the FY 2015 discharge data, we found that Medicare allowable charges for LTCH PPS standard Federal payment rate cases (had the dual rate LTCH PPS payment structure been in effect at the time of the discharges) increased approximately 7 percent. This higher inflation factor results in higher estimated costs for outlier cases and, therefore, more estimated outlier payments.

Fluctuations in the fixed-loss amount occurred in the first few years after the implementation of the LTCH PPS, due, in part, to the changes in LTCH behavior (such as Medicare beneficiary treatment patterns) in response to the new payment system and the lack of data and information available to predict how those changes would affect the estimate costs of LTCH cases. As we gained more experience with the effects and implementation of the LTCH PPS, the annual changes on the fixed-loss amount generally stabilized relative to the fluctuations that occurred in the early years of the LTCH PPS. At this time, we are not proposing any changes to our method for the inflation factor applied to update the costs of each case (that is, an inflation factor based on the most recent estimate of the proposed 2013-based LTCH market basket as determined by the Office of the Actuary) in determining the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017. We continue to believe that it is appropriate to continue to use our historical approach until we gain experience with the effects and implementation of the dual rate LTCH PPS payment structure that began with discharges occurring in cost reporting periods beginning on or after October 1, 2015, and the types of cases paid at the LTCH PPS standard Federal payment rate under this dual rate payment structure. We may revisit this issue in the future if data demonstrate such a change is warranted, and would propose any changes in the future through the notice-and-comment rulemaking process. However, we are inviting public

comments on potential improvements to the determination of the fixed-loss amount for LTCH PPS standard Federal payment rate cases, including the most appropriate method of determining an inflation factor for projecting the costs of each case when determining the fixed-loss threshold.

For the reasons discussed above, we believe it is necessary and appropriate to propose an increase to the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017 to maintain that, for LTCH PPS standard Federal payment rate cases, estimated HCO payments would equal 8 percent of estimated total LTCH PPS payments for those cases as required under § 412.525(a). (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 substantially more than the current regulatory 8 percent target that we are applying to total payments for LTCH PPS standard Federal payment rate cases because a lower fixed-loss amount would result in more cases qualifying as outlier cases, as well as higher outlier payments for qualifying HCO cases because the maximum loss that an LTCH must incur before receiving an HCO payment (that is, the fixed-loss amount) would be smaller.

#### b. Application of the High-Cost Outlier Policy to SSO Cases

Under our implementation of the dual rate LTCH PPS payment structure required by statute, LTCH PPS standard Federal payment rate cases (that is, LTCH discharges that meet the criteria for exclusion from the site neutral payment rate) will continue to be paid based on the LTCH PPS standard Federal payment rate, and will include all of the existing payment adjustments under § 412.525(d), such as the adjustments for SSO cases under § 412.529. Under some rare circumstances, an LTCH discharge can qualify as an SSO case (as defined in the regulations at § 412.529 in conjunction with § 412.503) and also as an HCO case, as discussed in the August 30, 2002 final rule (67 FR 56026). 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 applicable fixed-loss amount), the discharge is eligible for payment as an HCO. Therefore, for an SSO case in FY 2017, we are proposing 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 \$22,728 and the amount paid under the SSO policy as specified in § 412.529).

#### 4. Proposed High-Cost Outlier Payments for Site Neutral Payment Rate Cases

Under § 412.525(a), site neutral payment rate cases receive an additional HCO payment for costs that exceed the HCO threshold that is equal to 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold (80

FR 49618 through 49629). In the FY 2016 IPPS/LTCH PPS final rule, in examining the appropriate fixed-loss amount for site neutral payment rate cases issue, we considered how LTCH discharges based on historical claims data would have been classified under the dual rate LTCH PPS payment structure and the CMS' Office of the Actuary (OACT) projections regarding how LTCHs would likely respond to our proposed implementation of policies resulting from the statutory payment changes. For FY 2016, at that time our actuaries projected that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Although our actuaries did not project an immediate change in the proportions found in the historical data, they did project cost and resource changes to account for the lower payment rates. Our actuaries also projected that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS-DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. In light of these projections and expectations, we discussed that we believed that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. In addition, we discussed that we did not believe that it would be appropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS (80 FR 49618 through 49619). For those reasons, in the FY 2016 IPPS/LTCH PPS final rule (FR 80 49619), we stated that we believe that the most appropriate fixed-loss amount for site neutral payment rate cases for a given fiscal year, beginning with FY 2016, would be the IPPS fixed-loss amount for that fiscal year. Accordingly, we established that for FY 2016, a fixed-loss amount for site neutral payment rate cases of \$22,544, which was the same as the FY 2016 IPPS fixed-loss amount. (We note that the FY 2016 fixed-loss amount under the IPPS was updated, applicable for discharges on or after January 1, 2016, as a conforming change to the implementation of section 601 of the Consolidated Appropriations Act, 2016, which modified the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016 (Change Request 9523, Transmittal 3449, dated February 4, 2016).) Consistent with this change, the FY 2016 fixed-loss amount for site neutral payment rate cases under the LTCH PPS was updated, applicable for discharges on or after January 1, 2016, to \$22,538, which is the same as the updated IPPS outlier fixed-loss cost threshold for FY 2016. (We refer readers to Change Request 9527, Transmittal 3445, dated January 29, 2016, which also updated

the IPPS comparable amount calculation, applicable to discharges occurring on or after January 1, 2016, consistent with the conforming changes made as a result of the new IPPS payment requirement.)

For this proposed rule, in developing a proposed fixed-loss amount for site neutral payment rate cases for FY 2017, we considered the same factors we did developing a fixed-loss amount for such cases for FY 2016. For FY 2017, our actuaries currently project that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the dual rate LTCH PPS payment structure provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Based on FY 2014 LTCH claims data, LTCH claims data, we found that approximately 55 percent of LTCH cases would have been paid the LTCH PPS standard Federal payment rate and approximately 45 percent of LTCH cases would have been paid the site neutral payment rate if those rates had been in effect at that time.) At this time, our actuaries continue to project no immediate change in these proportions. However, they do continue to project that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS-DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49619), this actuarial assumption is based on our expectation that site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount under the statutory LTCH PPS payment changes that began in FY 2016, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. For these reasons, we continue to believe that the most appropriate fixed-loss amount for site neutral payment rate cases for FY 2017 is the IPPS fixed-loss amount for FY 2017.

Therefore, for FY 2017, we are proposing that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed-loss amount. That is, we are proposing a fixed-loss amount for site neutral payment rate cases of \$23,681, which is the same proposed FY 2017 IPPS fixed-loss amount discussed in section II.A.4.g.(1) of the Addendum to this proposed rule. We continue to believe that this policy will reduce differences between HCO payments for similar cases under the IPPS and site neutral payment rate cases under the LTCH PPS and promote fairness between the two systems. Accordingly, under this proposal, for FY 2017, we would calculate a HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount, which is equal to 80 percent of the difference between the estimated cost of the

case and the outlier threshold (the sum of site neutral payment rate payment and the proposed fixed-loss amount for site neutral payment rate cases of \$23,681). (We note that any site neutral payment rate case that is paid 100 percent of the estimated cost of the case (because that amount is lower than the IPPS comparable per diem amount) will not be eligible to receive a HCO payment because, by definition, the estimated costs of such cases would never exceed the IPPS comparable per diem amount by any threshold.)

In establishing a HCO policy for site neutral payment rate cases, we established a budget neutrality requirement at § 412.522(c)(2)(i). We established this requirement because we believe that the HCO policy for site neutral payment rate cases should be budget neutral, just as the HCO policy for LTCH PPS standard Federal payment rate cases are budget neutral, meaning that estimated site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments. Under § 412.522(c)(2)(i), we adjust all payments for site neutral payment rate cases by a budget neutrality factor so that the estimated HCO payments payable for site neutral payment rate cases do not result in any increase in aggregate LTCH PPS payments. Specifically, under § 412.522(c)(2)(i), we apply a budget neutrality factor to the site neutral payment rate portion of the transitional blended rate payment (that is applicable to site neutral payment rate cases during the 2-year transition period provided by the statute) that is established based on an estimated basis. (We refer readers to 80 FR 49621 through 49622 and 49805.)

Under the approach adopted for applying the budget neutrality adjustment to the site neutral payment rate portion of the transitional blended rate payment in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49805), we explained that there is no need to perform any calculation of the site neutral payment rate case HCO payment budget neutrality adjustment under our finalized policy. This is because, as discussed previously, based on our actuarial assumptions we project that our proposal to use the IPPS fixed-loss threshold for the site neutral payment rate cases would result in HCO payments for those cases that are similar in proportion as is seen in IPPS cases assigned to the same MS-DRG; that is, 5.1 percent. In other words, we estimated that HCO payments for site neutral payment rate cases would be 5.1 percent of the site neutral payment rate payments. Under the statutory transition period, payments to site neutral payment rate cases in FY 2017 will be paid under the blended transitional rate. As such, estimated HCO payments for site neutral payment rate cases in the FY 2017 proposal would be projected to be 5.1 percent of the portion of the blended rate payment that is based on the estimated site neutral payment rate payment amount (and would not include the LTCH PPS standard Federal payment rate payment amount as specified in § 412.522(c)(2)(i)). To ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2017 would not

result any increase in estimated aggregate FY 2017 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce the site neutral payment rate portion of the blended rate payment by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2017. In order to achieve this, for FY 2017, we are proposing to continue to apply a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as  $1.0 - 5.1/100 = 0.949$ ) to the site neutral payment rate portion of the blended rate payment (80 FR 49805). As stated previously, this adjustment is necessary so that the estimated HCO payments payable for site neutral payment rate cases do not result in any increase in aggregate LTCH PPS payments.

*E. Proposed Update to the IPPS Comparable/Equivalent Amounts to Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology*

In the FY 2014 IPPS/LTCH PPS final rule, we established a policy for reflecting the changes to the Medicare IPPS DSH payment adjustment methodology provided for by section 3133 of the Affordable Care Act in the calculation of the “IPPS comparable amount” under the SSO policy at § 412.529 and the “IPPS equivalent amount” under the 25-percent threshold payment adjustment policy at § 412.534 and § 412.536. Historically, the determination of both the “IPPS comparable amount” and the “IPPS equivalent amount” includes an amount for inpatient operating costs “for the costs of serving a disproportionate share of low-income patients.” Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under the age of 65 who are uninsured, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital’s amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all IPPS hospitals that receive Medicare DSH payments.

To reflect the statutory changes to the Medicare DSH payment adjustment methodology in the calculation of the “IPPS comparable amount” and the “IPPS equivalent amount” under the LTCH PPS, we stated that we will include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS

hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating DSH payment amount that has historically been reflected in the LTCH PPS payments that is based on IPPS rates). We also stated that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. We believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the “IPPS comparable amount” and the “IPPS equivalent amount” under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS (79 FR 50766 through 50767).

For FY 2017, as discussed in greater detail in section IV.D.3.d.(2) of the preamble of this proposed rule, based on the most recent data available, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) is adjusted to 56.74 percent of that amount to reflect the change in the percentage of individuals who are uninsured. The resulting amount is then used to determine the amount of uncompensated care payments that will be made to eligible IPPS hospitals in FY 2017. In other words, Medicare DSH payments prior to the amendments made by the Affordable Care Act would be adjusted to 42.56 percent (the product of 75 percent and 56.74 percent) and the resulting amount will be used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2017, we project that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the payments for uncompensated care under section 1886(r)(2) of the Act, would result in overall Medicare DSH payments of 67.56 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of amendments made by the Affordable Care Act (that is,  $25 \text{ percent} + 56.74 \text{ percent} = 67.56 \text{ percent}$ ).

In this proposed rule, for FY 2017, we are proposing that the calculation of the “IPPS comparable amount” under § 412.529 and the “IPPS equivalent amount” under new § 412.538 would include an applicable operating Medicare DSH payment amount that is equal to 67.5677 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula but for the amendments made by the Affordable Care Act. Furthermore, consistent with our historical practice, we are proposing to use more recent data, if available, to determine this factor in the final rule.

*F. Computing the Proposed Adjusted LTCH PPS Federal Prospective Payments for FY 2017*

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal payment rate. Under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the

statutory criteria to be excluded from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate. Under § 412.525(c), the LTCH PPS standard Federal payment rate is adjusted to account for differences in area wages by multiplying the labor-related share of the LTCH PPS standard Federal payment for a case by the applicable LTCH PPS wage index (the proposed FY 2017 values are shown in Tables 12A through 12B listed in section VI. of the Addendum of this proposed rule and are available via the Internet on the CMS Web site). The LTCH PPS standard Federal payment is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the proposed FY 2017 factors are shown in the chart in section V.D. of this Addendum) in accordance with § 412.525(b). In this proposed rule, we are proposing an LTCH PPS standard Federal payment rate for FY 2017 of \$42,314.31, as discussed in section V.A.2. of the Addendum to this proposed rule. We illustrate the methodology to adjust the proposed LTCH PPS standard Federal payment rate for FY 2017 in the following example:

*Example:* During FY 2017, a Medicare discharge that meets the criteria to be excluded from the site neutral payment rate, that is an LTCH PPS standard Federal payment rate case, is from an LTCH that is located in Chicago, Illinois (CBSA 16974). The FY 2017 LTCH PPS proposed wage index value for CBSA 16974 is 1.0486 (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 case is classified into MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a proposed relative weight for FY 2017 of 0.9107 (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 2017 in accordance with the LTCHQRP under section 1886(m)(5) of the Act.

To calculate the LTCH’s total proposed adjusted Federal prospective payment for this Medicare patient case in FY 2017, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted proposed FY 2017 LTCH PPS standard Federal payment rate (\$42,314.31) by the proposed labor-related share (66.6 percent) and the wage index value (1.0486). This wage-adjusted amount was then added to the proposed nonlabor-related portion of the unadjusted LTCH PPS standard Federal payment rate (33.4 percent; adjusted for cost of living, if applicable) to determine the adjusted proposed LTCH PPS standard Federal payment rate, which is then multiplied by the proposed MS–LTC–DRG relative weight (0.9107) to calculate the total proposed adjusted LTCH PPS standard Federal prospective payment for FY 2017 (\$39,782.95). The table below illustrates the components of the calculations in this example.



Proposed LTCH PPS Standard Federal Prospective Payment Rate .....	\$42,314.31
Proposed Labor-Related Share .....	× 0.666
Proposed Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate .....	= \$28,181.33
Proposed Wage Index (CBSA 16974) .....	× 1.0486
Proposed Wage-Adjusted Labor Share of LTCH PPS Standard Federal Payment Rate .....	= \$29,550.94
Proposed Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate (\$42,314.31 × 0.334) .....	+ \$14,132.98
Proposed Adjusted LTCH PPS Standard Federal Payment Amount .....	= \$43,683.92
Proposed MS–LTC–DRG 189 Relative Weight .....	× 0.9107
Total Proposed Adjusted LTCH PPS Standard Federal Prospective Payment .....	= \$39,782.95

**VI. Tables Referenced in This Proposed Rule and Available Only Through the Internet on the CMS Web Site**

This section lists the tables referred to throughout the preamble of this proposed rule and in this Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 through 2016, for the FY 2017 rulemaking cycle, the IPPS and LTCH tables will not be published in the **Federal Register** in the annual IPPS/LTCH PPS proposed and final rules and will be available only through the Internet. Specifically, all IPPS tables listed below, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E will be available only through the Internet. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register** as part of the annual proposed and final rules.

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49807), we streamlined and consolidated the wage index tables for FY 2016 and subsequent fiscal years.

As discussed in sections II.F.14., II.F.15.b., II.F.16., II.F.17.a., and II.F.19.a.1., a.3., and c.1. of the preamble of this proposed rule, we developed the following ICD–10–CM and ICD–10–PCS code tables for FY 2017: Table 6A—New Diagnosis Codes; Table 6B—New Procedure Codes; Table 6C—Invalid Diagnosis Codes; Table 6G.1—Proposed Secondary Diagnosis Order Additions to the CC Exclusion List; Table 6G.2—Proposed Principal Diagnosis Order Additions to the CC Exclusion List; Table 6H.1—Proposed Secondary Diagnosis Order Deletions to the CC Exclusion List; Table 6H.2—Proposed Principal Diagnosis Order Deletions to the CC Exclusion List; Table 6I—Proposed Complete MCC List; Table 6I.1—Proposed Additions to MCC List; Table 6I.2—Proposed Deletions to MCC List; Table 6J—Proposed Complete CC List; Table 6J.1—Proposed Additions to CC List; Table 6J.2—Proposed Deletions to CC List; Table 6L—Proposed Principal Diagnosis Is Its Own MCC List; Table 6M—Proposed Principal Diagnosis Is Its Own CC List; Table 6M.1—Proposed Additions to the Principal Diagnosis Is Its Own CC List; and Table 6P—ICD–10–CM and ICD–10–PCS Codes for Proposed MCE and MS–DRG Changes. Table 6P contains multiple tables, 6P.1a through 6P.4k, that include the ICD–10–CM and ICD–10–PCS code lists and translations relating to specific MCE and MS–DRG proposed changes. In addition, under the HAC Reduction Program established by section 3008 of the Affordable Care Act, a hospital’s total payment may be reduced by 1 percent if it is in the lowest HAC performance

quartile. However, as discussed in section IV.F. of the preamble of this proposed rule, we are not providing the hospital-level data as a table associated with this proposed rule. The hospital-level data for the FY 2017 HAC Reduction Program will be made publicly available once it has undergone the review and corrections process.

Finally, a hospital’s Factor 3 is the proportion of the uncompensated care amount that a DSH eligible hospital will receive under section 3133 of the Affordable Care Act. Factor 3 is the hospital’s estimated number of Medicaid days and Medicare SSI days (or for a Puerto Rico hospital, a proxy for its Medicare SSI days) relative to the estimate of all DSH hospitals’ Medicaid days and Medicare SSI days (or for Puerto Rico hospitals that are estimated to be eligible for DSH payments, a proxy for their Medicare SSI days). Table 18 associated with this proposed rule contains the FY 2017 Medicare DSH uncompensated care payment Factor 3 for all hospitals and identifies whether or not a hospital is projected to receive DSH and, therefore, eligible to receive the additional payment for uncompensated care for FY 2017.

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 2017 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 2017 IPPS Proposed Rule Home Page” or “Acute Inpatient—Files for Download”.

- Table 2.—Proposed Case-Mix Index and Wage Index Table by CCN—FY 2017
- Table 3.—Proposed Wage Index Table by CBSA—FY 2017
- Table 5.—Proposed List of Proposed Medicare Severity Diagnosis-Related Groups (MS DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2017
- Table 6A.—New Diagnosis Codes for FY 2017
- Table 6B.—New Procedure Codes for FY 2017
- Table 6C.—Invalid Diagnosis Codes for FY 2017
- Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2017
- Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2017
- Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2017

- Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2017
  - Table 6I.—Proposed Complete Major Complication and Comorbidity (MCC) List—FY 2017
  - Table 6I.1.—Proposed Additions to the MCC List—FY 2017
  - Table 6I.2.—Proposed Deletions to the MCC List—FY 2017
  - Table 6J.—Proposed Complete Complication and Comorbidity (CC) List—FY 2017
  - Table 6J.1.—Proposed Additions to the CC List—FY 2017
  - Table 6J.2.—Proposed Deletions to the CC List—FY 2017
  - Table 6L.—Proposed Principal Diagnosis Is Its Own MCC List—FY 2017
  - Table 6M.—Proposed Principal Diagnosis Is Its Own CC List—FY 2017
  - Table 6M.1.—Proposed Additions to the Principal Diagnosis Is Its Own CC List—FY 2017
  - Table 6P.—ICD–10–CM and ICD–10–PCS Codes for Proposed MCE and MS–DRG Changes—FY 2017
  - Table 7A.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2015 MedPAR Update—December 2015 GROUPER V33.0 MS–DRGs
  - Table 7B.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2015 MedPAR Update—December 2015 GROUPER V34.0 MS–DRGs
  - Table 8A.—Proposed FY 2017 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)
  - Table 8B.—Proposed FY 2017 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals
  - Table 10.—Proposed New Technology Add-On Payment Thresholds for Applications for FY 2018
  - Table 14.—List of Hospitals with Fewer Than 1,600 Medicare Discharges Based on the December 2015 Update of the FY 2015 MedPAR File and Potentially Eligible Hospitals for the Proposed FY 2017 Low Volume Hospital Payment Adjustment (eligibility for the low-volume hospital payment adjustment is also dependent upon meeting the mileage criteria specified at 42 CFR 412.101(b)(2)(ii).)
  - Table 15.—Proposed FY 2017 Proxy Readmissions Adjustment Factors
  - Table 16.—Proposed Proxy Hospital Inpatient Value-Based Purchasing (VBP) Adjustment Factors for FY 2017
  - Table 18.—Proposed FY 2017 Medicare DSH Uncompensated Care Payment Factor 3
- The following LTCH PPS tables for this FY 2017 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-1655-P:

Table 8C.—Proposed FY 2017 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 LTCH PPS Discharges Occurring from October 1, 2016 through September 30, 2017

Table 12A.—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2016 through September 30, 2017

Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2016 through September 30, 2017

Table 13A.—Proposed Composition of Low Volume Quintiles for MS-LTC-DRGs—FY 2017

Table 13B.—Proposed No Volume MS LTC-DRG Crosswalk for FY 2017

**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 2017**

Hospital submitted quality data and is a meaningful EHR user (update = 1.55 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = -0.55 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 0.850 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = -1.25 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
\$3,836.20	\$1,675.59	\$3,756.87	\$1,640.94	\$3,809.76	\$1,664.04	\$3,730.43	\$1,629.39

**TABLE 1B—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN 1)—FY 2017**

Hospital submitted quality data and is a meaningful EHR user (update = 1.55 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = -0.55 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 0.850 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = -1.25 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
\$3,417.31	\$2,094.48	\$3,346.64	\$2,051.17	\$3,393.76	\$2,080.04	\$3,323.09	\$2,036.73

**TABLE 1C—PROPOSED ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2017**

Standardized amount	Rates if wage index is greater than 1		Rates if wage index is less than or equal to 1	
	Labor	Nonlabor	Labor	Nonlabor
	National <sup>1</sup> .....	Not Applicable .....	Not Applicable .....	\$3,417.31

<sup>1</sup> For FY 2017, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

**TABLE 1D—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2017**

	Rate
National .....	\$446.35

**TABLE 1E—PROPOSED LTCH PPS STANDARD FEDERAL PAYMENT RATE—FY 2017**

	Full update (1.45 percent)	Reduced update* (-0.55 percent)
Standard Federal Rate .....	\$42,314.31	\$41,480.12

\* For LTCHs that fail to submit quality reporting data for FY 2017 in accordance with the LTCH Quality Reporting Program (LTCH QRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

**Appendix A: Economic Analyses**

**I. Regulatory Impact Analysis**

**A. Introduction**

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review

(September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104-4), Executive Order 13132

on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic,

environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year).

We have determined that this proposed rule is a major rule as defined in 5 U.S.C. 804(2). We estimate that the proposed changes for FY 2017 acute care hospital operating and capital payments would 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 \$693 million increase in FY 2017 proposed operating payments (or 0.7 percent change) and an estimated \$164 million increase in FY 2017 proposed capital payments (or 2.0 percent change). These proposed changes are relative to payments made in FY 2016. The impact analysis of the proposed capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience a decrease in payments by \$355 million in FY 2017 relative to FY 2016.

Our operating impact estimate includes the proposed -1.5 percent documentation and coding adjustment applied to the IPPS standardized amount, as discussed in section II.D. of the preamble of this proposed rule, which represents part of the recoupment required under section 631 of the ATRA. In addition, our operating payment impact estimate includes the proposed 1.55 percent hospital update to the standardized amount (which includes the estimated 2.8 percent market basket update less 0.5 percentage point for the proposed multifactor productivity adjustment and less 0.75 percentage point required under the Affordable Care Act). Our operating payment impact estimate also includes a proposed adjustment of (1/0.998) to permanently remove the -0.2 percent reduction and a proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 as a result of the 2-midnight policy (we refer readers to section IV.O. of the preamble of this proposed rule for an explanation of these proposed adjustments). The estimates of 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 proposed payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This proposed rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in

accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget has reviewed this proposed rule.

#### *B. Statement of Need*

This proposed rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This proposed rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS.

#### *C. Objectives of the IPPS*

The primary objective of the IPPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the 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 2017, 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, hospitals in Maryland are paid in accordance with the Maryland All-Payer Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 5 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of

reasonable costs, subject to a rate-of-increase ceiling.

As of March 2016, there were 3,330 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 1,374 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, 11 cancer hospitals, and 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts of changes to the prospective payment systems 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 2017 is discussed in section I.J. of this Appendix.

#### *F. Effects on Hospitals and Hospital Units Excluded From the IPPS*

As of March 2016, there were 98 children's hospitals, 11 cancer hospitals, 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa, and 18 RNHCIs being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCIs are paid under § 413.40.) Among the remaining providers, 262 rehabilitation hospitals and 869 rehabilitation units, and approximately 430 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 495 psychiatric hospitals and 1,122 psychiatric units are paid the Federal per diem amount under the IPF PPS. As stated previously, IRFs and IPFs are not affected by the rate updates discussed in this proposed rule. The impacts of the changes on LTCHs are discussed in section I.J. of this Appendix.

For children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNHCIs, the update of the rate-of-increase limit (or target amount) is the estimated FY 2017 percentage increase in the IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. As discussed in section IV. of the preamble of the FY 2014 IPPS/LTCH PPS final rule, we rebased the IPPS operating market basket to a FY 2010 base year. Therefore, we are using the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for FY 2017 and subsequent fiscal years for children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNHCIs that are paid based on reasonable costs subject to the rate-of-increase limits. Consistent with current law,

based on IHS Global Insight, Inc.'s first quarter 2016 forecast of the FY 2010-based IPPS market basket increase, we are estimating the FY 2017 update to be 2.8 percent (that is, the current estimate of the market basket rate-of-increase). However, the Affordable Care Act requires an adjustment for multifactor productivity (currently estimated to be 0.5 percentage point for FY 2017) and a 0.75 percentage point reduction to the market basket update, resulting in a 1.55 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section IV.B. of the preamble of this proposed rule. Children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNHCs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. Therefore, for those hospitals paid under § 413.40 of the regulations, the update is the percentage increase in the FY 2010-based IPPS operating market basket for FY 2017, estimated at 2.8 percent, without the reductions described previously under the Affordable Care Act.

The impact of the update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that would 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 2017 for operating costs of acute care hospitals. The proposed FY 2017 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2017 operating payments would increase by 0.7 percent compared to FY 2016. In addition to the applicable percentage increase, this amount reflects the proposed

FY 2017 recoupment adjustment for documentation and coding described in section I.I.D. of the preamble of this proposed rule of -1.5 percent to the IPPS national standardized amounts. This amount also reflects the proposed adjustment of (1/0.998) to permanently remove the 0.2 percent reduction and the proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy, which are discussed in section IV.O. of the preamble of this proposed rule. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which would also affect overall proposed 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 would allow us to estimate the payment impacts using this model. For those proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of proposed changes in payments per case presented in this section are taken from the FY 2015 MedPAR file and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the operating PPS do not incorporate cost data, data from the most recently available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each proposed change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2015 MedPAR file, we simulate payments under the operating IPPS given various combinations of payment parameters. As described previously, 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. Estimated payment impacts of the capital IPPS for FY 2017 are discussed in section I.I. of this Appendix.

We discuss the following proposed changes:

- The effects of the proposed application of the documentation and coding adjustment and the applicable percentage increase (including the proposed market basket update, the proposed 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 adjustment of (1/0.998) to permanently remove the 0.2 percent reduction and the proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy, as discussed in section IV.O. of the preamble of this proposed rule.

- The effects of the proposed changes to the relative weights and MS-DRG GROUPER.

- The effects of the proposed changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2013, compared to the FY 2012 wage data, to calculate the FY 2017 wage index.

- The effects of the geographic reclassifications by the MGCRB (as of publication of this proposed rule) that would be effective for FY 2017.

- The effects of the proposed rural floor and imputed floor with the application of the proposed national budget neutrality factor to the wage index.

- The effects of the last year of the 3-year transition for hospitals that were located in an urban county that became rural under the new OMB delineations or hospitals that were deemed urban where the urban area became rural under the new OMB delineations.

- The effects of the proposed frontier State wage index adjustment under the statutory provision that requires that hospitals located in States that qualify as frontier States to not have a wage index less than 1.0. This provision is not budget neutral.

- The effects of the implementation of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108-173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. This provision is not budget neutral.

- The total estimated change in payments based on the proposed FY 2017 policies relative to payments based on FY 2016 policies that include the applicable percentage increase of 1.55 percent (or 2.8 percent market basket update with a proposed reduction of 0.5 percentage point for the multifactor productivity adjustment, and a 0.75 percentage point reduction, as required under the Affordable Care Act).

To illustrate the impact of the proposed FY 2017 changes, our analysis begins with a FY 2016 baseline simulation model using: The FY 2016 applicable percentage increase of 1.7 percent and the documentation and coding recoupment adjustment of -0.8 percent to the Federal standardized amount; the FY 2016 MS-DRG GROUPER (Version 33); the FY 2016 CBSA designations for hospitals based on the new OMB definitions; the FY 2016 wage index; and no MGCRB reclassifications. Outlier payments are set at

5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Public Law 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111–5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111–148), provides that, for FY 2007 and each subsequent year through FY 2014, the update factor will include a reduction of 2.0 percentage points for any subsection (d) hospital that does not submit data on measures in a form and manner and at a time specified by the Secretary. Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act, or one-quarter of the market basket update. Therefore, for FY 2017, we are proposing that hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act would receive an applicable percentage increase of 0.85 percent. At the time that this impact was prepared, 90 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2016 because they failed the quality data submission process or did not choose to participate but are meaningful EHR users. For purposes of the simulations shown later in this section, we modeled the proposed payment changes for FY 2017 using a reduced update for these 90 hospitals.

For FY 2017, in accordance with section 1886(b)(3)(B)(ix) of the Act, a hospital that has been identified as not a meaningful EHR user would be subject to a reduction of three-quarters of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act. Therefore, for FY 2017, we are proposing that hospitals that are identified as not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act would receive an applicable percentage increase of –0.55 percent. At the time that this impact analysis was prepared, 147 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2017 because they are identified as not meaningful EHR users that do submit quality information under section 1886(b)(3)(B)(viii) of the Act. For purposes of the simulations shown in this section, we modeled the proposed payment changes for FY 2017 using a reduced update for these 147 hospitals.

Hospitals that are identified as not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act would receive an applicable percentage increase of –1.25 percent, which reflects a one-quarter reduction of the market basket update for failure to submit quality data and a three-quarter reduction of the market basket update for being identified as not a meaningful EHR user. At the time that this impact was prepared, 30 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2017 because they are identified as not meaningful EHR users that do not submit quality data under section 1886(b)(3)(B)(viii) of the Act.

Each proposed policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2017 model incorporating all of the proposed changes. This simulation would allow us to isolate the effects of each proposed change.

Our final comparison illustrates the percent change in payments per case from FY 2016 to FY 2017. Three factors not discussed separately have significant impacts here. The first factor is the proposed 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 2017 using a proposed applicable percentage increase of 1.55 percent. This includes our forecasted IPPS operating hospital market basket increase of 2.8 percent with a reduction of 0.5 percentage point for the multifactor productivity adjustment and a 0.75 percentage point reduction as required under the Affordable Care Act. Hospitals that fail to comply with the quality data submission requirements and are meaningful EHR users would receive a proposed update of 0.85 percent. This update includes a reduction of one-quarter of the market basket update for failure to submit these data. Hospitals that do comply with the quality data submission requirements but are not meaningful EHR users would receive an update of –0.55 percent, which includes a reduction of three-quarters of the market basket update. Furthermore, hospitals that do not comply with the quality data submission requirements and also are not meaningful EHR users would receive an update of –1.25 percent. Under section 1886(b)(3)(B)(iv) of the Act, the update to the hospital-specific amounts for SCHs and MDHs also is equal to the applicable percentage increase, or 1.55 percent if the hospital submits quality data and is a meaningful EHR user.

A second significant factor that affects the proposed changes in hospitals' payments per case from FY 2016 to FY 2017 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 2016 that are no longer reclassified in FY 2017. Conversely, payments may increase for hospitals not reclassified in FY 2016 that are reclassified in FY 2017.

A third significant factor is that we currently estimate that actual outlier payments during FY 2016 would be 5.3 percent of total MS–DRG payments. When the FY 2016 IPPS/LTCH PPS final rule was published, we projected FY 2016 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 2016 are reflected in the analyses in this section comparing our current estimates of FY 2016 payments per case to estimated FY 2017 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 2017. 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 3,330 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 2,512 hospitals located in urban areas included in our analysis. Among these, there are 1,378 hospitals located in large urban areas (populations over 1 million), and 1,134 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 818 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 2017 proposed 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 2,455; 1,372; 1,083; and 875, 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 2,275 nonteaching hospitals in our analysis, 804 teaching hospitals with fewer than 100 residents, and 251 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 three rows examine the impacts of the proposed changes on rural hospitals by special payment groups (SCHs, RRCs, and MDHs). There were 193 RRCs, 326 SCHs, 146 MDHs, 126 hospitals that are both SCHs and RRCs, and 15 hospitals that are both MDHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare utilization expressed as a percent of total patient days. These data were taken from the FY 2013 or FY 2012 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 2017. The second grouping shows the MGCRB rural reclassifications.

TABLE I—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPSS FOR OPERATING COSTS FOR FY 2017

	Number of hospitals <sup>1</sup>	Proposed hospital rate update and documentation and coding adjustment (1) <sup>2</sup>	Proposed FY 2017 weights and DRG changes with application of recalibration budget neutrality (2) <sup>3</sup>	Proposed FY 2017 wage data under new CBSA designations with application of wage budget neutrality (3) <sup>4</sup>	FY 2017 MGCRB reclassifications (4) <sup>5</sup>	Proposed rural and imputed floor with application of national rural and imputed floor budget neutrality (5) <sup>6</sup>	Proposed application of the frontier wage index and out-migration adjustment (6) <sup>7</sup>	All proposed FY 2017 changes (7) <sup>8</sup>
All Hospitals .....	3,330	0.9	0	0	0	0	0.1	0.7
By Geographic Location:								
Urban hospitals .....	2,512	0.8	0	0	-0.1	0	0.1	0.6
Large urban areas .....	1,378	0.8	0.1	0	-0.3	-0.1	0	0.6
Other urban areas .....	1,134	0.9	0	0	0.1	0.2	0.2	0.7
Rural hospitals .....	818	1.5	-0.4	0.1	1.4	-0.2	0.1	0.8
By Bed Size (Urban):								
0-99 beds .....	656	0.8	-0.2	0.2	-0.5	0.1	0.2	0.7
100-199 beds .....	765	0.9	-0.2	0	0	0.3	0.2	0.5
200-299 beds .....	449	0.9	-0.1	-0.1	0.1	0	0.1	0.5
300-499 beds .....	429	0.9	0.1	0.1	-0.2	0	0.2	0.7
500 or more beds .....	213	0.8	0.2	-0.1	-0.2	-0.1	0	0.8
By Bed Size (Rural):								
0-49 beds .....	320	1.3	-0.5	0.1	0.3	-0.2	0.3	0.6
50-99 beds .....	292	1.7	-0.6	0.1	0.8	-0.1	0.1	0.8
100-149 beds .....	119	1.5	-0.4	0	1.5	-0.2	0.2	0.6
150-199 beds .....	46	1.5	-0.2	0.1	1.7	-0.2	0	1.0
200 or more beds .....	41	1.5	-0.1	0.2	2.5	-0.2	0	1.2
By Urban Region:								
New England .....	116	0.7	0	-0.4	1.3	0.8	0	-0.6
Middle Atlantic .....	315	0.8	0.1	-0.3	0.5	-0.2	0.1	0.2
South Atlantic .....	406	0.9	0	-0.1	-0.4	-0.2	0.1	0.8
East North Central .....	390	0.8	0	0.1	-0.2	-0.3	0	1.1
East South Central .....	147	0.9	0	-0.2	-0.4	-0.3	0	1.0
West North Central .....	163	1	0.1	0	-0.7	-0.3	0.7	0.9
West South Central .....	384	0.8	0	0.3	-0.4	-0.3	0	1.2
Mountain .....	163	1	0	0.2	-0.4	0	0.2	0.7
Pacific .....	377	0.8	0	0.4	-0.4	1.1	0.1	0.4
Puerto Rico .....	51	0.8	0.1	-0.4	-0.9	0.2	0.1	0.3
By Rural Region:								
New England .....	21	1.2	-0.2	0.4	1.5	-0.2	0	1.2
Middle Atlantic .....	55	1.7	-0.4	0.1	0.6	-0.1	0.1	0.9
South Atlantic .....	127	1.4	-0.4	-0.1	2.5	-0.2	0.1	0.8
East North Central .....	115	1.6	-0.4	0	1	-0.1	0	0.9
East South Central .....	156	1	-0.3	0.4	2.1	-0.3	0.1	0.7
West North Central .....	99	2.1	-0.4	0	0.3	-0.1	0.3	1.0
West South Central .....	161	1.6	-0.5	0.2	1.6	-0.2	0.1	0.9
Mountain .....	60	1.6	-0.4	0.1	0.2	-0.1	0.1	0.7
Pacific .....	24	1.7	-0.5	-0.2	1.3	-0.1	0	0.8
By Payment Classification:								
Urban hospitals .....	2,455	0.8	0	0	-0.1	0	0.1	0.6
Large urban areas .....	1,372	0.8	0.1	0	-0.3	-0.1	0	0.6
Other urban areas .....	1,083	0.9	0	0	0.2	0.2	0.2	0.7
Rural areas .....	875	1.6	-0.4	0.1	1.1	-0.1	0.3	0.9
By Teaching Status:								
Nonteaching .....	2,275	1	-0.2	0	0.2	0.1	0.1	0.6
Fewer than 100 residents .....	804	0.9	0	0	-0.1	0	0.2	0.7
100 or more residents .....	251	0.8	0.2	-0.1	-0.1	-0.2	0	0.8
By Urban DSH:								
Non-DSH .....	597	0.9	0	-0.1	0.1	-0.1	0.1	0.5
100 or more beds .....	1,608	0.8	0.1	0	-0.1	0	0.1	0.7
Less than 100 beds .....	330	0.8	-0.3	0.1	-0.6	0.1	0.1	0.5
By Rural DSH:								
SCH .....	266	2	-0.5	0.1	0	0	0	0.9
RRC .....	347	1.5	-0.3	0.1	1.5	-0.2	0.3	0.9
100 or more beds .....	33	0.8	-0.4	-0.1	2.9	-0.3	0.1	0.5
Less than 100 beds .....	149	0.7	-0.4	0.1	1.4	-0.3	0.5	0.2
By Urban teaching and DSH:								
Both teaching and DSH .....	880	0.8	0.1	0	-0.2	-0.1	0.1	0.7
Teaching and no DSH .....	107	0.8	0	0	0.7	-0.1	0	0.2
No teaching and DSH .....	1,058	0.8	-0.1	0.1	0	0.2	0.1	0.5
No teaching and no DSH .....	410	0.8	0	-0.1	-0.3	0	0.1	0.7
By Special Hospital Types:								
RRC .....	193	0.8	-0.1	0.2	2	-0.1	0.4	1.1
SCH .....	326	2	-0.3	-0.1	0	0	0	1.0
MDH .....	146	1.6	-0.6	0	0.5	-0.1	0.2	0.8
SCH and RRC .....	126	2	-0.3	0.1	0.4	-0.1	0	1.2
MDH and RRC .....	15	1.8	-0.5	-0.1	0.8	-0.1	0	1.3
By Type of Ownership:								
Voluntary .....	1,914	0.9	0	0	0	0	0.1	0.7
Proprietary .....	858	0.9	0	0.1	0.1	0	0.1	0.8
Government .....	516	0.9	0	-0.2	-0.2	0.1	0.1	0.5

TABLE I—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2017—Continued

	Number of hospitals <sup>1</sup>	Proposed hospital rate update and documentation and coding adjustment (1) <sup>2</sup>	Proposed FY 2017 weights and DRG changes with application of recalibration budget neutrality (2) <sup>3</sup>	Proposed FY 2017 wage data under new CBSA designations with application of wage budget neutrality (3) <sup>4</sup>	FY 2017 MGCRB reclassifications (4) <sup>5</sup>	Proposed rural and imputed floor with application of national rural and imputed floor budget neutrality (5) <sup>6</sup>	Proposed application of the frontier wage index and out-migration adjustment (6) <sup>7</sup>	All proposed FY 2017 changes (7) <sup>8</sup>
Medicare Utilization as a Percent of Inpatient Days:								
0–25 .....	517	0.7	0.1	0	–0.4	0.1	0	0.7
25–50 .....	2,128	0.9	0	0	0	0	0.1	0.7
50–65 .....	546	1.1	–0.2	–0.1	0.6	0.1	0.1	0.5
Over 65 .....	94	1.1	–0.3	0.3	–0.5	0.3	0.2	0.9
FY 2017 Reclassifications by the Medicare Geographic Classification Review Board:								
All Reclassified Hospitals	853	0.9	0	0	2.1	–0.1	0	0.6
Non-Reclassified Hospitals	2,477	0.9	0	0	–0.9	0	0.1	0.7
Urban Hospitals Reclassified	576	0.8	0	0	2	–0.1	0	0.5
Urban Nonreclassified Hospitals	1,879	0.8	0.1	0	–0.9	0.1	0.1	0.7
Rural Hospitals Reclassified Full Year	277	1.6	–0.3	0.1	2.3	–0.2	0	1.0
Rural Nonreclassified Hospitals Full Year	484	1.5	–0.5	0.2	–0.2	–0.1	0.3	0.7
All Section 401 Reclassified Hospitals:	57	1.7	–0.2	0.2	–0.4	0	1.2	1.0
Other Reclassified Hospitals (Section 1886(d)(8)(B))	57	1.2	–0.4	0.1	3	–0.3	0	0.6

<sup>1</sup> 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 2015, and hospital cost report data are from reporting periods beginning in FY 2012 and FY 2013.

<sup>2</sup> This column displays the payment impact of the proposed hospital rate update and other proposed adjustments including the proposed 1.55 percent adjustment to the national standardized amount and hospital-specific rate (the estimated 2.8 percent market basket update reduced by the 0.5 percentage point for the proposed multifactor productivity adjustment and the 0.75 percentage point reduction under the Affordable Care Act), the –1.5 percent proposed documentation and coding adjustment to the national standardized amount and the proposed adjustment of (1/0.998) to permanently remove the –0.2 percent reduction, and the proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy.

<sup>3</sup> This column displays the payment impact of the proposed changes to the Version 34 GROUPE, the proposed changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2015 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 0.999006 in accordance with section 1886(d)(4)(C)(iii) of the Act.

<sup>4</sup> This column displays the payment impact of the proposed update to wage index data using FY 2013 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the proposed wage budget neutrality factor, which is calculated separately from the proposed 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 0.999785.

<sup>5</sup> Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB) along with the effects of the continued implementation of the new OMB labor market area delineations on these reclassifications. The effects demonstrate the FY 2017 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2017. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the proposed geographic budget neutrality factor of 0.988816.

<sup>6</sup> This column displays the effects of the proposed rural and imputed floor based on the continued implementation of the new OMB labor market area delineations. The Affordable Care Act requires the rural floor budget neutrality adjustment to be 100 percent national level adjustment. The proposed rural floor budget neutrality factor (which includes the proposed imputed floor) applied to the wage index is 0.993806. This column also shows the effect of the 3-year transition for hospitals that were located in urban counties that became rural under the new OMB delineations or hospitals deemed urban where the urban area became rural under the new OMB delineations, with a proposed budget neutrality factor of 0.999999.

<sup>7</sup> This column shows the combined impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0 and of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are non-budget neutral policies.

<sup>8</sup> This column shows the proposed changes in payments from FY 2016 to FY 2017. It reflects the impact of the proposed FY 2017 hospital update and the proposed adjustment for documentation and coding. It also reflects proposed changes in hospitals' reclassification status in FY 2017 compared to FY 2016. It incorporates all of the proposed changes displayed in Columns 1 through 6. The sum of these impacts may be different from the proposed percentage changes shown here due to rounding and interactive effects.

a. Effects of the Proposed Hospital Update, Documentation and Coding Adjustment, and Other Adjustments (Column 1)

As discussed in section IV.B. of the preamble of this proposed rule, this column includes the proposed hospital update, including the proposed 2.8 percent market basket update, the proposed reduction of 0.5 percentage point for the multifactor productivity adjustment, and the 0.75 percentage point reduction in accordance with the Affordable Care Act. In addition, as discussed in section II.D. of the preamble of this proposed rule, this column includes the

proposed FY 2017 documentation and coding recoupment adjustment of –1.5 percent on the national standardized amount as part of the recoupment required by section 631 of the ATRA and, as discussed in section IV.O. of the preamble of this proposed rule, the proposed adjustment of (1/0.998) to permanently remove the 0.2 percent reduction and the proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy. As a result, we are proposing to make a 0.9 percent update to the national standardized amount. This column also

includes the proposed 1.55 percent update to the hospital-specific rates which includes the proposed 2.8 percent market basket update, the proposed reduction of 0.5 percentage point for the multifactor productivity adjustment, the 0.75 percentage point reduction in accordance with the Affordable Care Act. In addition, this column includes the proposed adjustment to the hospital-specific rates of (1/0.998) to permanently remove the –0.2 percent reduction and the proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016, which are discussed in section IV.O. of

the preamble of this proposed rule. As a result, we are proposing to make a 2.35 percent update to the hospital-specific rates.

Overall, hospitals would experience a 0.9 percent increase in payments primarily due to the combined effects of the proposed hospital update and the proposed documentation and coding adjustment on the national standardized amount and the proposed hospital update to the hospital-specific rate as well as the proposed adjustment of (1/0.998) to permanently remove the -0.2 percent reduction and the proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy to both the national standardized amount and the hospital-specific rate. Hospitals that are paid under the hospital-specific rate, namely SCHs, would experience a 2.0 percent increase in payments; therefore, hospital categories with SCHs paid under the hospital-specific rate would experience increases in payments of more than 0.9 percent.

**b. Effects of the Proposed Changes to the MS-DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 2)**

Column 2 shows the effects of the proposed changes to the MS-DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we are calculating a recalibration budget neutrality factor to account for the changes in MS-DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this proposed rule, the FY 2017 MS-DRG relative weights would be 100 percent cost-based and 100 percent MS-DRGs. For FY 2017, the MS-DRGs are calculated using the FY 2015 MedPAR data grouped to the Version 34 (FY 2017) MS-DRGs. The methodology to calculate the relative weights and the reclassification changes to the GROUPER are described in more detail in section II.G. of the preamble of this proposed rule.

The "All Hospitals" line in Column 2 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 0.999006 on to the standardized amount. Hospital categories that generally treat more surgical cases than medical cases would experience increases in their payments under the relative weights. Rural hospitals would experience a 0.4 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 3)**

Column 3 shows the impact of updated wage data using FY 2013 cost report data, with the application of the wage budget neutrality factor. The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core Based Statistical Areas (CBSAs) established by OMB. The current statistical standards used in FY 2017 are based on OMB standards published on February 28, 2013 (75 FR 37246 and 37252), and 2010 Decennial Census data (OMB Bulletin No. 13-01). (We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion on our adoption of the OMB labor market area delineations based on the 2010 Decennial Census data, effective beginning with the FY 2015 IPPS wage index).

Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the proposed wage index for acute care hospitals for FY 2017 is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013. The estimated impact of the updated wage data using the FY 2013 cost report data and the OMB labor market area delineations on hospital payments is isolated in Column 3 by holding the other payment parameters constant in this simulation. That is, Column 3 shows the percentage change in payments when going from a model using the FY 2016 wage index, based on FY 2012 wage data, the labor-related share of 69.6 percent, under the OMB delineations and having a 100-percent occupational mix adjustment applied, to a model using the FY 2017 pre-reclassification wage index based on FY 2013 wage data with the labor-related share of 69.6 percent, under the OMB delineations, also having a 100-percent occupational mix adjustment applied, while holding other proposed payment parameters such as use of the Version 34 MS-DRG GROUPER constant. The proposed FY 2017 occupational mix adjustment is based on the CY 2013 occupational mix survey.

In addition, the column shows the impact of the proposed application of the wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage index changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2017, we are proposing to calculate the wage budget neutrality factor to ensure that payments under updated wage data and the 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 FY 2017 wage budget neutrality factor is 0.999785, and the overall payment change is 0.0 percent.

Column 3 shows the impacts of updating the wage data using FY 2013 cost reports. Overall, the new wage data and the labor-related share, combined with the proposed wage budget neutrality adjustment, would lead to no change for all hospitals as shown in Column 3.

In looking at the wage data itself, the proposed national average hourly wage would increase 1.02 percent compared to FY 2016. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the national 1.02 percent increase in average hourly wage. Of the 3,303 hospitals with wage data for both FYs 2016 and 2017, 1,634 or 49.5 percent would experience an average hourly wage increase of 1.02 percent or more.

The following chart compares the shifts in wage index values for hospitals due to proposed changes in the average hourly wage data for FY 2017 relative to FY 2016. Among urban hospitals, 5 would experience a decrease of 10 percent or more, and 14 urban hospitals would experience an increase of 10 percent or more. One hundred and thirty-nine urban hospitals would experience an increase or decrease of at least 5 percent or more but less than 10 percent. Among rural hospitals, 9 would experience an increase of at least 5 percent but less than 10 percent, but no rural hospitals would experience a decrease of greater than or equal to 5 percent but less than 10 percent. No rural hospital would experience increases of 10 percent or more, but 2 rural hospitals would experience decreases of 10 percent or more. However, 794 rural hospitals would experience increases or decreases of less than 5 percent, while 2,340 urban hospitals would experience increases or decreases of less than 5 percent. No urban hospital and no rural hospital would experience no change to their wage index. These figures reflect proposed changes in the "pre-reclassified, occupational mix-adjusted wage index," that is, the proposed wage index before the application of proposed 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. through III.L. 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 proposed "payment wage index," which is the proposed wage index that includes all such exceptions and adjustments (as reflected in Tables 2 and 3 associated with this proposed rule, which are available via the Internet on the CMS Web site) is used to adjust the 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



following chart may illustrate a somewhat larger or smaller change than would occur in

a hospital's proposed payment wage index and total payment.

The following chart shows the projected impact of proposed changes in the area wage index values for urban and rural hospitals.

PROPOSED FY 2017 PERCENTAGE CHANGE IN AREA WAGE INDEX VALUES

	Number of hospitals	
	Urban	Rural
Increase 10 percent or more .....	14	0
Increase greater than or equal to 5 percent and less than 10 percent .....	88	9
Increase or decrease less than 5 percent .....	2,340	794
Decrease greater than or equal to 5 percent and less than 10 percent .....	51	0
Decrease 10 percent or more .....	5	2
Unchanged .....	0	0

d. Effects of MGCRB Reclassifications (Column 4)

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 bases other than where they are geographically located). The proposed changes in Column 4 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2017.

By spring of each year, the MGCRB makes reclassification determinations that would 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 0.988816 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 1.4 percent. By region, all the rural hospital categories will experience increases in payments due to MGCRB reclassifications.

New Table 2 listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site reflects the proposed reclassifications for FY 2017.

e. Effects of the Proposed Rural Floor and Imputed Floor, Including Application of National Budget Neutrality (Column 5)

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, 2013, 2014, 2015, 2016 IPPS/LTCH PPS final rules, and this

proposed rule, section 4410 of Public Law 105-33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index received by rural hospitals in the same State. We would apply a uniform budget neutrality adjustment to the wage index. The imputed floor, which is also included in the calculation of the budget neutrality adjustment to the wage index, was extended in FY 2012 for 2 additional years and in FY 2014 and FY 2015 for 1 additional year. Prior to FY 2013, only urban hospitals in New Jersey received the imputed floor. As discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53369), we established an alternative temporary methodology for the imputed floor, which resulted in an imputed floor for Rhode Island for FY 2013. For FY 2014 and FY 2015, we extended the imputed rural floor, as calculated under the original methodology and the alternative methodology. Due to the adoption of the new OMB labor market area delineations in FY 2015, the State of Delaware also became an all-urban State and thus eligible for an imputed floor. For FY 2016, we extended the imputed floor for 1 year, as calculated under the original methodology and the alternative methodology, through September 30, 2016. For FY 2017, we are proposing to extend the imputed rural floor for 1 year, as calculated under the original methodology and the alternative methodology, through September 30, 2017. As a result, New Jersey, Rhode Island, and Delaware would be able to receive an imputed floor through September 30, 2017. In New Jersey, 20 out of 64 hospitals would receive the imputed floor, and 10 out of 11 hospitals in Rhode Island would receive the imputed floor for FY 2017. For FY 2017, no hospitals would benefit from the imputed floor in Delaware because the CBSA wage index for each CBSA in Delaware under the new OMB delineations is equal to or higher than the imputed rural floor.

The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally, and the imputed floor is part of the rural floor budget neutrality factor applied to the wage index nationally. We have calculated a proposed FY 2017 rural floor budget neutrality factor to be applied to the wage index of 0.993806, which would reduce wage indexes by 0.62 percent.

Column 5 shows the projected impact of the proposed rural floor and imputed floor

with the national rural floor budget neutrality factor applied to the wage index based on the OMB labor market area delineations. The column compares the proposed post-reclassification FY 2017 wage index of providers before the proposed rural floor and imputed floor adjustment and the proposed post-reclassification FY 2017 wage index of providers with the proposed rural floor and imputed floor adjustment based on the OMB labor market area delineations. Only urban hospitals can benefit from the rural and imputed floors. Because the provision is budget neutral, all other hospitals (that is, all rural hospitals and those urban hospitals to which the adjustment is not made) would experience a decrease in payments due to the budget neutrality adjustment that is applied nationally to their wage index.

We estimate that 401 hospitals would benefit from the proposed rural and imputed floors in FY 2017, while the remaining 2,929 IPPS hospitals in our model would have their wage index reduced by the rural floor budget neutrality adjustment of 0.993806 (or 0.62 percent). We project that, in aggregate, rural hospitals would experience a 0.2 percent decrease in payments as a result of the application of the proposed rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project hospitals located in urban areas would experience no change in payments because increases in payments by hospitals benefitting from the rural floor offset decreases in payments by nonrural floor urban hospitals whose wage index is downwardly adjusted by the rural floor budget neutrality factor. Urban hospitals in the New England region would experience a 0.8 percent increase in payments primarily due to the application of the proposed rural floor in Massachusetts and the proposed imputed floor in Rhode Island. Fifteen urban providers in Massachusetts are expected to receive the proposed rural floor wage index value, including the rural floor budget neutrality of 0.993806, increasing payments overall to Massachusetts by an estimated \$25 million. We estimate that Massachusetts hospitals would receive approximately a 0.8 percent increase in IPPS payments due to the application of the proposed rural floor in FY 2017.

Urban Puerto Rico hospitals are expected to experience a 0.2 percent increase in payments as a result of the application of the proposed rural floor budget neutrality factor, of 0.993806 or 0.62 percent, to the proposed rural floor wage index.

There are 20 hospitals out of the 64 hospitals in New Jersey that would benefit from the proposed extension of the imputed floor and would receive the imputed floor wage index value under the OMB labor market area delineations, including the rural floor budget neutrality of 0.993806, which we estimate would increase payments to those imputed floor hospitals by \$20 million (overall, the State would receive an increase of \$8 million in payments due to the other hospitals in the State that would experience decreases in payments due to the proposed rural floor budget neutrality adjustment). Ten hospitals out of the 11 hospitals in Rhode Island would benefit from the proposed imputed rural floor calculated under the alternative methodology and would receive an additional \$18 million. While some hospitals in Delaware are geographically located in CBSAs that are assigned the imputed floor, none of these hospitals benefit from the imputed floor because they are

reclassifying to CBSAs with a higher wage index than the imputed floor.

Column 5 also shows the projected effects of the last year of the 3-year hold harmless provision for hospitals that were located in an urban county that became rural under the new OMB delineations or hospitals deemed urban where the urban area became rural under the new OMB delineations. As discussed in section III.G.2. of the preamble of this proposed rule, under this transition, hospitals that were located in an urban county that became rural under the new OMB delineations will generally be assigned the urban wage index value of the CBSA in which they are physically located in FY 2014 for a period of 3 fiscal years (that is, FYs 2015, 2016, and 2017). In addition, as discussed in section III.G.3. of the preamble of this proposed rule, under this transition, hospitals that were deemed urban where the urban area became rural under the new OMB delineations will generally be assigned the area wage index value of hospitals reclassified to the urban CBSA (that is, the attaching wage index, if applicable) to which they were designated in FY 2014. For FY 2017, we are applying the 3-year transition wage index adjustments in a budget neutral

manner, with a budget neutrality factor of 0.999999.

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 following table 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 2017. Column 3 displays the percentage of total payments each State would receive or contribute to fund the rural floor and imputed floor with national budget neutrality. The column compares the proposed post-reclassification FY 2017 wage index of providers before the proposed rural floor and imputed floor adjustment and the proposed post-reclassification FY 2017 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.

PROPOSED FY 2017 IPPS ESTIMATED PAYMENTS DUE TO RURAL AND IMPUTED FLOOR WITH NATIONAL BUDGET NEUTRALITY

State	Number of hospitals	Number of hospitals that will receive the rural floor or imputed floor	Proposed percent change in payments due to application of rural floor and Imputed floor with budget neutrality	Proposed difference (in millions)
	(1)	(2)	(3)	(4)
Alabama .....	83	6	-0.3	\$ -4.43
Alaska .....	6	1	-0.2	-0.34
Arizona .....	57	7	-0.1	-1.55
Arkansas .....	44	0	-0.3	-3.07
California .....	300	185	1.4	139.3
Colorado .....	48	3	0.3	3.57
Connecticut .....	31	13	0	0.29
Delaware .....	6	0	-0.4	-1.64
Washington, DC .....	7	0	-0.3	-1.62
Florida .....	171	15	-0.2	-11.11
Georgia .....	105	0	-0.3	-7.76
Hawaii .....	12	0	-0.3	-0.76
Idaho .....	14	0	-0.2	-0.74
Illinois .....	126	3	-0.3	-14.43
Indiana .....	89	0	-0.3	-8.24
Iowa .....	35	0	-0.3	-2.83
Kansas .....	53	0	-0.3	-2.5
Kentucky .....	65	0	-0.3	-4.71
Louisiana .....	95	0	-0.3	-4.19
Maine .....	18	0	-0.3	-1.53
Massachusetts .....	58	15	0.8	25.4
Michigan .....	95	0	-0.3	-14.07
Minnesota .....	49	0	-0.2	-5.06
Mississippi .....	62	0	-0.3	-3.08
Missouri .....	75	2	-0.3	-6.19
Montana .....	12	4	0.3	0.96
Nebraska .....	26	0	-0.2	-1.67
Nevada .....	24	3	-0.1	-0.79
New Hampshire .....	13	9	0.4	2.24
New Jersey .....	64	20	0.2	7.84
New Mexico .....	25	0	-0.2	-0.88
New York .....	154	21	-0.3	-20.52
North Carolina .....	84	4	-0.2	-5.88
North Dakota .....	6	1	-0.2	-0.57

PROPOSED FY 2017 IPPS ESTIMATED PAYMENTS DUE TO RURAL AND IMPUTED FLOOR WITH NATIONAL BUDGET  
NEUTRALITY—Continued

State	Number of hospitals	Number of hospitals that will receive the rural floor or imputed floor	Proposed percent change in payments due to application of rural floor and Imputed floor with budget neutrality	Proposed difference (in millions)
	(1)	(2)	(3)	(4)
Ohio .....	130	8	-0.3	-9.5
Oklahoma .....	86	2	-0.3	-3.53
Oregon .....	34	2	-0.3	-3.1
Pennsylvania .....	152	5	-0.3	-15.88
Puerto Rico .....	51	12	0.2	0.26
Rhode Island .....	11	10	4.8	18.11
South Carolina .....	56	5	-0.1	-0.99
South Dakota .....	18	0	-0.2	-0.67
Tennessee .....	93	20	-0.2	-5.59
Texas .....	320	1	-0.3	-20.35
Utah .....	33	1	-0.3	-1.33
Vermont .....	6	0	-0.2	-0.39
Virginia .....	75	1	-0.2	-6.29
Washington .....	49	8	0.2	4.38
West Virginia .....	29	2	-0.2	-1.21
Wisconsin .....	65	12	-0.2	-2.85
Wyoming .....	10	0	-0.1	-0.15

f. Effects of the Application of the Proposed Frontier State Wage Index and Out-Migration Adjustment (Column 6)

This column shows the combined effects of the application of section 10324(a) of the Affordable Care Act, which requires that we establish a minimum post-reclassified wage-index of 1.00 for all hospitals located in "frontier States," and the effects of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108-173, which provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. These two wage index provisions are not budget neutral and increase payments overall by 0.1 percent compared to the provisions not being in effect.

The term "frontier States" is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, 5 States (Montana, Nevada, North Dakota, South Dakota, and Wyoming) are considered frontier States and 50 hospitals located in those States will receive a frontier wage index of 1.0000. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately \$56 million. Rural and urban hospitals located in the West North Central region would experience an increase in payments by 0.3 and 0.7 percent, respectively, because many of the hospitals located in this region are frontier State hospitals.

In addition, section 1886(d)(13) of the Act, as added by section 505 of Public Law 108-173, provides for an increase in the wage index for hospitals located in certain counties that have a relatively high

percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment are to receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. There are an estimated 249 providers that would receive the out-migration wage adjustment in FY 2017. Rural hospitals generally qualify for the adjustment, resulting in a 0.1 percent increase in payments. This provision appears to benefit section 401 hospitals and RRCs in that they would experience a 1.2 percent and 0.4 percent increase in payments, respectively. This out-migration wage adjustment also is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase would be approximately \$31 million.

g. Effects of All FY 2017 Changes (Column 7)

Column 7 shows our estimate of the proposed changes in payments per discharge from FY 2016 and FY 2017, resulting from all proposed changes reflected in this proposed rule for FY 2017. It includes combined effects of the previous columns in the table.

The proposed average increase in payments under the IPPS for all hospitals is approximately 0.7 percent for FY 2017 relative to FY 2016. This column includes the proposed annual hospital update of 1.55 percent to the national standardized amount. This proposed annual hospital update includes the 2.8 percent market basket update, the proposed reduction of 0.5 percentage point for the multifactor

productivity adjustment, and the 0.75 percentage point reduction under section 3401 of the Affordable Care Act. As discussed in section II.D. of the preamble of this proposed rule, this column also includes the proposed FY 2017 documentation and coding recoupment adjustment of -1.5 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 adjustment of (1/0.998) to permanently remove the 0.2 percent reduction, and the proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy, which are discussed in section IV.O. of the preamble of this proposed rule. Hospitals paid under the hospital-specific rate would receive a 1.55 percent proposed hospital update in addition to the proposed adjustment of (1/0.998) to permanently remove the 0.2 percent reduction, and the proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 previously described. As described in Column 1, the proposed annual hospital update with the proposed documentation and coding recoupment adjustment for hospitals paid under the national standardized amount, the proposed adjustment of (1/0.998) to permanently remove the 0.2 percent reduction and the proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 for hospitals paid under the national standardized amount and hospitals paid under the hospital-specific rates, which are discussed in section IV.O. of the preamble of this proposed rule, combined with the proposed annual hospital update for hospitals paid under the hospital-specific

rates would result in a 0.7 percent increase in payments in FY 2017 relative to FY 2016. The impact of moving from our estimate of FY 2016 outlier payments, 5.3 percent, to the proposed estimate of FY 2017 outlier payments, 5.1 percent, would result in a decrease of 0.2 percent in FY 2017 payments relative to FY 2016. 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 7 may not equal the sum of the estimated percentage changes described previously.

Overall payments to hospitals paid under the IPPS due to the proposed applicable percentage increase and proposed changes to policies related to MS-DRGs, geographic adjustments, and outliers are estimated to increase by 0.7 percent for FY 2017. Hospitals in urban areas would experience a 0.6 percent increase in payments per discharge in FY 2017 compared to FY 2016. Hospital payments per discharge in rural areas are estimated to increase by 0.8 percent in FY 2017.

3. Impact Analysis of Table II

Table II presents the projected impact of the proposed changes for FY 2017 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 2016 with the proposed estimated average payments per discharge for FY 2017, as calculated under our models. Therefore, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the proposed changes presented in Table I. The proposed estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 7 of Table I.

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2017 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM

[Payments per discharge]

	Number of hospitals	Estimated average FY 2016 payment per discharge	Estimated average FY 2017 payment per discharge	Proposed FY 2017 changes
	(1)	(2)	(3)	(4)
All Hospitals .....	3,330	11,524	11,599	0.7
By Geographic Location:				
Urban hospitals .....	2,512	11,869	11,944	0.6
Large urban areas .....	1,378	12,658	12,729	0.6
Other urban areas .....	1,134	10,924	11,004	0.7
Rural hospitals .....	818	8,614	8,686	0.8
Bed Size (Urban):				
0–99 beds .....	656	9,393	9,462	0.7
100–199 beds .....	765	10,006	10,052	0.5
200–299 beds .....	449	10,758	10,807	0.5
300–499 beds .....	429	12,068	12,153	0.7
500 or more beds .....	213	14,591	14,703	0.8
Bed Size (Rural):				
0–49 beds .....	320	7,187	7,230	0.6
50–99 beds .....	292	8,214	8,278	0.8
100–149 beds .....	119	8,457	8,506	0.6
150–199 beds .....	46	9,263	9,359	1.0
200 or more beds .....	41	10,175	10,295	1.2
Urban by Region:				
New England .....	116	12,947	12,870	–0.6
Middle Atlantic .....	315	13,445	13,469	0.2
South Atlantic .....	406	10,494	10,574	0.8
East North Central .....	390	11,167	11,290	1.1
East South Central .....	147	10,022	10,123	1.0
West North Central .....	163	11,589	11,694	0.9
West South Central .....	384	10,688	10,812	1.2
Mountain .....	163	12,273	12,361	0.7
Pacific .....	377	15,279	15,336	0.4
Puerto Rico .....	51	8,409	8,432	0.3
Rural by Region:				
New England .....	21	11,758	11,897	1.2
Middle Atlantic .....	55	8,646	8,726	0.9
South Atlantic .....	127	8,059	8,120	0.8
East North Central .....	115	8,947	9,023	0.9
East South Central .....	156	7,642	7,694	0.7
West North Central .....	99	9,464	9,555	1.0
West South Central .....	161	7,254	7,321	0.9
Mountain .....	60	10,142	10,214	0.7
Pacific .....	24	11,976	12,066	0.8
By Payment Classification:				
Urban hospitals .....	2,455	11,888	11,963	0.6
Large urban areas .....	1,372	12,664	12,735	0.6
Other urban areas .....	1,083	10,926	11,006	0.7
Rural areas .....	875	8,890	8,967	0.9
Teaching Status:				
Nonteaching .....	2,275	9,593	9,649	0.6
Fewer than 100 residents .....	804	11,122	11,194	0.7
100 or more residents .....	251	16,697	16,821	0.8
Urban DSH:				
Non-DSH .....	597	10,104	10,156	0.5

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2017 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued  
[Payments per discharge]

	Number of hospitals	Estimated average FY 2016 payment per discharge	Estimated average FY 2017 payment per discharge	Proposed FY 2017 changes
	(1)	(2)	(3)	(4)
100 or more beds .....	1,608	12,247	12,327	0.7
Less than 100 beds .....	330	8,718	8,759	0.5
Rural DSH:				
SCH .....	266	9,218	9,299	0.9
RRC .....	347	9,200	9,286	0.9
100 or more beds .....	33	7,070	7,102	0.5
Less than 100 beds .....	149	6,783	6,798	0.2
Urban teaching and DSH:				
Both teaching and DSH .....	880	13,362	13,456	0.7
Teaching and no DSH .....	107	11,418	11,438	0.2
No teaching and DSH .....	1,058	10,009	10,061	0.5
No teaching and no DSH .....	410	9,519	9,585	0.7
Special Hospital Types:				
RRC .....	193	9,673	9,782	1.1
SCH .....	326	10,357	10,459	1.0
MDH .....	146	7,202	7,262	0.8
SCH and RRC .....	126	10,814	10,940	1.2
MDH and RRC .....	15	9,216	9,334	1.3
Type of Ownership:				
Voluntary .....	1,914	11,704	11,781	0.7
Proprietary .....	858	10,110	10,188	0.8
Government .....	516	12,474	12,532	0.5
Medicare Utilization as a Percent of Inpatient Days:				
0–25 .....	517	14,964	15,062	0.7
25–50 .....	2,128	11,446	11,523	0.7
50–65 .....	546	9,341	9,387	0.5
Over 65 .....	94	6,966	7,025	0.9
FY 2017 Reclassifications by the Medicare Geographic Classification Review Board:				
All Reclassified Hospitals .....	853	11,571	11,641	0.6
Non-Reclassified Hospitals .....	2,477	11,504	11,581	0.7
Urban Hospitals Reclassified .....	576	12,191	12,256	0.5
Urban Nonreclassified Hospitals .....	1,879	11,774	11,852	0.7
Rural Hospitals Reclassified Full Year .....	277	8,994	9,080	1.0
Rural Nonreclassified Hospitals Full Year .....	484	8,193	8,250	0.7
All Section 401 Reclassified Hospitals: .....	57	10,782	10,892	1.0
Other Reclassified Hospitals (Section 1886(d)(8)(B)) .....	57	7,949	7,998	0.6

H. Effects of Other Proposed Policy Changes

In addition to those proposed policy changes discussed previously 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 in this section.

1. Effects of Proposed Policy Relating to New Medical Service and Technology Add-On Payments

In section II.H. of the preamble to this proposed rule, we discuss nine technologies for which we received applications for add-on payments for new medical services and technologies for FY 2017, as well as the status of the new technologies that were approved to receive new technology add-on payments in FY 2016. We note that one applicant withdraw its application prior to the issuance of this proposed rule. As

explained in the preamble to this proposed rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.H.5. of the preamble of this proposed rule, we have not yet determined whether any of these nine technologies for which we received applications for consideration for new technology add-on payments for FY 2017 will meet the specified criteria. Consequently, it is premature to estimate the potential payment impact of these nine technologies for any potential new technology add-on payments for FY 2017. We note that if any of the nine technologies are found to be eligible for new technology add-on payments for FY 2017, in the FY 2017 IPPS/LTCH PPS final rule, we would discuss the estimated payment impact for FY 2017.

In section II.H.4. of the preamble of this proposed rule, we are proposing to discontinue new technology add-on payments for the Argus® II Retinal Prosthesis System, Kcentra™, the MitraClip® System, and the Responsive Neurostimulator (RNS®)

for FY 2017 because these technologies will have been on the U.S. market for 3 years. We also are proposing to continue to make new technology add-on payments for the CardioMEMS™ HF (Heart Failure) Monitoring System, Blinatumomab (BLINCYTO™), and the LUTONIX® Drug Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) and IN.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter in FY 2017 because these technologies are still considered new. We note that new technology add-on payments for each 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 new technology add-on payments for FY 2017 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on

payment. For the CardioMEMS™ HF Monitoring System, based on the applicant's estimate from FY 2015, we currently estimate that new technology add-on payments for the CardioMEMS™ HF Monitoring System will increase overall FY 2017 payments by \$11,315,625. Based on the applicant's estimate for FY 2016, we currently estimate that new technology add-on payments for BLINCYTO™ will increase overall FY 2017 payments by \$4,593,034 (maximum add-on payment of \$27,017.85 \* 170 patients). Based on the weighted cost average for FY 2016 described in the FY 2016 IPPS/LTCH final rule (80 FR 49469 through 49470), we currently estimate that new technology add-on payments for the LUTONIX® DCB PTA and IN.PACT™ Admiral™ Pacliaxel Coated PTA Balloon Catheter will increase overall FY 2017 payments by \$36,120,735 (maximum add-on payment of \$1,035.72 \* 8,875 patients for LUTONIX® DCB PTA Balloon Catheter; maximum add-on payment of \$1,035.72 \* 26,000 patients for IN.PACT™ Admiral™ Pacliaxel Coated PTA Balloon Catheter).

2. Effects of the Proposed Changes to Medicare DSH Payments for FY 2017

As discussed in section IV.F. of the preamble of this proposed rule, under section 3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the former statutory formula for Medicare DSH payments. The remainder, equal to an estimate of 75 percent of what formerly would have been paid as Medicare DSH payments (Factor 1), reduced to reflect changes in the percentage of individuals under age 65 who are uninsured and additional statutory adjustments (Factor 2), is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. Each hospital eligible for Medicare DSH payments will receive an additional payment based on its estimated share of the total amount of uncompensated care for all hospitals eligible for Medicare DSH payments. The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's uncompensated care relative to the uncompensated care for all hospitals eligible for Medicare DSH payments (Factor 3). For FY 2017, because we are proposing to continue to use low-income insured patient days as a proxy for uncompensated care, the uncompensated care payment methodology has redistributive effects based on the

proportion of a hospital's low-income insured patient days (sum of Medicaid patient days and Medicare SSI patient days) relative to the low-income insured patient days for all hospitals eligible for DSH payments. The reduction to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this proposed rule, we are proposing to establish the overall amount available to be distributed as uncompensated care payments to DSH eligible hospitals, which for FY 2017 is \$6,054,458,492.68, or 75 percent of what otherwise would have been paid for Medicare DSH payment adjustments adjusted by a proposed Factor 2 of 56.74 percent. For FY 2016, the amount available to be distributed for uncompensated care was \$6,406,145,534.04, or 75 percent of what otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 63.69 percent. To calculate Factor 3 for FY 2017, we are proposing to use an average of data computed using Medicaid days from hospitals' 2011, 2012, and 2013 cost reports, Medicaid days from 2011 and 2012 cost report data submitted to CMS by IHS hospitals, and SSI days from the FY 2012, FY 2013, and FY 2014 SSI ratios. That is, for each hospital we are proposing to calculate an individual Factor 3 for cost reporting periods beginning during FYs 2011, 2012, and 2013, sum the individual amounts, and divide the sum by three in order to calculate an average Factor 3 for the hospital.

The FY 2017 proposal to use data on low-income insured days from 3 years of cost reports to determine Factor 3, as described earlier, is in contrast to the methodology used in FY 2016, when we used Medicaid days from the more recent of a hospital's full year 2012 or 2011 cost report from the March 2015 update of the HCRIS database, Medicaid days from 2012 cost report data submitted to CMS by IHS hospitals, and SSI days from the FY 2013 SSI ratios to calculate Factor 3. In addition, as explained in section IV.F. of the preamble of this proposed rule, we are proposing to make two additional modifications to the Factor 3 methodology: (1) To create proxy Medicare SSI values for Puerto Rico hospitals and (2) to include all hospitals' cost reports that begin during FYs 2011, 2012, and 2013, even in the instance where a hospital has more than one cost report beginning during a given fiscal year. Because residents of Puerto Rico are not eligible for SSI benefits, we are proposing to impute a Medicare SSI value for each Puerto Rico hospital equal to 14 percent of its Medicaid days. The proposed FY 2017 uncompensated care payment methodology

is discussed in more detail in section IV.F. of the preamble of this proposed rule.

To estimate the impact of the combined effect of reductions in the percent of individuals under age 65 who are uninsured and additional statutory adjustments (Factor 2) and changes in Medicaid and SSI patient days (components of Factor 3) on the calculation of Medicare DSH payments, including both empirically justified Medicare DSH payments and uncompensated care payments, we compared total DSH payments estimated in the FY 2016 IPPS/LTCH PPS final rule to total DSH payments estimated in this FY 2017 IPPS/LTCH PPS proposed rule. For FY 2016, for each hospital, we calculated the sum of: (1) 25 percent of the estimated amount of what would have been paid as Medicare DSH in FY 2016 in the absence of section 3133 of the Affordable Care Act; and (2) 75 percent of the estimated amount of what would have been paid as Medicare DSH payments in the absence of section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 63.69 percent and multiplied by a Factor 3 as stated in the FY 2016 IPPS/LTCH PPS final rule. For FY 2017, we would calculate the sum of: (1) 25 percent of the estimated amount of what would be paid as Medicare DSH payments in FY 2017 absent section 3133 of Affordable Care Act; and (2) 75 percent of the estimated amount of what would have been paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 56.74 percent and multiplied by a Factor 3 as previously stated.

Our analysis included 2,434 hospitals that are projected to be eligible for DSH in FY 2017. It did not include hospitals that terminated their participation from the Medicare program as of July 1, 2015, Maryland hospitals, and SCHs that are expected to be paid based on their hospital-specific rates. In addition, low-income insured days from merged or acquired hospitals were combined into the surviving hospital's CCN, and the nonsurviving CCN was excluded from the analysis. In contrast to FY 2016, hospitals participating in the Rural Community Hospital Demonstration program, which is scheduled to end in FY 2017, are included in the analysis if projected to be eligible for DSH payments during FY 2017. The estimated impact of the proposed changes in Factors 1, 2, and 3 across all hospitals projected to be eligible for DSH payments in FY 2017, by hospital characteristic, is presented in the following table.

MODELED DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR ESTIMATED FY 2017 DSHs BY HOSPITAL TYPE: MODEL DSH \$ (IN MILLIONS) FROM FY 2016 TO FY 2017

	Number of estimated DSHs (FY 2017)	FY 2016 final rule estimated DSH \$* (in millions)	FY 2017 proposed rule estimated DSH \$* (in millions)	Dollar difference: FY 2017–FY 2016 (in millions)	Percent change**
	(1)	(2)	(3)	(4)	(5)
Total .....	2,434	\$9,732	\$9,598	–\$134	–1.4%
By Geographic Location:					
Urban Hospitals .....	1,927	9,262	9,148	–114	–1.2

MODELED DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR ESTIMATED FY 2017 DSHs BY HOSPITAL TYPE: MODEL DSH \$ (IN MILLIONS) FROM FY 2016 TO FY 2017—Continued

	Number of estimated DSHs (FY 2017)	FY 2016 final rule estimated DSH \$* (in millions)	FY 2017 proposed rule estimated DSH \$* (in millions)	Dollar difference: FY 2017–FY 2016 (in millions)	Percent change**
	(1)	(2)	(3)	(4)	(5)
Large Urban Areas .....	1,048	5,861	5,789	-72	-1.2
Other Urban Areas .....	879	3,401	3,359	-42	-1.2
Rural Hospitals .....	507	470	450	-20	-4.3
Bed Size (Urban):					
0 to 99 Beds .....	337	184	186	2	0.9
100 to 249 Beds .....	841	2,199	2,171	-28	-1.3
250 to 499 Beds .....	749	\$6,879	\$6,791	-\$88	-1.3
Bed Size (Rural):					
0 to 99 Beds .....	375	205	192	-\$13	-6.3
100 to 249 Beds .....	118	209	202	-7	-3.4
250 to 499 Beds .....	14	56	56	0	-0.3
Urban by Region:					
East North Central .....	317	1,268	1,253	-\$15	-1.2
East South Central .....	132	575	566	-9	-1.6
Middle Atlantic .....	233	1,607	1,583	-24	-1.5
Mountain .....	122	447	449	2	0.4
New England .....	90	386	388	2	0.5
Pacific .....	313	1,459	1,453	-6	-0.4
Puerto Rico .....	42	100	113	12	12.2
South Atlantic .....	320	1,772	1,737	-35	-2.0
West North Central .....	103	450	440	-10	-2.3
West South Central .....	255	1,198	1,168	-30	-2.5
Rural by Region:					
East North Central .....	65	48	45	-3	-6.7
East South Central .....	142	151	142	-9	-6.0
Middle Atlantic .....	26	34	32	-2	-6.2
Mountain .....	21	16	16	0	0.1
New England .....	11	15	16	1	8.8
Pacific .....	7	8	7	-1	-16.2
South Atlantic .....	88	96	96	0	0.2
West North Central .....	34	20	19	-1	-5.4
West South Central .....	113	83	78	-5	-5.9
By Payment Classification:					
Urban Hospitals .....	1,896	9,212	9,097	-115	-1.2
Large Urban Areas .....	1,046	5,859	5,788	-72	-1.2
Other Urban Areas .....	850	3,353	3,310	-43	-1.3
Rural Hospitals .....	538	520	501	-20	-3.8
Teaching Status:					
Nonteaching .....	1,551	3,101	3,065	-36	-1.2
Fewer than 100 residents .....	644	3,206	3,157	-49	-1.5
100 or more residents .....	239	3,425	3,375	-50	-1.5
Type of Ownership:					
Voluntary .....	1,400	6,020	5,939	-81	-1.3
Proprietary .....	550	1,664	1,638	-26	-1.5
Government .....	482	2,022	1,996	-26	-1.3
Unknown .....	2	27	25	-2	-5.8
Medicare Utilization Percent:					
0–25 .....	430	3,008	2,972	-36	-1.2
25–50 .....	1,625	6,329	6,235	-94	-1.5
50–65 .....	320	382	379	-3	-0.8
Over 65 .....	59	14	12	-2	-12.9

Source: Dobson | DaVanzo analysis of 2011–2013 Hospital Cost Reports.

\* Dollar DSH calculated by [0.25 \* estimated section 1886(d)(5)(F) payments] + [0.75 \* estimated section 1886(d)(5)(F) payments \* Factor 2 \* Factor 3]. When summed across all hospitals projected to receive DSH payments, DSH payments are estimated to be \$9,372 million in FY 2016 and \$9,598 million in FY 2017.

\*\* Percentage change is determined as the difference between Medicare DSH payments modeled for the FY 2017 IPPS/LTCH PPS proposed rule (column 3) and Medicare DSH payments modeled for the FY 2016 IPPS/LTCH final rule (column 2) divided by Medicare DSH payments modeled for the FY 2016 final rule (column 2) 1 times 100 percent.

Changes in projected FY 2017 DSH payments from DSH payments in FY 2016 are primarily driven by three factors: (1) An increase in Factor 1 from \$13.411 billion to

\$14.227 billion; (2) a reduction in the percent of uninsured (Factor 2) from 63.69 percent to 56.74 percent; and (3) a revised proxy methodology for calculating Factor 3 values.

The proposed impact analysis found that, across all projected DSH eligible hospitals, FY 2017 DSH payments are estimated at approximately \$9.598 billion, or a decrease of

approximately 1.4 percent from FY 2016 DSH payments (approximately \$9.732 billion). Although Factor 1 increased by approximately 6.1 percent, the reduction in Factor 2 offsets this and results in a net decrease in the amount available to be distributed in uncompensated care payments.

As seen in the above table, percent reductions greater than 1.4 percent indicate that hospitals within the specified category are projected to experience a greater reduction in DSH payments, on average, compared to the universe of FY 2017 projected DSH hospitals. Conversely, percent reductions that are less than 1.4 percent indicate a hospital type is projected to have a smaller reduction than the overall average. The variation in the distribution of payments by hospital characteristic is largely dependent on the change in a given hospital's number of Medicaid days and SSI days used in the Factor 3 computation.

Rural hospitals, grouped by geographic location, payment classification, and bed size, are projected to experience a larger reduction in DSH payments than urban hospitals. Overall, urban hospitals are projected to receive a 1.2 percent decrease in DSH payments, and rural hospitals are projected to receive a 4.3 percent decrease in DSH payments. The smaller the rural hospital, the larger the projected reduction in DSH payments, with rural hospitals that have 0–99 beds projected to experience a 6.3 percent payment reduction, and larger rural hospitals with 250–499 beds projected to experience a 0.3 percent payment reduction. In contrast, the smallest urban hospitals (0–99 beds) are projected to receive an increase in DSH payments of 0.9 percent. Larger hospitals (100–250 beds and 250+ beds) are projected to receive reductions of 1.3 percent in DSH payments that are smaller than the overall average.

By region, projected DSH payment reductions for urban hospitals were largest in the West South Central, West North Central, and South Atlantic regions. The Mountain, New England, and Puerto Rico region hospitals are projected to receive an increase in DSH payments. Reductions in remaining urban hospital regions are generally consistent with the overall average percent reduction of 1.4. Regionally, rural hospitals are projected to receive a wider range of reductions. Rural hospitals in the South Atlantic, Mountain, and most notably New England regions are projected to receive an increase in DSH payments. Reductions are projected to be larger than the overall average in most remaining regions, particularly in the Pacific region.

Teaching hospitals are projected to receive relatively larger reductions than nonteaching hospitals. Voluntary, proprietary, and government hospitals are projected to receive payment reductions generally consistent with the overall average percent reduction of 1.4. Government hospitals are projected to receive slightly smaller reductions in DSH payments, while proprietary hospitals are projected to receive slightly larger reductions than the overall average. Hospitals with over 65 percent Medicare utilization are projected to receive a significant reduction in DSH payments, while lower Medicare utilization percentiles show smaller reductions.

Puerto Rico hospitals are projected to receive an increase in overall DSH payments, including both empirically justified DSH payments and uncompensated care payments, due to the proposal to create proxy values for SSI days for hospitals in Puerto Rico for purposes of calculating Factor 3 of the uncompensated care payment methodology. For FY 2017, Puerto Rico hospitals are projected to receive \$113 million in overall DSH and uncompensated care payments, or a 12.2 percent increase from FY 2016 payments (\$100 million). Of the estimated \$113 million for FY 2017, we estimate that \$75 million will be uncompensated care payments to Puerto Rico hospitals. This represents an increase of approximately 11.2 percent, or \$7.6 million, in FY 2017 compared to the estimated \$68 million in uncompensated care payments to Puerto Rico hospitals in FY 2016. Moreover, we estimate that uncompensated care payments to Puerto Rico hospitals for FY 2017 are 12.6 percent, or \$8.4 million, higher with the proposed SSI proxy than they otherwise would have been without the proposed SSI proxy for FY 2017. In other words, without the proposed SSI proxy, we would have expected uncompensated care payments to Puerto Rico hospitals to decline by approximately \$0.9 million between FY 2016 and FY 2017. We note that because the proposed SSI proxy for Puerto Rico hospitals increases the number of days in the denominator of Factor 3, this affects hospitals nationally. We estimate that uncompensated care payments to non-Puerto Rico hospitals for FY 2017 are approximately 0.1 percent lower with the proposed SSI proxy than they otherwise would have been without the proposed SSI proxy.

### 3. Effects of Proposed Reduction Under the Hospital Readmissions Reduction Program

In section IV.G. of the preamble of this proposed rule, we discuss our proposals for the FY 2017 Hospital Readmissions Reduction Program (established under section 3025 of the Affordable Care Act), which requires a reduction to a hospital's base operating DRG payments to account for excess readmissions. For FY 2017, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG). This provision is not budget neutral. A hospital's readmission adjustment is the higher of a ratio of the hospital's aggregate payments for excess readmissions to their aggregate payments for all discharges, or a floor, which has been defined in the statute as 0.97 (or a 3.0 percent reduction). A hospital's base operating DRG payment (that is, wage-adjusted DRG payment amount, as discussed in section IV.G. of the preamble of this proposed rule) is the portion of the IPPS payment subject to the readmissions payment adjustment (DSH, IME, outliers and low-volume add-on payments are not subject to the readmissions adjustment). In this proposed rule, we estimate that 2,603 hospitals would have their base operating DRG payments reduced by their proxy FY

2017 hospital-specific readmissions adjustment. As a result, we estimate that the Hospital Readmissions Reduction Program would save approximately \$523 million in FY 2017, an increase of \$100 million over the estimated FY 2016 savings.

### 4. Effects of Proposed Changes Under the FY 2017 Hospital Value-Based Purchasing (VBP) Program

In section IV.H. of the preamble of this proposed rule, we discuss the Hospital VBP Program under which the Secretary makes value-based incentive payments to hospitals based on their performance on measures during the performance period with respect to a fiscal year. These incentive payments will be funded for FY 2017 through a reduction to the FY 2017 base operating DRG payment amount for the discharge for the hospital for such fiscal year, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2017 and subsequent years is 2 percent. The total amount available for value-based incentive payments must be equal to the total amount of reduced payments for all hospitals for the fiscal year, as estimated by the Secretary.

In section IV.H. of the preamble of this proposed rule, we estimate the available pool of funds for value-based incentive payments in the FY 2017 program year, which, in accordance with section 1886(o)(7)(C)(v) of the Act, will be 2.00 percent of base operating DRG payments, or a total of approximately \$1.7 billion. This estimated available pool for FY 2017 is based on the historical pool of hospitals that were eligible to participate in the FY 2016 program year and the payment information from the December 2015 update to the FY 2015 MedPAR file.

The proposed estimated impacts of the FY 2017 program year by hospital characteristic, found in the table below, are based on historical TPSs. We used the FY 2016 program year's TPSs to calculate the proxy adjustment factors used for this impact analysis. These are the most recently available scores that hospitals were given an opportunity to review and correct. The proxy adjustment factors use estimated annual base operating DRG payment amounts derived from the December 2015 update to the FY 2015 MedPAR file. The proxy adjustment factors can be found in Table 16 associated with this proposed rule (available via the Internet on the CMS Web site).

The impact analysis shows that, for the FY 2017 program year, the number of hospitals that would receive an increase in their base operating DRG payment amount is higher than the number of hospitals that would receive a decrease. Among urban hospitals, those in the New England, South Atlantic, East North Central, East South Central, West North Central, West South Central, Mountain, and Pacific regions would have an increase, on average, in their base operating DRG payment amount. Urban hospitals in the Middle Atlantic region would receive an average decrease in their base operating DRG payment amount. Among rural hospitals, those in all regions would have an increase, on average, in their base operating DRG payment amounts.



On average, hospitals that receive a higher (50–65) percent of DSH payments would receive decreases in base operating DRG payment amount. With respect to hospitals' Medicare utilization as a percent of inpatient

days (MCR), those hospitals with an MCR above 65 percent would have the largest average increase in base operating DRG payment amount.

Nonteaching hospitals would have an average increase, and teaching hospitals would experience an average decrease in base operating DRG payment amount.

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNT PROPOSED CHANGES RESULTING FROM THE FY 2017 HOSPITAL VBP PROGRAM

	Number of hospitals	Average (%)
<b>By Geographic Location:</b>		
All Hospitals .....	3,041	0.244
Large Urban .....	1,247	0.117
Other Urban .....	1,046	0.202
Rural Area .....	748	0.514
Urban hospitals .....	2,293	0.156
0–99 beds .....	517	0.708
100–199 beds .....	719	0.143
200–299 beds .....	430	–0.035
300–499 beds .....	419	–0.146
500 or more beds .....	208	–0.171
Rural hospitals .....	748	0.514
0–49 beds .....	265	0.695
50–99 beds .....	286	0.540
100–149 beds .....	115	0.304
150–199 beds .....	45	0.159
200 or more beds .....	37	0.103
<b>By Region:</b>		
Urban By Region .....	2,293	0.156
New England .....	110	0.152
Middle Atlantic .....	297	–0.065
South Atlantic .....	389	0.108
East North Central .....	368	0.204
East South Central .....	141	0.126
West North Central .....	155	0.370
West South Central .....	324	0.211
Mountain .....	159	0.128
Pacific .....	350	0.225
Rural By Region .....	748	0.514
New England .....	20	0.528
Middle Atlantic .....	53	0.373
South Atlantic .....	117	0.621
East North Central .....	112	0.514
East South Central .....	138	0.389
West North Central .....	94	0.623
West South Central .....	135	0.416
Mountain .....	55	0.713
Pacific .....	24	0.677
<b>By MCR Percent:</b>		
0–25 .....	374	0.131
25–50 .....	2,024	0.205
50–65 .....	508	0.409
Over 65 .....	126	0.539
Missing .....	9	0.204
<b>BY DSH Percent:</b>		
0–25 .....	1,427	0.384
25–50 .....	1,320	0.154
50–65 .....	156	–0.067
Over 65 .....	138	0.007
<b>By Teaching Status:</b>		
Non-Teaching .....	2,041	0.381
Teaching .....	1,000	–0.036

Actual FY 2017 program year's TPSs will not be reviewed and corrected by hospitals until after the FY 2017 IPPS/LTCH PPS final rule has been published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2016 program year will be used for the updated impact analysis in that final rule.

5. Effects of Proposed Changes to the HAC Reduction Program for FY 2017

In section IV.I. of the preamble of this proposed rule, we discuss the proposed changes to the HAC Reduction Program for FY 2017. The table and analysis below show

the estimated cumulative effect of the measures and scoring system for the HAC Reduction Program proposed in this proposed rule. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49575 through 49576), we finalized a Total HAC Score methodology that assigns, for FY 2017, weights for Domain 1 and Domain 2 at 15 percent and 85 percent, respectively. Based on this methodology, the table below presents data on the estimated proportion of hospitals in the worst-performing quartile of the Total HAC Scores by hospital characteristic. We note that because scores will undergo a 30-day review and correction period by the hospitals that

will not conclude until after the publication of the FY 2017 IPPS/LTCH PPS final rule, we are not providing hospital-level data or a hospital-level payment impact in conjunction with this FY 2017 IPPS/LTCH PPS proposed rule.

To estimate the impact of the FY 2017 HAC Reduction Program, we used, as previously finalized, AHRQ PSI 90 measure results based on Medicare FFS discharges from July 2013 through June 2015 and version 5.0.1 (recalibrated) of the AHRQ software. For the CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI measure results, we used standardized

infection ratios (SIRs) calculated with hospital surveillance data reported to the NHSN for infections occurring between January 1, 2013 and December 31, 2014.

To analyze the results by hospital characteristic, we used the FY 2016 Final

Rule Impact File. This table includes 3,225 non-Maryland hospitals that had a Total HAC Score for FY 2017. Of these, 3,211 hospitals had information for geographic location, region, bed size, DSH percent, and teaching status, 3,197 had information for ownership,

and 3,191 had information for MCR percent. Maryland hospitals and hospitals without a Total HAC Score are not included in the table below.

ESTIMATED PROPORTION OF HOSPITALS IN THE WORST-PERFORMING QUARTILE (75TH PERCENTILE) OF THE TOTAL HAC SCORE FOR THE FY 2017 HAC REDUCTION PROGRAM

[By hospital characteristic]

Hospital characteristic	Number of hospitals <sup>a</sup>	Number of hospitals in the worst-performing quartile <sup>b</sup>	Percent of hospitals in the worst-performing quartile <sup>c</sup>
Total <sup>d</sup> .....	3,225	774	24.0
By Geographic Location:			
All hospitals:			
Urban .....	2,403	656	27.3
Rural .....	808	108	13.4
Urban hospitals:			
1–99 beds .....	593	90	15.2
100–199 beds .....	737	164	22.3
200–299 beds .....	436	128	29.4
300–399 beds .....	273	103	37.7
400–499 .....	151	62	41.1
500 or more beds .....	213	109	51.2
Rural hospitals:			
1–49 beds .....	306	44	14.4
50–99 beds .....	294	32	10.9
100–149 beds .....	120	11	9.2
150–199 beds .....	47	11	23.4
200 or more beds .....	41	10	24.4
By Region:			
New England .....	134	46	34.3
Mid-Atlantic .....	367	130	35.4
South Atlantic .....	520	131	25.2
East North Central .....	499	105	21.0
East South Central .....	299	58	19.4
West North Central .....	262	39	14.9
West South Central .....	510	79	15.5
Mountain .....	225	64	28.4
Pacific .....	395	112	28.4
By DSH Percent: <sup>e</sup>			
0–24 .....	1,512	336	22.2
25–49 .....	1,370	329	24.0
50–64 .....	170	48	28.2
65 and over .....	159	51	32.1
By Teaching Status: <sup>f</sup>			
Non-teaching .....	2,189	398	18.2
Fewer than 100 residents .....	1,022	366	35.8
100 or more residents .....	777	230	29.6
By Type of Ownership:			
Voluntary .....	1,874	480	25.6
Proprietary .....	834	160	19.2
Government .....	489	122	24.9
By MCR Percent:			
0–24 .....	480	143	29.8
25–49 .....	2,096	498	23.8
50–64 .....	533	104	19.5
65 and over .....	82	14	17.1

Source: FY 2017 HAC Reduction Program Proposed Rule Preliminary Results. Scores are based on AHRQ PSI 90 data from July 2013 through June 2015 and CDC CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia and CDI data from January 2013 to December 2014. Hospital Characteristics are based on the FY 2016 Final Rule Impact File updated on October 8, 2015.

<sup>a</sup> The total number of non-Maryland hospitals with a Total HAC Score with hospital characteristic data (3,211 for geographic location, region, bed size, DSH percent, and teaching status; 3,197 for type of ownership; and 3,191 for MCR) does not add up to the total number of non-Maryland hospitals with a Total HAC Score for the FY 2017 HAC Reduction Program (3,225) because 14 hospitals are not included in the FY 2016 Final Rule Impact File and not all hospitals have data for all characteristics.

<sup>b</sup> This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.

<sup>c</sup> This column is the percent of hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.

<sup>d</sup> Total excludes 47 Maryland hospitals and 64 non-Maryland hospitals without a Total HAC Score for FY 2017.

<sup>e</sup> A hospital is considered to be a DSH hospital if it has a disproportionate patient percentage (DPP) greater than zero.

<sup>f</sup> A hospital is considered to be a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.

#### 6. Effects of Proposed Policy Changes Relating to Direct GME and IME Payments for Rural Training Tracks at Urban Hospitals

In section IV.J. of the preamble of this proposed rule, we discuss our proposal to extend the period for establishing rural track FTE limitations from 3 years to 5 years for purposes of direct GME and IME payments to urban hospitals with rural track training programs. Specifically, we are proposing to revise the regulations to permit that, in the first 5 program years (rather than the first 3 program years) of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents training in the rural training track at the urban hospital, and beginning with the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural training track's existence, the rural track FTE limitation would take effect. This proposed change addresses concerns expressed by the hospital community that rural training tracks, like any program, should have a sufficient amount of time for a hospital to "grow" and to establish a rural track FTE limitation that reflects the number of FTE residents that it will actually train, once the program is fully grown. In section IV.J. of the preamble of this proposed rule, we explain that because we inadvertently did not also amend the separate direct GME and IME regulations regarding the growth window and effective date of FTE limitations for rural track training programs when we amended the regulations regarding the 5-year growth window in the FY 2013 IPPS/LTCH PPS final rule and regarding the additional changes we made in the FY 2015 IPPS/LTCH PPS final rule, we are proposing that the effective date regarding the change in the growth window also be effective for rural track training programs started on or after October 1, 2012. Mostly due to the relatively small size of rural track programs, we estimate that the proposal would cost approximately \$1 million by the end of the 10-year period, a negligible cost.

#### 7. Effects of Implementation of Rural Community Hospital Demonstration Program

In section IV.K. of the preamble of this proposed rule, for FY 2017, we discuss our implementation of section 410A of Public Law 108-173, as amended, which requires the Secretary to conduct a demonstration that would modify payments for inpatient services for up to 30 rural community hospitals. Section 410A(c)(2) requires that in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented.

As discussed in section IV.K. of the preamble of this proposed rule, in the IPPS final rules for each of the previous 12 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 have adjusted the national IPPS rates by an amount sufficient to account

for the added costs of this demonstration. In other words, we have applied budget neutrality across the payment system as a whole rather than across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented but does not identify the range across which aggregate payments must be held equal.

In this FY 2017 proposed rule, we are proposing a different methodology as compared to previous years for analyzing the costs attributable to the demonstration for FY 2017. The demonstration will have substantially phased out by the beginning of FY 2017. The 7 "originally participating hospitals", that is, those hospitals that were selected for the demonstration in 2004 and 2008, ended their participation in the 5-year extension period authorized by the Affordable Care Act prior to the start of FY 2016. In addition, the participation period for the 14 hospitals that entered the demonstration following the extension of the demonstration mandated by the Affordable Care Act and that are still participating will end on a rolling basis according to the end dates of the hospitals' cost report periods, respectively, from April 30, 2016 through December 31, 2016. Of these 14 hospitals, 10 hospitals will end participation on or before September 30, 2016, leaving 4 hospitals participating for the last 3 months of CY 2016 (that is, the first 3 months of FY 2017). Given the small number of participating hospitals and the limited time of participation, we are proposing to forego the process of estimating the costs attributable to the demonstration for FY 2017 and to instead analyze the set of finalized cost reports for reporting periods beginning in FY 2016 when they become available.

In previous IPPS/LTCH PPS final rules, we have determined the amount by which the actual costs of the demonstration for an earlier, previous year differed from the estimated costs of the demonstration set forth in the corresponding final rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. We note that we have calculated this difference between the actual costs of the demonstration for FYs 2005 through 2010, as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years. In this proposed rule, we are proposing to conduct this analysis for FYs 2011 through 2016 at one time, when all of the finalized cost reports for cost reporting periods beginning in FYs 2011 through 2016 are available. Given the general lag of 3 years in finalizing cost reports, we expect any such analysis to be conducted in FY 2020.

Because, as discussed earlier, we are proposing that we would not calculate and apply an estimated budget neutrality offset amount for FY 2017, but instead analyze the

set of finalized cost reports for cost reporting periods beginning in FY 2016 when they become available, and are proposing to reconcile the budget neutrality offset amounts for FYs 2011 through 2016 with the actual costs of the demonstration once the finalized cost reports for all of these years are available, we believe there would be no impact from the demonstration on the national IPPS rates for FY 2017.

#### 8. Effects of Proposed Implementation of the Notice of Observation Treatment and Implications for Care Eligibility Act (NOTICE Act)

In section IV.L. of the preamble of this proposed rule, we discuss our proposal to implement section 1866(a)(1)(Y) of the Act as amended by the NOTICE Act (Pub. L. 114-42) by revising the basic commitments providers agree to as part of participating in Medicare under a provider agreement by establishing regulations that would specify a process for hospitals and CAHs to notify an individual, orally and in writing, regarding the individual's receipt of observation services as an outpatient for more than 24 hours and the implications of receiving such services. The statute mandates the Secretary develop a plain language written notice for this purpose. The written notice must be delivered no later than 36 hours after observation services are initiated. We have developed a standardized format for the notice, which is undergoing OMB approval. The notice would be disseminated during the normal course of related business activities. In 2014, there were approximately 977,000 claims for Medicare outpatient observation services lasting greater than 24 hours furnished by 6,142 hospitals and CAHs.<sup>322</sup> We refer readers to section IX.B. of the preamble of this proposed rule for a discussion of the burden associated with this notice requirement.

#### 9. Effects of Proposed Technical Changes and Correction of Typographical Errors in Certain Regulations Under 42 CFR Part 413 Relating to Costs to Related Organizations and Medicare Cost Reports

In section IV.M. of the preamble of this proposed rule, we discuss a number of proposed technical changes or corrections of typographical errors in 42 CFR part 413 relating to costs to related organizations and Medicare cost reports that need to be made. We believe that the impact of these proposed technical changes and corrections is negligible.

#### 10. Effects of Proposed Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In section VI.B. of the preamble of this proposed rule, we discuss the implementation of the FCHIP demonstration, which will allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care, and other health care services to Medicare beneficiaries in no more than four

<sup>322</sup> Source: CMS Office of Enterprise and Data Analytics.

States. CMS has selected CAHs to participate in the demonstration, and budget neutrality estimates will be based on the demonstration period, which is expected to be August 1, 2016 through July 31, 2019. The selected CAHs are located in three States: Montana, Nevada, and North Dakota. The demonstration design includes three intervention prongs, under which specific waivers of Medicare payment rules will allow for enhanced payment: telemedicine, nursing facility, and ambulance services. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

We have specified the payment enhancements for the demonstration, and based our selection of CAHs for participation, with the goal of maintaining the budget neutrality of the demonstration on its own terms (that is, the demonstration will produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments resulting from the demonstration). However, because of the small size of this demonstration program and uncertainty associated with projected Medicare utilization and costs, we are proposing a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met. Accordingly, if analysis of claims data for the Medicare beneficiaries receiving services at each of the participating CAHs, as well as of other data sources, including cost reports for these CAHs, shows that increases in Medicare payments under the demonstration during the 3-year period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. The demonstration is projected to impact payments to participating CAHs under both Medicare Part A and Part B. Thus, in the event that we determine that aggregate payments under the demonstration exceed the payments that would otherwise have been made, we are proposing that CMS would recoup payments through reductions of Medicare payments to all CAHs under both Medicare Part A and Part B. Because of the small scale of the demonstration, it would be not be feasible to implement budget neutrality by reducing only payments to the participating CAH providers. We are proposing to make the reduction to payments to all CAHs, not just those participating in the demonstration, because the FCHIP program is specifically designed to test innovations that affect delivery of services by this provider category. We believe that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of the Act permits the agency to implement the budget neutrality provision in this manner. The statutory language refers merely to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Given the 3-year period of performance of the FCHIP demonstration and the time

needed to conduct the budget neutrality analysis, we are proposing that, in the event the demonstration is found not to have been budget neutral, any excess costs would be recouped over a period of three cost report periods, beginning in CY 2020. Therefore, this proposal does not impact any national payment system for FY 2017.

### *I. Effects of Proposed Changes in the Capital IPPS*

#### 1. General Considerations

For the impact analysis presented below, we used data from the December 2015 update of the FY 2015 MedPAR file and the December 2015 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 2015 update of the most recently available hospital cost report data (FYs 2013 and 2014) 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 later in this section.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the December 2015 update of the FY 2015 MedPAR file, we simulated payments under the capital IPPS for FY 2016 and FY 2017 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 the proposed capital IPPS payments in FY 2017 is as follows:

$$(\text{Standard Federal Rate}) \times (\text{DRG weight}) \times (\text{GAF}) \times (\text{COLA for hospitals located in Alaska and Hawaii}) \times (1 + \text{DSH Adjustment Factor} + \text{IME adjustment factor, if applicable}).$$

In addition to the other adjustments, hospitals may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the GAF and the hospital's case-mix. We then added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- We estimate that the Medicare case-mix index will increase by 0.5 percent in both FYs 2016 and 2017.

- We estimate that Medicare discharges will be approximately 11.3 million in FY 2016 and 11.5 million in FY 2017.

- 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 0.9 percent for FY 2017.

- In addition to the proposed FY 2017 update factor, the proposed FY 2017 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality adjustment factor of 0.9993, a proposed outlier adjustment factor of 0.9374, and a proposed adjustment of (1/0.998) to permanently remove the 0.2 percent adjustment, as well as a proposed temporary 2-midnight adjustment of 1.006. The 2-midnight adjustments are discussed in section V.C. of the preamble of this proposed rule and are consistent with the proposed 2-midnight adjustments on the operating Federal rate. As discussed in section V.C. of the preamble of this proposed rule, we are not proposing to make an additional MS–DRG documentation and coding adjustment to the capital IPPS Federal rates for FY 2017.

#### 2. Results

We used the actuarial model previously described in section I.I. of Appendix A of this proposed rule to estimate the potential impact of our proposed changes for FY 2017 on total capital payments per case, using a universe of 3,330 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the December 2015 update of the FY 2015 MedPAR file, the December 2015 update to the PSF, and the most recent cost report data from the December 2015 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2016 and estimated total payments per case for FY 2017 based on the proposed FY 2017 payment policies. Column 2 shows estimates of payments per case under our model for FY 2016. Column 3 shows estimates of payments per case under our model for FY 2017. Column 4 shows the total percentage change in payments from FY 2016 to FY 2017. The change represented in Column 4 includes the proposed 0.9 percent update to the capital Federal rate and other proposed changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, proposed capital payments per case in FY 2017 are expected to increase as compared to capital payments per case in FY 2016. This expected increase is due to the proposed approximately 1.7 percent increase in the capital Federal rate for FY 2017 as compared to the FY 2016 capital Federal rate and, to a lesser degree, changes to the MS–DRG reclassifications and recalibrations. (For a discussion of the determination of the capital Federal rate, we refer readers to section III.A. of the Addendum to this proposed rule.) The proposed increase in

capital payments per case due to the effects of changes to the MS-DRG reclassifications and recalibrations is expected to be slightly greater for urban hospitals than for rural hospitals. However, less than half of the hospitals in urban areas are expected to experience a slight increase in capital payments per case due to the effects of proposed changes to the GAFs, while the remainder of these urban area hospitals would experience no change or a decrease in capital payments per case due to proposed changes in the GAFs. For most hospitals in rural areas, proposed changes in the GAFs are expected to increase capital payments, to a greater or lesser extent, except for two rural areas where proposed changes in the GAFs are expected to decrease capital payments per case. These regional effects of the proposed changes to the GAFs on capital payments are consistent with the projected changes in payments due to proposed changes in the wage index (and proposed policies affecting the wage index) as shown in Table I in section I.G. of this Appendix A.

The net impact of these proposed changes is an estimated proposed 2.0 percent change in capital payments per case from FY 2016 to FY 2017 for all hospitals (as shown in Table III).

The geographic comparison shows that, on average, hospitals in all classifications (urban and rural) would experience an increase in capital IPPS payments per case in FY 2017 as compared to FY 2016. Capital IPPS

payments per case for hospitals in “large urban areas” have an estimated increase of 2.0 percent, while hospitals in rural areas, on average, are expected to experience a 2.1 percent increase in proposed capital payments per case from FY 2016 to FY 2017. Capital IPPS payments per case for “other urban hospitals” are also estimated to increase 2.1 percent. The primary factor contributing to the difference in the proposed projected increase in capital IPPS payments per case for urban hospitals as compared to rural hospitals is the proposed changes to the MS-DRGs reclassifications and recalibrations.

The comparisons by region show that the estimated increases in capital payments per case from FY 2016 to FY 2017 in urban areas range from a 2.7 percent increase for the West South Central urban region to a 0.7 percent increase for the New England urban region. For rural regions, the Middle Atlantic rural region is projected to experience the largest increase in capital IPPS payments per case of 2.9 percent; the Mountain rural region is projected to experience the smallest increase in capital IPPS payments per case of 0.7 percent. The proposed change in the GAFs is the main factor for the Mountain rural region experiencing the smallest projected increase in capital IPPS payments among rural regions, and it is also the main contributor for the smallest projected increase in capital IPPS payments for the New England urban region.

Hospitals of all types of ownership (that is, voluntary hospitals, government hospitals, and proprietary hospitals) are expected to experience an increase in capital payments per case from FY 2016 to FY 2017. The proposed increase in capital payments for voluntary and proprietary hospitals is estimated to be 2.0 percent and 2.2 percent, respectively. For government hospitals, the increase is estimated to be 1.8 percent.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2017. 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 2017, we show the average capital payments per case for reclassified hospitals for FY 2017. Urban reclassified hospitals are expected to experience an increase in capital payments of 2.0 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 2.1 percent. The estimated percentage increase for rural reclassified hospitals is 2.3 percent, and for rural nonreclassified hospitals, the estimated percentage increase is 1.5 percent. Other reclassified hospitals (section 1886(d)(8)(B) of the Act) are expected to experience the largest increase in capital payments of 2.6 percent.

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE  
[FY 2016 payments compared to FY 2017 payments]

	Number of hospitals	Average FY 2016 payments/case	Average FY 2017 payments/case	Change
<b>By Geographic Location:</b>				
All hospitals .....	3,330	895	913	2.0
Large urban areas (populations over 1 million) .....	1,378	991	1,010	2.0
Other urban areas (populations of 1 million of fewer) .....	1,134	855	873	2.1
Rural areas .....	818	607	619	2.1
Urban hospitals .....	2,512	929	948	2.0
0–99 beds .....	656	752	766	2.0
100–199 beds .....	765	805	819	1.8
200–299 beds .....	449	848	864	1.9
300–499 beds .....	429	943	963	2.1
500 or more beds .....	213	1,118	1,142	2.1
Rural hospitals .....	818	607	619	2.1
0–49 beds .....	320	509	519	2.0
50–99 beds .....	292	568	579	2.1
100–149 beds .....	119	599	610	1.8
150–199 beds .....	46	656	669	2.1
200 or more beds .....	41	727	744	2.3
<b>By Region:</b>				
Urban by Region .....	2,512	929	948	2.0
New England .....	116	1,011	1,018	0.7
Middle Atlantic .....	315	1,035	1,050	1.5
South Atlantic .....	406	826	843	2.1
East North Central .....	390	892	913	2.3
East South Central .....	147	780	800	2.5
West North Central .....	163	907	926	2.1
West South Central .....	384	839	862	2.7
Mountain .....	163	961	980	1.9
Pacific .....	377	1,194	1,218	2.0
Puerto Rico .....	51	426	450	5.5
Rural by Region .....	818	607	619	2.1
New England .....	21	847	866	2.3
Middle Atlantic .....	55	579	595	2.9

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE—Continued  
 [FY 2016 payments compared to FY 2017 payments]

	Number of hospitals	Average FY 2016 payments/case	Average FY 2017 payments/case	Change
South Atlantic .....	127	573	581	1.5
East North Central .....	115	627	642	2.4
East South Central .....	156	552	563	2.0
West North Central .....	99	655	666	1.8
West South Central .....	161	524	538	2.6
Mountain .....	60	710	715	0.7
Pacific .....	24	794	813	2.4
By Payment Classification:				
All hospitals .....	3,330	895	913	2.0
Large urban areas (populations over 1 million) .....	1,372	992	1,011	2.0
Other urban areas (populations of 1 million of fewer) .....	1,083	860	878	2.1
Rural areas .....	875	622	634	1.9
Teaching Status:				
Non-teaching .....	2,275	755	770	1.9
Fewer than 100 Residents .....	804	868	886	2.1
100 or more Residents .....	251	1,264	1,290	2.1
Urban DSH:				
100 or more beds .....	1,608	954	973	2.1
Less than 100 beds .....	330	688	700	1.8
Rural DSH:				
Sole Community (SCH/EACH) .....	266	590	603	2.2
Referral Center (RRC/EACH) .....	347	652	665	2.0
Other Rural:				
100 or more beds .....	33	537	545	1.4
Less than 100 beds .....	149	515	523	1.6
Urban teaching and DSH:				
Both teaching and DSH .....	880	1,029	1,051	2.1
Teaching and no DSH .....	107	928	942	1.5
No teaching and DSH .....	1,058	800	816	2.0
No teaching and no DSH .....	410	804	820	1.9
Rural Hospital Types:				
Non special status hospitals .....	2,522	931	949	2.0
RRC/EACH .....	193	754	774	2.6
SCH/EACH .....	326	689	702	2.0
SCH, RRC and EACH .....	126	735	749	1.9
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY2017 Reclassifications:				
All Urban Reclassified .....	576	952	971	2.0
All Urban Non-Reclassified .....	1,879	925	944	2.1
All Rural Reclassified .....	277	636	651	2.3
All Rural Non-Reclassified .....	484	570	578	1.5
Other Reclassified Hospitals (Section 1886(d)(8)(B)) .....	57	582	597	2.6
Type of Ownership:				
Voluntary .....	1,914	908	927	2.0
Proprietary .....	858	803	820	2.2
Government .....	516	946	963	1.8
Medicare Utilization as a Percent of Inpatient Days:				
0–25 .....	517	1,086	1,109	2.2
25–50 .....	2,128	899	917	2.0
50–65 .....	546	730	744	1.9
Over 65 .....	94	518	528	2.0

### J. Effects of Proposed Payment Rate Changes and Policy Changes Under the LTCH PPS

#### 1. Introduction and General Considerations

In section VII. of the preamble 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 2017. 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.

There are 420 LTCHs included in this impacts analysis, which includes data for 78 nonprofit (voluntary ownership control)

LTCHs, 325 proprietary LTCHs, and 17 LTCHs that are government-owned and operated. (We note that, although there are currently approximately 430 LTCHs, for purposes of this impact analysis, we excluded the data of all-inclusive rate providers consistent with the development of the proposed FY 2017 MS–LTC–DRG relative weights (discussed in section VII.C.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, which includes the

continued transition to the site neutral payment rate required by section 1886(m)(6)(A) of the Act (discussed in section VII.B. of the preamble of this proposed rule), the proposed 1.45 percent annual update to the LTCH PPS standard Federal payment rate in accordance with section 1886(m)(5)(C) of the Act (which is based on the full estimated increase of the proposed revised and rebased LTCH PPS market basket and the reductions required by sections 1886(m)(3) and (m)(4) of the Act), the proposed update to the MS–LTC–DRG classifications and relative weights, the proposed update to the wage index values and labor-related share, and the best available claims and CCR data to estimate the proposed change in payments for FY 2017.

Under the dual rate LTCH PPS payment structure, payment for LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) is based on the LTCH PPS standard Federal payment rate. Consistent with the statute, the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a); or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, there are two separate HCO targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases. The statute also establishes a transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 and FY 2017. The transitional payment amount for site neutral payment rate cases is a blended payment rate, which is calculated as 50 percent of the applicable site neutral payment rate amount for the discharge as determined under new § 412.522(c)(1) and 50 percent of the applicable LTCH PPS standard Federal payment rate for the discharge determined under § 412.523.

Based on the best available data for the 420 LTCHs in our database that were considered in the analyses used for this proposed rule, we estimate that overall LTCH PPS payments in FY 2017 would decrease by approximately 6.9 percent (or approximately \$355 million). This projection takes into account estimated payments for LTCH cases in our database that would have met the patient-level criteria and been paid the LTCH PPS standard Federal payment rate if those criteria had been in effect at the time of the discharge, and estimated payments for LTCH cases that would not have met the patient-level criteria and been paid under the site neutral payment rate if that rate had been in effect at the time of the discharge, as described in the following paragraph.

The statutory transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017 uses a blended payment rate, which is determined as 50 percent of the site neutral payment rate amount for the discharge and 50 percent of the standard Federal prospective payment rate amount for

the discharge (§ 412.522(c)(3)). The transitional blended payment rate uses the same blend percentages (that is, 50 percent) for both years of the 2-year transition period. Therefore, when estimating FY 2017 LTCH PPS payments for site neutral payment rate cases for this impact analysis, the transitional blended payment rate was applied to all such cases because all discharges in FY 2017 will either be in the hospital's cost reporting period that began during FY 2016 or in the hospital's cost reporting period that will begin during FY 2017. However, when estimating FY 2016 LTCH PPS payments for site neutral payment rate cases for this impact analysis because the statute specifies that the site neutral payment rate effective date for a given LTCH is determined based on the date on which that LTCH's cost reporting period begins during FY 2016, we included an adjustment to account for this rolling effective date, consistent with the approach used for the LTCH PPS impact analysis presented in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49831). This approach accounts for the fact that LTCHs with discharges in FY 2016 that are in cost reporting periods that begin *before* October 1, 2015, continued to be paid for all discharges (including those that did not meet the patient-level criteria for exclusion from the site neutral payment rate) at the LTCH PPS standard Federal payment rate until the start of their first cost reporting period beginning *after* October 1, 2015.

For purposes of this impact analysis, to estimate total FY 2016 LTCH PPS payments for site neutral payment rate cases, we used the same approach as was used in the FY 2016 IPPS/LTCH PPS final rule. In summary, under this approach, we grouped LTCHs based on the quarter of FY 2016 their cost reporting periods began during FY 2016. For example, LTCHs with cost reporting periods that began during October through December 2015 began during the first quarter of FY 2016. For LTCHs grouped in each quarter of FY 2016, we modeled those LTCHs' estimated FY 2016 site neutral payment rate payments under the transitional blended payment rate based on the quarter in which the LTCHs in each group become subject to the site neutral payment rate. Then, we modeled for LTCHs grouped in each quarter of FY 2016, estimated FY 2016 payments under the LTCH PPS standard Federal payment rate based on the quarter in which the LTCHs in each group become subject to the site neutral payment rate. (For additional details on our method of taking into account the rolling effective date of the application of the site neutral payment rate when estimating payments for FY 2016, we refer readers to the description presented in FY 2016 IPPS/LTCH PPS final rule (80 FR 49831).) We continue to believe that this approach is a reasonable means of taking the rolling effective date into account when estimating FY 2016 payments.

Based on the fiscal year start dates recorded in the December 2015 update of the PSF, of the 420 LTCHs in our database of LTCH claims from the December 2015 update of the FY 2015 MedPAR files used for this proposed rule, the following percentages apply in the approach previously described:

9.9 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the first quarter of FY 2016; 26.4 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the second quarter of FY 2016; 10.3 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the third quarter of FY 2016; and 53.4 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the fourth quarter of FY 2016.

Based on the FY 2015 LTCH cases that were used for the analyses in this proposed rule, approximately 45 percent of those LTCH cases would have been classified as site neutral payment rate cases if the site neutral payment rate had been in effect in FY 2015 (that is, 45 percent of such LTCH cases would not have met the patient-level criteria for exclusion from the site neutral payment rate). Our Office of the Actuary estimates that the percent of LTCH PPS cases that will be paid at the site neutral payment rate in FY 2017 will not change significantly from the historical data. Taking into account the transitional blended payment rate and other proposed changes that would apply to the site neutral payment rate cases in FY 2017, we estimate that aggregate LTCH PPS payments for these site neutral payment rate cases would decrease by approximately 21 percent (or approximately \$367 million).

Approximately 55 percent of LTCH cases are expected to meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2017, and will be paid based on the LTCH PPS standard Federal payment rate for the full year. We estimate that total LTCH PPS payments for these LTCH PPS standard Federal payment rate cases in FY 2017 would increase approximately 0.3 percent (or approximately \$12 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2017 is primarily due to the combined effects of the proposed 1.45 percent annual update to the LTCH PPS standard Federal payment rate for FY 2017 (discussed in section V.A. of the Addendum to this proposed rule) and an estimated decrease in HCO payments for these cases (discussed in section V.D.3. of the Addendum to this proposed rule).

Based on the 420 LTCHs that were represented in the FY 2015 LTCH cases that were used for the analyses in this proposed rule, we estimate that aggregate FY 2017 LTCH PPS payments would be approximately \$4.757 billion, as compared to estimated aggregate FY 2016 LTCH PPS payments of approximately \$5.112 billion, resulting in an estimated overall decrease in LTCH PPS payments of approximately \$355 million. Because the combined distributional effects and estimated payment changes exceed \$100 million, this proposed rule is a major economic rule. We note that this estimated \$355 million decrease in LTCH PPS payments in FY 2017 (which includes estimated payments for LTCH PPS standard Federal payment rate cases and site neutral payment rate cases) does not reflect changes in LTCH admissions or case-mix intensity, which would also affect the overall payment effects of the proposals in this proposed rule.

The LTCH PPS standard Federal payment rate for FY 2016 is \$41,762.85. For FY 2017, we are proposing an LTCH PPS standard Federal payment rate of \$42,314.31, which reflects the proposed 1.45 percent annual update to the LTCH PPS standard Federal payment rate and the proposed area wage budget neutrality factor of 0.998723 to ensure that the proposed changes in the wage indexes and labor-related share do not influence aggregate payments. For LTCHs that fail to submit data for the LTCH QRP, in accordance with section 1886(m)(5)(C) of the Act, we are proposing an LTCH PPS standard Federal payment rate of \$41,480.12. This proposed reduced LTCH PPS standard Federal payment rate reflects the updates previously described as well as the required 2.0 percentage point reduction to the annual update for failure to submit data under the LTCH QRP. We note that the factors previously described to determine the proposed FY 2017 LTCH PPS standard Federal payment rate are applied to the FY 2016 LTCH PPS standard Federal rate set forth under § 412.523(c)(3)(xi) (that is, \$41,762.85).

Table IV shows the estimated impact for LTCH PPS standard Federal payment rate cases. The estimated change attributable solely to the proposed annual update to the LTCH PPS standard Federal payment rate is projected to result in an increase of 1.3 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017, on average, for all LTCHs (Column 6). In addition to the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2017, the estimated increase of 1.3 percent shown in Column 6 of Table IV also includes estimated payments for SSO cases that will be paid using special methodologies that are not affected by the proposed annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the proposed annual update of LTCHs that do not submit the required LTCH QRP data. Therefore, for all hospital categories, the projected increase in payments based on the proposed LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases is somewhat less than the proposed 1.45 percent proposed annual update for FY 2017.

For FY 2017, we are proposing to update the wage index values based on the most recent available data, and we are proposing to continue to use labor market areas based on the OMB CBSA delineations (as discussed in section V.B. of the Addendum to this proposed rule). In addition, we are proposing an increase in the labor-related share from 62.0 percent to 66.6 percent under the LTCH PPS for FY 2017, based on the most recent available data on the relative importance of the labor-related share of operating and capital costs of the proposed 2013-based LTCH market basket (as discussed in section VII.D. of the preamble of this proposed rule). We also are proposing to apply an area wage level budget neutrality factor of 0.998723 to ensure that the proposed changes to the wage data and labor-related share do not result in a change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal

payment rate cases, which decreases the LTCH PPS standard Federal payment rate by approximately 0.13 percent.

We currently estimate total HCO payments for LTCH PPS standard Federal payment rate cases would decrease from FY 2016 to FY 2017. Based on the FY 2015 LTCH cases that were used for the analyses in this proposed rule, we estimate that the FY 2016 HCO threshold of \$16,423 (as established in the FY 2016 IPPS/LTCH PPS final rule) would result in estimated HCO payments for LTCH PPS standard Federal payment rate cases in FY 2016 that are above the estimated 8 percent target. Specifically, we currently estimate that HCO payments for LTCH PPS standard Federal payment rate cases would be approximately 9.1 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2016. Combined with our estimate that FY 2017 HCO payments for LTCH PPS standard Federal payment rate cases would be 8.0 percent of estimated total LTCH PPS standard Federal payment rate payments in FY 2017, this results in the estimated decrease in HCO payments of approximately 1.1 percent between FY 2016 and FY 2017.

In calculating these estimated HCO payments, we increased estimated costs by our actuaries' projected market basket percentage increase factor. This increase in estimated costs also results in a projected increase in SSO payments in FY 2017 (because 100 percent of the estimated cost of the case is an option in the SSO payment formula (§ 412.529)). We estimate that these increased SSO payments in FY 2017 would increase total payments for LTCH PPS standard Federal payment rate cases by approximately 0.25 percent. (Payments for SSO cases represent approximately 14 percent of the estimated total FY 2017 payments for LTCH PPS standard Federal payment rate cases.)

Table IV shows the estimated impact of the proposed payment rate and policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2017 by comparing estimated FY 2016 LTCH PPS payments to estimated FY 2017 LTCH PPS payments. (As noted earlier, our analysis does not reflect changes in LTCH admissions or case-mix intensity.) The projected increase in payments from FY 2016 to FY 2017 for LTCH PPS standard Federal payment rate cases of 0.3 percent is attributable to the impacts of the change to the LTCH PPS standard Federal payment rate (1.3 percent in Column 6) and the effect of the estimated decrease in HCO payments for LTCH PPS standard Federal payment cases (– 1.1 percent), and the estimated increase in payments for SSO cases (0.25 percent). We note that these impacts do not include LTCH PPS site neutral payment rate cases for the reasons discussed in section I.J.3. of this Appendix.

As we discuss in detail throughout this proposed rule, based on the most recent available data, we believe that the provisions of this proposed rule relating to the LTCH PPS, which are projected to result in an overall decrease in estimated aggregate LTCH PPS payments, and the resulting LTCH PPS payment amounts would result in

appropriate Medicare payments that are consistent with the statute.

## 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 0.3 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases. This estimated impact is based on the FY 2015 data for the 21 rural LTCHs (out of 420 LTCHs) that were used for the impact analyses shown in Table VI.

## 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 payment 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.

Section 1886(m)(6)(A) of the Act establishes a dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, LTCH discharges that meet the patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. LTCH discharges paid at the site neutral payment rate are generally paid the lower of the IPPS comparable per diem amount, including any applicable HCO payments, or 100 percent of the estimated cost of the case. The statute also establishes a transitional payment method for cases that are paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017, under which the site neutral payment rate cases are paid based on a blended payment rate calculated as 50 percent of the applicable site neutral payment rate amount for the discharge and 50 percent of the applicable LTCH PPS standard Federal payment rate for the discharge.

As discussed in section I.J.1. of this Appendix, we project a decrease in aggregate LTCH PPS payments in FY 2017 of approximately \$355 million. This estimated decrease in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately \$12 million and the projected decrease in payments to site neutral payment rate cases of approximately \$367 million under the dual rate LTCH PPS payment rate structure required by the statute beginning in FY 2016.

As discussed in section VII.B.7.b. of the preamble of this proposed rule, our actuaries project cost and resource changes for site neutral payment rate cases due to the site



neutral payment rates required under the statute. Specifically, our actuaries project that the costs and resource use for cases paid at the site neutral payment rate will likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate, and will likely mirror the costs and resource use for IPPS cases assigned to the same MS-DRG. While we are able to incorporate this projection at an aggregate level into our payment modeling, because the historical claims data that we are using in this proposed rule to project estimated FY 2017 LTCH PPS payments (that is, FY 2015 LTCH claims data) do not reflect this actuarial projection, we are unable to model the impact of the change in LTCH PPS payments for site neutral payment rate cases at the same level of detail with which we are able to model the impacts of the changes to LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, Table IV only reflects proposed changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases and, unless otherwise noted, the remaining discussion in section I.J.3. of this Appendix refers only to the impact on LTCH PPS payments for LTCH PPS standard Federal payment rate cases. In the following section, we present our provider impact analysis for the changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

#### b. Impact on Providers

Under the dual rate LTCH PPS payment structure, there are two distinct payment rates for LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2016. Under that statute, any discharges that occur on or after October 1, 2015, but prior to the start of the LTCH's FY 2016 cost reporting period, will be paid at the LTCH PPS standard Federal payment rate. On or after the start of an LTCH's FY 2017 cost reporting period, discharges are paid based on the nature of the case. As described previously, LTCH PPS standard Federal payment rate cases are defined as LTCH discharges that meet the patient-level criteria to be excluded from the typically lower site neutral payment rate, and site neutral payment rate cases are defined as LTCH discharges that do not meet the patient-level criteria and generally will be paid the lower site neutral payment rate. However, for discharges occurring in cost reporting periods beginning in FY 2016 or 2017, the statute specifies that site neutral payment rate cases are paid based on a transitional payment method that is calculated as 50 percent of the applicable site neutral payment rate amount and 50 percent of the applicable LTCH PPS standard Federal payment rate.

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is currently set forth under §§ 412.515 through 412.536. In addition to adjusting the LTCH PPS standard Federal payment rate by the MS-LTC-DRG relative weight, we make adjustments to account for area wage levels and SSOs. LTCHs located in Alaska and Hawaii also have their payments adjusted by a COLA. Under our application of the dual

rate LTCH PPS payment structure, the LTCH PPS standard Federal payment rate is generally only used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate). LTCH discharges that do not meet the patient-level criteria for exclusion are paid the site neutral payment rate, which we are calculating as the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments, or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, when certain thresholds are met, LTCHs also receive HCO payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

To understand the impact of the changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this proposed rule on different categories of LTCHs for FY 2017, it is necessary to estimate payments per discharge for FY 2016 using the rates, factors, and the policies established in the FY 2016 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2017 using the rates, factors, and the policies proposed in this FY 2017 IPPS/LTCH PPS proposed rule (as discussed in section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule). As discussed elsewhere in this proposed rule, these estimates 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. The resulting analyses can then be used to compare how our proposed policies applicable to LTCH PPS standard Federal payment rate cases affect different groups of LTCHs.

For the following analysis, we group hospitals based on characteristics provided in the OSCAR data, FY 2012 through FY 2013 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.

#### c. Calculation of LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases

For purposes of this impact analysis, to estimate the per discharge payment effects of our proposed policies on payments for LTCH PPS standard Federal payment rate cases, we simulated FYs 2016 and 2017 payments on a case-by-case basis using historical LTCH claims from the FY 2015 MedPAR files that would have met the criteria to be paid at the LTCH PPS standard Federal payment rate if the statutory patient-level criteria had been in effect at the time of discharge for those cases. For modeling FY 2016 LTCH PPS payments, we used the FY 2016 standard Federal payment rate of \$41,762.85, or \$40,941.55 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP. Similarly, for

modeling payments based on the FY 2017 LTCH PPS standard Federal payment rate, we used the proposed FY 2017 standard Federal payment rate of \$42,314.31, or \$41,480.12 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP. In each case, we applied the applicable proposed adjustments for area wage levels and the COLA for LTCHs located in Alaska and Hawaii. Specifically, for modeling FY 2016 LTCH PPS payments, we used the current FY 2016 labor-related share (62.0 percent); the wage index values established in the Tables 12A through 12D listed in the Addendum to the FY 2016 IPPS/LTCH PPS final rule (which are available via the Internet on the CMS Web site); the FY 2016 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of \$16,423 (as discussed in section V.D. of the Addendum to that final rule) and the FY 2016 COLA factors (shown in the table in section V.C. of the Addendum to that final rule) to adjust the FY 2016 nonlabor-related share (38.0 percent) for LTCHs located in Alaska and Hawaii. Similarly, for modeling FY 2017 LTCH PPS payments, we used the proposed FY 2017 LTCH PPS labor-related share (66.6 percent), the proposed FY 2017 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this proposed rule (which are available via the Internet on the CMS Web site), the proposed FY 2017 fixed-loss amount for LTCH PPS standard Federal payment rate cases of \$22,728 (as discussed in section V.D.3. of the Addendum to this proposed rule), and the proposed FY 2017 COLA factors (shown in the table in section V.C. of the Addendum to this proposed rule) to adjust the proposed FY 2017 nonlabor-related share (33.4 percent) for LTCHs located in Alaska and Hawaii.

As previously discussed, our impact analysis reflects an estimated change in payments for SSO cases, as well as an estimated decrease in HCO payments for LTCH PPS standard Federal payment rate cases (as described previously in section I.J.1. of this Appendix). In modeling proposed payments for SSO and HCO cases for LTCH PPS standard Federal payment rate cases, we applied an inflation factor of 4.8 percent (determined by the Office of the Actuary) to update the 2015 costs of each case.

The impacts that follow reflect the estimated "losses" or "gains" among the various classifications of LTCHs from FY 2016 to FY 2017 based on the proposed payment rates and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. Table IV illustrates the estimated aggregate impact of the change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among various classifications of LTCHs. (As discussed previously, these impacts do not include LTCH PPS site neutral payment rate cases.)

- 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 expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2016 payment per discharge for LTCH

cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).

- The fifth column shows the estimated FY 2017 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).

- The sixth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria

from FY 2016 to FY 2017 due to the annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this proposed rule).

- The seventh column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017 for proposed changes to the area wage level adjustment (that is, the proposed wage indexes and the proposed labor-related share), including the application of the

proposed area wage level budget neutrality factor (as discussed in section V.B. of the Addendum to this proposed rule).

- The eighth column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 (Column 4) to FY 2017 (Column 5) for all proposed changes (and includes the effect of estimated changes to HCO and SSO payments).

TABLE IV—IMPACT OF PROPOSED PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR STANDARD PAYMENT RATE CASES FOR FY 2017

[Estimated FY 2016 payments compared to estimated FY 2017 payments]

LTCH classification	Number of LTCHs	Number of LTCH PPS standard Federal payment rate cases	Average FY 2016 LTCH PPS payment per case	Proposed average FY 2017 LTCH PPS standard Federal payment rate payment per case <sup>1</sup>	Proposed percent change in payments per case due to the annual update to the LTCH PPS standard Federal rate <sup>2</sup>	Proposed percent change in payments per case due to changes to the area wage level adjustment with budget neutrality <sup>3</sup>	Percent change in payments per case from FY 2016 to FY 2017 for all proposed changes <sup>4</sup>
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
ALL PROVIDERS .....	420	72,064	\$46,944	\$47,105	1.3	0.0	0.3
BY LOCATION:							
RURAL .....	21	2,271	38,858	38,808	1.3	-0.6	0.2
URBAN .....	399	69,793	47,207	47,375	1.3	0.0	0.3
LARGE .....	202	41,448	49,428	49,738	1.3	0.2	0.3
OTHER .....	197	28,345	43,959	43,920	1.3	-0.3	0.2
BY PARTICIPATION DATE:							
BEFORE OCT.							
1983 .....	14	1,929	42,951	43,133	1.3	0.0	0.3
OCT. 1983–SEPT. 1993 .....	42	8,856	53,153	53,438	1.2	0.3	0.4
OCT. 1993–SEPT. 2002 .....	174	31,584	45,536	45,721	1.3	0.1	0.2
OCTOBER 2002 and AFTER .....	190	29,695	46,849	46,947	1.3	-0.2	0.2
BY OWNERSHIP TYPE:							
VOLUNTARY .....	78	10,016	47,838	47,719	1.3	-0.3	0.2
PROPRIETARY .....	325	60,366	46,633	46,844	1.3	0.1	0.3
GOVERNMENT .....	17	1,682	52,773	52,799	1.3	0.0	0.3
BY REGION:							
NEW ENGLAND ...	13	2,792	43,643	43,864	1.3	0.0	0.3
MIDDLE ATLANTIC .....	26	5,486	51,620	52,093	1.3	0.5	0.3
SOUTH ATLANTIC	63	12,021	46,804	46,754	1.3	-0.4	0.3
EAST NORTH CENTRAL .....	69	11,588	46,982	47,092	1.3	-0.2	0.2
EAST SOUTH CENTRAL .....	34	5,367	44,251	44,005	1.3	-0.8	0.2
WEST NORTH CENTRAL .....	29	3,877	46,850	46,623	1.3	-0.4	0.2
WEST SOUTH CENTRAL .....	128	18,590	42,312	42,344	1.3	-0.1	0.2
MOUNTAIN .....	33	4,287	49,026	49,174	1.3	0.2	0.2
PACIFIC .....	25	8,056	56,476	57,556	1.2	1.2	0.4
BY BED SIZE:							
BEDS: 0–24 .....	26	1,497	43,923	44,126	1.3	-0.1	0.2
BEDS: 25–49 .....	194	24,575	44,012	44,018	1.3	-0.4	0.2
BEDS: 50–74 .....	119	19,597	48,823	48,938	1.3	0.1	0.3
BEDS: 75–124 .....	48	12,941	49,992	50,356	1.3	0.3	0.3
BEDS: 125–199 .....	23	8,347	46,472	46,688	1.3	0.1	0.3
BEDS: 200 + .....	10	5,107	47,771	48,242	1.2	0.4	0.3

<sup>1</sup> Estimated proposed FY 2017 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the proposed payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this proposed rule.

<sup>2</sup>Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017 for the proposed annual update to the LTCH PPS standard Federal payment rate. The temporary exclusion from the site neutral payment rate provided by section 231 of Public Law 114-113 is not reflected in these estimated FY 2017 LTCH PPS payments.

<sup>3</sup>Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017 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).

<sup>4</sup>Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 (shown in Column 4) to FY 2017 (shown in Column 5), including all of the proposed changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this proposed rule. We note that 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 LTCH PPS standard Federal payment 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 for LTCH PPS standard Federal payment rate cases (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

#### d. Results

Based on the FY 2015 LTCH cases (from 420 LTCHs) that were used for the analyses in this proposed rule, we have prepared the following summary of the impact (as shown in Table IV) of the proposed LTCH PPS payment rate and proposed policy changes for LTCH PPS standard Federal payment rate cases presented in this proposed rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS standard Federal payment rate cases are expected to increase 0.3 percent, on average, for all LTCHs from FY 2016 to FY 2017 as a result of the proposed payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. This estimated 0.3 percent increase in LTCH PPS payments per discharge was determined by comparing estimated FY 2017 LTCH PPS payments (using the proposed payment rates and factors discussed in this proposed rule) to estimated FY 2016 LTCH PPS payments for LTCH discharges which would be LTCH PPS standard Federal payment rate cases if the dual rate LTCH PPS payment structure had been in effect at the time of the discharge (as described in section I.J.3. of this Appendix).

As stated previously, we are proposing to update the LTCH PPS standard Federal payment rate for FY 2017 by 1.45 percent based on the estimate of the proposed 2013-based LTCH PPS market basket increase (2.7 percent), the proposed reduction of 0.5 percentage point for the MFP adjustment, and the 0.75 percentage point reduction consistent with sections 1886(m)(3) and (m)(4) of the Act. For LTCHs that fail to submit quality data under the requirements of the LTCH QRP, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction is applied to the proposed annual update to the LTCH PPS standard Federal payment rate. As explained earlier in this section, for most categories of LTCHs (as shown in Table IV, Column 6), the estimated payment increase due to the 1.45 percent proposed annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 1.3 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for all LTCHs from FY 2016 to FY 2017. This is because our estimate of the changes in payments due to the proposed update to the LTCH PPS standard Federal payment rate also reflects estimated payments for SSO cases that are paid using special methodologies that are not affected by the proposed update to the LTCH PPS standard

Federal payment rate. Consequently, for certain hospital categories, we estimate that payments to LTCH PPS standard Federal payment rate cases may increase by less than 1.45 percent due to the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2017.

##### (1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 3 percent of all LTCH PPS standard Federal payment rate cases are expected to be treated in these rural hospitals. The impact analysis presented in Table IV shows that the overall average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017 for all hospitals is 0.3 percent. For rural LTCHs, the overall percent change for LTCH PPS standard Federal payment rate cases is estimated to be a 0.2 percent increase, while for urban LTCHs, we estimate the increase will be 0.3 percent. Large urban LTCHs are projected to experience an increase of 0.3 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017, and other urban LTCHs are projected to experience an increase of 0.2 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017, as shown in Table IV.

##### (2) Participation Date

LTCHs are grouped by participation date into four categories: (1) Before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) October 2002 and after. Based on the most recent available data, the categories of LTCHs with the largest expected percentage of LTCH PPS standard Federal payment rate cases (approximately 44 percent) are in LTCHs that began participating in the Medicare program between October 1993 and September 2002, and they are projected to experience a 0.2 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017, as shown in Table IV.

Approximately 3.3 percent of LTCHs began participating in the Medicare program before October 1983, and these LTCHs are projected to experience an average percent increase (0.3 percent) in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017, as shown in Table IV. Approximately 10

percent of LTCHs began participating in the Medicare program between October 1983 and September 1993. These LTCHs are projected to experience a larger than average increase (0.4 percent) in estimated payments for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017, which is primarily due to a projected larger than average increase in payments due to the proposed changes to the area wage adjustment. LTCHs that began participating in the Medicare program after October 1, 2002, which treat approximately 41 percent of all LTCH PPS standard Federal payment rate cases, are projected to experience a 0.2 percent increase in estimated payments from FY 2016 to FY 2017.

##### (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 19 percent of LTCHs are identified as voluntary (Table IV). The majority (approximately 77 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 4 percent of LTCHs. Based on ownership type, voluntary LTCHs are expected to experience an average increase in payments to LTCH PPS standard Federal payment rate cases of 0.2 percent. Both proprietary and government owned and operating LTCHs are expected to experience an increase of 0.3 percent in payments to LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017.

##### (4) Census Region

Estimated payments per discharge for LTCH PPS standard Federal payment rate cases for FY 2017 are projected to increase for LTCHs located in all regions in comparison to FY 2016. Of the 9 census regions, we project that the increase in estimated payments per discharge to LTCH PPS standard Federal payment rate cases would have the largest positive impact on LTCHs in the Pacific region (0.4 percent as shown in Table IV), which is largely attributable to the proposed changes in the area wage level adjustment.

In contrast, LTCHs located in the East North Central, East South Central, West North Central, West South Central, and Mountain regions are projected to experience the smallest increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017. The lower than national average estimated increase in payments of 0.2 percent is primarily due to estimated decreases in payments associated with the proposed changes to the area wage level adjustment.

#### (5) Bed Size

LTCHs are grouped into six categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds. All bed size categories are projected to receive an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017. We project that LTCHs with 50 or more beds (that is, LTCHs in the 50–74 beds; 75–124 beds; 125–199 beds; and 200+ beds categories) would experience an average increase in payments for LTCH PPS standard Federal payment rate cases (0.3 percent). LTCHs with less than 50 beds (that is, LTCHs in the 0–24 beds and 25–49 beds categories) are expected to experience a smaller than average increase in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017 (0.2 percent), mostly due to estimated decreases in payments from the proposed area wage level adjustment.

#### 4. Effect on the Medicare Program

As stated previously, we project that the provisions of this proposed rule would result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2017 relative to FY 2016 of approximately \$12 million (or approximately 0.3 percent) for the 420 LTCHs in our database. Although, as stated previously, the hospital-level impacts do not include LTCH PPS site neutral payment rate cases, we estimate that the provisions of this proposed rule would result in a decrease in estimated aggregate LTCH PPS payments to site neutral payment rate cases in FY 2017 relative to FY 2016 of approximately \$367 million (or approximately 21 percent) for the 420 LTCHs in our database. Therefore, we project that the provisions of this proposed rule would result in a decrease in estimated aggregate LTCH PPS payments to all LTCH cases in FY 2017 relative to FY 2016 of approximately \$355 million (or approximately 6.9 percent) for the 420 LTCHs in our database.

#### 5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries as a result of this proposed rule, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program.

#### *K. Effects of Proposed Requirements for the Hospital Inpatient Quality Reporting (IQR) Program*

In section VIII.A. of the preamble of this proposed rule, we discuss our requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for the FY 2019 payment determination.

In section VIII.A.3.b. of the preamble of this proposed rule, we are proposing to remove 15 measures: 13 eCQMs (2 of which we are proposing to remove also in their chart-abstracted form) and 2 structural measures.

We are proposing to remove the electronic versions of: (1) AMI–2: Aspirin Prescribed at Discharge for AMI (NQF #0142); (2) AMI–7a: Fibrinolytic Therapy Received Within 30 minutes of Hospital Arrival; (3) AMI–10: Statin Prescribed at Discharge; (4) HTN: Healthy Term Newborn (NQF #0716); (5) PN–6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF #0147); (6) SCIP-Inf-1a: Prophylactic Antibiotic Received within 1 Hour Prior to Surgical Incision (NQF #0527); (7) SCIP-Inf-2a: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528); (8) SCIP-Inf-9: Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero; (9) STK–4: Thrombolytic Therapy (NQF #0437); (10) VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373); (11) VTE–4: Venous Thromboembolism Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram); (12) VTE–5: Venous Thromboembolism Discharge Instructions; and (13) VTE–6: Incidence of Potentially Preventable Venous Thromboembolism.

We are also proposing to remove: (1) STK–4: Thrombolytic Therapy (NQF #0437); and (2) VTE–5: Venous Thromboembolism Discharge Instructions in their chart-abstracted form. Finally, we are also proposing to remove two structural measures: (1) Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care; and (2) Participation in a Systematic Clinical Database Registry for General Surgery.

As further explained in section X.B.6. of the preamble of this proposed rule, we believe that there would be a reduction in burden for hospitals due to the removal of two chart-abstracted measures (STK–4 and VTE–5). Due to the burden associated with the collection of chart-abstracted data, we estimate that the removal of STK–4 would result in a burden reduction of approximately 303,534 hours across all hospitals participating in the Hospital IQR Program for the FY 2019 payment determination. We estimate that the removal of VTE–5 would result in a burden reduction of approximately 653,565 hours across all hospitals participating in the Hospital IQR Program for the FY 2019 payment determination. We believe that removing 13 eCQMs would reduce burden for hospitals, however, if our proposal to require hospitals to submit data on all of the available eCQMs included in the Hospital IQR Program measure set is finalized as proposed, this modest reduction in burden would be offset by the increased burden associated with submitting data on 15 eCQMs instead of 4 eCQMs. We believe that there would be a negligible burden reduction due to the removal of the two structural measures.

Also, we are proposing refinements to two previously adopted measures: (1) Expanding the population cohort for the Hospital-Level, Risk-Standardized 30-Day Episode-of-Care Payment Measure for Pneumonia; and (2) Patient Safety and Adverse Events Composite (NQF #0531). As further explained in section X.B.6. of the preamble of this proposed rule,

we believe no additional burden on hospitals will result from the proposed refinements to these two claims-based measures.

In addition, we are proposing to add four claims-based measures to the Hospital IQR Program measure set beginning with the FY 2019 payment determination: (1) Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure; (2) Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure; (3) Spinal Fusion Clinical Episode-Based Payment Measure; and (4) Excess Days in Acute Care after Hospitalization for Pneumonia. We believe no additional burden on hospitals would result from the addition of these four proposed claims-based measures.

For the FY 2019 payment determination and subsequent years, we are proposing to require hospitals to submit data for all available eCQMs included in the Hospital IQR Program measure set in a manner that will permit eligible hospitals to align Hospital IQR Program requirements with some requirements under the Medicare and Medicaid EHR Incentive Programs. Specifically, hospitals would be required to submit a full calendar year of data for all eCQMs, on an annual basis beginning with CY 2017 reporting for the FY 2019 payment determination, as further explained in section X.B.6. of the preamble of this proposed rule. In total, we expect that this proposal would increase burden by 30,800 hours across all hospitals participating in the Hospital IQR Program.

As we noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49763), for validation of chart-abstracted data, we require hospitals to provide 72 charts per hospital per year (with an average page length of 1,500), including 40 charts for HAI validation and 32 charts for clinical process of care validation, for a total of 108,000 pages per hospital per year. We reimburse hospitals at 12 cents per photocopied page for a total per hospital cost of \$12,960. For hospitals providing charts digitally via a re-writable disc, such as encrypted CD-ROMs, DVDs, or flash drives, we will reimburse hospitals at a rate of 40 cents per disc, and additionally hospitals will be reimbursed \$3.00 per record. For hospitals providing charts via secure file transfer, we will reimburse hospitals at a rate of \$3.00 per record. We will maintain these requirements for the FY 2019 payment determination and subsequent years.

In this proposed rule, we are proposing to modify the existing validation process for Hospital IQR Program data to include a random sample of up to 200 hospitals for validation of eCQMs in the Hospital IQR Program. As further explained in section X.B.5. of the preamble of this proposed rule, we estimate that 43 hours of work for up to 200 hospitals reflects a total burden increase of 8,533 labor hours. As such, we estimate an hourly labor cost of \$32.84 and a cost increase of \$280,224 (8,533 additional burden hours × \$32.84 per hour) across the up to 200 hospitals selected for eCQM validation, on an annual basis.

Finally, we are proposing to update our Extraordinary Circumstances Extensions or Exemptions (ECE) policy. We believe the proposed updates would have no effect on burden for hospitals.

Historically, 100 hospitals, on average, that participate in the Hospital IQR Program do not receive the full annual percentage increase in any fiscal year due to the requirements of this program. We anticipate that, because of the new requirements for reporting we are proposing for the FY 2019 payment determination, the number of hospitals not receiving the full annual percentage increase may be higher than average. At this time, information is not available to determine the precise number of hospitals that would not meet the proposed requirements to receive the full annual percentage increase for the FY 2019 payment determination. If the number of hospitals failing to receive the full annual percentage increase does increase because of the new requirements, we anticipate that, over the long run, this number would decline as hospitals gain more experience with these requirements.

Under OMB number 0938–1022, considering the policies proposed above, we estimate a total burden decrease of 917,766 hours, at a total cost decrease of approximately \$30 million across approximately 3,300 hospitals participating in the Hospital IQR Program for the FY 2019 payment determination. 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.

#### *L. Effects of Proposed Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program*

In section VIII.B. of the preamble of this proposed rule, we discuss our policies for the quality data reporting program for PPS-exempt cancer hospitals (PCHs), which we refer to as the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. The PCHQR Program is authorized under section 1866(k) of the Act, which was added by section 3005 of the Affordable Care Act.

In section VIII.B.3. of the preamble of this proposed rule, we are proposing updates to one of the measures on which PCHs currently submit data: Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382). In addition, in section VIII.B.4.b. of the preamble of this proposed rule, we are proposing the addition of one claims-based quality measure for the PCHQR Program: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy.

The impact of the proposed new requirements for the PCHQR Program is expected to be minimal overall since beginning with Q1 2016 events, PCHs have been reporting Clinical Process/Oncology Care Measures using a sampling methodology which requires reporting no more than 25 cases per facility (79 FR 28259). As the measure cohort expansion for Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) does not expand the maximum required sample, we do not anticipate that this cohort expansion will significantly impact the operational burden for PCHs.

In addition, the Admissions and Emergency Department (ED) Visits for

Patients Receiving Outpatient Chemotherapy measure is a claims-based measure and, therefore, poses no additional burden for PCHs to submit data beyond that which they currently submit as part of the claims process.

One expected effect of the PCHQR Program is to keep the public informed of the quality of care provided by PCHs. We will display publicly the quality measure data collected under the PCHQR Program as required under the Act. These data will be displayed on the *Hospital Compare* Web site. The goals of making these data available to the public in a user-friendly and relevant format include, but are not limited to: (1) Allowing the public to compare PCHs in order to make informed health care decisions regarding care setting; and (2) providing information about current trends in health care. Furthermore, PCHs can use their own health care quality data for many purposes such as in risk management programs, healthcare associated infection prevention programs, and research and development activities, among others.

#### *M. Effects of Proposed Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP) for the FY 2018 Payment Determination and Subsequent Years*

In section VIII.C.1. of the preamble of this proposed rule, we discuss the implementation of section 1886(m)(5) of the Act, which was added by section 3004(a) of the Affordable Care Act. Section 1886(m)(5) of the Act provides that, for rate year 2014 and each subsequent year, any LTCH that does not submit data to the Secretary in accordance with section 1886(m)(5)(C) and (F) of the Act shall receive a 2 percentage point reduction to the annual update to the standard Federal rate for discharges for the hospital during the applicable fiscal year.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49838 through 49839), we estimated that only a few LTCHs will not receive the full annual percentage increase in any fiscal year as a result of failure to submit data under the LTCH QRP. There are approximately 432 LTCHs currently reporting quality data to CMS. At the time that this analysis was prepared, 39, or approximately 9.5 percent, of 412 eligible LTCHs were determined to be noncompliant and therefore will receive a 2 percentage point reduction to their FY 2016 annual payment update.

Information is not available to determine the precise number of LTCHs that will not meet the requirements to receive the full annual percentage increase for the FY 2017 payment determination.

We believe that a majority of LTCHs will continue to collect and submit data for the FY 2017 payment determination and subsequent years because they will continue to view the LTCH QRP as an important step in improving the quality of care patients receive in the LTCHs. We believe that the burden associated with the LTCH QRP is the time and effort associated with data collection.

Currently, LTCHs use two separate data collection mechanisms to report quality data to CMS: The CDC's NHSN, which is used to

report all Healthcare Associated Infections (HAI) (CAUTI, CLABSI, MRSA Bacteremia, CDI, VAE) and vaccination data, (Influenza Vaccination Coverage Among Healthcare Personnel measure); and the LTCH CARE Data Set, which is submitted to the QIES ASAP system.

The data collection burden associated with reporting quality measures via the CDC's NHSN is discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49838 through 49839). These measures are stewarded by the CDC, and the reporting burden is approved under OMB control number 0920–0666.

The All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals (NQF #2512) measure is calculated based on Medicare FFS claims data, and therefore does not have any associated data reporting burden for LTCHs.

The remaining assessment-based quality measure data are reported to CMS by LTCHs using the LTCH CARE Data Set. As of April 1, 2016, LTCHs use the LTCH CARE Data Set Version 3.00 (approved under OMB control number 0938–1163) which includes data elements related to the following quality measures: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678), Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680); Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674); Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); and Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632).

In this proposed rule, we are retaining 13 previously finalized quality measures and are proposing 4 additional measures for use in the LTCH QRP. In section VII.C.6. of the preamble of this proposed rule, we are proposing three measures for the FY 2018 payment determination and subsequent years: (1) MSPB–PAC LTCH QRP; (2) Discharge to Community—PAC LTCH QRP; and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for the PAC LTCH QRP. These three measures are Medicare claims-based measures, and because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe there would be no additional burden if any of these measures are finalized.

In section VIII.C.9.d. of the preamble of this proposed rule, we are proposing to expand the data collection timeframe for the measure NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (77 FR 53624 through 53627), beginning with the FY 2019 payment determination. The data collection time frame and associated data submission

deadlines are currently aligned with the Influenza Vaccination Season (IVS) (October 1 of a given year through March 31 of the subsequent year), and only require data collection during the two calendar year quarters that align with the IVS. We have proposed to expand the data collection timeframe from just two quarters (covering the IVS) to a full four quarters or 12 months. We refer readers to section VIII.C.9.d. of the preamble of this proposed rule for further details on the proposed expansion of data collection for this measure (NQF #0680), including data collection timeframes and associated submission deadlines. We originally finalized this measure for use in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627). Although we finalized data collection for this measure to coincide with the IVS, we originally proposed year-round data collection. The associated PRA package, which was approved under OMB control number 0938–1163, included burden calculations that aligned with our original proposal for year-round data collection. All subsequent PRA packages, and the PRA package that is currently under review by OMB, included burden calculations reflecting year-round (12 month) data collection for this measure. Because of this, the proposed change in the data collection timeframe for this measure, and any associated burden related to increased data collection, has already been accounted for in the total burden figures included in this section of the preamble of this proposed rule.

In section VIII.C.7. of the preamble of this proposed rule, we are proposing to adopt one measure for the FY 2020 payment determination and subsequent years: Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC LTCH QRP. In addition, we are proposing that data for this measure will be collected and reported using the LTCH CARE Data Set Version 4.00 (effective April 1, 2018).

While reporting quality measure data involves collecting information, we believe that the burden associated with modifications to the LTCH CARE Data Set discussed in this proposed rule fall under the PRA exceptions provided in section 1899B(m) of the Act. Section 1899B(m) of the Act, which was added by the IMPACT Act, states that the PRA requirements do not apply to section 1899B of the Act and the sections referenced in section 1899B(a)(2)(B) of the Act that require modifications in order to achieve standardized patient assessment data. However, the PRA requirements and burden estimates will be submitted to OMB for review and approval when modifications to the LTCH CARE Data Set or other applicable PAC assessment instruments are not used to achieve standardized patient assessment data.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49838 through 49840), we discussed burden estimates for the 13 previously finalized quality measures which we are retaining in this proposed rule using the LTCH CARE Data Set Version 2.01. Based on a revised PRA package for the LTCH CARE Data Set Version 3.00, we estimate the total cost for the previously finalized assessment-based measures was \$13,929 per LTCH

annually or \$6,017,146 for all LTCHs annually. In addition, we estimate that the cost to report the previously finalized quality measures via the CDC's NHSN was \$10,896 per LTCH annually or \$4,706,857 for all LTCHs annually. The revised total estimate for all 13 previously finalized measures was \$24,825 per LTCH annually or \$10,724,003 for all LTCHs annually. The two estimates discussed above, as well as the comprehensive estimate discussed below, include overhead; however, obtaining data on other overhead costs is challenging. Overhead costs vary greatly across industries and firm sizes. In addition, the precise cost elements assigned as "indirect" or "overhead" costs, as opposed to direct costs or employee wages, are subject to some interpretation at the firm level. Therefore, we have chosen to calculate the cost of overhead at 100 percent of the mean hourly wage. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Because we are proposing to add the Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC LTCH QRP measure in the LTCH CARE Data Set Version 4.00, the estimated burden and cost would increase if this measure is finalized. The additional data elements for this proposed quality measure will take 6 minutes of nursing/clinical staff time to report data on admission and 4 minutes of nursing/clinical staff time to report data on discharge, for a total of 10 minutes. We believe that the additional LTCH CARE Data Set items we are proposing would be completed by registered nurses and pharmacists. As a result, we estimate that the total cost related to the proposed Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC LTCH QRP measure would be \$3,080 per LTCH annually, or \$1,330,721 for all LTCHs annually. Because the three measures proposed in section VII.C.6. of the preamble of this proposed rule are claims-based and would be calculated based on data that are already reported to the Medicare program for payment purposes, we believe that there would be no additional LTCH burden if any of these measures is finalized.

Overall, we estimate the total cost for the 13 previously adopted measures and the 4 proposed measures would be \$27,905 per LTCH annually or \$12,054,724 for all LTCHs annually. This is an average increase of 14 percent to all LTCHs over the burden discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49838 through 49840), which included all quality measures that LTCHs are required to report under the LTCH QRP, with the exception of those 4 new measures we are proposing in this proposed rule.

We intend to continue to closely monitor the effects of the LTCH QRP on LTCHs and help facilitate successful reporting outcomes through ongoing stakeholder education, national trainings, LTCH announcements,

Web site postings, CMS Open Door Forums, and general and technical help desks.

#### *N. Effects of Proposed Updates to the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program*

As discussed in section VIII.D. of the preamble of this proposed rule and in accordance with section 1886(s)(4)(A)(i) of the Act, we will implement a 2.0 percentage point reduction in the FY 2019 market basket update for IPFs that have failed to comply with the IPFQR Program requirements for FY 2019, including reporting on the required measures. In section VIII.D. of the preamble of this proposed rule, we discuss how the 2 percentage point reduction will be applied. For FY 2016, of the 1,684 IPFs eligible for the IPFQR Program, 51 did not receive the full market basket update because of the IPFQR Program; 24 of these IPFs chose not to participate and 27 did not meet the requirements of the program. We anticipate that even fewer IPFs will receive the reduction for FY 2017 as IPFs become more familiar with the requirements. Thus, we estimate that this policy will have a negligible impact on overall IPF payments for FY 2017.

Based on the proposals in this proposed rule, we estimate a total increase in burden due to the proposed addition of a chart-abstracted measure set of 212 hours per IPF or 357,008 hours across all IPFs, resulting in a total increase in financial burden of approximately \$6,962 per IPF or \$11,724,143 across all IPFs. We also estimate a total increase in burden for training of 2 hours per IPF or 3,368 hours across all IPFs, resulting in a total increase in financial burden of \$65.68 per IPF or \$110,605 across all IPFs. Our estimate for the total increase in burden, including the newly proposed chart-abstracted measure set and training, is 360,376 hours across all IPFs, which at \$32.84 labor cost per hour, totals \$11,834,748. As discussed in section X.B.10. of the preamble of this proposed rule, we will attribute the costs associated with the finalized proposals to the year in which these costs begin; for the purposes of all the proposed changes made in this proposed rule, that year is FY 2017. Further information on these estimates can be found in section X.B.10. of the preamble of this proposed rule.

We intend to closely monitor the effects of this quality reporting program on IPFs and help facilitate successful reporting outcomes through ongoing stakeholder education, national trainings, and a technical help desk.

#### *O. Effects of Proposed Requirements Regarding Electronic Health Record (EHR) Meaningful Use Program*

In section VIII.E. of the preamble of this proposed rule, we discuss proposed requirements for the Medicare and Medicaid EHR Incentive Programs. We are proposing CQM reporting requirements, including reporting periods and submission periods, as well as CQMs required and information about CQM specifications' updates, for the Medicare and Medicaid EHR Incentive Programs for eligible hospitals and CAHs for 2017. We note that these proposals would

only apply for eligible hospitals and CAHs submitting CQMs electronically in CY 2017. Because these proposals for data collection would align with the reporting requirements in place for the Hospital IQR Program and eligible hospitals and CAHs still have the option to submit their clinical quality measures via attestation for the Medicare and Medicaid EHR Incentive Programs, we do not believe these proposals would have a significant impact.

*P. 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.

*Q. 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 a projected overall increase of 0.7 percent in operating payments. As discussed in section I.G. of this Appendix, we estimate that operating payments would increase by approximately \$693 million in FY 2017 relative to FY 2016. However, when we account for the impact of the proposed changes in Medicare DSH payments and the impact of the proposed additional payments based on uncompensated care in accordance with section 3133 of the Affordable Care Act, based on estimates provided by the CMS Office of the Actuary, consistent with our policy discussed in section IV.F. of the preamble of this proposed rule, we estimate that operating payments would increase by approximately \$525 million relative to FY 2016. We currently estimate that the proposed changes in new technology add-on payments for FY 2017 would decrease spending by approximately \$50 million due to the expiration of new technology add-on payments for four technologies. In addition, the proposed changes to the Hospital Readmissions Reduction Program for FY 2017 would decrease spending by \$100 million, as a result of the proposed inclusion of the refinement to the pneumonia readmissions measure that expanded the measure cohort, along with the addition of the CABG readmission measure, in the calculation of the FY 2017 payment adjustment factor. This estimate, combined with our estimated increase in FY 2017 operating payment of \$525 million, would result in an estimated increase of approximately \$375 million for FY 2017. We estimate that hospitals would experience a 2.0 percent increase in capital payments per case, as shown in Table III of section I.I. of this Appendix. We project that there would be a \$164 million increase in capital payments in FY 2017 compared to FY 2016. The cumulative operating and capital payments would result in a net increase of approximately \$539 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 a decrease in estimated payments per discharge in FY 2017. In the impact analysis, we are using the proposed rates, factors, and policies presented in this proposed rule, including updated wage index values and relative weights, and the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2017. Accordingly, based on the best available data for the 420 LTCHs in our database, we estimate that FY 2017 LTCH PPS payments would decrease approximately \$355 million relative to FY 2016 as a result of the proposed payment rates and factors presented in this proposed rule.

**II. 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 the following Table V, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the proposed changes to the IPPS presented in this proposed rule. All expenditures are classified as transfers to Medicare providers.

The costs to the Federal Government associated with the proposed policies in this proposed rule are estimated at \$539 million.

**TABLE V—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2016 TO FY 2017**

Category	Transfers
Annualized Monetized Transfers. From Whom to Whom.	\$539 million. Federal Government to IPPS Medicare Providers.

*B. LTCHs*

As discussed in section I.J. of this Appendix, the impact analysis of the proposed payment rates and factors presented in this proposed rule under the LTCH PPS is projected to result in a decrease in estimated aggregate LTCH PPS payments in FY 2017 relative to FY 2016 of approximately \$355 million based on the data for 420 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, 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 change 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 420 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 policies for LTCHs in this proposed rule are estimated at \$355 million.

**TABLE VI—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2016 LTCH PPS TO THE FY 2017 LTCH PPS**

Category	Transfers
Annualized Monetized Transfers. From Whom to Whom.	-\$355 million. Federal Government to LTCH Medicare Providers

**III. Regulatory Flexibility Act (RFA) Analysis**

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$7.5 million to \$38.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 36 of the Table of Small Business Size Standards for NAIC 622 found on the SBA Web site at: [http://www.sba.gov/sites/default/files/files/Size\\_Standards\\_Table.pdf](http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf).)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We believe that the provisions of this proposed rule relating to acute care hospitals would have a significant impact on small entities as explained in this Appendix. Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary LTCHs. Therefore, we are assuming that all LTCHs are considered small entities for the purpose of the analysis in section I.J. of this Appendix. MACs are not considered to be small entities. Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this proposed rule constitutes our regulatory flexibility analysis. In this proposed rule, we are soliciting public comments on our estimates and analysis of the impact of our proposals on those small entities. Any public comments that we receive and our responses will be presented in the final rule.

**IV. Impact on Small Rural Hospitals**

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals. (We refer readers to Table I in section I.G. of this Appendix for the quantitative effects of the proposed policy changes under the IPPS for operating costs.)

**V. Unfunded Mandates Reform Act Analysis**

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold level is approximately \$146 million. This proposed rule would not mandate any requirements for State, local, or tribal governments, nor would it affect private sector costs.

**VI. Executive Order 12866**

In accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget reviewed this proposed rule.

**Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services**

**I. Background**

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration

the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules, respectively. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the hospital-specific rate for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we have made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2017 consistent with approach for FY 2016, we are including 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 2017**

*A. Proposed FY 2017 Inpatient Hospital Update*

As discussed in section IV.B. of the preamble to this proposed rule, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a reduction

of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful electronic health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment), and an additional reduction of 0.75 percentage point as required by section 1886(b)(3)(B)(xii) of the Act. Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that application of the MFP adjustment and the additional FY 2017 adjustment of 0.75 percentage point may result in the applicable percentage increase being less than zero.

Based on the most recent data available for this FY 2017 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to base the proposed FY 2017 market basket update used to determine the applicable percentage increase for the IPPS on the IHS Global Insight, Inc. (IGI’s) first quarter 2016 forecast of the FY 2010-based IPPS market basket rate-of-increase with historical data through fourth quarter 2015, which is estimated to be 2.8 percent. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.B. of the preamble of this proposed rule, we are proposing an MFP adjustment of 0.5 percent for FY 2017. Therefore, based on IGI’s first quarter 2016 forecast of the FY 2010-based IPPS market basket, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount. Below we provide a table summarizing the four proposed applicable percentage increases.

FY 2017	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Proposed Market Basket Rate-of-Increase .....	2.8	2.8	2.8	2.8
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act .....	0.0	0.0	–0.7	–0.7
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act .....	0.0	–2.1	0.0	–2.1
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act .....	–0.5	–0.5	–0.5	–0.5
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act .....	–0.75	–0.75	–0.75	–0.75
Proposed Applicable Percentage Increase Applied to Standardized Amount	1.55	–0.55	0.85	–1.25

*B. Proposed Update for SCHs and MDHs for FY 2017*

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2017 applicable

percentage increase in the hospital-specific rate for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the

same update factor as for all other hospitals subject to the IPPS).

As discussed in section IV.N. of the preamble of this proposed rule, section 205 of the Medicare Access and CHIP



Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) extended the MDH program (which, under previous law, was to be in effect for discharges on or before March 31, 2015 only) for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017).

As previously mentioned, the update to the hospital specific rate for SCHs and MDHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are proposing the same four possible applicable percentage increases in the table above for the hospital-specific rate applicable to SCHs and MDHs.

#### *C. Proposed FY 2017 Puerto Rico Hospital Update*

As discussed in section IV.A. of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of Public Law 114–113 amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to propose an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section IV.B.1. of the preamble of this proposed rule. Accordingly, for FY 2017, we are proposing an applicable percentage increase of 1.55 percent to the standardized amount for hospitals located in Puerto Rico.

#### *D. Proposed Update for Hospitals Excluded From the IPPS for FY 2017*

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under the provisions of § 413.40, which also use section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern

Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. As we finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50156 through 50157), we are applying the FY 2017 percentage increase in the IPPS operating market basket to the target amount for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. For this proposed rule, the current estimate of the IPPS operating market basket percentage increase for FY 2017 is 2.8 percent.

#### *E. Proposed Update for LTCHs for FY 2017*

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this proposed rule, we are proposing to establish an update to the LTCH PPS standard Federal rate for FY 2017 based on the full proposed 2013-based LTCH PPS market basket increase estimate (for this proposed rule, estimated to be 2.7 percent), subject to an adjustment based on changes in economy-wide productivity and an additional reduction required by sections 1886(m)(3)(A)(ii) and (m)(4)(F) of the Act. In accordance with the LTCHQR Program under section 1886(m)(5) of the Act, we are proposing to reduce the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. The MFP adjustment described in section 1886(b)(3)(B)(xi)(ii) of the Act is currently estimated to be 0.5 percent for FY 2017. In addition, section 1886(m)(3)(A)(ii) of the Act requires that any annual update for FY 2017 be reduced by the “other adjustment” at section 1886(m)(4)(F) of the Act, which is 0.75 percentage point. Therefore, based on IGI's first quarter 2016 forecast of the proposed FY 2017 LTCH PPS market basket increase, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 1.45 percent (that is, the current FY 2017 estimate of the proposed market basket rate-of-increase of 2.7 percent less a proposed adjustment of 0.5 percentage point for MFP and less 0.75 percentage point). Accordingly, we are proposing to apply an update factor of 1.0145 percent in determining the LTCH PPS standard Federal rate for FY 2017. For LTCHs that fail to submit quality data for FY 2017, we are proposing to apply an annual update to the LTCH PPS standard Federal rate of –0.55 percent (that is, the proposed annual update for FY 2017 of 1.45 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying a proposed update factor of 0.9945 percent in determining the LTCH PPS standard Federal rate for FY 2017.

### **III. Secretary's Recommendations**

MedPAC is recommending an inpatient hospital update in the amount specified in

current law for FY 2017. MedPAC's rationale for this update recommendation is described in more detail below. As mentioned above, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending the four applicable percentage increases to the standardized amount listed in the table under section II. of this Appendix B. We are recommending that the same applicable percentage increases apply to SCHs and MDHs.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa of 2.8 percent.

For FY 2017, consistent with policy set forth in section VII. of the preamble of this proposed rule, for LTCHs that submit quality data, we are recommending an update of 1.45 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2017, we are recommending an annual update to the LTCH PPS standard Federal rate of –0.55 percent.

### **IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare**

In its March 2016 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 in the amount specified in current law. We refer the reader to the March 2016 MedPAC report, which is available for download at [www.medpac.gov](http://www.medpac.gov) for a complete discussion on this recommendation. MedPAC expects Medicare margins to remain low in 2016. At the same time, MedPAC's analysis finds that efficient hospitals have been able to maintain positive Medicare margins while maintaining a relatively high quality of care.

*Response:* We agree with MedPAC and consistent with current law we are proposing an applicable percentage increase for FY 2017 of 1.55 percent, provided the hospital submits quality data and is a meaningful EHR user, consistent with statutory requirements.

We note that, because the operating and capital prospective payment systems remain separate, we are continuing to use separate updates for operating and capital payments. The update to the capital rate is discussed in section III. of the Addendum to this proposed rule.

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